ISRCTN97662203 https://doi.org/10.1186/ISRCTN97662203

CANFit: A personalised home-based exercise programme for people with cancer in Yorkshire

Submission date
24/11/2023

Recruitment status
No longer recruiting

Registration date
15/01/2024

Overall study status
Ongoing

Last Edited
08/07/2024

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Regular exercise can help people who are undergoing treatment for cancer by helping manage their symptoms and improve their quality of life. However, it is not known if physical activity improves people's health or survival after treatment. This study aims to find out if a personalised, home-based exercise programme helps improve health and survival in people aged 18 or over, who have had treatment for early-stage breast, lung, or bowel cancer. It will also study whether this programme is practical and suitable for patients who have received treatments for these cancers.

Who can participate?
Adults aged 18 years old and over who are within 12 weeks of completing their first treatment for their bowel, breast or lung cancer (such as surgery plus chemotherapy, or radiotherapy).

What does the study involve?
This study will compare a personalised, multicomponent, home-based exercise programme with support, against NHS standard care. People who have finished their primary treatments for early-stage, high-risk lung, breast or bowel cancers, who are at higher risk of their cancer returning, will take part for 2 years. Comparing an intervention group vs standard care will inform the design of a larger-scale trial and provide initial evidence of whether more active people have longer, healthier lives without their cancer returning than those who are less active after cancer treatments. Some patients will be invited to undergo an interview at the end of the intervention.

The intervention group's exercise programme will be tailored to their baseline measurements (including cancer type) and access they have (if any) to outside space or exercise equipment. The programme will include cardio, strength, and flexibility/balance training. The intervention will include weekly sessions with a qualified exercise professional via video chat or telephone where participants will be offered counselling on other aspects of health that affect physical activity, such as goal setting. The counselling appointment will initially be 3 times per week, progressively tapering to none by 6 months.

What are the possible benefits and risks of participating?
If the participant is in the personalised exercise group they may become more active which is

associated with an improvement in quality of life, and may also improve some cancer-related outcomes. However, it is not known if exercise can lead to longer-term benefits for survival or cancer recurrence. Their taking part will also help the study team answer important questions on how to best deliver an activity programme that will benefit people with cancer in the future. It is also possible that by taking part in the study they will learn new ways to be active that fit within their daily routine during and after cancer treatments.

There are no disadvantages expected from taking part in the study, but participants may find attendance at the study visits time-consuming. If they are in the personalised exercise group it is possible that they may become tired or experience mild discomfort after activity – if so, they can stop the exercises at any time if they wish. If they take part in an interview, some of the issues that are discussed are sensitive and they might find this upsetting. If they have any concerns, they will be able to speak about them with the researcher or their healthcare team. The researcher will provide them with the contact details of the support services and health professionals available to them. Participation in this study will not cost anything and is voluntary. All the sessions within the intervention are delivered remotely. However, this study is running at several hospital sites. Any face-to-face appointments will be at the hospital where the participant is receiving their current treatment, at a local university, or at their home. Involvement in the study will last for 12 months and will involve 3 visits in total.

Where is the study run from?
University of Hull (UK)

When is the study starting and how long is it expected to run for?
September 2022 to August 2026

Who is funding the study?
1. Yorkshire Cancer Research (UK)
2. National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr. Cindy Forbes, cindy.forbes@hyms.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Cindy Forbes

ORCID ID
http://orcid.org/0000-0002-3259-1832

Contact details
University of Hull
Allam Medical Building
Cottingham Road
Hull
United Kingdom
HU67RX

+44 (0)1482473741
cindy.forbes@hyms.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327663

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56318, IRAS 327663

Study information

Scientific Title
A phase II, randomised feasibility basket trial of a personalised, multi-component, home-based exercise programme on disease-free survival among early-stage high-risk recurring cancers in Yorkshire

Acronym
CANFit

Study objectives
H1. The personalised home-based exercise programme will significantly increase the disease-free survival rate in patients with early-stage, high-risk cancers (bowel, lung and breast) by the 24-month mark.
H2. Delivering a large-scale, multi-component, multi-centre, randomised controlled personalised home-based exercise intervention on people with early-stage, high-risk cancers (bowel, lung and breast) is feasible and can obtain sufficient participant engagement.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/06/2023, South East Scotland Research Ethics Committee 1 (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH13EG, United Kingdom; +44 (0)131 465 5473, (0)7814 764 241; Sandra.Wyllie@nhslothian.scot.nhs.uk), ref: 23/SS/0060

Study design
Phase II randomized feasibility basket trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Home, Hospital, Internet/virtual, Medical and other records, Telephone, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Home-based exercise programme on disease-free survival among early-stage high-risk recurring cancers

Interventions
This is a multi-centre, phase II randomised controlled feasibility trial in at least 10 hospital sites in Yorkshire and the North of England to compare a personalised, multicomponent exercise programme (intervention) and NHS usual care (control). This is a 'basket trial' whereby three separate trials (one looking at breast cancer, one at lung and one at bowel), run concurrently, using the same study master protocol, with the same personalised exercise interventions. This is an efficient design resulting in essentially three trials with robust data for comparison within and between groups.
The study will explore the use of the intervention in 3 cancer types, whereby all cancer types and sites have access to the same multicomponent intervention. Patients will be identified by their usual clinical team or hospital research nurses after diagnosis for one of the three main cancers in the Yorkshire region – lung, breast, and bowel.
Patients will be randomly allocated to either the intervention group (who will receive the personalised exercise programme) or the control group (who will receive usual care). They will be randomised using a separate online randomisation system, developed by the Hull Health Trials Unit (HHTU), at the University of Hull.
The intervention group will take part in a six-month, personalised, multi-component, home-based exercise programme, that is tailored to their baseline measurements (e.g. physical function, equipment access, physical activity history, etc.) and adapted from exercise interventions, designed to improve activity behaviour, that have been used previously among a variety of cancer populations.
The intervention will include weekly appointments with a trained exercise professional (the trainer) via video chat or telephone. The programme will include cardio, strength, and flexibility /balance training. Appointments with the trainer will be 3 times per week initially, then progressively taper to none by 6 months, with the offer of a support appointment once every 6 months for maintenance. These appointments are counselling/check-in only, not exercise sessions - they are there to provide coaching, and advice, and to review participant safety. Participants can complete their exercise sessions on any day of the week.
Patients will be identified and screened by a clinician or research nurse at each site. Potential participants will be informed of their eligibility to be in the study by a member of the clinical team or research nurse. Potential participants will be asked for verbal consent to be contacted by a member of the research team. Once verbal consent for contact by the research team has been made, participants will be contacted by a member of the research team to further discuss the study, and if agreeable to being involved, will be consented.

After informed consent, participants will complete a series of physical tests and self-report questionnaires to establish baseline measures. These measures will be completed at a university site, the participant's hospital site, or, if unable to attend these, at their home, by a trained team member of the research team, and self-reported questionnaires will be administered online via a secure online platform, or paper copies if participants do not have access to a computer.
Health outcomes will be collected from medical notes including cancer diagnosis and treatment, routinely reported blood biomarkers, recurrence, and death during the study period. We ask participants if we can access routinely collected NHS data (via NHS Digital) for disease-free survival (the primary outcome) to test the feasibility of this for longer-term outcomes in a larger trial, but we will also check against medical notes (case note review).
Other outcomes will include body composition (height, weight, percentage body fat), physical fitness (measured using predicted maximal oxygen uptake, muscle strength and endurance, flexibility) and patient-reported outcomes (general and cancer-specific quality of life, sleep, lifestyle behaviours, attitudes/motivation for exercise).
Full outcome measures will be completed at baseline, 6-months (post-intervention), and 12 months (one-year follow-up).
The 24-month measures (primary endpoint; two-year follow-up) will be questionnaires and case notes review only.
In addition, routinely collected NHS data from NHS Digital will be collected for up to 5 years, with the participant's consent, to test the feasibility of this data collection method for longer-term outcomes in a full definitive trial and to enable us to continue to follow-up patients in this study as a cohort.
Participant Study Activity flow:
1. Eligibility screening
2. Informed consent
3. Baseline measures
4. Randomisation to either ARM 1 or ARM 2 ARM 1 - Tailored Exercise Intervention (see below "Intervention" section for a schedule of events) ARM 2 - Usual Care
5. 6-month measures (post-intervention)
6. 12-month measures (1 year follow-up)
7. 24-month measures (2 year follow-up) (primary efficacy outcome)
Intervention
The intervention group will take part in a personalised, multicomponent, home-based exercise programme specific to their baseline measurements (including cancer type) and what (if any) access they have to outside space and exercise facilities or equipment. This will be adapted from existing activity behaviour change interventions used before among a variety of cancer populations. Behaviour-change techniques (BCTs) - associated with improved health behaviours – include tailored education and instructions for behaviours, setting graded tasks (building on success), barrier identification and problem-solving, goal setting (behaviours), self-monitoring of behaviours, and feedback on outcomes.
We have included time in the set-up phase of the study to manualise the intervention. The intervention will include weekly appointments with a trained exercise professional (the trainer) to deliver the intervention by the study team via video chat or telephone, and the programme will include cardio, strength, and flexibility/balance training. Appointments with a trainer will be 3 times per week initially, one longer (~60 minutes) to deliver behaviour change counselling, then progressively taper to none by 6 months. Twelve weeks should be sufficient to build habits among most people the additional appointments aim to provide minimal support for maintenance.
Additional, optional appointments will be offered to support exercise maintenance. Participants will be able to indicate their preference for additional appointments at their final scheduled trainer appointment. Appointments will include exercise review with modifications if necessary, and discussions of a weekly topic, e.g., the importance of goal setting and planning, being active

during treatment and how physical activity can help mitigate side effects, reducing sedentary behaviour whenever possible, other lifestyle behaviours, how physical activity helps anxiety and depression, motivation, habit formation, and social support.
All information will also be accessible via the study website to allow participants to refer to, and revisit information whenever they like. If they have no internet access, they will be posted personalised materials.
Participants will be asked to keep track of the exercises they do and report it to us via a study website or app that can be configured within the HHTU data capture system.
Again, if participants have no internet access, they will be able to report adherence by phone. These reports will be used to progress participants as appropriate.
Trainer appointments (counselling/check-in only, no exercise)
Month One - 3 times per week
Month Two - 2 times per week
Month Three - 1 time per week Month Four - 2 times per month
Month Five - 1 time per month
Month Six - 1 final appointment (optional 'check-in' appointments will be offered after initial study period)

Intervention Type
Mixed

Primary outcome measure
Feasibility outcome measures:
1. Site set-up measured using the length of time in months from site approach to recruitment opening from data recorded in the study record at the study end
2. Recruitment measured using a traffic light system (≥70% target within the time allocated frame: Green; 40-70%: Amber; <40% target within the allocated time frame: Red) based on the recruitment rate reported on the study record (the number of people recruited at 16 months divided by the original sample aim (660)) at 24 months
3. Intervention delivery and adherence measured using the traffic light system (≥ 80% of participants completed ≥ 75% of personal prescription: Green; 50 – 79% of participants completed ≥ 75% of personal prescription: Amber; <50% of participants completed ≥ 75% of personal prescription: Red) from data recorded in the study records at the end of month 19 (end of tailored intervention delivery)
4. Intervention adherence measured using the number of people completing at least 75% of their personalised exercise prescription from data recorded in the study records at 12 months
5. Data completion measured using the percentage of missing data for questionnaires and physical measures from data recorded in the study records at baseline, 6 months, 12 months, and 24 months
6. Adverse events measured using the number of adverse events and serious adverse events from data in study records at 24 months
7. Adverse events measured using the number of adverse events and serious adverse events at 24 months

Primary efficacy aim/objective:
To determine the efficacy of moderate-to-vigorous exercise on 2-year disease-free survival for people diagnosed with
lung, breast, or bowel cancers that have a higher risk of early recurrence after the completion of primary treatment
(surgery +/- chemotherapy and/or radiotherapy) measured after 24 months via case note review /NHS digital record.

Secondary outcome measures
1. Physical fitness assessed as submaximal VO2 via 6 min walk test at baseline, 6 and 12 months
2. Patient-reported quality of life (cancer-specific) measured via self-reported questionnaires, SQUASH questionnaire, EQ-5D-5L, EQ-VAS, Functional Assessment of Cancer Therapy plus fatigue subscale questionnaires at baseline, 6, 12 and 24 months
3. Variables related to meeting MVE guidelines (e.g., age, performance status, attitudes, self-efficacy, etc.,) via the Australian Karnosfsky Performance Scale (AKPS), short physical performance battery (SSPB), grip strength and body composition (BMI) at baseline, 6 and 12 months. Plus, case notes and self-reported questionnaires, SQUASH questionnaire, EQ-5D-5L, EQ-VAS, Functional Assessment of Cancer Therapy plus fatigue subscale questionnaires at baseline, 6, 12 and 24 months.

To explore the use of NHS Digital to support longer-term data collection in a full definitive trial measured at 24 months:
1. Willingness for use of NHS Digital data measured using the number of people consenting to have data linkage at baseline
2. Ability to obtain data on cancer recurrence and survival from NHS Digital up to 5 years after study participation measured using the number of consented participants with completed 5-year collected from NHS Digital at 5 years.

Overall study start date
01/09/2022

Completion date
30/08/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 or older
2. Diagnosed with early-stage high-risk cancer, defined as:
2.1. Non-small cell lung cancer: diagnosed with stages II or IIIA disease
2.2. Breast: Triple-negative breast cancer: diagnosed with ≤ stage II (defined as an Allred score < = 4 and her2 negative),
2.3. Bowel: diagnosed with stage II, T4 disease only or any stage III disease
3. Within 12 weeks of completing primary treatment (e.g., surgery +/- chemo and/or radiation therapy) with curative intent, or for those on adjuvant immunotherapy or tyrosine kinase inhibitors, as soon as they begin this phase of their adjuvant treatment,
4. Willing and able to complete study measures and be randomised,
5. Able to provide informed consent,
6. Willing and able to engage remotely either by phone or video-based communications.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 660; UK Sample Size: 660

Key exclusion criteria
1. Being treated for low-risk early-stage or incurable cancers,
2. Having an irreversible unstable acute condition (e.g. acute infection, severe uncontrolled symptoms) or underlying chronic condition or disease (e.g. severe arthritis or dementia) that would impact study compliance.
3. Mental capacity impaired to the extent that a course of systemic anti-cancer therapy is considered inappropriate by treating oncologist

Date of first enrolment
04/12/2023

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Northern General Hospital
Herries Road
Sheffield

United Kingdom
S5 7AU

Study participating centre
York District Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Barnsley Hospital NHS Foundation Trust
Gawber Road
Barnsley
United Kingdom
S75 2EP

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
University of Hull
Cottingham Road
Hull
United Kingdom
HU6 7RX

Study participating centre
Sheffield Hallam University
City Campus
Pond Street
Sheffield
United Kingdom
S1 1WB

Study participating centre
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Sponsor information

Organisation
University of Hull

Sponsor details
Cottingham Road
Hull
England
United Kingdom
HU6 7RX
+44 (0)1482466732
pvc-re@hull.ac.uk

Sponsor type
Hospital/treatment centre

Website
https://www.hull.ac.uk/

ROR

https://ror.org/04nkhwh30

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

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

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The investigation results are intended to be disseminated through peer-reviewed scientific journals, and conference presentations with an intent to publish between one and two years from the trial finishing date.

Intention to publish date
31/08/2028

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date