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Is a lifestyle intervention designed to support muscle mass in people with advanced bowel cancer during their chemotherapy feasible?

Submission date
25/03/2024

Recruitment status
No longer recruiting

Registration date
26/03/2024

Overall study status
Ongoing

Last Edited
17/07/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Loss of muscle mass is common in people with bowel cancer (cancer of the colon or rectum). Previous research has shown that physical activity and nutrition support with a focus on strength training and increased daily protein intake can reduce muscle loss in people with cancer. Improved muscle mass can minimise the negative effects of cancer treatments, improve quality of life, and, in some circumstances, improve the response to cancer treatments. However, to date, little is known about whether this type of support is feasible or beneficial during treatment for advanced bowel cancer (cancer that cannot be removed surgically or has spread to other parts of the body).

Who can participate?
This single-centre, single-arm feasibility study based in Belfast, Northern Ireland will recruit adults with advanced bowel cancer due to commence cancer treatment.

What does the study involve?
Participants will undergo fitness testing, assessment of their muscle mass using specialised scales, assessment of their diet using a food diary, and complete questionnaires about their general health. They will then be offered weekly face-to-face, one-on-one sessions with a physical activity and nutrition coach in the hospital outpatient gym over twelve weeks. These sessions will include supervised strength training as well as goal-setting and support for improving physical activity and protein intake at home. Assessments will be repeated at the end of the twelve-week programme. After the programme has finished, participants will be signposted to further support for diet and exercise going forward. Participants will be invited to take part in a recorded interview after the programme is completed.

What are the possible benefits and risks of participating?
Previous activity and nutrition support studies involving people recently diagnosed with cancer suggest that taking part in this type of study helps:
• Decreased fatigue.
• Maintain or improve physical functioning.

• Improve quality of life.
• Reduce anxiety and depression.
• Improve ability to control your weight.
• Decrease your risk of chemotherapy side effects.

The health risks of taking part in the study are extremely low as participants will be screened for their suitability prior to taking part and shown how to exercise safely. There is a risk however of mild side effects from taking part in strength training exercise including muscle soreness/injury and bone and joint injury. There is a rare risk of falls, abnormal health rhythms and heart damage, hernia around stoma site (if applicable) associated with strength exercises. There is a risk of bruising from around the site of research blood samples taken.

What are the outcomes?
The main outcome will be to assess whether this type of programme is feasible in people with advanced colorectal cancer during their treatment. Muscle mass, strength, quality of life, chemotherapy response and side effects will also be measured, and participant experiences will be analysed from their interviews.

Where is the study run from?
The study will recruit participants due to undergo anticancer treatment for advanced bowel cancer in the Belfast City Hospital, Northern Ireland. Patients who wish to join this study may be able to have their care transferred to Belfast to facilitate this.

When is the study starting and how long is it expected to run for?
November 2022 to January 2027

Who is funding the study?
The study is funded by the Belfast Health and Social Care Trust Charitable Research Fund (UK)

Who is the main contact?
The Chief Investigator for this study is Professor Vicky Coyle, nictn@belfasttrust.hscni.net
For enquiries about this study please contact the Northern Ireland Clinical Trials Network on 028 9615 2652

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
338992

Study information

Scientific Title
Feasibility of A Co-designed Lifestyle Intervention during Treatment for Advanced colorecTal cancEr: a single centre pilot study.

Acronym
FACILITATE

Study objectives
It is possible to deliver a physical activity and nutrition support programme designed to counter sarcopenia in patients with advanced (unresectable and/or metastatic) colorectal cancer alongside their chemotherapy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/06/2024, South West - Cornwall & Plymouth Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048071; cornwallandplymouth.rec@hra.nhs.uk), ref: 24/SW/0079

Primary study design
Interventional

Study design
Single-arm single-centre feasibility study of physical activity and nutrition support intervention

Study type(s)
Quality of life, Safety, Other

Health condition(s) or problem(s) studied
Advanced (unresectable and/or metastatic) colorectal cancer undergoing chemotherapy

Interventions
12-week physical activity and nutrition programming with weekly face-to-face sessions with a physical activity and nutrition coach with a focus on strength training and increasing protein intake.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rate – measured by record of number of participants enrolled as a proportion of number of eligible participants approached about study, and by recorded time to recruit to target (20 participants). Reason for participation and non-participation will be explored qualitatively with semi-structured interviews.
2. Retention – measured by drop-out rate of enrolled participants prior to intervention completion and final assessments, this will include descriptive record of number of sessions attended prior to drop-out. Reasons for drop-out will be explored qualitatively in semi-structured interviews.
3. Adherence to intervention – measured objectively by record of number of planned face-to-face sessions attended by participants, and subjectively by description of self-reported adherence to home physical activity and nutrition prescription as recorded in participant booklet and recorded by the researcher on case report forms during weekly face-to-face sessions.
4. Acceptability of intervention – assessed by thematic analysis of semi-structured qualitative interviews with 5-10 participants (until data saturation). Eligible participants who decline to participate will be invited to discuss rationale for this. Nominated friends and family members of participants will also be invited to semi-structured interviews about their experience of supporting someone participating in the study. Healthcare professionals involved in the study will also be invited to interviews to discuss the acceptability of the intervention. All interviews will undergo thematic analysis.

Key secondary outcome(s)
1. Muscle mass measured using cross-sectional area of muscle at L3 on standard-of-care CT and by bioimpedance analysis at baseline and after 12-week programme.
2. Muscle strength measured by handgrip strength and repetition maximal testing at baseline and after 12-week programme.
3. Physical function measured by six-minute walk test and 30 second sit-to-stand at baseline and after 12-week programme.
4. Participant reported physical activity measured by IPAQ-SF and MSEQ-SF questionnaires at baseline and after 12-week programme.
5. Protein and calorie intake estimated from self-reported three day food diaries at baseline and after 12-week programme.
6. Participant reported quality-of-life measured by QLQ-C30 questionnaire at baseline and after 12-week programme.
7. Nominated friend/family member of participant reported quality of life measured by SF-36 questionnaire at baseline and after 12-week programme.
8. Safety of intervention as assess by description of intervention-associated adverse events

recorded during face-to-face sessions.
9. Qualitative thematic analysis of experience of intervention (in participants, nominated friend /family members and healthcare professionals) and reasons for non-participation (in patients approached who decline to participate).
10. Assessment of chemotherapy response as measured by RECIST v1.1 criteria on standard-of-care response CT
11. Collection of longitudinal blood samples and access to historic tumour biopsy samples for exploratory cancer biomarker research

Completion date
01/01/2027

Eligibility

Key inclusion criteria
Main participants:
1. Age of at least 18 years.
2. Histologically-confirmed unresectable Stage III or Stage IV adenocarcinoma of the colon or rectum.
3. Planned for systemic anti-cancer treatment (SACT) with a 5-flourouracil-based regimen with palliative intent.
4. Greater than 12 weeks from any prior SACT.
5. Greater than 4 weeks from any prior major surgery and fully recovered.
6. ECOG performance status 0-2 and anticipated life expectancy greater than 4 months.
7. Adequate haematological, renal and hepatic function to undergo standard of care SACT as assessed by treating oncologist.
8. Medical clearance by treating physician to undergo symptom-limited muscle strength testing, physical function testing, and tailored resistance-based exercise training.
9. Ability (i.e. sufficiently fluent) and willingness to effectively communicate with the Physical Activity and Nutrition Coach.
10. Willingness to eat an unrestricted diet. Includes participants willing to eat an otherwise unrestricted vegetarian diet.
11. Ability to provide written informed consent.

Nominated friend/family members (for questionnaires and interview):
1. One person nominated by the main study participant.
2. Ability to provide written informed consent.

Healthcare professionals involved in study (for interview).
1. Ability to provide written informed consent.

Potential participants who decline to participate (for interview):
1. Ability to provide written informed consent.

Participant type(s)
Carer, Health professional, Patient

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Significant cognitive impairment or co-morbid conditions precluding participation in a resistance-training programme as determined by the investigator.
2. Peripheral neuropathy > grade 2.
3. Unlikeliness to participate in a physical activity and nutrition intervention as determined by the investigator.
4. Patients undergoing adjuvant-intent chemotherapy in the setting of radically treated oligometastatic hepatic disease.
5. Concurrent treatment for a second malignancy.
6. Treatment with any medications deemed by the investigator as likely to preclude participation in a resistance-training programme.
7. Individual already participating in structured resistance-training ≥ 2 days per week.

No specific exclusion criteria for nominated friends/family members, healthcare professionals, and non-participants taking part in questionnaires and interviews.

Date of first enrolment
26/01/2025

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Belfast City Hospital
51 Lisburn Rd
Belfast
Northern Ireland
BT9 7AB

Sponsor information

Organisation
Queen's University Belfast

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Belfast Health and Social Care Trust Charitable Research Fund

Results and Publications

Individual participant data (IPD) sharing plan
Clinical outcome data will be made available via a gatekeeper approach. Researchers will be able to apply to access an anonymised dataset via a trial summary and contact details available on the Northern Ireland Clinical Trials Unit (NICTU) website (https://nictu.hscni.net/). Any requests for access to data will require approval as per NICTU standard operating procedures.
Note: the NICTU will update its website with details on the FACILITATE study when the study opens.
The researchers propose to make an aggregated dataset of clinical outcomes available to maximise the applicability of the dataset for future research while safeguarding participant confidentiality by not providing individual patient records or tabular data to a low level of aggregation.
Study data will be made available for sharing once the primary study analysis has been published. Information on data sharing will be provided in the participant information sheet. Written consent will be obtained for data sharing from all participants.
All datasets shared will be anonymised to protect participant confidentiality. Shared data will undergo a level of aggregation to ensure participant confidentiality while maintaining the maximal utility of the dataset for future research.
Only anonymised data will be made available, and it will be processed in accordance with the Data Protection Act (UK).
The only major milestone for sharing is the publication of the primary analysis; the researchers anticipate this would occur within 12 months of study completion. The summary information will include contact details for the chief investigator (CI) or their designated representative. Applicants will be required to provide proof of identity and employment and to provide details of the intended research addressing specific queries including study aims and objectives,

statistical analysis, and relevant expertise. The CI and trial management group (TMG) will review applications for data usage. All proposals will be reviewed for their scientific merit by the clinical trials unit (CTU) and the study CI. Only data relevant to the objectives of a particular proposal will be provided. An independent review process will be undertaken in cases of disagreement between the applicant and the CTU / CI. A data-sharing agreement will be put in place prior to any data transfer. The NICTU is committed to furthering cancer research by sharing de-identified data from its studies with others in the field who wish to use the data for high-quality science.

IPD sharing plan summary

Available on request