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Title: Improving Brain Health After Chemotherapy Through Prehabilitation

Short Title: ChemoBrain Prehab Project

RESEARCH REFERENCE NUMBER: 25/EM/0250

STUDY REGISTRY NUMBER AND DATE:

PROTOCOL VERSION NUMBER AND DATE: Version 1.0 (04/12/2025)

SPONSOR NUMBER:

FUNDER NUMBER: AR2024.07

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the national guidelines for the conduct of clinical research.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies and serious breaches of Good Clinical Practice (GCP) from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

.....

Date:
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Name (please print):

.....

Position:

.....

Chief Investigator:

Date: 23/06/25

Signature:

.....

Name: (please print): Dr Christopher Gaffney

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i. KEY STUDY CONTACTS

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Principal Investigators For Each Participating Site	Mr. Daren Subar Department of General Surgery East Lancashire Teaching Hospitals NHS Trust Blackburn, BB2 3HH +44 (0) 1524 735 604 daren.subar@elht.nhs.uk

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Funder(s)	North West Cancer Research Mr Alastair Richards 131 Mount Pleasant, Liverpool, L3 5TF alastair@nwcr.org

ii. LIST OF ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
BDNF	Brain-Derived Neurotrophic Factor
CPET	Cardiopulmonary Exercise Test
ECG	electrocardiogram
EEG	Electroencephalogram
ERP	Event Related Potentials
GCP	Good Clinical Practice
GP	General Practitioner
IPAQ	International Physical Activity Questionnaire
ISRCTN	International Standard Randomised Controlled Study's Number
NHS	National Health Service
PAR-Q+	Physical Activity Readiness Questionnaire
PIS	Participant Information Sheet
PPI	Public and Patient Involvement
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SOP	Standard Operating Procedure
SSC	Study Steering Committee
VEGF	Vascular Endothelial Growth Factor

iii. STUDY SUMMARY

Study Title	Improving Brain Health After Chemotherapy Through Prehabilitation
Short Title	ChemoBrain Prehab Project
Study Design	Multi-Centre Randomised Control Trial Intervention: Prehabilitation Group Control Group: Standard Care Group
Study Participants	Stage II and III colorectal cancer patients who are undergoing chemotherapy
Planned Sample Size	86 patients with colorectal cancer were divided into Group 1: Intervention (Prehabilitation; n = 43), and Group 2: Control (Standard Care With No Prehabilitation; n = 43).
Randomisation	Block randomisation will be performed at an independent site (Lancaster University), and the sequence will be shared with the recruitment team via sealed envelopes.
Allocation Concealment	The study arm allocation will be provided in sealed envelopes.
Counties of Recruitment	Lancashire
Intervention	Supervised moderate-intensity exercise programme for participants to attend twice per week [online] and two unsupervised, self-paced exercise sessions. Totally to 4 exercise sessions per week at home. This will include warm-up and cool-down sessions. Strength training will focus on muscle groups and avoiding core exercise, which can increase the risk of excessive abdominal pressure. Grades of resistance band (or equivalent) will be provided, and regression and progression to exercise will be offered to individualise exercise programmes according to participants' mobility and capabilities. Participants will be provided with four-week supply of multivitamins (Forceval) before chemotherapy, and then X amount as part of standard of care (dependent on the number of rounds of chemotherapy (4-24 weeks supply)). The multivitamins will be taken in addition to the exercise programme.

Control	Standard care group.	
Intervention duration	The maximum duration of prehabilitation participation will last a maximum of 28 weeks, however, there may be delays to treatment due to chemotherapy-related side effects (e.g., low white blood cell count).	
Follow up duration	3 months	
Planned Study Period	5th January 2026 to 16th September 2027	
	Objectives	*Outcome Measures*
Primary	Use physiological blood-based markers to establish if prehabilitation promotes an improvement in brain health in colorectal cancer patients prior to starting chemotherapy.	Brain-Derived Neurotrophic Factor (BDNF) and Vascular Endothelial Growth Factor (VEGF).
	We will use neuroscientific measures of brain function (electroencephalography (EEG)) and cognitive function at baseline and post-chemotherapy to determine if prehabilitation neuroplasticity reduces the negative effects of chemotherapy on the brain.	EEG spectral ratios and oscillation analysis that focuses on brain activity during a battery of cognitive function tests. Cognitive outcomes (executive function, memory, attention, and processing speed; with audition)
Secondary	We will measure changes in cognitive-related quality of life in colorectal cancer patients at Study Visit 1 and at 3 months after chemotherapy cessation to determine whether prehabilitation had an impact.	Quality-of-life questionnaire

iv. FUNDING

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
North West Cancer Research: Mr Alastair Richards, CEO, alastair@nwcr.org. Funding for the research study was also provided.	£237,181.19

v. ROLE OF STUDY SPONSOR AND FUNDER

Lancaster University, as the Sponsor, assumes overall responsibility for the initiation and governance of the study. This includes ensuring that the research complies with relevant ethical, legal, and regulatory standards, and that appropriate risk management, insurance, and oversight mechanisms are in place. The Sponsor, in its supervisory role, will monitor and support the project through established protocols delivered by the university's Clinical Research Governance Team, ensuring that the study is conducted to high scientific and ethical standards, and that outcomes are appropriately reported and disseminated.

North West Cancer Research, as the Funder, is a registered charity, whose role is to provide financial support to enable the research to be conducted. While the Funder may outline strategic priorities and conditions for the use of funds, it does not assume legal or regulatory responsibility in this study. The Funder is not the Sponsor and is therefore not involved in the management, oversight, or conduct of the research. The sponsor and the research team are responsible for ensuring that the study meets ethical, legal, and governance requirements. The Funder may require progress updates, a final report, and evidence of dissemination in line with its commitment to transparency and impact.

vi. ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The public and patient involvement (PPI) steering committee will consist of individuals with lived experience of colorectal cancer, including experience of chemotherapy-related cognitive impairments ('brain fog,' 'chemo-brain'), and carers of people who have undergone chemotherapy treatment. The group will be facilitated and chaired by the lead investigator, who will ensure inclusive, well-managed discussions and support the contribution of all members in informing the design, management, and dissemination of the research.

The Study Steering Committee (SSC) will provide overall oversight of the study and ensure that it is conducted according to the highest standards of scientific and ethical integrity. The committee will include the Lead Investigator (Hoad), Chief Investigator (Gaffney), Co-Investigator (Nuttall), Clinical Lead (Subar), and three academic members with expertise in clinical trial management and oversight. In alignment with the best practice in PPI, a representative from the study's PPI advisory group will also participate in quarterly SSC

meetings to ensure that the perspectives of those with lived experience inform study governance. Management challenges may arise in the timing of recruitment and enrolment into the exercise prehabilitation, especially across multiple hospital sites. Recruitment and retention issues will be addressed in our steering group meetings and monitoring of the testing protocol.

vii. PROTOCOL CONTRIBUTORS & ROLES AND RESPONSIBILITIES

Hoad is a research associate currently based at Lancaster Medical School with a background in exercise physiology. She was involved in cerebrovascular and cardiovascular health in patients with stroke and during cardiac rehabilitation. Hoad is employed for 2.5 years to conduct this project. Hoad will recruit all participants, conduct all data collection (CPET/Bloods/EEG/Cognitive Battery) during hospital visits, run the intervention (exercise sessions), manage data, and analyse all data with guidance from Gaffney and Nuttall.

Gaffney (Lecturer in Sports Science, Lancaster University, UK) is a physiologist based in Lancaster Medical School with expertise in skeletal muscle metabolism. His experience covers research involving patients, elite athletes, and his industrial partners including work with NASA and SpaceX. Gaffney will provide oversight of the project, support the lead investigator (Hoad) in CPET and blood panels data and prepare data for publication.

Nuttall (Lecturer in Cognitive Neuroscience, Lancaster University, UK) is a neuroscientist with expertise in cognitive neuroscience and sensorimotor function, using auditory brainstem responses (ABRs), frequency following responses (FFRs), electroencephalography (EEG), transcranial magnetic stimulation (TMS), and motor evoked potentials (MEPs). Nuttall will support the lead investigator (Hoad), assist with all EEG and cognitive-related data, and prepare data for publication.

Subar is a consultant laparoscopic and Hepato-Pancreato-Biliary surgeon with an interest in minimal access surgery. He is the lead for robotic HPB in the department, which will soon be launched. He is also the lead in research and development in the Department of General Surgery. Subar will be the clinical co-investigator/lead clinician of the project and principal investigator at East Lancashire NHS Teaching Hospitals and will review lists of patients weekly throughout the recruitment window.

Williamson is a consultant clinical oncologist based at the Lancashire Teaching Hospital NHS Trust. Her research has focused on cancer, specifically the optimisation of chemoradiotherapy and standardisation of clinical trial outcomes. Williamson will be the clinical co-investigator of the work, principal investigator at Lancashire Teaching Hospital NHS Trust and will review lists of patients weekly throughout the recruitment window**.**

Ton is a consultant medical oncologist at the Royal Lancaster Infirmary, University Hospitals Morecambe Bay Trust. Ton will be the clinical co-investigator of the work, principal investigator

at University Hospitals Morecambe Bay Trust, and will review lists of patients weekly throughout the recruitment window.

viii. KEY WORDS: Prehabilitation, Colorectal Cancer, Chemo-Brain, Chemotherapy-Induced Cognitive Impairment, Exercise, Quality of Life.

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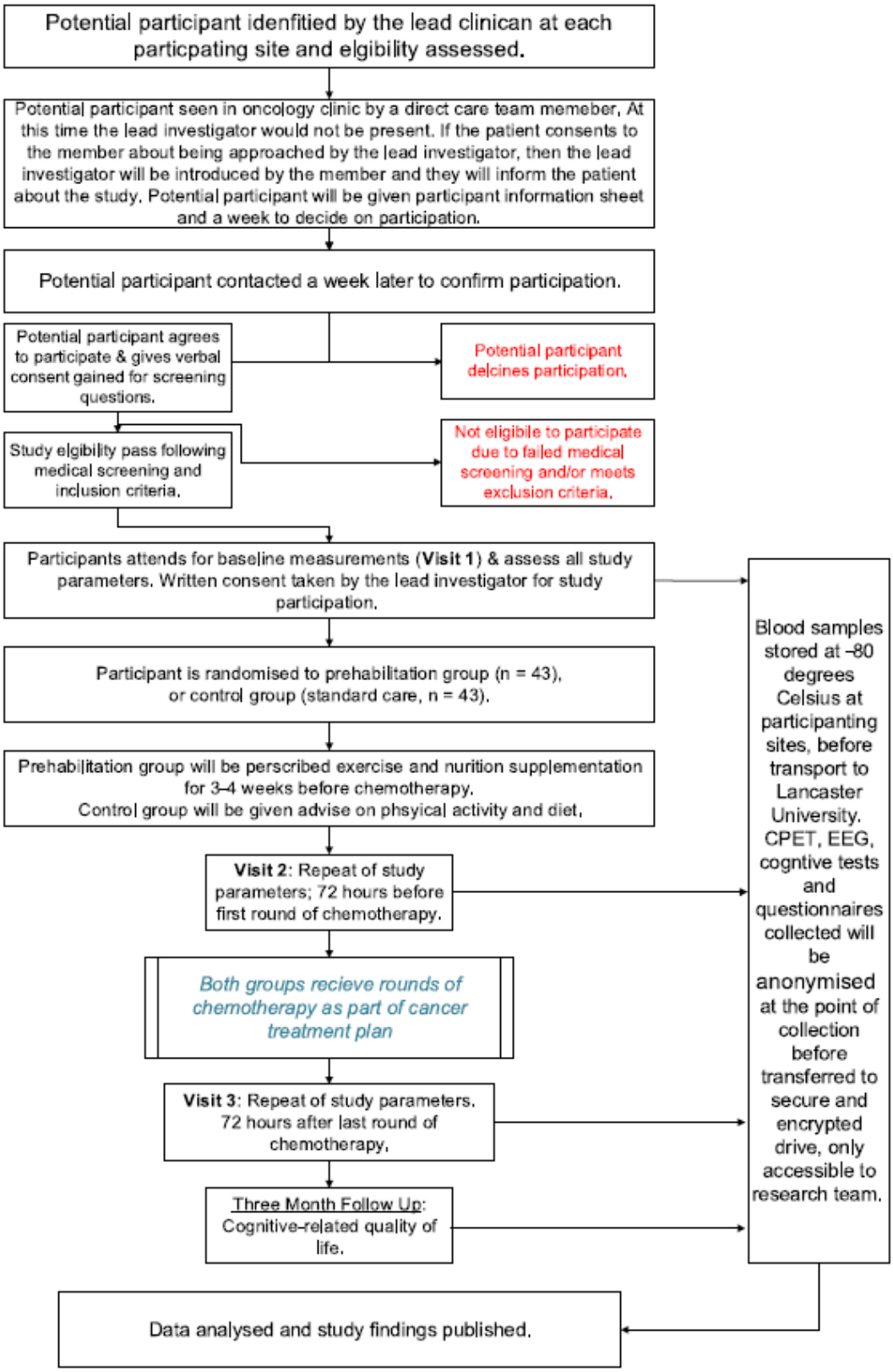
ix. STUDY FLOW CHART



1. BACKGROUND & RATIONALE

Colorectal cancer is 37% higher in the North-West than the national average, and recent analysis suggests that overall survival in the North-West is the worst in England at 58.1% (95% CI: 57.3%, 58.9%)[1,2]. Colorectal cancer is treated with chemotherapy, including fluorouracil, capecitabine, and oxaliplatin. These drugs do not just kill the tumour, they also damage cells across the body, which can lead to common side effects, such as hair loss. A further common side effect is “chemo-brain,” which describes a range of symptoms, including problems with memory and thinking speed. Such symptoms reduce the quality of life and increase stress in patients.

One of the most promising new avenues for optimising patient treatment in cancer is “prehabilitation” [3,4] a term used to capture exercise and nutrition interventions to prepare patients before treatment. Prehabilitation has excellent surgical benefits. It can improve cardiorespiratory fitness before cancer treatment, improves functional capacity, reduces post-operative complications, and reduces hospital length of stay[3-5], thus offering patient-centred and economic benefits. The benefits before chemotherapy are less well defined, but the mechanisms that improve outcomes for surgery remain intact in patients who undergo chemotherapy.

Exercise improves both the body and brain. For the body, it improves cardiovascular function and promotes muscle protein synthesis and skeletal muscle accretion[5]. In the brain, exercise increases growth factors in the blood, which collectively improves brain health and cognitive reserve. These include Brain-Derived Neurotrophic Factor (BDNF) and Vascular Endothelial Growth Factor (VEGF)[6]. Exercise-induced increases in new cells in the nervous system result in increased white matter volume, gray matter volume, and neural activity in the brain[7]. Exercise also promotes greater connectivity within the nervous system and the formation of new blood vessels, which increases cerebral blood flow[7]. Therefore, exercise can improve brain health and function. Exercise can help build the body up before chemotherapy breaks the body down, alleviating some side effects associated with chemotherapy. We will use an existing prehabilitation intervention we have developed, which increases fitness and reduces hospital length of stay in colorectal cancer patients undergoing surgery, to try and improve the symptoms of chemo-brain of those undergoing chemotherapy and improve quality of life. Given the known link between cardiorespiratory fitness and markers of brain health[7], we hypothesise that prehabilitation will also improve chemo-brain symptoms resulting from chemotherapy.

2. ASSESSMENT AND MANAGEMENT OF RISK

Potential Risks

Cardiopulmonary exercise testing (CPET) carries a small but important risk of adverse events. To minimise the risk of exertional arrhythmias, cardiac events, or syncope, participants will be pre-screened using the Physical Activity Readiness questionnaire (PAR-Q+), with medical clearance obtained if needed before the first visit to the hospital for testing. Resting electrocardiography (ECG) may be performed as part of the test prior to cycling. All tests will be supervised by the lead investigator who has appropriate first aid training, with access to medical personnel readily available at each participating hospital site. To reduce the risk of musculoskeletal injury from sudden or excessive exertion, functional movement screening will

be conducted prior to testing, and a gradual ramping protocol will be used. Each test will include an appropriate warm-up and cool-down period.

There are no potential risks associated with EEG recordings; however sanitiser/disinfectant for cleaning skin where the cap is to be placed. Participant could potentially experience an allergic reaction, or sensitive skin following chemotherapy compared to normal. EEG hydro-links will be a fitted into the cap, therefore also maintaining a sterile field. Although the EEG system is not diagnostic, any incidental EEG findings which warrants further investigation will be reported to the direct care team. These would include any EEG findings that also suggest underlying symptoms. The EEG data would not be analysed in real time and does not have any direct diagnostic value, but as part of good clinical practice, as outlined above, will be discussed with them if any incidental findings are noted. Additionally, the cognitive function test battery and physical evaluation can potentially lead to fatigue, frustration, or emotional disturbance. The study will be conducted with close attention to patient safety and will not interfere with or alter the standard of care that patients would normally receive. If they do suffer any other symptoms or they become concerned in any way prior to their next study visit or after the study has finished, they should contact the lead investigator or any investigators named on this sheet (chief or principal investigators) prior to their next visit.

Home-based exercises carry potential risks in both supervised and unsupervised sessions. Such risks include adverse events: cardiovascular events, neurological complications such as neuropathy-related balance issues, as well as general safety such as falls and musculoskeletal injuries. All exercises (aerobic and resistance/strength) will include adaptations to suit the participants' individual circumstances. For example, providing a chair to perform resistance band exercises. Family, friends, or caregivers must be present in the household for both supervised and unsupervised sessions. If the participant is unable to contact the emergency services, someone will be present to assist. Support will also be provided during supervised exercise sessions. The participant will be provided with an emergency contact list. Calls between the lead investigator (or member of the research team) will provide an opportunity to screen for any injuries and side effects of treatment (e.g. neuropathy) which will inform any appropriate adaptations to exercise sessions.

Regarding the use of multivitamins (Forceval), the principal investigator during the screening process will exclude participants with any contraindications to taking these multivitamins (e.g. impaired kidney and liver function, listed in Section 6.2) which can be indicated through markers and medical history on patient medical records. Routine blood count checks conducted as part of the standard of cancer care will provide additional monitoring for potential adverse changes. The multivitamin used will be dispensed and recorded by the participating hospital, ensuring that the direct care team (oncologists, oncology nurses, and PIs) is aware of supplementation but remains blinded to group assignment. Awareness of multivitamin use alongside blood count results may help the direct care team identify potential concerns and, in collaboration with the research team, determine whether further steps are needed. Participation may be terminated if clinically indicated to safeguard patient wellbeing.

Venepuncture for the collection of blood samples for neuroplasticity assessment carries minor risks, including bruising, haematoma, infection, and vasovagal syncope. To minimise these risks, all procedures will be carried out by a trained healthcare clinician or nurse using an

aseptic technique. Pressure will be applied to the puncture site following sample collection to reduce the likelihood of bruising and haematoma. Participants will be observed post-procedure to monitor for any adverse reactions, including signs of fainting or discomfort, ensuring a proper and appropriate response if required. The blood samples for the brain markers are not for clinical use and will be analysed at the end of the testing period, i.e., when the last participant is tested at Visit 3. Thus, the findings of these samples will not be communicated to a clinician (member of the direct care team or general practitioner (GP)) as it will be weeks/months from when they were collected.

Before the first visit to the hospital for testing, the Informant Questionnaire On Cognitive Decline In The Elderly (IQCODE, self-report form) (via Qualtrics, https://lancasteruni.eu.qualtrics.com) and the Mini-Cog (WebCog, https://rishik4.github.io/webcog/#/) will be used to assess cognitive function, and physical activity engagement via the Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) and International Physical Activity Questionnaire (IPAQ) can be found in the appendices. All questionnaires will be completed to check eligibility to take part, and if the participant is eligible, they will be scheduled into a testing slot at their participating hospital site (visit 1). It is important to highlight that these questionnaires cannot be used as clinical assessment tools in this setting and that the lead researcher is not qualified to provide a diagnosis of cognitive impairment. If the patient is concerned by the results of the questionnaires or would like further information, they will be advised to contact their direct care team or GP. A GP letter can be provided by the research team to the patient to give details about the screening questionnaires used and evidence about potential cognitive decline if they seek to speak to their GP for advice.

3. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1. Primary objective

1. We will use physiological blood-based markers of (VEGF and BDNF) to establish if prehabilitation promotes an improvement in brain health in colorectal cancer patients prior to starting chemotherapy.
2. We will use neuroscientific measures of brain function (EEG) and cognitive outcomes at baseline and post-chemotherapy to determine if prehabilitation neuroplasticity reduces the negative effects of chemotherapy on the brain.

3.2. Secondary objectives

1. We will measure changes in the FACT-COG questionnaire in colorectal cancer patients at Study Visit 1 and at 3 months after chemotherapy cessation to determine if prehabilitation improves quality of life.

3.3. Outcome measures/endpoints

We will use a range of physiological (CPET, blood panels), neuroscientific (EEG) and psychological (cognitive function test battery, quality of life questionnaire) to determine if our

prehabilitation intervention improves chemo-brain and quality of life in patients with colorectal cancer. Our intervention will be delivered across Lancashire, with the aim of reducing health inequalities and negative health outcomes associated with cancer treatment in the region.

3.4. Primary endpoint/outcome

We will measure brain function at three-time points; baseline (after diagnosis/before prehabilitation, visit 1), after 3-4 weeks prehabilitation (before chemotherapy, visit 2) and after the final round of chemotherapy (3-4 days after infusion of the final round, visit 3). Outline in Figure 1. Chemotherapy typically range from to 2-8 rounds of infusion, with each round being spaced out by 2-3 weeks. The maximum duration of prehabilitation participation is approx. 28 weeks; however, the intervention may be extended (endpoint to visit 3) due to delays to treatment from chemotherapy-related side effects (e.g., low blood cell counts). Thus, time is needed to be given to participants in order to recover, reduce the risk of infection and worsened side effects. Participation in the prehabilitation programme will not influence or delay the timing of any scheduled chemotherapy treatment.

3.5. Secondary endpoint/outcome

There will be a 3 month follow up following chemotherapy to assess changes in quality of life. This data collection is feasible to complete within a 2 year period.

3.6. Table of endpoints/outcomes

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Primary Objective	We will use physiological blood-based markers of (VEGF and BDNF) to establish if prehabilitation promotes an improvement in brain health in colorectal cancer patients prior to starting chemotherapy.	Visit 1 (day 0), Visit 2 (3-4 weeks), Visit 3 (8-24 weeks)
	We will use neuroscientific measures of brain function (electroencephalography (EEG)) and cognitive outcomes at baseline and post-chemotherapy to determine if prehabilitation neuroplasticity reduces the	Visit 1 (day 0), Visit 2 (> 3 days before first chemotherapy), Visit 3 (3-4 days after final chemotherapy)

	negative effects of chemotherapy on the brain.	
Secondary Objectives	We will measure changes in the FACT-COG questionnaire in colorectal cancer patients at Study Visit 1 and at 3 months after chemotherapy cessation to determine if prehabilitation improves cognitive-related quality of life.	Visit 1 (day 0) and Follow Up (3 months following chemotherapy)

4. STUDY DESIGN

A multi-centre randomised control trial (RCT) using a prehabilitation group (exercise and nutrition programme) and a control group (standard care).

5. STUDY SETTING

Participants will be recruited via weekly clinician reviews by the principal investigators at the East Lancashire Teaching Hospitals Trust (Subar), Lancashire Teaching Hospitals NHS Trust (Williamson), and University Hospitals Morecambe Bay NHS Trust (Ton). Recruitment and testing will be conducted at each participating site. These Trusts are affiliated with Lancaster University.

East Lancashire Teaching Hospitals Trust (ELTH): The research environment at the East Lancashire Hospitals NHS Trust is dynamic and rapidly advancing, reflecting its commitment to delivering high-quality, patient-centred research. The East Lancashire Hospitals NHS Trust has expanded its research portfolio over the past decade, actively participating in national and international studies across specialities, including oncology. In collaboration with the NIHR Clinical Research Network Greater Manchester, East Lancashire Hospitals NHS Trust has enhanced its research infrastructure, providing patients with greater access to innovative clinical trials.

Lancashire Teaching Hospital NHS Trust (LTHTR): The research environment at Lancashire Teaching Hospital NHS Trust is nationally recognised, underpinned by its designation as an NIHR Clinical Research Facility in partnership with the Lancashire Care NHS Foundation Trust and Lancaster University. The Trust activity supports over 150 research projects across a broad spectrum of clinical areas, including oncology, consistently surpassing NIHR recruitment targets. The Lancashire Teaching Hospital NHS Trust is committed to research excellence is further demonstrated by its strategic partnership with Lancaster University, fostering a robust clinical academic faculty and supporting the development of early phase clinical trials.

University Hospitals Morecambe Bay NHS Trust (UHMBT): The research environment at University Hospitals Morecambe Bay NHS Trust is collaborative, reinforced by strong partnerships with Lancaster University and the University of Cumbria across its three main hospital sites: Furness General Hospital, Royal Lancaster Infirmary, and Westmorland General Hospital. These formalised agreements focus on joint initiatives in research, innovation, education, and workforce development; aiming to enhance health outcomes across the region. The University Hospitals Morecambe Bay NHS Trust actively participates in clinical research areas of oncology. The Trust research and development department comprises a multidisciplinary team that supports the governance, performance, and quality of research studies.

6. PARTICIPANT ELIGIBILITY CRITERIA

All eligible participants will be given a patient information sheet at the first meeting with their direct care team. This will be determined before the randomisation process. The eligibility criteria were carefully decided to ensure that participants were medically appropriate for selection. Participants will be considered for participation once they meet the inclusion criteria and none of the exclusion criteria, as detailed below.

6.1. Inclusion criteria

The inclusion criteria: participants aged 60-85 years and diagnosis of stage II or III colorectal cancer undergoing chemotherapy, including fluorouracil, capecitabine, or oxaliplatin. Confirmation of patient medical records of participants being scheduled to receive either neoadjuvant or adjuvant chemotherapy, with suitability and tolerability to receive chemotherapy confirmed by their direct care team via patient medical records (e.g., dependent how the patient's health and recovery following surgery). The duration between surgery and the start of chemotherapy is typically 6+ weeks, dependent on the patients' recovery. Participant is fluent in English. Prehabilitation benefits those most who are not habitually active; therefore, exclusion criteria include structured exercise in the 6 months prior to the point of consent. Equal numbers of males and females will be included.

6.2. Exclusion criteria

The exclusion criteria: participants with co-morbidities which impact the metabolic response to exercise, for example diabetes, current musculoskeletal injury/physically rendering them unable to undergo CPET, atrial fibrillation, palliative disease, haematological malignancy, synchronous cancer disease, and lack the capacity to consent. Evidence of pre-existing cognitive impairment, including diagnosis of dementia, other neurodegenerative disorders, or clinically indicated mild cognitive impairment. Participant has no diagnosis of profound hearing loss. Participants without access to the internet within their home will not be able to take part due to the online element of the exercise programme.

Further exclusion criteria related to multivitamins (Forceval): Participants will be excluded if they have hypercalcaemia, haemochromatosis, or allergic to peanut or soya. Concomitant use of medications that interact with Forceval, such as phenytoin or tetracycline antibiotics will also lead to exclusion. Individuals with impaired kidney or liver function (e.g., chronic kidney disease) will not be eligible.

7. STUDY PROCEDURES

7.1. Recruitment

The principal investigator or suitably trained member of the direct care team with delegated duties to do so, at each participating hospital site will review lists of colorectal cancer patients weekly throughout the recruitment window. Potential participants meeting the inclusion criteria will be passed to the lead investigator who will select patients while consulting with the lead clinician of the project (Subar). Recruitment will continue for a period of 8-12 months. At three monthly periods the recruitment rate will be assessed to gauge progress and address recruitment issues.

7.1.1. Screening

Initial eligibility will first be assessed by the principal investigator or a suitably trained and delegated direct care team member at each participating hospital site, who will screen for potential participants meeting the eligibility criteria through patient medical records through on-site system(s) (Section 6.1 and 6.2). Eligible patients must receive adjuvant chemotherapy (after surgery or radiotherapy) confirmed within their treatment plans to be suitable for study participation. This usually refers to the period of six or more weeks from the point at which the patient begins chemotherapy after surgery. If a suitable patient is identified, the principal investigator/member of the direct care team will liaise with the lead investigator to arrange a date and time for screening, coordinated around the patient's oncology appointment. No identifiable patient information will be disclosed at this stage. The direct care team member will briefly introduce the study to the participant in the clinical consultation and obtain verbal consent from the lead investigator to approach them or join the consultation to discuss the study further. The lead investigator will enter the consultation and discuss the study. Patients who expresses interest will be given a study participant information sheet and provide verbal consent to be contacted in a one-week follow-up call. Those who confirm interest within this time period will provide verbal consent to proceed and will begin the formal screening process during the telephone call. Screening questionnaires will include the International Physical Activity Questionnaire (IPAQ) to confirm the absence of structured exercise participation within the previous six months, a key exclusion criterion. The physical activity readiness questionnaire (PAR-Q+) will be used to assess whether participants are safe to exercise with medical clearance, if needed. These questionnaires were completed during telephone calls. The IQCODE and Mini-Cog will be administered to screen for cognitive impairment. The IQCODE assesses self-reported cognitive changes in older adults, and the Mini-Cog self-reported cognitive function. These questionnaires will be sent to the potential participant via an online

link following the telephone call which needs to be returned as soon as possible, before a testing visit can be scheduled (if eligible). Screening questionnaires (IPAQ, PAR-Q+, IQCODE, and Mini-Cog) will be completed before the baseline visit (visit 1) to confirm eligibility. Eligible participants will also be re-contacted, verbal consent to take part will be obtained, and the first research visit will be arranged.

After completing the above, if an individual is found to be ineligible during screening with the lead investigator, efforts will be made to minimise disappointment and reduce distress. They will be encouraged to seek advice about exercise chemotherapy from their direct care team. Additionally, the patient will be directed to the Macmillan Cancer Support to access the Physical Activity and Cancer booklet (https://www.macmillan.org.uk) as well as the exercise guidelines provided by Cancer Research UK (https://www.cancerresearchuk.org). If there are any concerns that the individual expresses from the cognitive function questionnaires (IQCODE or Mini-Cog) then the researcher will advise for them to speak to their direct care team or GP. The researcher can provide details of the questionnaires in a GP letter to provide support. The questionnaires are not diagnostic tools.

7.1.2. Payment

Participants will be reimbursed for travel costs to and from each study visit. Car travel will be reimbursed at a rate of 45p per mile, which reflects with standard mileage reimbursement within the UK. Participants will complete the claims forms to receive payment through the project's funding. Public transport costs will be reimbursed at the exact price paid for tickets or fares. Participants must provide proof of purchase such as a ticket or receipt to ensure transparency and accurate reimbursement across all modes of travel.

7.2. Consent

Verbal consent for the patient to be approached about this study will first be obtained by the principal investigator or direct care team member. The direct care team member will then introduce the lead investigator, who will inform the patient about the study. They patient will be provided with the participant information sheet and ask for verbal consent to follow-up one week later via telephone. At the follow-up telephone call, if the potential participant expresses interest in the study, they will undergo the screening for cognitive function and physical activity. The participant will then receive another call with the outcome of these assessments and, if eligible, arrangements will be made for the first study visit. At Visit 1 (baseline assessment), written informed consent will be obtained, signed, and dated only after the participant has received full information about the study and confirmed their decision. Participants remain free to withdraw from the study at any point without giving a reason and without prejudice.

7.3. The randomisation scheme

Using a permuted block randomiser, we will randomise 86 patients with colorectal cancer into Group 1: Intervention (Prehabilitation; n = 43) and Group 2: Control (Standard Care With No Prehabilitation; n = 43).

7.3.1. Method of implementing the randomisation/allocation sequence

A computer-generated randomised sequence will be performed at the Lancaster University Health Statistics Department. Randomisation will be stratified by sex, staging, and rounds of chemotherapy required. This sequence will be delivered to the investigating team via sealed envelopes. Eligible participants will be randomised on a 1:1 basis to standard care: exercise and nutrition. To ensure 1:1 randomisation allocation, the lead investigator will review allocation at the end of the recruitment period. Allocation details will be contained in sealed envelopes. Eligible patients who have consented will be given a unique participant number. The participants will be randomised after the baseline CPET.

7.4. Baseline data

All participants recruited in both the intervention and control group will undergo a baseline measurement on cardiopulmonary fitness (CPET), blood samples (BDNF and VEGF), brain activity (EEG), cognitive function, and cognitive-related quality of life at visit 1. This baseline data will be collected before group assignment (assigned following CPET).

7.5. Study Intervention and Assessments

7.5.1. Intervention (Prehabilitation)

Exercise Programme

Participants will be taught how to perform exercises safely at home. For the intervention group, the CPET-derived parameters at baseline such as VO_2 peak will be used to prescribe an individualised exercise programme at the precise target moderate intensity for the aerobic components of the intervention (60% of VO_2 peak). This will consider the participants' capabilities to perform the exercises along with functional fitness assessments performed at the baseline visit. The exercise programme will be designed, delivered, and overseen by the lead investigator, who will hold a valid exercise-instructor level 4 qualification in cancer care. The supervised exercise programmes can be delivered by a suitably qualified exercise instructor in the lead investigator's absence. The intervention is underpinned by the Theory of Planned Behaviour, which suggests that intention to exercise is shaped by attitudes, social norms, and perceived controls. To encourage adherence, the approach aims to promote positive beliefs about exercise, provide support from family/friends/peers to reinforce social norms, and enhance perceived control by helping participants integrate physical activity into their routine and environments, especially before starting chemotherapy.

The exercise programme will be performed four times per week before and during chemotherapy. There will be 2 supervision sessions and 2 unsupervised sessions, self-paced sessions that will be performed remotely from the participant's home. An online supervised

exercise sessions will be delivered by the lead investigator. The online sessions will be held on Microsoft Teams call, in which participants will be provided with links to join the call. The exercise programme will involve 40-minute sessions of aerobic and strengthening exercise: to include 5-minute warm up, 20-minute aerobic exercises at moderate intensity (60% $\dot{V}O_2$ peak determined by the CPET), 10-15 minutes of strength/resistance training, followed by a 5-minute cool down. The strengthening exercises will focus on upper and lower muscle groups. Different grades of resistance bands and dumbbells will be provided and used. Alternative and equivalent exercises, through regressions and progressions, will be employed by the lead investigator based on the participants mobility capabilities. For unsupervised sessions, participants will be provided with an exercise booklet, along with exercise videos created for the study, to be performed independently. Participants will be educated in the primary exercises of this programme with progression and regression versions of each exercise. The exercise programme will be updated on a frequent basis but will continuously include the primary exercises with slight variations or the inclusion of similar exercises to prevent participants losing interest in the exercise programme. The participants involvement in the exercise programme and any changes to their individual exercise prescription will be managed by the lead investigator in liaison with the clinical team, if required. For all supervised and unsupervised exercise sessions, participants in the prehabilitation group will be required to have a family member, carer, or friend present to provide immediate assistance in the event of an emergency incident. Participant will provide the contact details of their next of kin to the lead investigator prior to the supervised exercise sessions. A sample of the exercise programme can be found in the appendix.

Psychological Support

In addition to the supervised and unsupervised exercise sessions, participants will receive weekly telephone calls from a member of the research team. These calls will provide behavioural support to help participants achieve their weekly exercise targets and will be structured using the Theory of Planned Behaviour. Discussions will focus on identifying individual motivators and barriers to exercise, with this information used to adapt both the exercise sessions (through progressions and regressions) and the overall approach to supporting each participant's engagement in the intervention. The lead investigator is not a healthcare professional. If any medical concerns are raised during the call, participants will be advised to contact their direct care team or the oncology helpline. If urgent situations they will be instructed to call 999 or 111.

Nutrition

At the first visit (baseline), participants will have a nutritional blood test using the Abridged Scored Patient-Generated Subjective Global Assessment (abPG-SGA)[5] that will collect several markers: full blood count, urea and electrolytes, glucose, liver function tests, magnesium & phosphate, calcium & albumin, clotting function, copper, zinc, selenium, iron, ferritin, B12, folate, manganese, C-reactive protein and vitamin D). The lead investigator will be present at all initial visits and with the research team's support will collect the blood samples. Samples will be labelled before being sent to the pathology laboratory at each participating site. Any queries

regarding results from the nutritional blood tests will be assessed by the dietitian as part of standard of care.

Prehabilitation participants will be given a multivitamin (Forceval Capsules, United Kingdom), to be taken orally once per day throughout the duration of the intervention (before and during chemotherapy). The multivitamins will be taken in addition to the exercise programme. Compliance will be checked by asking participants to bring in used capsule trays at visits 2 and 3.

Forceval capsules are a multivitamin supplement that contains a combination of 24 essential vitamins (Vitamin A, D_2, $B_{1,2,6,12}$, C, E, Biotin, Nicotinamide, Pantothenic Acid and Folic Acid), minerals and trace elements (Calcium, Iron, Copper, Phosphorus, Magnesium, Potassium, Zinc, Iodine, Manganese, Selenium, Chromium, Molybdenum). Each vitamin and mineral plays a vital role in the efficient daily maintenance of the body. Multivitamin administration will be managed and dispensed as part of the standard of care and will be monitored by the participating hospital, with appropriate documentation and oversight. Patients with contraindications to multivitamin use will be excluded prior to enrolment (Section 6.2). Blood samples will be collected in this study and provided to the hospital for routine analysis of nutritional tests (abPG-SGA), in which the research team will collect nutritional marker data relevant to this study following analysis. As part of standard care, the direct care team will have access to the test results and will be able to take action, if required. Notably, only participants within the prehabilitation arm will receive multivitamin supplementation as an adjunct to standard care. Beyond the prescriber, the other members of the direct care team will remain blinded to group allocation to minimise bias. If the research team needs to report any concerns during the collection of blood samples, they will follow the notification cascade steps from the reporting workflow in Section 8.2.

Support During Intervention

To further support participants' efforts to increase their activity and engage in exercise sessions, they will be provided with online resources, including exercise programmes and videos. Participants will also have the option to join a private Microsoft Teams group chat, moderated by the lead investigator. In this group chat:

1. Announcements about weekly dates/times of online supervised exercise sessions will be posted.
2. Participants can indicate which sessions they will attend.
3. All exercise programmes, exercise videos and additional resources will be archived in the group chat for easy access.
4. Links for online supervised exercise sessions will be posted in the chat.

When participants opt in (via the consent form), they are informed that names and email addresses may be visible to others during Microsoft Teams exercise sessions. All participants will be reminded to keep any visible information strictly confidential and to avoid using it for any purpose outside the study, including contacting other participants directly. The use of Microsoft Teams is covered by the University's existing Office 365 data protection documentation,

ensuring full compliance with institutional and legal requirements. This is further explained in the Data Protection Impact Assessment (DPIA). Members of the Microsoft Teams group will include the lead investigator and participants in the prehabilitation group.
If a participant wishes to opt out of the Microsoft Teams group, they will still receive all the same resources, updates, and Teams call links (for the supervised exercise sessions) via email.

Habitual Activity

All participants, including those in the standard care group, will have their habitual physical activity measured using the activity device (ActiGraph wGT3X-BT1, Ametris, Florida). This device is a triaxial accelerometer that captures bodily acceleration at a sampling rate of 30 Hz. Data will be processed using ActiLife software, with step counts derived using the Freedson algorithm and extracted in 10-second epochs. Participants will wear the device on the non-dominant wrist for seven consecutive days during three distinct periods: the first week of prehabilitation before chemotherapy, the first week of chemotherapy, and the week before the final chemotherapy cycle. The device will provide measures of total movement, moderate to vigorous physical activity (minutes), non-sedentary time (minutes), and step count (steps per day) over each 7-day period. Data from these measures will be transferred directly from the device when participants return to their participating hospital site. Habitual physical activity measures obtained from this device will be used to compare the prehabilitation and standard care groups.
The prehabilitation group will use the Xiaomi Smart Band 9 (Xiaomi, China) to motivate and monitor activity during the exercise programme (both supervised and unsupervised) and daily living activities. This wrist-worn device includes an accelerometer, gyroscope, six-axis motion sensor, heart rate sensor (photoplethysmography, PPG), and blood oxygen sensor. Participants will wear the device on their dominant hand throughout the intervention. It provides objective quantification of total daily activity through step count (steps per day), distance (metres), standing time (minutes), and time spent in moderate to high-intensity activity (minutes). Moderate intensity reflects activity that elevates heart rate to 50–75% of the individual's estimated maximum, while high intensity exceeds 70% of maximum, making conversation difficult. Based on established thresholds for step count, fewer than 3,000 steps indicates low activity, and 3,000–10,000 steps indicates moderate activity.
Data collection will be synchronised with the fitness application, which can remotely export measures every two weeks as CSV files accessible only to the research team. The lead investigator will provide prompts during supervised sessions and check-in calls to encourage device use. If participants experience skin irritation from the silicone straps, these can be replaced with nylon straps. Any day containing null values will be treated as non-wear or device failure. The device will be collected at the final visit (visit 3). If a participant withdraws from the study, they will be asked to return the device to their participating hospital or, alternatively, will be provided with a pre-paid postage envelope.

Adherence To The Intervention

Adherence to the intervention will be assessed in four ways: (1) marking attendance at supervised sessions, (2) weekly check-ins during telephone calls, (3) null data values from the

Xiaomi device, and (4) data from the activity device (ActiGraph) measuring minutes of moderate intensity or greater activity, excluding habitual activity outside prescribed sessions.

Ongoing care

Both groups will be seen in the outpatient setting at time intervals predetermined by their direct care team. Each participant's cancer care plan will not be affected by study visits or the prehabilitation programme (intervention group). Visits will be arranged, where possible, to coincide with appointments with the direct care team to minimise the burden of travel.

7.5.2. Assessments

In summary, cardiopulmonary fitness (CPET), blood sampling, brain activity, cognitive function, and cognitive-related quality of life will be assessed at visit 1 (baseline). Visits 2 and 3 will include repeated assessments of cardiorespiratory fitness, blood sampling, brain activity, and cognitive function. At the three-month follow-up after the final chemotherapy session, cognitive-related quality of life will be reassessed via telephone or post. Visit 1 (baseline) takes place 3–4 weeks before chemotherapy (time-to-treatment). Visit 2 occurs within 72 hours of starting chemotherapy and visit 3 will take place 3–4 days after the last chemotherapy session. See Figure 1.

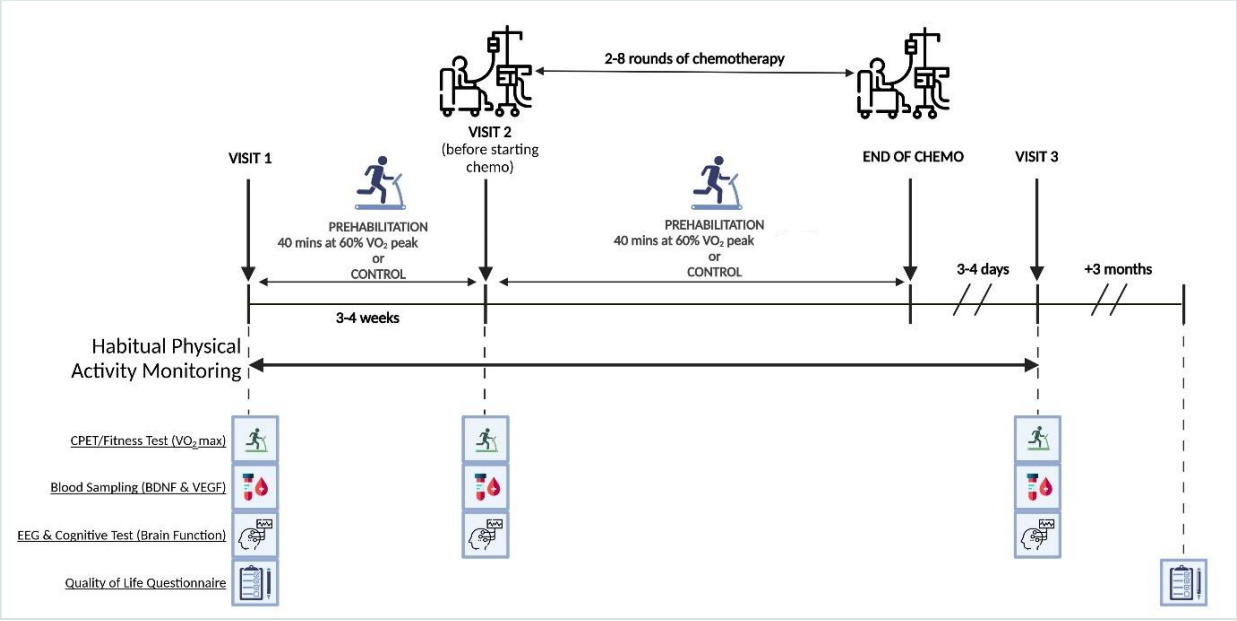


Figure 1. Illustration of the timeline of the study visits, assessments, and intervention.

Cardiopulmonary Exercise Test (CPET) & Functional Fitness

Participants will be advised to take their regular medication but to avoid caffeine, alcohol, cigarettes, and strenuous exercise on the day of each visit. For two hours prior to testing, patients must fast except for water. They should wear comfortable sports clothing and appropriate shoes. The CPET will be performed using a cycle ergometer at each participating site. Cycle ergometry allows accurate determination of work rate, enabling evaluation of the

VO2–work rate relationship. Gaseous analysis will be conducted using a gas analyser, and continuous oxygen saturation will be monitored with a pulse oximeter.

After explaining the test protocol to the participant, a resting data collection period (rest phase/baseline) will be followed by resistance-free pedalling (unloaded cycling phase), then a continuous, gradual, uniform increase in work rate until the participant reaches their limit of tolerance (incremental phase). Pedalling frequency will be maintained between 60 and 80 rotations per minute. Increments will be adjusted based on the participant's physical fitness level, aiming to reach maximal effort.

Additionally, overall functional fitness will be assessed prior to CPET to track changes in participants' abilities across testing visits. This will allow personalised adjustments to the exercise programme during prehabilitation, based on any functional limitations. Following the Senior Fitness Test protocol[8], participants will perform sit-to-stand tests, arm curls, grip strength using a dynamometer, sit and reach, back scratch, up-and-go test, six-minute walk test, and three-minute step test. Their scores will be compared to age- and sex-specific norms (men and women aged 60–64, 65–69, 70–74, 75–79, 80–84, and 85–89 years) outlined by Jones and Rikli[8]. Normal score ranges and test descriptions are provided in the appendix.

Brain Activity and Cognitive Function

The participant will be fitted with an EEG cap using saline-based hydro-links during each testing visit at the participating sites. The participant will then complete a resting measure, followed by a modified change detection task to assess memory while EEG activity is recorded.

Electrophysiological measures of brain activity will be used to assess brain function and are sensitive to neural changes resulting from chemotherapy-induced cognitive impairment. In chemotherapy-induced cognitive impairment, there is an overall slowing of brain activity. Using the EEG system, brain activity during the cognitive test battery will be recorded throughout each testing session. Subsequent analysis will focus on frequency band oscillations, including theta (4–8 Hertz) and alpha (8–13 Hertz) bands. Power spectral density will be calculated to quantify the relative contribution of each band, enabling identification of neural activation patterns associated with cognitive performance in subdomains such as executive function, attention, memory, and processing speed. Specific regions of interest will be defined to examine spatial variation in oscillatory activity; however, all hydro-link sites will be assessed.

The cognitive test battery will be objectively assessed using the National Institutes of Health (NIH) Toolbox Cognitive Domain (http://nihtoolbox.org/). This toolbox comprises a series of researcher-administered, computer-adaptive tests that take approximately 20 minutes to complete. The adaptive feature of the tests is designed to minimise practice effects, as well as floor and ceiling effects. We will examine age-standardised scores from four tests to assess all subdomains: executive function and attention will be assessed using the Flanker Inhibitory Control and Attention Test; memory will be assessed using the List Sorting Working Memory Test; and processing speed will be assessed using the Oral Symbol Digit Test.

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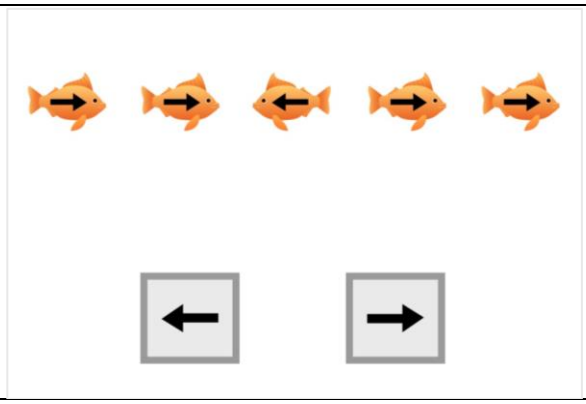
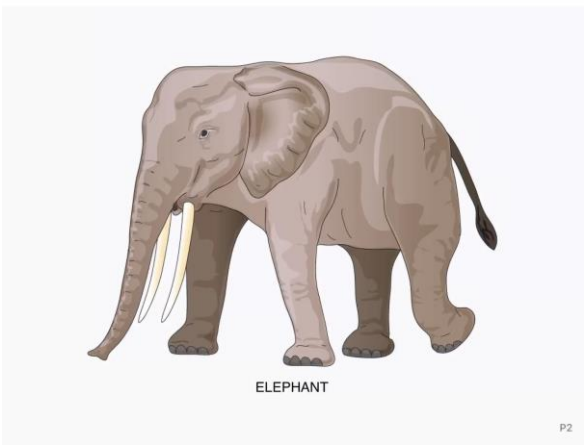
To ensure that any deficits in auditory instructions and cues are not due to hearing loss, an audition test (Words-In-Noise Test) will be used to differentiate between hearing loss and chemotherapy-related cognitive impairment. The tests will be administered by the researcher, and participants will use a digital tablet with audio guidance for each test. Each test will take between three and seven minutes to complete.

The EEG and cognitive assessment will last approximately 50 minutes: 15 minutes for setup and 35 minutes to complete the resting measure and cognitive test battery, with breaks between tests (see Figure 3). Detailed descriptions of these tests have been previously published, and the battery has been validated in adults and normed for individuals aged 3 to 85 years[9,10].



Flanker Inhibitory Control and Attention Test

The participant is asked to focus on a particular stimulus (centre fish) while inhibiting attention to the stimuli flanking it.



List Sorting Working Memory Test

The participant is asked to recall and sequence different stimuli that are presented visually and via audio.

Oral Symbol Digit Test

Participants are asked to orally call out the number that corresponds to each symbol in a grid.

Figure 3. Illustration of what participants will see for each cognitive sub-domain being assessed.

Blood Samples

Chronic exercise can increase brain-derived neurotrophic factor (BDNF), which in turn has neurotrophic and neuroprotective properties that can improve cognitive function. BDNF and vascular endothelial growth factor (VEGF) will be measured using an Enzyme-Linked Immunosorbent Assay (ELISA) from blood serum. The lead investigator will be present at all initial visits, and a research nurse or suitably trained staff member will collect, process, and label the samples before storing them at each participating site. All samples will be transported via courier from each site to Lancaster University for ELISA analysis following the final participant test visit.

Blood will be drawn by site staff from a cubital vein into a S-Monovette 7.5 ml Z tube (with clotting activator; Sarstedt), left to coagulate for 30 minutes at room temperature, and centrifuged at 2000 g at room temperature for 10 minutes. The serum supernatant will be stored at -80°C in 0.5 ml aliquots within one hour of blood sampling. Blood samples will be used to determine BDNF and VEGF levels. The timing of blood samples will be consistent across testing visits at each site (± 2 hours).

Cognitive-Related Quality of Life

To evaluate cognitive-related quality of life, we will use the FACT-Cog questionnaire. This validated tool is currently used to measure cognitive-related quality of life in cancer patients and its impact on daily activities. The questionnaire includes several subscales: perceived cognitive impairment, perceived cognitive abilities, impact on quality of life, and comments from others. Each item is scored from 0 (not at all) to 4 (very much), with some items reverse scored.

We will measure changes in cognitive-related quality of life using the FACT-Cog questionnaire in colorectal cancer patients at Study Visit 1 and again at three months after chemotherapy cessation to determine whether prehabilitation improves quality of life post-treatment.

7.6. Withdrawal criteria

Any study participant can withdraw from the study at any time by contacting the lead investigator or any member of the research team, without providing a reason and without affecting their legal rights. If they withdraw, the information collected up to that point cannot be erased and may still be used in the project analysis.

7.7. Storage and analysis of clinical samples

Lancaster University does not hold a Human Tissue License. However, according to the Human Tissue Authority, blood serum is not classified as relevant material when extracted using standardised methods that guarantee the sample is completely acellular. This study will use a method that renders the material acellular. Therefore, there are no external storage regulations for serum. Nonetheless, Lancaster University maintains its own sample tracking database, and samples will be analysed and stored under the NHS Research Ethics

Committee's Favourable Opinion. The serum supernatant will be stored at -80°C in 0.5 ml aliquots within one hour of centrifugation following blood sampling. All samples will be transported by a licensed biological samples courier from each participating site to Lancaster University for analysis using an Enzyme-Linked Immunosorbent Assay (ELISA) on blood serum. No samples will be stored outside the listed institutions (Lancaster University and participating hospitals involved in this study). Samples will not be shared with other institutions, either within or outside the UK.

Following Lancaster University's disposal procedures, blood samples will be handled as hazardous clinical waste, disposed of via clinical waste bins, and destroyed by incineration. All blood samples will be destroyed once analyses of blood-based markers of brain health via ELISAs are complete at the end of the study. All procedures will comply with the seventh revision of the Declaration of Helsinki and Good Clinical Practice guidelines. Blood samples will be stored in accordance with Human Tissue Authority Codes of Practice. The study protocol will be preregistered on the ISRCTN registry, and findings will be published within 12 months of trial completion. The ISRCTN registry will be updated throughout the study and with any outputs generated.

7.8. Definition of the end of Study

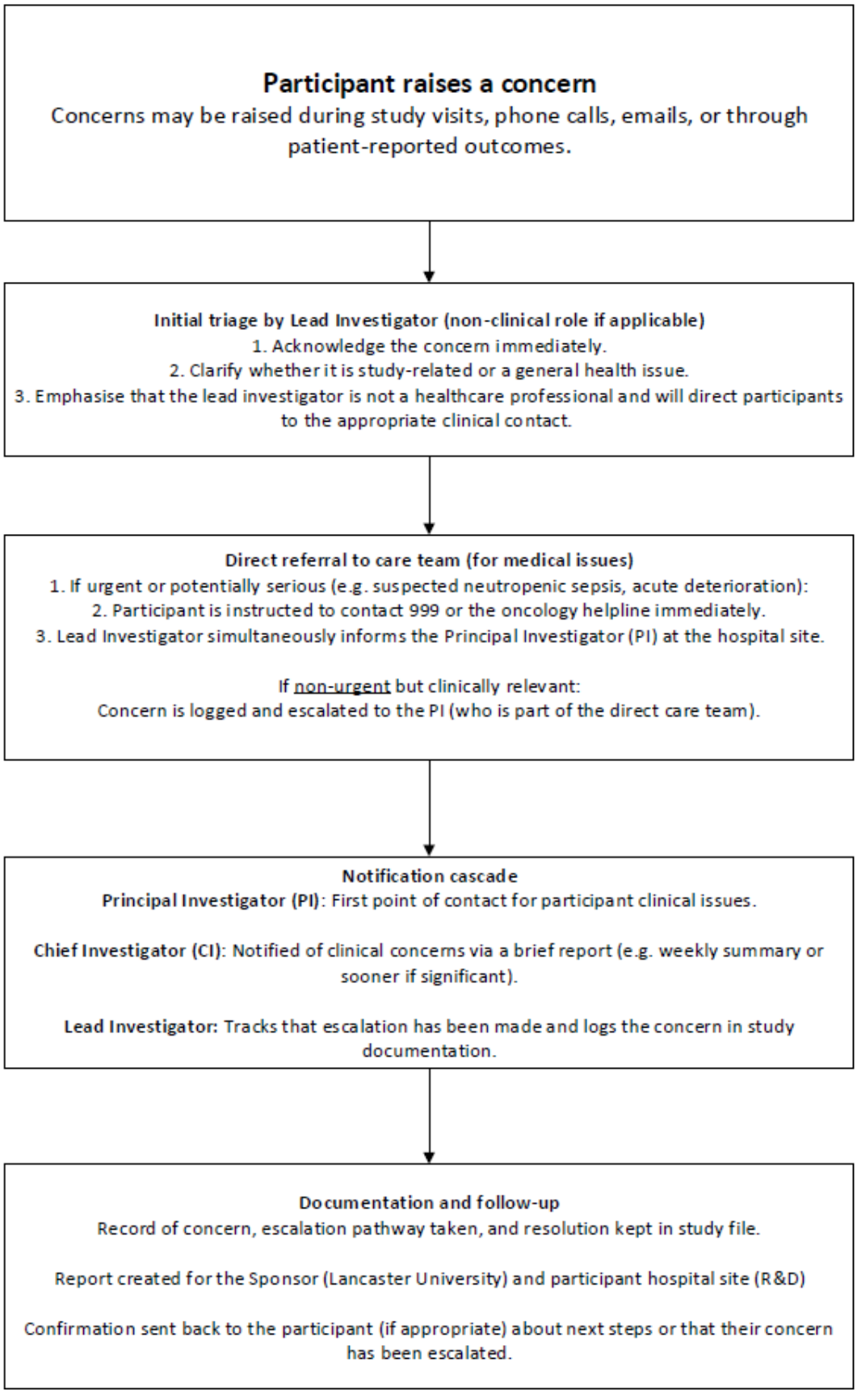
The final follow-up at three months, using the quality of life questionnaire (FACT-Cog) completed by the last participant, will signal the end of the study. However, not all participants will have identical cancer treatment plans, as the number of chemotherapies rounds and their duration may vary.

8. SAFETY REPORTING

8.1. Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant to whom an intervention has been administered, including occurrences which are not necessarily caused by or related to that intervention.
Adverse Reaction (AR)	An untoward and unintended response in a participant to the intervention
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which might have caused death if it were more severe.
Serious Adverse Reaction (SAR)	An adverse event that is both serious and, in the opinion of the reporting investigator, believed with reasonable probability to be due to one of the Study treatments, based on the information provided.

8.2. Workflow of reporting concerns to the direct care team and documentation



9. STATISTICS AND DATA ANALYSIS

9.1. Sample size calculation

Sample sizes were calculated in G*Power based on repeated measures mixed models to detect medium effect sizes (f = 0.25), with a power of 0.8 and an alpha of 0.01. A sample size of 34 participants per group meets the power criteria. To allow for 20% attrition, 43 participants per group will be recruited. While the power calculation is based on the primary outcome, the study is sufficiently powered for each of the secondary outcomes.

9.2. Planned recruitment rate

Total recruitment rate will be 86: 43 participants in the interventional group and 43 participants in the control group.

9.3. Statistical analysis plan

9.3.1. Summary of baseline data and flow of patients

Baseline comparability between the randomised groups will be assessed descriptively, without statistical testing, in accordance with CONSORT guidelines for randomised trials. Variables used to assess baseline characteristics will include:

- Age (continuous)
- Sex (categorical: male/female)
- Cancer Stage (categorical: stage II and III)
- Chemotherapy regimen (categorical)
- Anthropometrics (continuous: e.g., height and weight)
- Comorbidity status (categorical)
- Education (categorical)
- IPAQ physical activity level and PAR-Q (categorical)
- Mini-Cog score (ordinal)

These variables will be summarised using appropriate descriptive statistics: means and standard deviations for continuous normally distributed data, medians, and interquartile ranges for non-normally distributed data, and counts and percentages for categorical variables. No inferential statistical comparisons will be conducted on baseline data, in line with best practice in RCT reporting.

The flow of participants through each stage of the trial (enrolment, allocation, follow-up, analysis) will be presented in a CONSORT flow diagram. This will include the number of participants assessed for eligibility, excluded (with reasons), randomised, receiving the allocated intervention, lost to follow-up, and included in the final analyses. Reasons for exclusion or withdrawal will be recorded and reported where available.

9.3.2. Primary outcome analysis

Anonymised data spreadsheets will be password protected and transferred on encrypted storage devices to Lancaster University for analysis. All data will be analysed on Lancaster University computers and backed up to the Lancaster University servers.

We will employ mixed ANCOVAs with Group (control vs prehabilitation) as the between-subjects factor and Time (Study Visit 1, Study Visit 2) as the within-subjects factor, with physiological outcomes as the dependent variables. Staging will be included as a covariate. Significance level will be corrected to account for multiple testing. Additionally, we will employ mixed ANCOVAs with Group (control vs prehabilitation) as the between-subjects factor and Time (Study Visit 1, Study Visit 3) as the within-subjects factor. Cancer staging and rounds of chemotherapy will be used as covariates, with EEG spectral ratios/cognitive outcomes as the dependent variables. The threshold of significance will be corrected to account for multiple testing.

9.3.3. Secondary outcome analysis

We will employ mixed ANCOVAs with Group (control vs prehabilitation) as the between-subjects factor and Time (Study Visit 1, 3-month follow-up after chemotherapy cessation) as the within-subjects factor, with quality-of-life score on the FACT-Cog as the dependent variable. Staging and rounds of chemotherapy will be included as covariates.

9.4. Procedure(s) to account for missing or spurious data

Efforts will be made throughout the study to minimise missing data. Strategies include flexible scheduling of study visits, where possible, and prompt data entry with certification against source documents. The reasons for any missing data will be systematically recorded, including participant withdrawal, clinical contraindications loss to follow-up, or technical issues.

10. DATA MANAGEMENT

10.1. Data collection tools and source document identification

Participants will be issued a unique participant identification number. All study encounters, including consent, will be recorded in the participants' native hospital notes. Data will be entered into a purpose-built master database held on a secure NHS server. Members of the immediate research team (lead investigator and co-investigators) will be responsible for entering this data. Physical paper copies will also be filed in a Trial Master File and stored in a designated locked cabinet in the principal lead's office at each participating site.

Some electronic data will be automatically generated and transcribed into the master spreadsheet. Laboratory analysis data will be stored on secure Lancaster University computer servers.

Questionnaires will be issued to participants at their baseline visit and requested to be completed. If participants are unable to complete them on the day, pre-paid envelopes will be provided for return. The second round of questionnaires will be issued at the three-month

follow-up assessment (FACT-Cog) and participants will be asked to return them via pre-paid envelopes if they are unable to complete them over the telephone. A letter will accompany the questionnaires, indicating that completion is voluntary and there is no obligation should the questionnaire cause anxiety or distress. Contact details of the lead investigator will be provided for participants wishing to discuss any aspect of the questionnaire.

10.2. Data handling and record keeping

The research team will preserve the confidentiality of participants in accordance with the Data Protection Act. All data collected will be accurately recorded and securely stored by the team, and no identifiable information will be accessible to individuals outside the study team. Clinical, demographic, CPET, blood panel, and EEG data will be anonymised at the point of collection before being transferred outside the participating hospital's clinical areas to Lancaster University. Data will be identified only by ID numbers, with personal information accessible only via a code held by the lead and chief investigators.

All data transfers will be conducted via the secure, encrypted university cloud (OneDrive) managed by Lancaster University and verified by the participating hospital site's IT team. The only non-digital data will be the signed consent forms, which will be securely stored in the principal lead's office at each participating site and transferred to the chief investigator's office at Lancaster University once all visit assessments are complete. All collected data will reside on Lancaster University's secure, encrypted network, accessible only through password-protected computers within the university. After the study concludes, data will be stored for the minimum period specified in the protocol and then destroyed accordingly.

Participants retain the right to withdraw from the study at any time without providing a reason. If a reason is given, it will be recorded as well as any 'loss to follow-up.' Participants will be asked to consent to the retention of any data collected up to the point of withdrawal.

10.3. Access to Data

There will be no access to identifiable participant data outside the research team at any stage of the project. Trust guidelines on data protection and General Data Protection Regulations (GDPR) guidance will be adhered.

11. ETHICAL AND REGULATORY CONSIDERATIONS

11.1. Research Ethics Committee (REC) review & reports

Before the initiation of the trial, all trial-related materials—including consent forms, the participant information sheet (PIS), protocol, and other relevant documentation—will be submitted to the relevant Research Ethics Committee (REC) for approval, as well as to the Health Research Authority via the Integrated Research Application System (IRAS).
Any subsequent amendments to these documents will be submitted for further approval.
Participants' rights to refuse participation in the trial without providing a reason must be

respected. After a participant has entered the trial, the clinician remains free to provide alternative treatment to that specified in the protocol at any stage if they consider it to be in the participant's best interest. The reasons for doing so must be documented.
Following randomisation, participants cannot change their allocated group (i.e., prehabilitation or standard care), and data will be analysed according to this allocation. However, participants remain free to withdraw from testing, the intervention (prehabilitation group), or follow-up at any time without giving a reason and without prejudice to their treatment.

11.2. Public and Patient Involvement (PPI)

The PPI steering committee includes four individuals with lived experience of colorectal cancer (including chemotherapy and "brain fog"-type symptoms) and two carers of people undergoing chemotherapy. Initial meetings have helped shape the study design, including the delivery of the intervention and testing visits. For example, the committee reviewed the frequency and duration of the proposed testing sessions to ensure they are realistic alongside treatment schedules and minimise participant burden. Reflections from these early discussions have directly informed considerations of participant burden, such as scheduling tests flexibly around hospital appointments (where possible), providing comprehensive instructions for home-based exercises (e.g., offering different formats such as programme booklets and videos), recommending multivitamin capsules once a day rather than a drink version, and addressing barriers and facilitators to exercising at home.
The PPI steering committee has reviewed participant-related documents (e.g., participant information sheet and consent form) to ensure they are accessible, sensitive, and avoid overwhelming language. The committee will continue to meet throughout the study and advise on strategies to support participants who may experience chemotherapy-related symptoms. Current recommendations include offering rest breaks, splitting sessions into shorter segments (e.g., aerobic and resistance exercises separated during the day instead of back-to-back), and providing prompts for study activities.
All meetings will be chaired by the lead investigator to ensure effective time management and that every voice is heard. Members will receive INVOLVE rates of payment, and travel expenses will be reimbursed. A support plan will be implemented to encourage engagement and minimise burden for steering group members. At the end of the study, members will receive the final report and will be invited to contribute to dissemination plans and outputs to ensure findings are communicated in a way that is meaningful to patients and carers. All patient-facing documents will be reviewed by the steering group for any submissions or amendments to NHS ethics.

11.3. Regulatory Compliance

The trial will be conducted in compliance with the approved protocol, the Declaration of Helsinki (2013), the principals of Good Clinical Practice (2016), the UK Data Protection Act, and the UK Policy Framework for Health and Social Care Research.

11.4. Protocol compliance

The trial steering committee (TSC) will be established by and operate under the authority of Lancaster University [Sponsor]. Membership will comprise the lead investigator, chief investigator, co-investigators, three independent academics external to the study team, and a PPI Advisor drawn from the PPI Steering Committee. Mrs Becky Gordon, as the Sponsor's representative, will also attend TSC meetings to maintain direct oversight.

The TSC is authorised to provide independent oversight of the study's conduct, progress, and compliance with protocol, ethics, and regulatory requirements. It will advise the lead investigator and research team on operational issues and emerging challenges, such as risks to participant safety, data integrity, and overall study delivery, and recommend mitigation actions as needed. The TSC will report concerns or escalate decisions to the Sponsor or Funder [North West Cancer Research] when necessary to ensure proper governance is maintained.

An authorised individual, external to the project and not employed by Lancaster University, will be responsible for data monitoring. This includes overseeing data quality, participant safety, and overall trial integrity by reviewing data for accuracy, completeness, and compliance with protocols. In the event of concerns, this individual will conduct unbiased interim analyses, review safety data, identify potential risks or benefits, and make recommendations for protocol modifications or, if necessary, trial termination to ensure participant safety and the scientific validity of the study. The lead and chief investigators, along with the lead clinician, will support this authorised individual in monitoring activities as required.

11.5. Data protection and patient confidentiality

The study will be conducted in compliance with the approved protocol, the Declaration of Helsinki (2013), and the UK Data Protection Act. The principal investigator, or a suitably trained member of the direct care team with delegated duties, will review lists of colorectal cancer patients (via medical records) weekly throughout the recruitment period. Patients will be given the PIS at their initial outpatient clinic appointment. Verbal consent will be obtained to contact potential participants by phone. The lead investigator of the research team will follow up via telephone and, if the prospective participant agrees to take part, obtain informed consent at the participant's baseline assessment visit. The lead investigator will code the samples; no identifying information will be available to anyone outside the research team. All documentation will be accurately recorded and secured on password-protected databases and in a physically held site file.

Participants retain the right to withdraw from the study at any time without providing a reason. If a reason is given, it will be recorded along with any 'loss to follow-up.' Participants will be asked to consent to the retention of any data collected up to the point of withdrawal.

Blood samples will be transported to Lancaster University for data analysis and will not be shared externally outside the research team for additional research. All data will be stored only on Lancaster University computers, and loaned laptops will be used to access data, with access restricted to authorised research members involved in this study.

11.6. Financial and other competing interests for the Chief investigator, Principal Investigators at each site and committee members for the overall study management

On behalf of all investigators, we declare that we have developed the research questions and authored the research proposal herein. We further have no conflicts of interest to declare relating to this work.

11.7. Amendments

If an amendment is needed during a study, the Amendment Tool must be completed to determine its category (A, B or C), which reflects its impact on participating sites; separate from whether the amendment is substantial or non-substantial. The Sponsor, Lancaster University, is responsible for authorising the amendment and completing the declaration section of the Amendment Tool; no amendment should be submitted without prior sponsor authorisation.

Once submitted, the amendment and relevant documents must be shared with affected participating sites. Category A and B amendments require to be reviewed within 35 days, assess whether they can support and implement the changes. Category C amendments still need to be shared to take appropriate administrative action, but they do not require a capacity and capability review.

Communication to affected participating sites is important to agree implementations plans, discuss any impact on activities or costs, and address concerns. If a site cannot support the amendment, options such as site closure should be discussed. Investigators and participating sites should work to the most recent approved documents relevant to their role in the study.

11.8. Post Study Care

The chief investigator will have control of the data and act as the custodian for all data generated by the study and will be responsible for ensuring the secure storage of this data for a period of 12-36 months following the end of the study; this includes data from CPET, EEG, cognitive assessments, and quality of life measures.

11.9. Access To The Final Study Dataset

Only the lead and chief investigators and the research team will have access to the code which will be linked to patient identifiable details kept in the Trial Master File.

12. DISSEMINIATION POLICY

12.1. Dissemination policy

This work is expected to yield several publications in reputable international journals, and the findings will be presented at regional and international conferences. Following study completion, we will host a Results Open Evening for participants, GPs, scientists, and the general public. If the intervention is successful, we will have identified a potential target group of patients likely to benefit from prehabilitation and will seek to implement our intervention at scale.

12.2. Authorship eligibility guidelines and any intended use of professional writers

Authorship on the overall study report will be granted to the Lead Investigator (first author), Chief Investigator (senior/final author), and Co-Investigators (co-authors) based on substantial contributions to the study's design, data acquisition, analysis or interpretation, and manuscript preparation. No professional medical writers will be involved, or if they are, they will be appropriately acknowledged for their contributions.

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14. APPENDICES

Appendix –Schedule of Assessment

Procedures	Visits (3 visits & follow up)				
	Screening	Baseline	Assessments		Follow Up
		Visit 1	Visit 2	Visit 3	
Eligibility Assessment	/				
Informed Consent	/	/			
Screening Questionnaires	/				
Demographics	/	/			
Medical History	/				
Physical Examination		/			
Randomisation		/			
Functional Fitness		/	/	/	
Cardiopulmonary Exercise Test		/	/	/	
Randomisation		/			
Electroencephalogram		/	/	/	
Cognitive Test Battery		/	/	/	
Blood Samples		/	/	/	
Quality Of Life Questionnaire		/			/
Nutrition Assessment		/	/	/	
Physical Activity Monitor		/	/	/	

Appendix – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

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Appendix - Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE), Self-Report Version (Patient)

Questionnaire on Cognitive Decline in the Elderly (Short IQCODE, Self Report)

You will be asked 16 questions about everyday situations relating to memory and the management of daily tasks. You will be asked if there have been any changes in the way you respond/manage in these contexts compared to ten years ago (2016). Each question is scored from 1 (much improved) to 5 (much worse).

Compared with 10 years ago (201_), how are you at...

Remembering things about family and friends - eg, occupations, birthdays, addresses?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Remembering things that have happened recently?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Recalling conversations a few days later?

- Much Improved
- A bit improved
- Not much change
- A bit worse
- Much worse

Remembering your address and telephone number?

- Much Improved
- A bit improved
- Not much change
- A bit worse
- Much worse

Remembering what day and month it is?

- Much Improved
- A bit improved
- Not much change
- A bit worse
- Much worse

Remembering where things are usually kept?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Remembering where to find things which have been put in a different place from usual?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Knowing how to work familiar machines around the house?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Learning to use a new gadget or machine around the house?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Learning new things in general?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Following a story in a book or on TV?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Making decisions on everyday matters?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Handling money for shopping?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Handling financial matters - eg, the pension, dealing with the bank?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Handling other everyday arithmetic problems - eg, knowing how much food to buy, knowing how long between visits from family or friends?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

Using your intelligence to understand what is going on and to reason things through?

- ○ Much Improved
- ○ A bit improved
- ○ Not much change
- ○ A bit worse
- ○ Much worse

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Appendix – Mini-Cog

Mini-Cog©

Instructions for Administration & Scoring

ID:_____ Date:_____

Step 1: Three Word Registration

Look directly at person and say, "Please listen carefully. I am going to say three words that I want you to repeat back to me now and try to remember. The words are [select a list of words from the versions below]. Please say them for me now." If the person is unable to repeat the words after three attempts, move on to Step 2 (clock drawing).

The following and other word lists have been used in one or more clinical studies.[1-3] For repeated administrations, use of an alternative word list is recommended.

Version 1	Version 2	Version 3	Version 4	Version 5	Version 6
Banana	Leader	Village	River	Captain	Daughter
Sunrise	Season	Kitchen	Nation	Garden	Heaven
Chair	Table	Baby	Finger	Picture	Mountain

Step 2: Clock Drawing

Say: "Next, I want you to draw a clock for me. First, put in all of the numbers where they go." When that is completed, say: "Now, set the hands to 10 past 11."

Use preprinted circle (see next page) for this exercise. Repeat instructions as needed as this is not a memory test. Move to Step 3 if the clock is not complete within three minutes.

Step 3: Three Word Recall

Ask the person to recall the three words you stated in Step 1. Say: "What were the three words I asked you to remember?" Record the word list version number and the person's answers below.

Word List Version:_____ Person's Answers:_____ _____ _____

Scoring

Word Recall: _____ (0-3 points)	1 point for each word spontaneously recalled without cueing.
Clock Draw: _____ (0 or 2 points)	Normal clock = 2 points. A normal clock has all numbers placed in the correct sequence and approximately correct position (e.g., 12, 3, 6 and 9 are in anchor positions) with no missing or duplicate numbers. Hands are pointing to the 11 and 2 (11:10). Hand length is not scored. Inability or refusal to draw a clock (abnormal) = 0 points.
Total Score: _____ (0-5 points)	Total score = Word Recall score + Clock Draw score. A cut point of <3 on the Mini-Cog™ has been validated for dementia screening, but many individuals with clinically meaningful cognitive impairment will score higher. When greater sensitivity is desired, a cut point of <4 is recommended as it may indicate a need for further evaluation of cognitive status.

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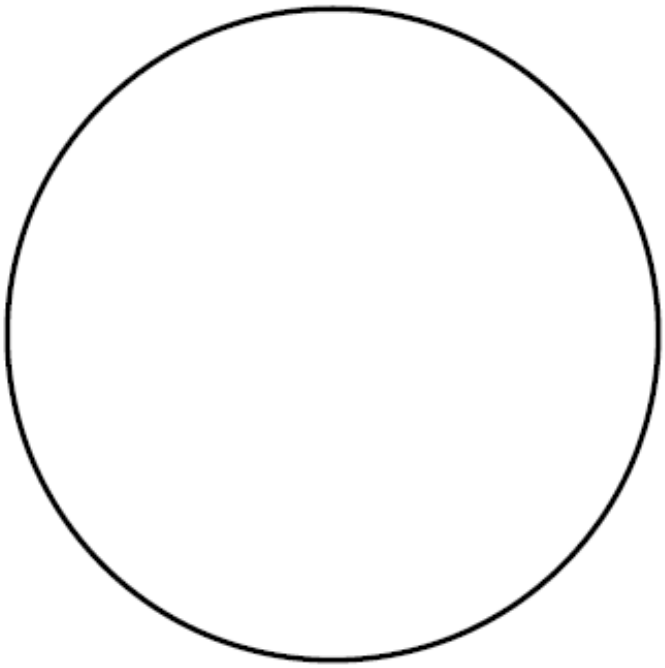
Clock Drawing

ID:_____ Date:_____



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Appendix – International Physical Activity Questionnaire (IPAQ)

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (October 2002)

LONG LAST 7 DAYS SELF-ADMINISTERED FORMAT

FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS (15-69 years)

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health–related physical activity.

Background on IPAQ

The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken across 12 countries (14 sites) during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages, and are suitable for national population-based prevalence studies of participation in physical activity.

Using IPAQ

Use of the IPAQ instruments for monitoring and research purposes is encouraged. It is recommended that no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments.

Translation from English and Cultural Adaptation

Translation from English is encouraged to facilitate worldwide use of IPAQ. Information on the availability of IPAQ in different languages can be obtained at www.ipaq.ki.se. If a new translation is undertaken we highly recommend using the prescribed back translation methods available on the IPAQ website. If possible please consider making your translated version of IPAQ available to others by contributing it to the IPAQ website. Further details on translation and cultural adaptation can be downloaded from the website.

Further Developments of IPAQ

International collaboration on IPAQ is on-going and an ***International Physical Activity Prevalence Study*** is in progress. For further information see the IPAQ website.

More Information

More detailed information on the IPAQ process and the research methods used in the development of IPAQ instruments is available at www.ipaq.ki.se and Booth, M.L. (2000). *Assessment of Physical Activity: An International Perspective.* Research Quarterly for Exercise and Sport, 71 (2): s114-20. Other scientific publications and presentations on the use of IPAQ are summarized on the website.

LONG LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised October 2002.

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INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

   ☐ Yes

   ☐ No → ***Skip to PART 2: TRANSPORTATION***

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

   _____ **days per week**

   ☐ No vigorous job-related physical activity → ***Skip to question 4***

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

   _____ **hours per day**
   _____ **minutes per day**

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

   _____ **days per week**

   ☐ No moderate job-related physical activity → ***Skip to question 6***

LONG LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised October 2002.

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

_____ **hours per day**
_____ **minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

_____ **days per week**

☐ No job-related walking → ***Skip to PART 2: TRANSPORTATION***

7. How much time did you usually spend on one of those days **walking** as part of your work?

_____ **hours per day**
_____ **minutes per day**

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

_____ **days per week**

☐ No traveling in a motor vehicle → ***Skip to question 10***

9. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

_____ **hours per day**
_____ **minutes per day**

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No bicycling from place to place → ***Skip to question 12***

LONG LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised October 2002.

11. How much time did you usually spend on one of those days to **bicycle** from place to place?

_____ **hours per day**
_____ **minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No walking from place to place → ***Skip to PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY***

13. How much time did you usually spend on one of those days **walking** from place to place?

_____ **hours per day**
_____ **minutes per day**

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

_____ **days per week**

☐ No vigorous activity in garden or yard → ***Skip to question 16***

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

_____ **days per week**

☐ No moderate activity in garden or yard → ***Skip to question 18***

LONG LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised October 2002.

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

_____ **days per week**

☐ No moderate activity inside home → ***Skip to PART 4: RECREATION, SPORT AND LEISURE-TIME PHYSICAL ACTIVITY***

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

_____ **hours per day**
_____ **minutes per day**

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

_____ **days per week**

☐ No walking in leisure time → ***Skip to question 22***

21. How much time did you usually spend on one of those days **walking** in your leisure time?

_____ **hours per day**
_____ **minutes per day**

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

_____ **days per week**

☐ No vigorous activity in leisure time → ***Skip to question 24***

LONG LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised October 2002.

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

_____ **hours per day**
_____ **minutes per day**

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

_____ **days per week**

☐ No moderate activity in leisure time → ***Skip to PART 5: TIME SPENT SITTING***

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?
_____ **hours per day**
_____ **minutes per day**

PART 5: TIME SPENT SITTING

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

_____ **hours per day**
_____ **minutes per day**

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

_____ **hours per day**
_____ **minutes per day**

This is the end of the questionnaire, thank you for participating.

LONG LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised October 2002.

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Appendix – The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+)

PAR-Q+

The Physical Activity Readiness Questionnaire for Everyone

The health benefits of regular physical activity are clear; more people should engage in physical activity every day of the week. Participating in physical activity is very safe for MOST people. This questionnaire will tell you whether it is necessary for you to seek further advice from your doctor OR a qualified exercise professional before becoming more physically active.

GENERAL HEALTH QUESTIONS

Please read the 7 questions below carefully and answer each one honestly: check YES or NO.	YES	NO
1) Has your doctor ever said that you have a heart condition ☐ **OR** high blood pressure ☐?	☐	☐
2) Do you feel pain in your chest at rest, during your daily activities of living, **OR** when you do physical activity?	☐	☐
3) Do you lose balance because of dizziness **OR** have you lost consciousness in the last 12 months? Please answer **NO** if your dizziness was associated with over-breathing (including during vigorous exercise).	☐	☐
4) Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)? **PLEASE LIST CONDITION(S) HERE:** _____	☐	☐
5) Are you currently taking prescribed medications for a chronic medical condition? **PLEASE LIST CONDITION(S) AND MEDICATIONS HERE:** _____	☐	☐
6) Do you currently have (or have had within the past 12 months) a bone, joint, or soft tissue (muscle, ligament, or tendon) problem that could be made worse by becoming more physically active? Please answer **NO** if you had a problem in the past, but it **does not limit your current ability** to be physically active. **PLEASE LIST CONDITION(S) HERE:** _____	☐	☐
7) Has your doctor ever said that you should only do medically supervised physical activity?	☐	☐

☑ **If you answered NO to all of the questions above, you are cleared for physical activity.**
Please sign the PARTICIPANT DECLARATION. You do not need to complete Pages 2 and 3.

- Start becoming much more physically active – start slowly and build up gradually.
- Follow Global Physical Activity Guidelines for your age (https://www.who.int/publications/i/item/9789240015128).
- You may take part in a health and fitness appraisal.
- If you are over the age of 45 yr and NOT accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.
- If you have any further questions, contact a qualified exercise professional.

PARTICIPANT DECLARATION

If you are less than the legal age required for consent or require the assent of a care provider, your parent, guardian or care provider must also sign this form.

I, the undersigned, have read, understood to my full satisfaction and completed this questionnaire. I acknowledge that this physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if my condition changes. I also acknowledge that the community/fitness center may retain a copy of this form for its records. In these instances, it will maintain the confidentiality of the same, complying with applicable law.

NAME _____ DATE _____

SIGNATURE _____ WITNESS _____

SIGNATURE OF PARENT/GUARDIAN/CARE PROVIDER _____

If you answered YES to one or more of the questions above, COMPLETE PAGES 2 AND 3.

Delay becoming more active if:

- You are currently experiencing a temporary illness, such as a cold or fever. It is best to wait until you feel better.
- You are pregnant. In this case, talk with your health care practitioner, physician, qualified exercise professional, and/or complete the ePARmed-X+ at www.eparmedx.com before becoming more physically active.
- Your health changes. Answer the questions on Pages 2 and 3 of this document and/or talk to your health care practitioner, physician, or qualified exercise professional before proceeding with any physical activity program.

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01-11-2024

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PAR-Q+

FOLLOW-UP QUESTIONS ABOUT YOUR MEDICAL CONDITION(S)

1. Do you have Arthritis, Osteoporosis, or Back Problems?

If the above condition(s) is/are present, answer questions 1a-1c — If **NO** ☐ go to question 2

1a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
1b.	Do you have joint problems causing pain, a recent fracture or fracture caused by osteoporosis or cancer, displaced vertebra (e.g., spondylolisthesis), and/or spondylolysis/pars defect (a crack in the bony ring on the back of the spinal column)?	YES ☐ NO ☐
1c.	Have you had steroid injections or taken steroid tablets regularly for more than 3 months?	YES ☐ NO ☐

2. Do you currently have Cancer of any kind?

If the above condition(s) is/are present, answer questions 2a-2b — If **NO** ☐ go to question 3

2a.	Does your cancer diagnosis include any of the following types: lung/bronchogenic, multiple myeloma (cancer of plasma cells), head, and/or neck?	YES ☐ NO ☐
2b.	Are you currently receiving cancer therapy (such as chemotheraphy or radiotherapy)?	YES ☐ NO ☐

3. Do you have a Heart or Cardiovascular Condition? This includes Coronary Artery Disease, Heart Failure, Diagnosed Abnormality of Heart Rhythm

If the above condition(s) is/are present, answer questions 3a-3d — If **NO** ☐ go to question 4

3a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
3b.	Do you have an irregular heart beat that requires medical management? (e.g., atrial fibrillation, premature ventricular contraction)	YES ☐ NO ☐
3c.	Do you have chronic heart failure?	YES ☐ NO ☐
3d.	Do you have diagnosed coronary artery (cardiovascular) disease and have not participated in regular physical activity in the last 2 months?	YES ☐ NO ☐

4. Do you currently have High Blood Pressure?

If the above condition(s) is/are present, answer questions 4a-4b — If **NO** ☐ go to question 5

4a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
4b.	Do you have a resting blood pressure equal to or greater than 160/90 mmHg with or without medication? (Answer **YES** if you do not know your resting blood pressure)	YES ☐ NO ☐

5. Do you have any Metabolic Conditions? This includes Type 1 Diabetes, Type 2 Diabetes, Pre-Diabetes

If the above condition(s) is/are present, answer questions 5a-5e — If **NO** ☐ go to question 6

5a.	Do you often have difficulty controlling your blood sugar levels with foods, medications, or other physician-prescribed therapies?	YES ☐ NO ☐
5b.	Do you often suffer from signs and symptoms of low blood sugar (hypoglycemia) following exercise and/or during activities of daily living? Signs of hypoglycemia may include shakiness, nervousness, unusual irritability, abnormal sweating, dizziness or light-headedness, mental confusion, difficulty speaking, weakness, or sleepiness.	YES ☐ NO ☐
5c.	Do you have any signs or symptoms of diabetes complications such as heart or vascular disease and/or complications affecting your eyes, kidneys, **OR** the sensation in your toes and feet?	YES ☐ NO ☐
5d.	Do you have other metabolic conditions (such as current pregnancy-related diabetes, chronic kidney disease, or liver problems)?	YES ☐ NO ☐
5e.	Are you planning to engage in what for you is unusually high (or vigorous) intensity exercise in the near future?	YES ☐ NO ☐

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PAR-Q+

6. Do you have any Mental Health Problems or Learning Difficulties? This includes Alzheimer's, Dementia, Depression, Anxiety Disorder, Eating Disorder, Psychotic Disorder, Intellectual Disability, Down Syndrome

If the above condition(s) is/are present, answer questions 6a-6b — If **NO** ☐ go to question 7

6a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
6b.	Do you have Down Syndrome **AND** back problems affecting nerves or muscles?	YES ☐ NO ☐

7. Do you have a Respiratory Disease? *This includes Chronic Obstructive Pulmonary Disease, Asthma, Pulmonary High Blood Pressure*

If the above condition(s) is/are present, answer questions 7a-7d — If **NO** ☐ go to question 8

7a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
7b.	Has your doctor ever said your blood oxygen level is low at rest or during exercise and/or that you require supplemental oxygen therapy?	YES ☐ NO ☐
7c.	If asthmatic, do you currently have symptoms of chest tightness, wheezing, laboured breathing, consistent cough (more than 2 days/week), or have you used your rescue medication more than twice in the last week?	YES ☐ NO ☐
7d.	Has your doctor ever said you have high blood pressure in the blood vessels of your lungs?	YES ☐ NO ☐

8. Do you have a Spinal Cord Injury? *This includes Tetraplegia and Paraplegia*

If the above condition(s) is/are present, answer questions 8a-8c — If **NO** ☐ go to question 9

8a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
8b.	Do you commonly exhibit low resting blood pressure significant enough to cause dizziness, light-headedness, and/or fainting?	YES ☐ NO ☐
8c.	Has your physician indicated that you exhibit sudden bouts of high blood pressure (known as Autonomic Dysreflexia)?	YES ☐ NO ☐

9. Have you had a Stroke? *This includes Transient Ischemic Attack (TIA) or Cerebrovascular Event*

If the above condition(s) is/are present, answer questions 9a-9c — If **NO** ☐ go to question 10

9a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
9b.	Do you have any impairment in walking or mobility?	YES ☐ NO ☐
9c.	Have you experienced a stroke or impairment in nerves or muscles in the past 6 months?	YES ☐ NO ☐

10. Do you have any other medical condition not listed above or do you have two or more medical conditions?

If you have other medical conditions, answer questions 10a-10c — If **NO** ☐ read the Page 4 recommendations

10a.	Have you experienced a blackout, fainted, or lost consciousness as a result of a head injury within the last 12 months **OR** have you had a diagnosed concussion within the last 12 months?	YES ☐ NO ☐
10b.	Do you have a medical condition that is not listed (such as epilepsy, neurological conditions, kidney problems)?	YES ☐ NO ☐
10c.	Do you currently live with two or more medical conditions?	YES ☐ NO ☐

PLEASE LIST YOUR MEDICAL CONDITION(S) AND ANY RELATED MEDICATIONS HERE: _____

_____

GO to Page 4 for recommendations about your current medical condition(s) and sign the PARTICIPANT DECLARATION.

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PAR-Q+

If you answered NO to all of the FOLLOW-UP questions (pgs. 2-3) about your medical condition, you are ready to become more physically active - sign the PARTICIPANT DECLARATION below:

- It is advised that you consult a qualified exercise professional to help you develop a safe and effective physical activity plan to meet your health needs.
- You are encouraged to start slowly and build up gradually - 20 to 60 minutes of low to moderate intensity exercise, 3-5 days per week including aerobic and muscle strengthening exercises.
- As you progress, you should aim to accumulate 150 minutes or more of moderate intensity physical activity per week.
- If you are over the age of 45 yr and **NOT** accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.

If you answered **YES** to **one or more of the follow-up questions** about your medical condition:

You should seek further information before becoming more physically active or engaging in a fitness appraisal. You should complete the specially designed online screening and exercise recommendations program - the **ePARmed-X+ at www.eparmedx.com** and/or visit a qualified exercise professional to work through the ePARmed-X+ and for further information.

Delay becoming more active if:

- You are currently experiencing a temporary illness, such as a cold or fever. It is best to wait until you feel better.
- You are pregnant. In this case, talk to your health care practitioner, physician, qualified exercise professional, and/or complete the ePARmed-X+ at www.eparmedx.com before becoming more physically active.
- Your health changes. Talk to your health care practitioner, physician, or qualified exercise professional before continuing with any physical activity program.

- You are encouraged to photocopy the PAR-Q+. You must use the entire questionnaire and NO changes are permitted.
- The authors, the PAR-Q+ Collaboration, partner organizations, and their agents assume no liability for persons who undertake physical activity and/or make use of the PAR-Q+ or ePARmed-X+. If in doubt after completing the questionnaire, consult your doctor prior to physical activity.

PARTICIPANT DECLARATION

- All persons who have completed the PAR-Q+ please read and sign the declaration below.
- If you are less than the legal age required for consent or require the assent of a care provider, your parent, guardian or care provider must also sign this form.

I, the undersigned, have read, understood to my full satisfaction and completed this questionnaire. I acknowledge that this physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if my condition changes. I also acknowledge that the community/fitness center may retain a copy of this form for records. In these instances, it will maintain the confidentiality of the same, complying with applicable law.

NAME _____ DATE _____

SIGNATURE _____ WITNESS _____

SIGNATURE OF PARENT/GUARDIAN/CARE PROVIDER _____

For more information, please contact

www.eparmedx.com
Email: eparmedx@gmail.com

Citation for PAR-Q+
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The PAR-Q+ was created using the evidence-based AGREE process (1) by the PAR-Q+ Collaboration chaired by Dr. Darren E. R. Warburton with Dr. Norman Gledhill, Dr. Veronica Jamnik, and Dr. Donald C. McKenzie (2). Production of this document has been made possible through financial contributions from the Public Health Agency of Canada and the BC Ministry of Health Services. The views expressed herein do not necessarily represent the views of the Public Health Agency of Canada or the BC Ministry of Health Services.

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Appendix – FACT-Cog (version 3)

FACT-Cog (Version 3)

Below is a list of statements that other people with your condition have said are important. **Please circle or mark one number per line to indicate your response as it applies to the past 7 days.**

	PERCEIVED COGNITIVE IMPAIRMENTS	Never	About once a week	Two to three times a week	Nearly every day	Several times a day
CogA1	I have had trouble forming thoughts	0	1	2	3	4
CogA3	My thinking has been slow	0	1	2	3	4
CogC7	I have had trouble concentrating	0	1	2	3	4
CogM9	I have had trouble finding my way to a familiar place	0	1	2	3	4
CogM10	I have had trouble remembering where I put things, like my keys or my wallet	0	1	2	3	4
CogM12	I have had trouble remembering new information, like phone numbers or simple instructions	0	1	2	3	4
CogV13	I have had trouble recalling the name of an object while talking to someone	0	1	2	3	4
CogV15	I have had trouble finding the right word(s) to express myself	0	1	2	3	4
CogV16	I have used the wrong word when I referred to an object	0	1	2	3	4
CogV17b	I have had trouble saying what I mean in conversations with others	0	1	2	3	4
CogF19	I have walked into a room and forgotten what I meant to get or do there	0	1	2	3	4
CogF23	I have had to work really hard to pay attention or I would make a mistake	0	1	2	3	4
CogF24	I have forgotten names of people soon after being introduced	0	1	2	3	4

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FACT-Cog (Version 3)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

		Never	About once a week	Two to three times a week	Nearly every day	Several times a day
CogF25	My reactions in everyday situations have been slow.....	0	1	2	3	4
CogC31	I have had to work harder than usual to keep track of what I was doing	0	1	2	3	4
CogC32	My thinking has been slower than usual	0	1	2	3	4
CogC33a	I have had to work harder than usual to express myself clearly	0	1	2	3	4
CogC33c	I have had to use written lists more often than usual so I would not forget things	0	1	2	3	4
CogMT1	I have trouble keeping track of what I am doing if I am interrupted.....	0	1	2	3	4
CogMT2	I have trouble shifting back and forth between different activities that require thinking	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	COMMENTS FROM OTHERS	Never	About once a week	Two to three times a week	Nearly every day	Several times a day
CogO1	Other people have told me I seemed to have trouble remembering information.....	0	1	2	3	4
CogO2	Other people have told me I seemed to have trouble speaking clearly.....	0	1	2	3	4
CogO3	Other people have told me I seemed to have trouble thinking clearly.....	0	1	2	3	4
CogO4	Other people have told me I seemed confused.....	0	1	2	3	4

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FACT-Cog (Version 3)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	PERCEIVED COGNITIVE ABILITIES	Not at all	A little bit	Somewhat	Quite a bit	Very much
CogPC1	I have been able to concentrate	0	1	2	3	4
CogPV1	I have been able to bring to mind words that I wanted to use while talking to someone	0	1	2	3	4
CogPM1	I have been able to remember things, like where I left my keys or wallet	0	1	2	3	4
CogPM2	I have been able to remember to do things, like take medicine or buy something I needed	0	1	2	3	4
CogPF1	I am able to pay attention and keep track of what I am doing without extra effort	0	1	2	3	4
CogPCH1	My mind is as sharp as it has always been	0	1	2	3	4
CogPCH2	My memory is as good as it has always been	0	1	2	3	4
CogPMT 1	I am able to shift back and forth between two activities that require thinking	0	1	2	3	4
CogPMT 2	I am able to keep track of what I am doing, even if I am interrupted	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	IMPACT ON QUALITY OF LIFE	Not at all	A little bit	Somewhat	Quite a bit	Very much
CogQ35	I have been upset about these problems	0	1	2	3	4
CogQ37	These problems have interfered with my ability to work	0	1	2	3	4
CogQ38	These problems have interfered with my ability to do things I enjoy	0	1	2	3	4
CogQ41	These problems have interfered with the quality of my life	0	1	2	3	4

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Appendix –Sample Exercise Programme

Warm Up	Time (seconds)	Notes (All body weight)
Shoulder Rolls	30	**Regression**: Seated / **Progression**: Lightly March
Shoulder Shrugs	30	**Regression**: Seated / **Progression**: Lightly March
Hip Rotation	30	**Regression**: Seated / **Progression**: Larger Rotations
High Knees	30	**Regression**: Chair Or Wall Support Or Seated / **Progression**: Lightly March
Squat	30	**Regression**: Seated Squat / **Progression**: Add Weight

Aerobic Exercise	Time (seconds)	Reps	Sets	Note
Arm Circles	20-30	10	2-3	Body Weight **Regression**: Seated / **Progression:** Lightly March
Side Moving Jacks	20-30	10	2-3	Body Weight **Regression**: No Arm Movement / **Progression**: Jumping Jacks
Marching (Front)	20-30	10	2-3	Body Weight **Regression**: Seated / **Progression**: Weights
Shadow Boxing	20-30	10	2-3	Body Weight / Weights **Regression**: Forward Pointing / **Progression**: Weights (Increase)
V Steps	20-30	10	2-3	Body Weight **Regression**: Step Straight Forward / **Progression**: Punching Forward

Resistance Exercise	Time (seconds)	Reps	Sets	Note
Front Raises	20-30	10	2-3	Resistance Band/Weight **Regression**: Less tension/weight / **Progression**: Increase tension/weight
Side Raises	20-30	10	2-3	Resistance Band/Weight **Regression**: Less tension/weight / **Progression**: Increase tension/weight
Seated Squats	20-30	10	2-3	Resistance Band/Weight **Regression**: Less tension/weight / **Progression**: Increase tension/weight
Seated Abduction Extension	20-30	10	2-3	Resistance Band **Regression**: Less tension / **Progression**: Increase tension
Seated Leg Press	20-30	10	2-3	Resistance Band Regression: Less tension / Progression: Increase tension

Cool Down	Time (seconds)	Repetitions	Sets	Notes (All body weight)
Overhead Stretch	10	10	2	Chair or Standing
Neck Stretch	10	10	2	Chair or Standing
Side Lean Stretch	10	10	2	Chair or Standing
Hamstring Stretch	10	10	2	Chair or Standing
Ankle Stretch	10	10	2	Chair or Standing

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Appendix - Functional Fitness Assessment For Elderly Adults

Normal scores based on age and sex

Table 1: Normal range of scores for men, with *normal* defined as the middle 50% of the population. Those scoring above this range would be considered *above average* for their age and those below the range as *below average*.

Normal Range of Scores - Men

	60-64	65-69	70-74	75-79	80-84	85-89	90-94
Chair stand (no. of stands)	14 - 19	12 - 18	12 - 17	11 - 17	10 - 15	8 - 14	7 - 12
Arm Curl (no. of reps)	16 - 22	15 - 21	14 - 21	13 - 19	13 - 19	11 - 17	10 - 14
6-Min Walk (no. of yds)	610 - 735	560 - 700	545 - 680	470 - 640	445 - 605	380 - 570	305 - 500
2-Min Step (no. of steps)	87 - 115	86 - 116	80 - 110	73 - 109	71 - 103	59 - 91	52 - 86
Chair Sit-&-Reach (inches +/-)	-2.5 - +4.0	-3.0 - +3.0	-3.5 - +2.5	-4.0 - +2.0	-5.5 - +1.5	-5.5 - +0.5	-6.5 - -0.5
Back Scratch (inches +/-)	-6.5 - +0.0	-7.5 - -1.0	-8.0 - -1.0	-9.0 - -2.0	-9.5 - -2.0	-10.0 - -3.0	-10.5 - -4.0
8-Ft Up-&-Go (seconds)	5.6 - 3.8	5.7 - 4.3	6.0 - 4.2	7.2 - 4.6	7.6 - 5.2	8.9 - 5.3	10.0 - 6.2

Table 2: Normal range of scores for women, with *normal* defined as the middle 50% of the population. Those scoring above this range would be considered *above average* for their age and those below the range as *below average*.

Normal Range of Scores - Women

	60-64	65-69	70-74	75-79	80-84	85-89	90-94
Chair stand (no. of stands)	12 - 17	11 - 16	10 - 15	10 - 15	9 - 14	8 - 13	4 - 11
Arm Curl (no. of reps)	13 - 19	12 - 18	12 - 17	11 - 17	10 - 16	10 - 15	8 - 13
6-Min Walk (no. of yds)	545 - 660	500 - 635	480 - 615	430 - 585	385 - 540	340 - 510	275 - 440
2-Min Step (no. of steps)	75 - 107	73 - 107	68 - 101	68 - 100	60 - 91	55 - 85	44 - 72
Chair Sit-&-Reach (inches +/-)	-0.5 - +5.0	-0.5 - +4.5	-1.0 - +4.0	-1.5 - +3.5	-2.0 - +3.0	-2.5 - +2.5	-4.5 - +1.0
Back Scratch (inches +/-)	-3.0 - +1.5	-3.5 - +1.5	-4.0 - +1.0	-5.0 - +0.5	-5.5 - +0.0	-7.0 - -1.0	-8.0 - -1.0
8-Ft Up-&-Go (seconds)	6.0 - 4.4	6.4 - 4.8	7.1 - 4.9	7.4 - 5.2	8.7 - 5.7	9.6 - 6.2	11.5 - 7.3

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Description and Instructions For The Functional Fitness Assessment

30-Second Chair Stand

Purpose
To assess lower body strength, needed for numerous tasks such as climbing stairs, walking and getting out of a chair, tub or car. Also reduces the chance of falling.

Description
Number of full stands that can be completed in 30 seconds with arms folded across chest.

Risk zone
Less than 8 unassisted stands for men and women.

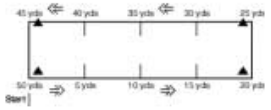
Arm Curl

Purpose
To assess upper body strength, needed for performing household and other activities involving lifting and carrying things such as groceries, suitcases and grandchildren.

Description
Number of bicep curls that can be completed in 30 seconds holding a hand weight of 5 lbs (2.27 kg) for women; 8 lbs (3.63 kg) for men.

Risk zone
Less than 11 curls using correct form for men and women.

6-Minute Walk



Purpose
To assess aerobic endurance, which is important for walking distances, stair climbing, shopping, sightseeing while on vacation, etc.

Description
Number of yards/meters that can be walked in 6 minutes around a 50-yard (45.7 meter) course. (5 yds = 4.57 meters)

Risk zone
Less than 350 yards for men and women.

2-Minute Step Test

Purpose
Alternate aerobic endurance test, for use when space limitations or weather prohibits taking the 6-minute walk test.

Description
Number of full steps completed in 2 minutes, raising each knee to a point midway between the patella (kneecap) and iliac crest (top hip bone). Score is number of times right knee reaches the required height.

Risk zone
Less than 65 steps for men and women.

Chair Sit-and-Reach

Purpose
To assess lower body flexibility, which is important for good posture, for normal gait patterns and for various mobility tasks, such as getting in and out of a bathtub or car.

Description
From a sitting position at front of chair, with leg extended and hands reaching toward toes, the number of inches (cm) (+ or -) between extended fingers and tip of toe.

Risk zone
Men: Minus (-) 4 inches or more
Women: Minus (-) 2 inches or more

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Continued on page 30

Back Scratch

Purpose
To assess upper body (shoulder) flexibility, which is important in tasks such as combing one's hair, putting on overhead garments and reaching for a seat belt

Description
With one hand reaching over the shoulder and one up the middle of the back, the number of inches (cm) between extended middle fingers (+ or -).

Risk zone
Men: Minus (-) 4 inches or more
Women: Minus (-) 2 inches or more

8-Foot Up-and-Go

Purpose
To assess agility/dynamic balance, which is important in tasks that require quick maneuvering, such as getting off a bus in time or getting up to attend to something in the kitchen, to go to the bathroom or to answer the phone.

Description
Number of seconds required to get up from a seated position, walk 8 feet (2.44 m), turn, and return to seated position.

Risk zone
More than 9 seconds.

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The *Senior Fitness Test Manual* and accompanying training video and software can be purchased through Human Kinetics: 1-800-747-4457 (U.S.), 1-800-465-7301 (Canada), or www.humankinetics.com

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