Cancer Rehabilitation Exercise and Activity via TElehealth COVID 19 (CREATE-C) Feasibility Study

Participant Information Sheet

Summary

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take the time to read the following information carefully. Discuss it with your doctor, friends and relatives if you wish.
- You are free to decide whether or not to take part in this research. If you choose not to take part, this will not affect the care you get from your health care provider.
- Please do ask us if there is anything that is not clear or if you would like more information.
- The information and results collected will be used for research purposes only.
- Thank you for considering supporting our research and help improve cancer care.

Contents

Key information

- Participating in physical activity during cancer treatment can reduce certain treatment side effects, help maintain muscle mass and reduce the risk of developing other long term health conditions.
- We are testing a new physical activity programme designed specifically for colorectal cancer patients that can be followed remotely from home.
- No additional clinic visits are required, all information will be collected remotely using digital devices and online questionnaires.
- If you decide to take part, you would be free to stop taking part in the study at any time, without giving a reason and without affecting your clinical care.
- Your confidentiality would be maintained at all times. All information collected about you regarding this study will be stored securely by the University of Cambridge.

How to contact us

If you have any questions about this study please contact:

Cancer Rehabilitation Exercise and Activity via Telehealth study team

Study Coordinator: Nicola Kimber

Email: CREATE-C.study@mrc-epid.cam.ac.uk

Tel: 01223 928271

1. About this study

Research so far suggests that keeping physically active and participating in exercise during your cancer treatment may reduce treatment side effects, help maintain muscle mass and reduce the risk of developing other long term health conditions. As a result of the COVID-19 pandemic, face to face physical activity programmes for cancer patients in hospital and community settings have largely been suspended. We would like to try out a new physical activity programme tailored for colorectal cancer patients, which you can do from the comfort of your own home.

What is being studied?

The CREATE-C feasibility study is designed to see if a remote physical activity programme for colorectal cancer is acceptable and easy to follow during your treatment, including measurements of activity and health. We also want to find out what you think of the remote programme.

The programme builds on the established hospital based CUHT Cancer Rehabilitation and Exercise (REACT) programme. It includes a group educational session delivered online by a specialist physiotherapist and three recorded exercise sessions that can be accessed online at any time. The sessions will offer options for different abilities and target the specific needs of colorectal cancer patients during their cancer treatment (including post-surgery).

During this study, you would not be required to come in for any additional clinical visits, as all measurements collected remotely using digital devices.

What do you hope to find out?

We will look at the suitability of the physical activity intervention programme delivered fully online. We also want to collect feedback from you about your experiences of this programme and the study in general.

2. Why am I being asked to take part?

You have been invited to take part in this feasibility study as you will shortly be starting a course of chemotherapy as part of your treatment for colorectal cancer. We hope to recruit between 20-30 patients at Cambridge University Hospital NHS Foundation Trust.

Do I have to take part?

No, it is up to you to decide whether or not to take part in the study. You are free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

3. What will happen and how will I be involved?

You will have received information about this study from a member of the Clinical Team at your outpatient appointment. With your permission they will pass on your contact details to us, the CREATE-C study team at the University of Cambridge.
We will then contact you by telephone or email to explain the study in more detail and answer any questions. We will ask you some questions to check you are able to take part, including confirmation that you have access to a computer, tablet or smartphone in order to be able to take part in the online questionnaires.
If you would like to take part, we will send you a weblink to an electronic consent form for you to complete.

Online study questionnaires

After you have consented to take part in the study and before you start each of your next two treatment cycles, we will send you an email with a link to complete a series of short online questionnaires about how you are feeling. We expect it to take between 15-30 minutes to complete these questionnaires.

Physical Activity monitor

We will also ask you to wear a physical activity monitor on your wrist. It is completely waterproof. We would like you to wear it for 7 days continuously. This monitor will be sent to you in the post on three separate occasions; before you start treatment and the 7 days before the next two chemotherapy treatments. You will be provided with a pre-addressed and pre-paid package so that you can return the monitor to us, after each 7 day wear. You do not need to go into a post office to post it. Monitors will be thoroughly cleaned before being sent to you.

The monitor does not have GPS, and does not measure your location. It only measures body movement i.e. whether it moves up/down, forward/back and side-to-side.

The Physical Activity programme

Before starting the physical activity programme you will be sent an information booklet, including information on how to exercise safely and contact information for the physiotherapist team leading the programme. You will also be sent some resistance bands to use for some of the activity sessions. We will send you an email with a weblink and further information on how to access the education sessions and exercise videos.

- Group Educational Session

A member of our team will contact you to arrange for you to attend an online group educational session. This initial group session only requires a 1-1 ½ hours commitment and you will be able to choose to attend at a convenient time. There are daytime and evening sessions available. The Physical Activity educational session will be delivered by a specialist oncology physiotherapist, who specialises in treatment for cancer. With your permission, the physiotherapist will check your medical records at the hospital prior to the session to check if any changes to the programme are needed for you.

- Online on-demand exercise sessions

After you have completed the online education session, you will be given access to the online activity sessions. The sessions will focus on different types of exercises for strength and aerobic exercise (to increase your heart rate and blood flow), core stability exercises to aid abdominal recovery and some exercises to help you relax. The physiotherapist will have discussed how to incorporate exercise into your weekly routine during the group education session. You will also have the opportunity to discuss any questions you have individually with the physiotherapist at the end of the session or you can email the oncology physiotherapy team using the email provided.

Participants are asked to exercise throughout the study period during their treatment following the education session and are encourage to participate in the exercise videos up to 5 times per week. You will be able to access these videos beyond your time in the study.

Health Records

With your permission we would like to collect information from your medical notes about your health, treatment, health care use and start date of chemotherapy treatment. We will also collect details on your age, gender, height and weight at the time of starting chemotherapy.

Interviews

You may be asked to take part in a discussion about your experience and views of the physical activity programme after you have finished the programme. The interview would take place online via Zoom using log in with password. We would digitally record this discussion so that we can make notes on the discussion afterwards. Any information discussed in these interviews will be strictly confidential. Direct quotes used from these interviews will be made anonymous and your identity protected. You can decide if you want to take part in these interviews.

4. Possible benefits and disadvantages of taking part

What are the possible benefits of taking part?

The information that you will provide us in this feasibility study will help us shape a physical activity programme for colorectal cancer patients that they can do from the comfort of their home.

You will receive a tailor-made physical activity programme, as well as support online from a specialist oncology physiotherapist. You will continue to have access to the online programme after the end of the study if you wish for the period of your treatment.

What are the possible disadvantages and risks of taking part?

Whenever undertaking any exercise there is always a small risk you may injure yourself. However, you will be shown how to exercise in a safe way, by a specialist oncology physiotherapist.
In some instances, participants may experience a mild irritation from wearing the physical activity monitor. If this happens we would ask you to remove the monitor and contact the study team.
Other than the time it takes to complete the online questionnaires and physical activity programme, there really is little disadvantage taking part in this study.

5. More information about taking part

Do I have to take part?

No, it is up to you to decide whether or not to take part in this study. You are free to withdraw at any time, without giving a reason. This will not affect the standard or type of care you receive. If you decide to withdraw from the study we will keep the data we have already collected from you up until that time. Any information will be stored securely and will only be accessible by the CREATE-C study team.

Will I receive any payment for taking part?

It will not be possible to provide payment for taking part.

What if there is a problem?

If you have a concern about any aspect of this study you should speak to your doctor, or contact the research team at: CREATE-C.study@mrc-epid.cam.ac.uk
If you remain unhappy and wish to complain formally, you can do so by contacting the Head of Department at the MRC Epidemiology Unit, University of Cambridge, Prof. Nick Wareham : Telephone: 01223 330315 or email: nick.wareham@mrc-epid.cam.ac.uk

In addition, you can also contact the Cambridge University Hospitals NHS Foundation Trust Patient Advice and Liaison Service (PALS): telephone: 01223 216756 or email: pals@addenbrookes.nhs.uk

Cambridge University Hospitals NHS Foundation Trust, is a member of the NHS Clinical Negligence Scheme for Trusts, and will accept full financial liability for harm caused to participants in the study caused through the negligence of its employees and honorary contract holders. There are no specific arrangements for compensation should a participant be harmed through participation in the study, but no-one has acted negligently.
The University of Cambridge will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participation in the study.

6. How will my information be looked after?

What will happen to information about me collected during the study?

Information we collect during the study will be kept strictly confidential**.**
With your permission, information we collect will be stored anonymously at the MRC Epidemiology Unit, University of Cambridge. You will be assigned a unique code when you first take part in CREATE-C. This code will be used to label all data collected during the study and is used in place of personal information. People will use this information to do the research or to check your records to make sure that the research is being done properly.

Personal identifiable information, such as the contact details we use to keep in touch with you, will be kept separate from any other data we collect. The database containing personal information is on a secured network drive on computers in the MRC Epidemiology Unit, University of Cambridge. Notes will be taken from the interview recordings by a member of the research team. Recordings and interview notes will be saved using an ID code, rather than your name. They will be stored in a secure file on a secure server at the MRC Epidemiology Unit.

We will need to use information from your medical records for this research project. Information collected from your medical notes will only be accessed by an approved member of the research team, and they will only look at specific information relevant to this study. Information will be de-personalised before it is transferred from your medical notes to a secure research data system at the MRC Epidemiology Unit.

Two commercial companies are being used to help deliver the study: i) BEAM Research which will host the activity programme; ii) Gorilla™ will host the online questionnaires. The University of Cambridge hold contracts with both parties, which includes data protection assurances. Participant Data collected using Gorilla is de-personalised, identified by a unique ID. Both platforms will store email addresses for the purpose of sending email reminders. Your email address will be deleted by Gorilla at the end of the study.
Cambridge University Hospitals NHS Foundation Trust (CUHNFT) and University of Cambridge are joint sponsors for this study based in the United Kingdom.

CUHNFT and the University of Cambridge will be using information from you in order to undertake this study and will act as joint data controllers. This means that both organisations are responsible for looking after your information and using it properly. CUHNFT and the University of Cambridge will keep identifiable information about you

for 20 year after the study has finished and it will then be destroyed.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.
You can find out more about how we use your information at:

- https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/
- https://www.hra.nhs.uk/information-about-patients/
- Or by asking one of the research team by email: CREATE-C.study@mrc-epid.cam.ac.uk

For Cambridge University Hospitals NHS Foundation Trust, please visit: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk

What will happen to the results of the study?

The overall results may lead to a clinical trial which will examine in greater detail how the physical activity programme affects health in a larger group of patients. When the study is completed, the results will be presented at scientific meetings and published in peer reviewed journals and made available on the MRC Epidemiology Unit website. We expect that results will become available within a year after completing the data collection. If published, your identity and personal details will be kept confidential. No information that could identify you, like your name, will be published in any report about this study.

Who is organising and funding the study?

This study is organised by the MRC Epidemiology Unit, part of the University of Cambridge. The study is funded by the National Institute for Health Research (NIHR). The study is joint sponsored with Cambridge University Hospital Trust (CUHFT) and University of Cambridge.

Who has reviewed the study?

This study has been reviewed by an independent group of people, the Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. The study has been given a favourable opinion by Cambridge South Research Ethics Committee.

7. Contact for further information

If you have any questions regarding the study or how you might be involved, further contact information can be found below:
The CREATE-C Study Team
Email: CREATE-C.study@mrc-epid.cam.ac.uk

Chief Investigator

Dr Kirsten Rennie
Senior Research Associate, NIHR Cambridge Biomedical Research Centre (BRC) Theme on Diet, Lifestyle and Nutrition, MRC Epidemiology Unit, School of Clinical Medicine, University of Cambridge

Co-Investigators

Dr Elizabeth Smyth,
Clinical Consultant in gastrointestinal oncology, Department of Oncology, Cambridge University Hospitals NHS Foundation Trust

Nicola Day, Clinical Specialist Physiotherapist in Oncology Rehabilitation & Exercise. Service Lead – R.E.A.C.T Programme, Cambridge University Hospitals NHS Foundation Trust.

Cancer Rehabilitation Exercise and Activity via TElehealth-COVID 19 (CREATE-C) Feasibility Study

Participant study number:

CONSENT FORM

Version 1.1 (14/04/2021)

REC Ref: 21/EE/0087 IRAS ID: 295385 Chief Investigator: Dr Kirsten Rennie

Please tick each box

1. I confirm that I have read and understood the information sheet **version 1.1, 14/04/2021** for the above study and have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected. I understand that the data I provide will be retained if I decide to withdraw from the study. ☐

3. I understand that the information collected about me can be stored by the MRC Epidemiology Unit, University of Cambridge. ☐

4. I understand that sections of my medical notes will be looked at by members of the research team, regulatory authorities and by the NHS Trust, where it is relevant to my taking part in this research study. I give permission for these individuals to have access to my records, and for this data to be linked to my study data. ☐

5. In order to access the online materials and questionnaires for this study, I give permission for my email address to be shared with BEAM Research and Gorilla™, to be used to create an account and for email reminders to be sent from their web-based platforms. ☐

6. I understand that I will not benefit financially if this research leads to the development of a new treatment, medical test or other commercial product. ☐

7. I agree to take part in this study. ☐

OPTIONAL:

	Yes	No
8. I agree to take part in a semi-structured interview.	☐	☐

	Yes	No
9. I understand that interviews will be recorded and transcriptions from these interviews may be shared with other researchers. Recordings and transcriptions will be anonymised, so that it will not be possible to identify me.	☐	☐

	Yes	No
10. I understand that direct quotes may be used in scientific publications, presentations to clinicians, other scientists, the public or press. Any direct quotes used will be anonymised, so that it will not be possible to identify me	☐	☐

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Name of Participant (BLOCK CAPITALS)	**Date**	**Signature**

Thank you for taking the time to consider taking part in this study