Funded by Yorkshire Cancer Research

APPROACH: an app for health & wellbeing after cancer– a randomised controlled trial

Participant Information Sheet

This document provides information about a research study for people diagnosed with breast, prostate or bowel cancer. Before you decide if you wish to take part, it is important for you to understand why the research is being done and what it will involve.

The study summary below provides a brief summary of the study. If you are interested, please read the more detailed information on the following pages.

Please ask us if there is anything that is not clear or if you would like more information. You can contact us on [APPROACH telephone]. Please take time to decide whether or not you wish to take part.

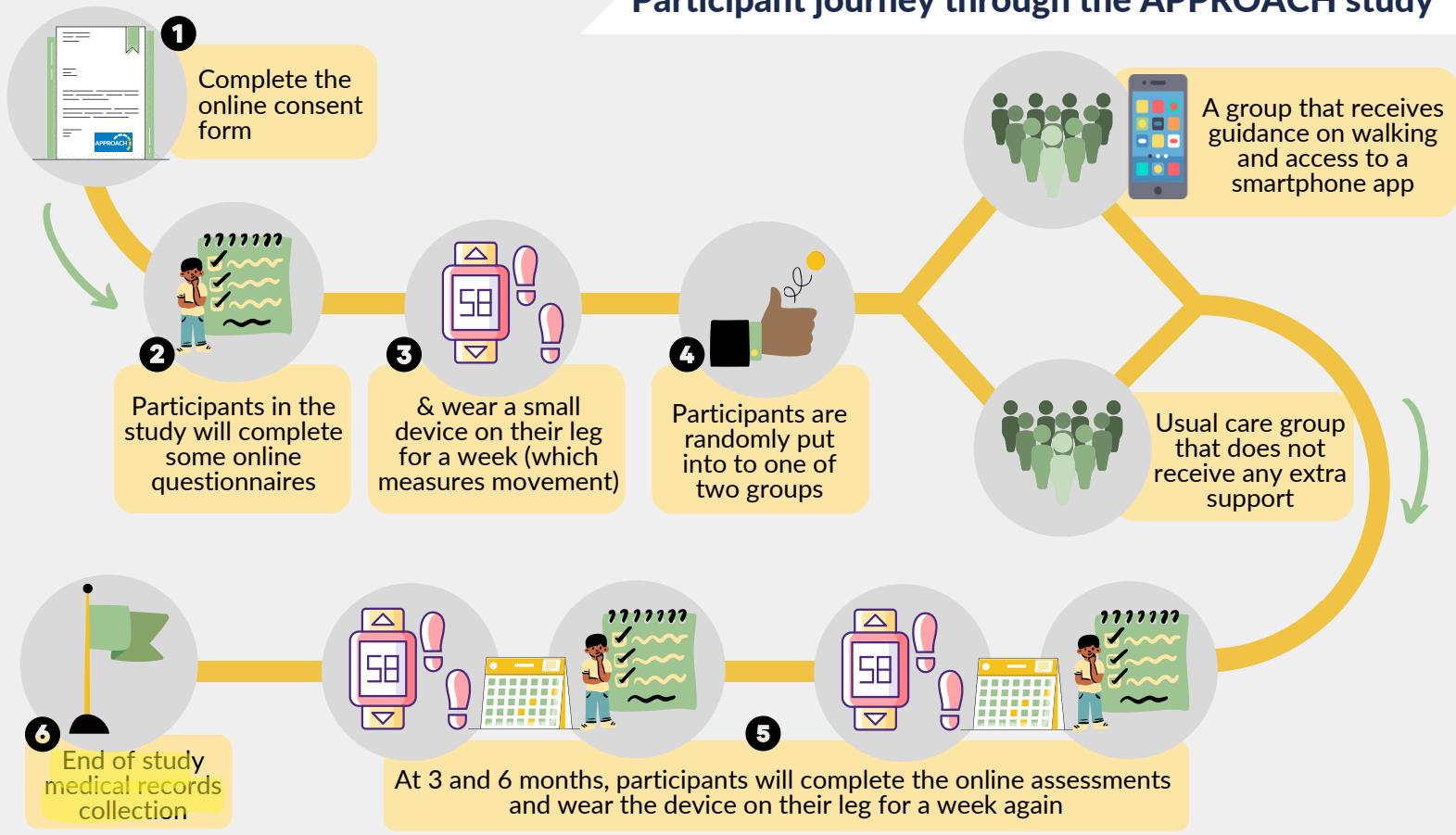
- We know that physical activity is beneficial to patients after a diagnosis of cancer. This research study will look at whether use of a smartphone app on your mobile phone, that aims to help you to walk more, can improve the health and wellbeing of people affected by cancer. This study may help improve services for people affected by cancer.
- We are inviting you to take part because you have been diagnosed with either breast, prostate or bowel cancer in the last 2 years. Approximately 480 people can take part either before, during or after any cancer treatment.
- It is your decision whether or not to take part – you do not have to. If you do take part, you can withdraw at any time without giving a reason. Your medical care or treatment will not be affected.
- The study involves completing online questionnaires about different aspects of your health and wearing a small device which measures your movement on your thigh for 7 days, on 3 occasions over 6 months. We will then randomly assign you to one of two groups. One group will receive a leaflet and two telephone calls/video calls about a smartphone app. We are aiming to see if there are any differences in health and wellbeing between the group who receive advice/app, versus the usual medical care and advice you would receive normally.
- We will access information from your hospital records. We only use information that we need for the study.

If you think you might be interested in taking part in this study, please read the full details below. If you are not interested please let us know (phone number and email) and we will not contact you again.

1 What do I have to do for this study?

START

Participant journey through the APPROACH study



1 Consent

First, you will need to complete the online consent form. You will be asked to enter your contact details and agree to the study procedures. You will be able to download a copy of the consent form for your records. To access the online consent form go to [web address for online PIS/consent form].

2 Baseline measures

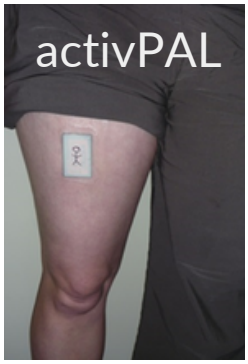
If you choose to take part you will fill in an online questionnaire that asks about different aspects of your health. This is expected to take up to 30 minutes to complete, but you can stop and restart later if you need to.

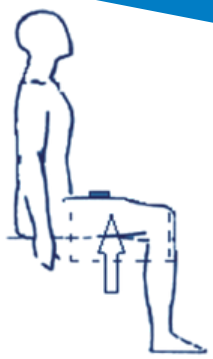
We will send you a new set of weighing scales and a measuring tape, and ask you to send us your height, weight and waist circumference at the start of the study. This is optional, you can still participate in the study without providing these measurements. You can keep the weighing scales and measuring tape.

3 Activity monitoring

We will ask you to wear a small device called an activPAL for 7 days and then send it back to us.

It is attached to your thigh with a medical dressing and measures the amount of time you spend sitting, lying down and moving around. The devices fit easily underneath your clothes and are waterproof, so you can keep them on at all times, including when washing and showering. They are expensive and reusable, but you will not be asked to pay for the device if it is lost, misplaced or damaged.

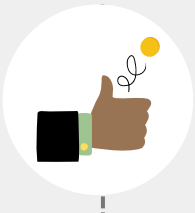




4 Group assignment

After this, a computer program will randomly assign you (like tossing a coin) to one of two groups. You will be told which group you are in. Nobody will have any control over which group you are put in.

Both groups will continue to receive the medical care and advice they would normally receive.



The intervention group

The intervention group will be posted a leaflet with details about a free smartphone app that can encourage them to do more walking.

The app is available on smartphones that use Android or iOS (Apple) operating systems. The study does not get any data directly from the app itself.

They will also receive two telephone/video calls from a member of the study team to provide support.

The sound from these telephone/video calls may be recorded, but if you do not want us to we will not record them. You will be asked at the beginning of the call.

The usual care group

To enable comparison, this group will not receive any additional information during the study.

This group helps us to understand how receiving extra support (the app, leaflet and calls) compares to the current medical care/advice.

Being in this group is extremely important to help us answer this question.

5 Follow up

3 & 6 months

online questionnaire

wear activPAL for 7 days

After 3 months and 6 months, we will ask people in both groups to fill in an online questionnaire (approx. 30 minutes) and wear the activPAL device for 7 days again.

We will also ask for another weight and waist measurement from those who previously provided this. We will organise this via telephone, email and post.

The intervention group will be asked extra questions about the support they received, and we will ask some people in the intervention group to take part in a recorded telephone interview to gather further information about using the app. Taking part in these interviews is optional.

6 End of study medical records data collection

At the end of the study we will also collect some information from your medical records. The data collected will include: your cancer diagnosis, date of diagnosis, stage of disease, treatment details, details about other health conditions diagnosed up to end of study (defined as 30 weeks after study entry) and number/length of any admissions to hospital, and number of other contacts with the hospital (e.g. day case, outpatient procedures and appointments) during the study.
This is information that helps us accurately describe our study sample and understand more about what people have experienced medically in the time they've been involved in the study. It's most practical to collect this all at the end in one go.

APPROACH study activities

This table summarises the study activities in each group with the estimated amount of time for each:

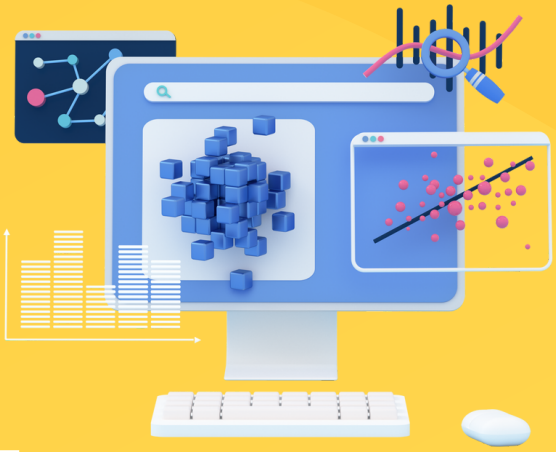
Study activities (estimated time for each activity is shown in brackets)	Intervention group	Control group
Read information sheet and complete consent form (20 mins)	X	X
Baseline assessments - Questionnaire (30 mins) - Measure height, weight and waist circumference (5 mins, optional) - Wear activPAL device (7 days continuously)	X	X
Read study leaflet (5 mins) and receive two phone/video calls (45 mins and 10 mins) about the app	X	
Follow-up assessments (3 months from the start) - Questionnaire (30 mins) - Measure height, weight and waist circumference (5 mins, optional) - Wear activPAL device (7 days continuously)	X	X
With the 3-month follow-up questionnaire: Feedback questionnaire (5 mins)	X	
Follow-up assessments (6 months from the start) - Questionnaire (30 mins) - Measure height, weight and waist circumference (5 mins, optional) - Wear activPAL device (7 days continuously)	X	X
With the 6-month follow-up questionnaire: Feedback questionnaire (5 mins)	X	
End of study semi-structured interviews (optional) (30 mins)	X	

If we become aware during the study that a participant has lost the capacity to consent (for example due to a cognitive impairment) they would be withdrawn from the study. Data already collected would be retained but they would not be asked to complete any further assessments.

Optional extra: Linking in with NHS Digital

This part of the study is optional, so it is up to you to choose if you wish to be involved in this part.

We would also like to see if there is a longer term impact of participating in this study on your health. We do not currently have funding for this part of the research but will apply for this in the future. With your permission, we would use your NHS number, and other information (e.g. name, date of birth) to identify your records held by the National Disease Registration Service (NDRS) and Hospital Episode Statistics (HES) currently held by NHS Digital. We will then obtain information about your cancer and health from these registries. NDRS registries collect data on all cases of cancer. The data is used to support public health, healthcare and research. More information about NDRS can be found at: https://www.ndrs.nhs.uk/ or NDRS has a patient information leaflet: https://www.ndrs.nhs.uk/wp-content/uploads/2019/01/Cancer-Registration-information-leaflet-JAN-19-WEB.pdf. The HES database collects data on all hospital admissions, attendances and appointments.



NHS Digital data will help us see if the intervention has any effect on long term future health

We may access this registry for up to 12 years after the study has ended, so that we can measure how being in the group that received the intervention affects future health and wellbeing, compared to not receiving this, without having to contact you to fill in more questionnaires in the future. **You can still participate in this study, even if you choose not to give us permission to access the information held in NDRS/HES.**

2 What are the possible benefits of taking part?

- There may not be any direct benefit for you in taking part in this study. We hope that people in the intervention group may notice an improvement in their health or wellbeing, but at the moment, it is unknown what effect the intervention will have.
- The information that we get from this study will tell us whether the intervention (leaflet, app and advice) is beneficial or not, and will help shape future research and health services for people affected by cancer.

3 What are the possible disadvantages and risks of taking part?

- Some people may find the study assessments (e.g. completing questionnaires, wearing the activPAL) inconvenient. The activPAL devices are very small, are worn underneath your clothes, so they are not visible. The device should not interfere with usual activities, but some people may find them uncomfortable. A small number of people may find that wearing the device irritates their skin and if this is the case the device should be removed. We can provide alternative dressings to see if that helps.
- Some people may find answering the questions about their physical/emotional wellbeing upsetting. If you feel any distress during the study, please contact the research team who, with your permission, can inform a member of your clinical team, or signpost you to appropriate support services (see box on next page). Section 9 contains their contact details.

4 How will we use information about you?

- We will use information from you and from your hospital records and, if you consent to it from NDRS/HES, for this research project.
- This will include your name, contact details (telephone number, email address, postal address), date of birth, and NHS number (if consented to NDRS/HES). We will use this information to do the research or to check your records to make sure that the research is being done properly.
- Researchers who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
- We will keep all information about you safe and secure.
- Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

5 What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would still like to collect information about your health from your hospital records (for the 6 months you would have been on the study, as detailed in section 1, point 6 above) and NDRS/HES (if you consented to this). If you do not want this to happen, tell us and we will not do this.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- Through taking part in this study, your data may be used in future research. An anonymous version of the dataset in which it is not possible to identify you will be shared publicly at the end of the trial.

Other sources of support:

MACMILLAN CANCER SUPPORT
0808 239 3371
7 days a week, 8am to 8pm
https://www.macmillan.org.uk/

BREAST CANCER NOW The research & care charity
0808 800 6000
Monday - Friday 9am-4pm; Saturday 9am-1pm
https://breastcancernow.org/

PROSTATE CANCER UK
0800 074 8383
Monday - Friday 9am to 5pm
https://prostatecanceruk.org/

Bowel Cancer UK
020 7940 1760
Monday - Friday 9am to 5pm
https://www.bowelcanceruk.org.uk/

6 Where can you find out more about how your information is used?

- By asking one of the research team or reading our local data privacy notice at the end of this document
- By visiting https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies
- https://www.hra.nhs.uk/information-about-patients/
- By asking the Sponsor Data Protection Officer at data-protection@ucl.ac.uk

7 What if something goes wrong?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by staff working on this study, NHS or University College London (UCL) complaints mechanisms are available to you. Any concerns will be investigated and if poor practices are identified, immediate steps will be taken to correct these. In the unlikely event that you are harmed by taking part in this study, compensation may be available. After discussing with your research doctor, please make the claim in writing to Professor Abigail Fisher who is the Chief Investigator for the research and is based at UCL. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

If you have a concern about any aspect of this study, you should speak to the researchers (contact details below) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this via the hospital's Patient Advisory Liaison Service (PALS).

[contact details for site's PALS to be inserted]

8 About the APPROACH research study

Who is organising and funding the research?

The study is sponsored and run by University College London (UCL). This study is being overseen by Professor Abi Fisher in the Department of Behavioural Science & Health, and involves a team of researchers from UCL, University of Leeds, University of Sheffield, Sheffield Teaching Hospitals NHS Foundation Trust, and Anglia Ruskin University. The study is funded by Yorkshire Cancer Research.

What will happen to the results of the research project?

The results of this study will be published in scientific/medical journals and discussed at conferences/meetings, so that other researchers, health professionals and members of the public know what we have found. You will not be identified in any reports, publications or presentations about the study. When the study is finished, we will write the study results into a brief report and send this to you.

How have patients and the public been involved in this study?

We have conducted development work (including selecting the app) with people affected by breast, prostate and bowel cancer and healthcare professionals. The materials provided to participants in this study have been reviewed by people affected by cancer and adapted based on their advice. We have run a pilot trial where 90 people completed a very similar study but without the 6-month assessment. Some small changes were made based on their feedback but overall they were happy with the study procedures.

Who has reviewed this study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee (REC), which is there to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable ethical opinion by the [insert name of ethics committee] and the Health Research Authority (HRA) in accordance with UK regulations.

9

Contact details for further information

If you are thinking of taking part and have a question, please contact:
[APPROACH/Leeds team phone number/email]

If you you have given consent, and have a question or concern, please contact:
[**UCL trial phone number / email]**

Chief Investigator of the study: **Professor Abigail Fisher**
Tel: 020 7679 1722 Email: abigail.fisher@ucl.ac.uk
Department of Behavioural Science & Health, University College London, Gower Street, London WC1E 6BT

Thank you for reading this information sheet & for considering taking part in this study.

If having read this you would like to participate, please click next to go to the consent form.

If you would rather provide consent over the phone, please contact us on:
[APPROACH study email]
or [phone number]

APPROACH study - Local Data Protection Privacy Notice

The information that is required to be provided to participants under data protection legislation (GDPR and Data Protection Act 2018) is provided across both the 'local' and 'general' privacy notices.
This 'local' privacy notice sets out the information that applies to this particular study. Further information on how University College London (UCL) uses participant information can be found in our 'general' privacy notice, which you can view at this web address: https://www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice.

Notice:

University College London is the sponsor for this study (based in the UK) and will be the controller for this project. The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk

The items (categories) of personal data used will be as follows:

- Name
- Contact details (telephone number, email address, postal address)
- Date of birth
- NHS number (if consented to NDRS/HES)
- Gender
- Education
- Employment
- Marital status and living arrangements
- Ethnic origin
- Details of your cancer diagnosis and treatment
- Other health conditions you might have been diagnosed with before or after participating in the study
- Measures of physical and mental health (e.g. fatigue, sleep, quality of life, activity, height & weight, thoughts and feelings)

The lawful basis that will be used to process your personal data will be performance of a task in the public interest. The lawful basis used to process special category personal data will be for scientific and historical research or statistical purposes.This means that we use personally-identifiable information to conduct research that serves the interests of society (e.g. to improve health, care and services). This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Because of this, your rights to access, change or move your information are limited. If you choose to withdraw from the study, we will keep the information about you that you have already provided (e.g. your answers to questionnaires).

If you withdraw before we access information held about you in NDRS/HES, we will ask you if you are still happy for us to do this or not. If not, then we will delete your personally identifiable data from our study database. We will keep the information you entered on the online consent form, including your name and signature, in order to be able to provide proof of consent to regulatory agencies.

Your personal data will be processed so long as it is required for the research project. We will pseudonymise the data you provide as early as possible by using an ID number to identify you, and will endeavour to minimise the processing of personal data wherever possible. All data will be anonymised 12 years after the trial end date (all personally identifiable data, including consent forms will be deleted).

APPROACH study - Local Data Protection Privacy Notice

An anonymised version of the data set in which you can not be identified will be made publicly available at the end of the trial. This is so that other researchers can check our results and so that further analysis can be conducted using the data.

Study data will be collected using REDCap electronic data capture system hosted at UCL. This means that you, or a researcher, will enter data through an online questionnaire and it will be instantly stored securely at UCL.

Researchers at UCL, University of Leeds, and [insert hospital site name], will have access to information that identifies you. Only the CI, trial manager and nominated members of the research team (at these organisations) who require access to the personal identifiable data will be able to access this information. Other members of the research team (who do not require access to the personal identifiable data) will only be able to identify participants via a pseudonym (their trial ID number).

Personal data will not be shared outside of UCL, University of Leeds, and [insert hospital site], unless you have given us permission to access health information held about you in the NDRS/HES.

If you give us permission to access information about your long term health from NDRS/HES, we will access your NHS number, and share your personal information such as your name, date of birth, address, sex and NHS number, with the national bodies who hold this data (currently NHS Digital) so that they can identify you in their records.

All interviews will be audio-recorded and uploaded directly to a secure area of UCL's computer systems, saved under the relevant ID number, and deleted from all other devices. The same procedure will be followed for participants in the intervention group who are happy for us to record the telephone/video calls that are part of the intervention. They may be transcribed by a specialist external transcription company (TP Transcription: Their data protection policy can be found at https://www.tptranscription.co.uk/data-protection-personal-data-and-gdpr-policy). When they are transcribed, any names mentioned will be changed to maintain confidentiality. Direct quotes from these telephone calls may be used in presentations, written reports, journal publications or for teaching purposes, but it will not be possible to personally identify you. No other use will be made of the original recordings without your written permission, and no one outside the project will be allowed access to the original recordings.

Assurances on confidentiality will be strictly adhered to unless evidence of wrongdoing or potential harm is uncovered. In such cases the University may be obliged to contact relevant statutory bodies/agencies.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk. If you remain unsatisfied, you may wish to contact the Information Commissioner's Office (ICO). Contact details, and further details of data subject rights, are available on the ICO website at: www.ico.org.uk