

 **Participant Information Sheet**

**Title of Study:** APPROACH: an app for health & wellbeing after cancer

This information sheet provides information about a study for people diagnosed with breast, prostate or bowel (colorectal) cancer. In order to 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.

This page provides a brief summary of the key details of the study. If you are interested, please read the more detailed information in the rest of the document.

**If you would prefer to talk to a member of our team about the study, would like more information, or if there is anything that is not clear, please contact us using the contact details provided in Section 13 below.** Please take time to decide whether or not you wish to take part.

*Thank you for reading this.*

**STUDY SUMMARY**

* This research study will look at whether use of a smartphone app, that aims to help you to walk more, can improve the health and wellbeing of people affected by cancer. This study is a pilot study. This means we will use the results to help us plan a bigger study that will be able to tell us whether the app is beneficial or not.
* You are invited because you have been diagnosed with either breast, prostate or bowel cancer. Only 90 people can take part in this study and you can take part before, during or after any cancer treatment.
* It is up to you to decide whether or not to take part – you do not have to. If you do, you may withdraw at any time without giving a reason. Your medical treatment will not be affected.
* If you decide to take part, we will ask you to fill in an online questionnaire about different aspects of your health and to wear a small device on your thigh for 7 days. This device measures the amount of time you spend sitting, lying down, asleep and moving around, and means you don’t have to record this for the study.
* After this, we will randomly assign you to one of two groups. Both groups will continue to receive standard medical care and advice. One group will also receive a leaflet and two telephone calls/video calls about a smartphone app that they might find useful. After 3 months, we will ask everyone to complete another questionnaire and wear the same device again for another 7 days. This is so we can see if there are any differences in health and wellbeing between the group who receive advice and a recommendation to use this app, versus the usual medical care and advice you would receive normally.
* In this research study we will use information from you and your hospital records. We will use information about your health that is routinely collected and held in national registries (currently held by Public Health England/NHS Digital), only if you choose to consent to this optional part of the study. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data so that we can check the results. We will make sure no-one can work out who you are from the reports we write. The information below tells you more about this.
* The knowledge that we get from carrying out this study will help shape future health services for people affected by cancer and future research studies in this area.

**If you think you might be interested in taking part in this study, please read the rest of this information sheet for the full details.**

Please contact us if you would like to know any more details or have any questions.

1. **What do I have to do for this study?**
* Firstly, you will need to complete the online consent form. If you have an appointment to meet with a researcher you can complete the form at the hospital once you have spoken with them. If you do not have an appointment with a researcher and are happy to complete the form please go to the website (STUDY WEBSITE) once you have read all of the information below.
* On the study website, all the information in this document is presented again and you can then click through to find the consent form. Here 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.
* If you choose ***not*** to take part, it would be helpful to the research team to find out if there are any specific reasons for this. This is entirely optional and you do not have to provide a reason for not taking part if you do not want to. If you are happy to share your reasons, we will ask you to briefly describe why (e.g. via email or over the phone) or you can participate in a short recorded telephone interview and give us a few more details. Telephone interviews will be recorded and transcribed by a company called TP Transcription, as decribed in section 2. You can consent to participating in an interview, but not the rest of the study, on the consent form at the end of the study website.
* If you choose to take part, we will collect some information about you, your cancer diagnosis & treatment, and other aspects of your health held in your hospital records. We will also ask you to fill in an online questionnaire that asks about different aspects of your health and is expected to take up to 30 minutes to complete. There will be an option on the questionnaire to stop and restart later if you need to do this.
* We will also measure your height, weight and waist circumference (or ask you to do so if we do not meet you in person). We will give you a new set of weighing scales and a measuring tape so you can send us your weight and waist circumference (using another online questionnaire) at the start of the study, if we do not meet with you, and again later in the study. You can keep the weighing scales and measuring tape.
* We will ask you to wear a small device called an activPAL for 7 days, before sending 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 over a week, and means you don’t have to record this for us with daily questionnaires. The devices are 2.4cm wide (less than an inch), 4.3cm long (less than 2 inches), and 0.5cm thick. They fit easily underneath your clothes and should not cause any discomfort or inconvenience in your usual activities or sleeping. They are waterproof, so you can keep them on at all times. They are expensive and reusable, so please make sure you send them back to us. However, please note that you will not be asked to pay for the device if it is lost, misplaced or damaged.
* After this, a computer program will randomly assign you to one of two groups, and you will be informed which group you are in. Neither you, the research team or any of your health professionals have any control over which group you are assigned to – it is selected completely at random by the computer program.
* Both groups will continue to receive the medical care and advice that they would normally have, regardless of taking part in this study.
* One group (known as the intervention group) will also receive a specially designed leaflet via post with further details about a **free** smartphone app that can encourage you to do more walking to help you to move more. This group will also receive two telephone calls/video calls from a member of the study team, to further explain the purpose of the app, and to help with any problems downloading or using the app. The app is only available on smartphones that use Android or iOS (Apple) operating systems. The sound from these telephone/video calls may be recorded and you will be informed at the beginning of the telephone/video call if this is the case.
* The second group (the usual care group) will not receive any additional information throughout the study. This group is very important as it helps us to understand how receiving extra support (the app, a leaflet and two telephone calls/video calls) compares to the current medical care/advice that is offered. If you are assigned to this group, your participation will be extremely important to help us answer this question and to help us design future research and healthcare services.
* After 3 months, we will ask people in both groups to fill in another online questionnaire (approx. 30 minutes to complete) and to wear the activPAL device again for another 7 days. We will also ask everyone to weigh themselves and measure their waist circumference again. We will organise this via telephone, email or post. Those who are in the intervention group will also be asked to answer some brief additional questions to provide feedback about the support they received.
* We will ask some people (from both groups) to take part in a telephone interview at the end of the 3 month period to discuss their experiences of taking part in the study. If you are in the group that received the app, we will also ask about your opinions and experiences of using the app. These telephone interviews will be recorded and participants will be reminded of this at the start of the call. Taking part in these interviews is optional.
* A summary of what we would like you to do to take part in this study if you are allocated to either group, and the estimated amount of time for each activity, is shown in the table below:

|  |  |  |
| --- | --- | --- |
| **Study activities (estimated time taken 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)
* Wear activPAL device (7 days continuously)
 | **x** | **x** |
| Read study leaflet (5 mins) and receive two phone/video calls (30 mins and 10 mins) about the app  | **x** |  |
| Follow-up assessments (3 months later)* Questionnaire (30 mins)
* Measure height, weight and waist circumference (5 mins)
* Wear activPAL device (7 days continuously)
 | **x** | **x** |
| With the follow-up questionnaireFeedback questionnaire (10 mins) | **x** |  |
| End of study semi-structured interviews (optional) (30 mins) | **x** | **x** |

* We would like to see if there is a longer term impact of participating in this study on your health. With your permission, we will use your NHS number (taken from your hospital records), and other information (e.g. name, date of birth) to identify your records held by the National Cancer Registration and Analysis Service (NCRAS) and the linked Hospital Episodes Statistics (HES) registries currently held by Public Health England and NHS Digital. We will then obtain information about your cancer and your health from these registries. NCRAS and HES registries collect data on all cases of cancer and all times that people are admitted to hospital, or attend A&E or outpatient appointments at hospitals in England. The data is used to support public health, healthcare and research. More information about NCRAS can be found at: <https://www.ndrs.nhs.uk/>. NCRAS also has a patient information leaflet which can be found at: <https://www.ndrs.nhs.uk/wp-content/uploads/2019/01/Cancer-Registration-information-leaflet-JAN-19-WEB.pdf>. We may access these registries for up to 12 years after the study has ended, so that we can measure how being in the group that received information about the app 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 these registries.**
1. **What are the possible benefits of taking part?**
* The information that we get from carrying out this study will help us design a larger trial to test the potential benefits of the intervention, compared to usual care. This larger trial will be able to tell us whether the intervention is beneficial or not, and help shape future research and health services for people affected by cancer.
* 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.
1. **What are the possible disadvantages and risks of taking part?**
* Some people may find the study assessments (e.g. completing questionnaires, wearing the activPAL device) inconvenient. The activPAL devices are very small and are worn underneath your clothes, so they are not visible. Wearing the device should not interfere with usual activities, but some people may find them uncomfortable.
* We will interview a number of participants from both groups at the end of the study about what they thought was good and bad about the research. This would be an opportunity for you to let us know what you thought about taking part or if you experienced any disadvantages of taking part.
1. **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 NCRAS/HES registries, for this research project.

This information will include your name, contact details (telephone number, email address, postal address), date of birth, and NHS number. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People 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.

1. **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, and have consented to us doing so, we would like to continue collecting information about your health from NCRAS/HES registries. If you do not want this to happen, tell us and we will stop.

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.

If you agree to take part in this study, your data may be used in future research as the anonymous research data will be stored in the UCL Data Repository.

1. **Where can you find out more about how your information is used?**

You can find out more about how we use your information:

* In our local data privacy notice below (Section 14)
* www.ucl.ac.uk/legal-services/privacy
* [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
* by asking one of the research team (study email and mobile number)
* by asking the Sponsor Data Protection Officer at data-protection@ucl.ac.uk
1. **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 members of staff working on this study, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. Alternatively if you have concerns please contact the study team (study email and mobile number). Everyone working on the trial will have been trained in how to maintain Good Clinical Practice (the international ethical, practical and sceintific standards to which all clinical research is conducted) but 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. If you suspect that the harm is the result of the Sponsor’s (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr Abi 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 ask to speak to the researchers who will do their best to answer your questions. The researcher’s contact details are at the end of the document. If you remain unhappy and wish to complain formally, you can do this via the hospital’s Patient Advisory Liaison Service (PALS).

Patient Experience Team

Doncaster Royal Infirmary

Armthorpe Road

Doncaster

DN2 5LT

01302 642764 or 01302 642767

dbth.pals.dbh@nhs.net

1. **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 in the UK and abroad, so that other researchers, health professionals and members of the public know what we have found.
* You will not be identified in any written reports, publications or presentations about the study.
* When the study is finished and we have looked at the results, we will write these up into a brief report and send this to you.
1. **Who is organising and funding the research?**

The study is sponsored and run by University College London (UCL). This study is being overseen by Dr 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.

1. **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 Yorkshire & The Humber - South Yorkshire Research Ethics Committeeand the Health Research Authority (HRA) in accordance with UK regulations.

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

We have conducted development work with people affected by breast, prostate and colorectal cancer and healthcare professionals working with patients diagnosed with these cancers. The app used in this study was selected based on feedback from interviews with these groups. The materials provided to participants in this study have been reviewed by people affected by cancer and adapted based on their advice.

1. **What if relevant new information becomes available**?

If new information becomes available during the research that is deemed relevant to a participant's continued participation in the study, the Chief Investigator will contact you to let you know about this and you can decide if you wish to continue with the study or not.

1. **Contact for further information**

Please contact the Principal Investigator, Dr Abi Fisher in the first instance:

**Dr Abi 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 and for considering taking part in this research study. You can find the Local Data Protection Privacy Notice on the next page**

1. **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 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
		- 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, diet, 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 HES/NCRAS registries, 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). The anonymised data will be entered into the UCL Data Repository and retained for at least 20 years from the trial end date. The information collected about you may be used to support other research in the future, and may be shared anonymously with other researchers.
* Study data will be collected using REDCap electronic data capture tools hosted at UCL[94, 95]. 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 Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust, 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 Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust, unless you have given us permission to access health information held about you in the NCRAS/HES registries Anonymised/pseudonymised data may be shared with other researchers in other organisations/institutions for data analysis. These organisations may be universities, NHS organisations or companies involved in health and care research. This information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>). This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or affect your care. It will not be used to make decisions about future services available to you, such as insurance.
* If you give us permission to access information about your long term health from NCRAS/HES registries, we will access your NHS number from the hospital, 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 Public Health England/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 will 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](http://www.ico.org.uk).