

# APPROACH: a mobile phone app to encourage increased health & wellbeing after cancer

<b>Submission date</b> 06/09/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/09/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/11/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

People living with and beyond cancer are at increased risk of many long-term consequences of cancer and its treatment, including fatigue, pain, sleep disturbance, anxiety and depression. Physical activity has many benefits after a cancer diagnosis, including reduction of these symptoms as well as reduced risk of cancer recurrence and mortality. Cancer patients have reported that they view walking as the type of physical activity they would be most likely to engage in. The aim of this study is to explore the clinical and cost-effectiveness of a smartphone app-based intervention (with additional support) that promotes brisk walking among those living with localised breast, prostate or colorectal cancer across hospital sites in Yorkshire and some additional surrounding areas. This is a potentially low-cost intervention which could be integrated into routine care and increase activity levels in this group and therefore improve their health and well-being.

### Who can participate?

Men and women, aged over 16 years old, who are not currently meeting physical activity guidelines and have been diagnosed with breast, prostate or colorectal cancer at one of the recruiting NHS hospital sites in Yorkshire and surrounding areas listed below.

### What does the study involve?

At the start of the study, participants will be asked to complete an online questionnaire about different aspects of their health, including their physical activity, quality of life, fatigue, sleep, anxiety and depression, their confidence about doing physical activity and managing their cancer, habit strength for walking and health and social care service use. They will also be asked to weigh and measure themselves and to wear a small device (an accelerometer) on their thigh for 7 days. This device measures the amount of time spent sitting, lying down, asleep and moving around. These measures will be repeated at 3 and 6 months after they are randomised. Participants will be randomly allocated to an intervention or control group. The control group will continue to receive their usual care. The intervention group will receive a leaflet about physical activity and cancer, guidance about how to download the app being recommended to participants (the app promotes and tracks brisk walking) and a walking planner. Intervention participants will also receive two behavioural support telephone/video calls, focusing on the benefits of brisk walking and how participants may use the app to increase their walking and

resolve any problems downloading the app. Participants in the intervention group may also be invited to participate in an interview to tell the researchers what they thought about participating in the study and how they found using the app.

What are the possible benefits and risks of participating?

It is hoped 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 (if any). Some people may find the study assessments (e.g. completing questionnaires, wearing the accelerometer device) inconvenient. The accelerometers are very small and are worn underneath clothes, so they are not visible. Wearing the device should not interfere with usual activities, but some people may find them uncomfortable.

Where is the study run from?

The study is run by University College London (UCL), with collaborators at the University of Leeds, Anglia Ruskin University, the University of Sheffield, Sheffield Teaching Hospitals NHS Foundation Trust and the recruiting hospital sites in the UK.

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

Who is funding the study?

1. Yorkshire Cancer Research (UK)
2. National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

1. Dr Fiona Kennedy, [f.r.kennedy@leeds.ac.uk](mailto:f.r.kennedy@leeds.ac.uk)
2. Prof Abigail Fisher, [abigail.fisher@ucl.ac.uk](mailto:abigail.fisher@ucl.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Fiona Kennedy

### ORCID ID

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### Type(s)

Principal investigator

**Contact name**

Prof Abigail Fisher

**ORCID ID**

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**Contact details**

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WC1E 6BT

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

330862

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

CPMS 58274, IRAS 330862

## **Study information**

**Scientific Title**

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

**Acronym**

APPROACH RCT

**Study objectives**

The primary research objective is to compare the effect of a theory-driven, app-based intervention that promotes brisk walking in addition to usual care and usual care, on activPAL-assessed average minutes of brisk walking ( $\geq 100$  steps per minute) in adults living with breast, prostate or colorectal cancer after 3 months.

The key secondary objectives are:

1. To compare the effect of a theory-driven, app-based intervention that promotes brisk walking in addition to usual care and usual care, in adults living with breast, prostate or colorectal cancer on:
  - 1.1. activPAL-assessed average minutes of brisk walking ( $\geq 100$  steps per minute) after 6 months

- 1.2. activPAL-assessed average total steps, minutes of light physical activity, standing time and sitting time at 3 and 6 months
- 1.3. Body Mass Index (BMI) at 3 and 6 months (self-reported)
- 1.4. Waist circumference at 3 and 6 months (self-reported)
- 1.5. Self-reported physical activity at 3 and 6 months
- 1.6. Health status, cancer-specific quality of life, fatigue, sleep quality, anxiety, depression, social support, self-efficacy to manage cancer and physical activity self-efficacy at 3 and 6 months
- 1.7. Habit strength for walking at 3 and 6 months
2. To assess the cost-effectiveness of a theory-driven, app-based intervention that promotes brisk walking in addition to usual care and usual care, in adults living with breast, prostate or colorectal cancer.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 03/10/2023, London-Surrey Research Ethics Committee (Meeting held by video-conference via Zoom, London, None available, United Kingdom; +44 (0)207 104 8088, (0)207 104 8131; surrey.rec@hra.nhs.uk), ref: 23/LO/0740

## **Study design**

Randomized interventional process of care study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Cancer

## **Interventions**

Participants will be randomised into intervention or control groups using minimisation with a 1:1 allocation ratio. Stratification factors will be cancer type (breast, prostate or colorectal) and hospital location. The first participant will be randomly allocated, then each subsequent participant will be allocated based on the imbalance scores (calculated as a function of current allocations after a hypothetical allocation of the new participant in each study arm). The new participant will be allocated to the arm with the lowest imbalance score. A 20% random element will be included in the algorithm. Researchers collecting follow-up assessments and statisticians will be blind to group allocation.

Control: Usual care

Intervention: An app that promotes and tracks brisk walking. A leaflet that provides information on physical activity guidelines and promotes brisk walking and the use of the app. Two telephone calls with a researcher to provide behavioural support for increasing brisk walking and using the app.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Daily average minutes of brisk walking ( $\geq 100$  steps per minute) measured using an objective measure (an activPAL accelerometer), worn for 7 days at baseline, 3 and 6 months

## **Key secondary outcome(s)**

1. Average total steps, minutes of light physical activity, standing time and sitting time measured using an activPAL accelerometer at baseline, 3 and 6 months
2. Body Mass Index (BMI) self-reported using scales provided by the study at baseline, 3 and 6 months
3. Waist circumference self-reported using tape measure provided by the study at baseline, 3 and 6 months
4. Self-reported physical activity measured using the Godin Leisure Time Exercise Questionnaire (GLTEQ) at baseline, 3 and 6 months
5. Self-reported health status (using the five-level EuroQol-5D questionnaire, EQ-5D-5L), cancer-specific quality of life (using the Functional Assessment of Cancer Therapy-general, FACT-G), fatigue (FACT-F), sleep quality (Pittsburgh Sleep Quality Index, PSQI), anxiety (Generalised Anxiety Disorder Assessment, GAD-7), depression (Patient Health Questionnaire, PHQ-9), social support (brief form of the Perceived Social Support Questionnaire, F-Soz-UK-6), self-efficacy to manage cancer (Cancer Survivorship Self-Efficacy Scale, CS-SES) and physical activity self-efficacy (Physical Activity Appraisal Inventory, PAAI) at baseline, 3 and 6 months
6. Habit strength for walking measured using the Self-Report Behavioural Automaticity Index (SRBAI) at baseline, 3 and 6 months
7. App usage (in the intervention group) measured using questions from the Digital Behaviour Change Interventions Engagement Scale at 3 and 6 months
8. Health and social care service use measured using the Client Service Receipt Inventory (CSRI) at baseline, 3 and 6 months
9. Hospital service use measured using medical records over the 30 weeks after randomisation

## **Completion date**

31/03/2027

# **Eligibility**

## **Key inclusion criteria**

Note, points 1 and 2 are checked by the clinical care team in the initial medical record eligibility screening.

1. Diagnosed with breast, prostate or colorectal cancer within the last 2 and a half years at a participating hospital site
2. Aged 16 years or older
3. Own a smartphone (that uses Android or iOS (Apple) operating systems)
4. Willing and able to provide informed consent
5. Has access to a computer or tablet and an email address, and is willing to complete online questionnaires.
6. Willing to wear an accelerometer for a week at the assessment points

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

16 years

**Upper age limit**

99 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

Note, points 1a, 4, 5, 6 and 13 are checked by the clinical care team in the initial medical record eligibility screening.

1. Patients who are more than 2 years post-diagnosis at the point of screening by hospital staff. Due to the potential time gap between screening/inviting participants and then consenting we will exclude patients who are more than 2 and a half years post-diagnosis at consent.
2. Unable to understand spoken/written English
3. ECOG status > 3
4. Diagnosed cognitive impairment (e.g. dementia)
5. Cognitive and/or physical impairment that prevents participation in brisk walking
6. Those who have a current diagnosis of metastatic disease
7. Due to have surgery to remove cancer in the next 5 months
8. < 6 weeks after surgery to remove cancer at consent
9. Reports achieving 150 minutes of at least moderate intensity PA weekly [80]
10. Report previous/current use of the study app
11. Current participation in a health behaviour change study
12. Live with someone already participating in the trial
13. Incarcerated (i.e. address is a prison)
14. Already participated in the APPROACH pilot study (only applies at the pilot hospital site)

**Date of first enrolment**

23/10/2023

**Date of final enrolment**

31/12/2025

**Locations****Countries of recruitment**

United Kingdom

**Study participating centre**

Doncaster Royal Infirmary

Armthorpe Road

Doncaster  
England  
DN2 5LT

**Study participating centre**  
**Northern General Hospital**  
Herries Road  
Sheffield  
England  
S5 7AU

**Study participating centre**  
**St James's University Hospital**  
Beckett Street  
Leeds  
England  
LS9 7TF

**Study participating centre**  
**Barnsley Hospital NHS Foundation Trust**  
Gawber Road  
Barnsley  
England  
S75 2EP

**Study participating centre**  
**Pinderfields Hospital**  
Aberford Road  
Wakefield  
England  
WF1 4DG

**Study participating centre**  
**Calderdale and Huddersfield NHS Foundation Trust**  
Trust Headquarters  
Acre Street  
Lindley  
Huddersfield  
England  
HD3 3EA

**Study participating centre**  
**University College London**  
Behavioural Science and Health  
Gower Street  
London  
England  
WC1E 6BT

**Study participating centre**  
**University of Leeds**  
School of Medicine  
Worsley Building, Woodhouse  
Leeds  
England  
LS2 9TU

**Study participating centre**  
**Rotherham District General Hospital**  
Moorgate Road  
Rotherham  
England  
S60 2UD

**Study participating centre**  
**Bradford Teaching Hospitals NHS Foundation Trust**  
Bradford Royal Infirmary  
Duckworth Lane  
Bradford  
England  
BD9 6RJ

**Study participating centre**  
**The Christie**  
550 Wilmslow Road  
Withington  
Manchester  
England  
M20 4BX



**Study participating centre****Sherwood Forest Hospitals NHS Foundation Trust**

Kings Mill Hospital  
Mansfield Road  
Sutton-in-ashfield  
England  
NG17 4JL

**Study participating centre****Scarborough Hospital**

Woodlands Drive  
Scarborough  
England  
YO12 6QL

**Study participating centre****South Tyneside and Sunderland NHS Foundation Trust**

Sunderland Royal Hospital  
Kayll Road  
Sunderland  
England  
SR4 7TP

## **Sponsor information**

**Organisation**

University College London

**ROR**

<https://ror.org/02jx3x895>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health and Care Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Yorkshire Cancer Research

**Alternative Name(s)**

YCR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. At the end of the trial, a dataset that is functionally anonymous in the hands of the public (ID number and hospital site removed and date of birth translated into an age bracket for the age of the participant on the date of randomisation) will be shared publicly on Open Science Framework. This has been approved by UCLs Data Protection Officer. 12 years after the end of the trial all identifiable information will be deleted and the data will remain available on the Open Science Framework. The consent form states "I understand that information collected about me may be used to support other research in the future, and may be shared anonymously with other researchers. I will not be identified."

**IPD sharing plan summary**

Stored in publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 5		17/10/2023	No	Yes

<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes