

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

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| Submission date 06/09/2023 | Recruitment status Recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 11/09/2023 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 20/05/2025 | Condition category 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. 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.

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 June 2026

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
2. Prof Abigail Fisher, abigail.fisher@ucl.ac.uk

Study website

<https://www.ucl.ac.uk/epidemiology-health-care/approach-using-mobile-app>

Contact information

Type(s)

Scientific

Contact name

Dr Fiona Kennedy

ORCID ID

<http://orcid.org/0000-0002-4910-2505>

Contact details

Leeds Institute of Health Sciences
University of Leeds
Worsley Building, Level 10
Clarendon Way
Leeds
United Kingdom
LS2 9NL
+44 (0)113 3430813
f.r.kennedy@leeds.ac.uk

Type(s)

Principal Investigator

Contact name

Prof Abigail Fisher

ORCID ID

<http://orcid.org/0000-0001-9284-6780>

Contact details

University College London

Gower Street

London

United Kingdom

WC1E 6BT

+44 (0)2076791722

abigail.fisher@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

330862

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 (≥ 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 (≥ 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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

See study outputs table

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2022

Completion date

30/06/2026

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

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

Planned Sample Size: 472; UK Sample Size: 472

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

30/09/2025

Locations

Countries of recruitment

United Kingdom

Study participating centre

Doncaster Royal Infirmary

Armthorpe Road

Doncaster

United Kingdom

DN2 5LT

Study participating centre

Northern General Hospital

Herries Road

Sheffield

United Kingdom

S5 7AU

Study participating centre

St James's University Hospital

Beckett Street

Leeds

United Kingdom

LS9 7TF

Study participating centre

Barnsley Hospital NHS Foundation Trust

Gawber Road

Barnsley

United Kingdom

S75 2EP

Study participating centre

Pinderfields Hospital

Aberford Road

Wakefield

United Kingdom

WF1 4DG

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

Study participating centre
University College London
Behavioural Science and Health
Gower Street
London
United Kingdom
WC1E 6BT

Study participating centre
University of Leeds
School of Medicine
Worsley Building, Woodhouse
Leeds
United Kingdom
LS2 9TU

Study participating centre
Rotherham District General Hospital
Moorgate Road
Rotherham
United Kingdom
S60 2UD

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

Sponsor information

Organisation

University College London

Sponsor details

UCLH/UCL Joint Research Office

4th Floor, West

250 Euston Road

London

England

United Kingdom

NW1 2PG

+44 (0)20 7679 2000

uclh.randd@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.ucl.ac.uk/>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2026

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? |
|---|-----------|--------------|------------|----------------|-----------------|
| Participant information sheet | version 5 | | 17/10/2023 | No | Yes |