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

Submission date
06/09/2023

Recruitment status
No longer recruiting

Registration date
11/09/2023

Overall study status
Ongoing

Last Edited
21/01/2026

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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
2. Prof Abigail Fisher, abigail.fisher@ucl.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
330862

Central Portfolio Management System (CPMS)
58274

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

Primary study design
Interventional

Study design
Randomized interventional process of care study

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 (≥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
476

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 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
21/01/2026

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 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?
Protocol article		13/01/2026	14/01/2026	Yes	No
Participant information sheet	version 5		17/10/2023	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes