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A pilot randomised controlled trial of an app with brief behavioural support to promote physical activity after a cancer diagnosis

Submission date
02/04/2021

Recruitment status
No longer recruiting

Registration date
16/04/2021

Overall study status
Completed

Last Edited
07/05/2025

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 with. The aim of this pilot study is to assess whether it is possible to run a randomised controlled trial to test the impact of a walking intervention delivered via smartphone app (with behavioural support) in people affected by breast, prostate or colorectal cancer. This trial will be a small-scale version (a pilot) of a planned larger trial and will examine whether it is feasible and acceptable to conduct this research. The main focus of the pilot study will be on the recruitment rate (how many, of those we invite to participate, choose to do so), how acceptable it is to randomise participants, if it is possible to deliver the intervention as planned and if participants find this acceptable, how many people drop-out of the study, if participants complete the assessments, and how they feel about these.

Who can participate?
Men and women, over the age of 16, who are not currently meeting physical activity guidelines and have been diagnosed with breast, prostate or colorectal cancer at Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust.

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 about 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 3 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, and guidance about how to download the app being recommended to participants (the app promotes and tracks brisk walking). 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 resolving any problems downloading the app.
Participants may also be invited to participate in an interview to tell the researchers what they thought about participating in the study and, in the intervention group, how they found using the app. Interviews will also be conducted with those who choose not to participate in the study to gain more detailed insight into why this might be and how this can be addressed in future studies.

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 from UCL, with collaborators at the University of Leeds, Anglia Ruskin University, the University of Sheffield, Sheffield Teaching Hospitals NHS Foundation Trust and Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2019 to February 2023

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Dr Phillippa Lally, p.lally@surrey.ac.uk
Dr Abigail Fisher, abigail.fisher@ucl.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
235354

Central Portfolio Management System (CPMS)
48241

Protocol serial number
Sponsor protocol number 125203, , , Grant Codes: UCL420

Study information

Scientific Title
APPROACH: an app for health and wellbeing after cancer – a pilot randomised controlled trial

Acronym
APPROACH: pilot

Study objectives
The primary research objective is to assess the feasibility and acceptability of the trial procedures. Feasibility and acceptability will be considered by estimating recruitment rates among those eligible to take part, assessing the acceptability of randomization, feasibility and acceptability of administering the intervention to participants, retention to the study in the two experimental groups, acceptability of outcome assessments, and willingness of participants to consent to linkage with Hospital Episode Statistics (HES) and National Cancer Registration and Analysis Service (NCRAS) registries for long-term follow-up.

The secondary research objectives are to:
1. Obtain initial estimates of the parameters for the intended primary outcome measure (activPAL measured brisk walking [>100 steps/minute]) for the sample size calculation for the future definitive randomized controlled trial (RCT)
2. Assess app usage and engagement

3. Assess the proportion of eligible/ineligible participants and reasons for ineligibility
4. Assess the proportion of participants consented but not randomised (i.e. non-completion of baseline assessment)
5. Assess the proportion of participants requiring help to complete online questionnaires.
6. Assess the acceptability of providing informed consent online
7. Assess potential sociodemographic biases in recruitment (i.e. representativeness of study sample from a wider eligible sample)
8. Perform an early economic evaluation, modelling the potential cost-effectiveness of the intervention and an assessment of the value associated with obtaining further information by conducting a definitive trial
9. Assess the fidelity of intervention delivery in the telephone/video calls (the Behaviour Change Techniques used)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/03/2021, Yorkshire and The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048091; southyorks.rec@hra.nhs.uk), REC ref: 21/YH/0029

Primary study design
Interventional

Study design
Single-site pilot interventional randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Health and wellbeing after breast, prostate or colorectal cancer

Interventions
Participants will be randomized to intervention or control groups using minimisation with a 1:1 allocation ratio. Stratification factors will be cancer type (breast, prostate or colorectal) and disease status (advanced/metastatic disease vs. not). 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)

A number of primary outcomes will be used to meet the primary objective of determining the feasibility and acceptability of the trial procedures. These outcomes will be:
1. Recruitment rate (percentage of eligible participants who are randomised)
2. Acceptability of randomisation (immediate withdrawal upon informing participants of allocation)
3. Feasibility of administering the intervention (proportion of those in the intervention group who receive the behavioural support calls, and self-report successfully downloading the app. All intervention participants will be sent the letter of endorsement from the clinical team, and the intervention leaflet including the Active 10 app recommendation)
4. Acceptability of the intervention, measured using intervention feedback questionnaires, self-reported app usage and engagement, withdrawal from intervention group (and reasons, where provided)
5. Retention rate (loss to follow-up in both intervention and control participants)
6. Acceptability of outcome assessments (completion rates for baseline and T1 follow-up outcome measures intended for definitive RCT, and proportion of participants who provide consent who complete baseline assessments)
7. Willingness of participants to consent to linkage with HES/NCRAS registries for long-term follow-up (percentage of participants who consent vs not for this aspect of the study)
8. Qualitative methods will also be used to explore the acceptability of the intervention (intervention arm participants), the acceptability of the trial procedures, outcome assessments, randomisation and linkage with HES/NCRAS registries for long-term follow-up (intervention and control arm participants, and study decliners)

The study includes a baseline and 3-month assessment.

Key secondary outcome(s)

1. Initial estimates of the parameters (e.g. mean, standard deviation) for the intended primary outcome measures (activPAL measured brisk walking [>100 steps/minute]) for the sample size calculation for the future definitive RCT measured using ActivPAL accelerometers at baseline
2. Self-reported app usage and engagement measured using a questionnaire (including items from the Digital Behavior Change Intervention Engagement Scale) and qualitative interviews at 3 months
3. Proportion of eligible/ineligible participants and reasons for ineligibility measured using records of the recruitment process before baseline
4. Potential sociodemographic biases in recruitment measured using aggregated data from hospital records (age, gender, ethnicity, Index of Multiple Deprivation [IMD]) of those who were invited and did and did not participate
5. Early indications of the potential cost-effectiveness of the intervention calculated using data from the EuroQol-5D (EQ-5D) and Client Service Receipt Inventory (CSRI) at baseline and 3 months
6. Acceptability of online assessments measured using the number of participants who require help to complete the questionnaires online at baseline or 3 months, or who give this method of data collection as a reason for declining to participate
7. Acceptability of providing informed consent online measured using the number who decline to participate because they state that they are unable/unwilling to provide consent online
8. Fidelity of intervention delivery in the telephone/video calls (Behaviour Change Techniques used) measured using a check-list of content included in the script to assess how many of the planned techniques were covered

Completion date

27/02/2023

Eligibility

Key inclusion criteria
1. Diagnosed with breast, prostate or colorectal cancer at Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust
2. Aged 16 years or older
3. Own a smartphone (that uses Android or iOS (Apple) operating systems)
4. Able to provide informed consent
5. Has access to a computer and an email address, and is willing to complete online questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
90

Key exclusion criteria
1. For those with localised disease: more than 6 months after completion of radical treatment (i.e. surgery, radiotherapy, systemic therapy with curative intent)
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. Clinicians' estimate life expectancy <6 months or receiving end of life care
7. Due to have surgery in next 5 months
8. <6 weeks after surgery
9. Reports achieving 150 minutes of at least moderate-intensity PA weekly
10. Report previous/current use of Active 10 app
11. Report current or previous (within 6 months) participation in a health behaviour change study

Date of first enrolment
01/05/2021

Date of final enrolment
01/06/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Doncaster Royal Infirmary
Doncaster and Bassetlaw Teach Hospitals NHS Foundation Trust
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

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

Data will be available on request from Dr Phillippa Lally (p.lally@surrey.ac.uk) until 12 years after the study end date at which point it will be anonymised and entered in the UCL Data Repository. 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.” In the information sheet it is stated that their data will only be used for the purpose of health and care research. If a researcher wishes to access the quantitative or qualitative data collected during this study for the purposes of answering an appropriate analysis that the study team are not planning to conduct themselves then the data will be shared.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/03/2022	07/05/2025	Yes	No
Basic results		01/08/2023	01/08/2023	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V2		16/04/2021	No	Yes
Protocol (preprint)		20/09/2021	14/12/2021	No	No