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A study to test whether women who have been treated for cervical cancer enjoy a physical activity programme which aims to increase walking and improve quality of life

Submission date
28/09/2020

Recruitment status
No longer recruiting

Registration date
30/09/2020

Overall study status
Completed

Last Edited
08/04/2025

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Physical activity has wide-ranging health and well-being benefits after cancer. Physical activity has been shown to improve some of the symptoms that women experience after treatment for cervical cancer, such as fatigue, sleep quality, pain as a result of lymphedema (swelling), pelvic floor strength and mood. However, it is not known what the best types of physical activity are, specifically for women who are recovering from cervical cancer treatment. Therefore, researchers have developed a physical activity programme which aims to increase walking and improve quality of life among women treated for cervical cancer. The aim of this study is to provide this programme to women and to understand whether they enjoy the programme or not and what aspects of the programme they like or do not like. After doing so, they can then alter the programme based on feedback and can potentially provide the programme to more women across the UK.

Who can participate:
Women who have received treatment for cervical cancer at least 6 months ago, who are aged between 18 and 60 and who do not take part in 150 minutes of aerobic physical activity per week.

What does the study involve?
The study involves a 12-week physical activity programme where participants will be given resources to help them to increase their physical activity levels, including education on physical activity (at a programme launch event), individualised support and coaching about how to increase physical activity (via fortnightly telephone/video calls), a Fitbit monitor, a diary to keep track of well-being and physical activity, and the opportunity to walk with other women who have received treatment for cervical cancer. The study also asks participants to complete a questionnaire and wear a physical activity measurement device (this looks like a sports watch) for 8 days. Participants will be asked to do this at four time points throughout the study, which are before starting the programme, mid programme (week 6), at the end of the programme

(week 12), and at 6 months. Finally, the study involves the completion of three more short questionnaires during the programme and one interview after the 6-month timepoint.

What are the possible benefits and risks of participating?
Participants will receive an activity monitor to keep (a Fitbit). This monitor will provide insight and information about their physical activity levels and daily step count. Fortnightly health coaching via telephone calls will also be provided for participants to review their current physical activity levels and to help them to overcome issues that may be stopping them from being active. At the programme launch, participants will receive education on the benefits of physical activity and walking specifically. They will also be given a leaflet to reinforce these points and to provide tips on how to increase step count. In addition, they will also have the chance to meet other women who have been treated for cervical cancer and potentially build a peer support network. Little research exists about what physical activity should be recommended for women after treatment for cervical cancer. By taking part in this study, participants will be providing invaluable information and knowledge which can be used to develop and design effective physical activity programmes for women who have been treated for cervical cancer.

Where is the study run from?
The study is based at the University Hospitals of Leicester. However, due to the restrictions in place as a result of COVID-19, the study will primarily be run on virtual platforms (e.g. Microsoft Teams)

When is the study starting and how long is it expected to run for?
October 2019 to December 2021 (updated 03/08/2021, previously: September 2021)

Who is funding the study?
1. Economic Social and Research Council (UK)
2. Loughborough University (UK)
3. Leicester Hospitals Charity (UK)

Who is the main contact?
Ms Nessa Millet
N.millet@lboro.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Nessa Millet

ORCID ID
http://orcid.org/0000-0001-5468-5197

Contact details
National Centre for Sport and Exercise Medicine (PhD area)
Towers Way
Loughborough University
Loughborough
United Kingdom

LE113TU
+44 (0)7527246852
N.millet@lboro.ac.uk

Type(s)
Scientific

Contact name
Dr Hilary McDermott

ORCID ID
http://orcid.org/0000-0002-2809-9888

Contact details
Chief Investigator
National Centre for Sport and Exercise Medicine, 1.52
Towers Way
Loughborough University
Loughborough
United Kingdom
LE11 3TU
+44 (0)1509 223098
H.J.McDermott@lboro.ac.uk

Type(s)
Scientific

Contact name
Dr Esther Moss

ORCID ID
http://orcid.org/0000-0002-2650-0172

Contact details
Principal Investigator
Room 4.27, 4th floor Robert Kilpatrick Building
University of Leicester
Leicester
United Kingdom
LE2 7LX
+44 (0)116 2523170
em321@leicester.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
256875

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 45627, IRAS 256875

Study information

Scientific Title
A multicomponent physical activity programme for women who have been treated for cervical cancer: a feasibility study

Acronym
ACCEPTANCE

Study objectives
The components of the intervention will be acceptable and feasible amongst women who have been treated for cervical cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/05/2020, West of Scotland REC 1 (Ward 11, Dykebar Hospital, Grahamston Road, Paisley PA2 7DE, UK; +44 (0)141 314 0212; WosRec1@ggc.scot.nhs.uk), REC ref: 20/WS/0062

Study design
Non-randomized; Both; Design type: Process of Care, Education or Self-Management, Psychological & Behavioural, Other, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Improving symptoms and quality of life in women who have been treated for cervical cancer

Interventions

This feasibility trial aims to implement and evaluate a 12-week intervention programme to increase physical activity in women who have been treated for cervical cancer. A mixed-methods design will be applied to fulfil the evaluation aims.

Sample: As this intervention will be a feasibility trial, one group of women will be recruited, all of whom will receive the intervention and evaluation procedures.

Hypotheses: The components of the intervention will be acceptable and feasible amongst women who have been treated for cervical cancer.

Recruitment: Women who are eligible to participate will be approached via two recruitment strategies.
1. Research nurses at the university hospitals of Leicester (UHL) will identify women who may be eligible to participate. Women who are at follow-up at the UHL will be approached by a research nurse if they might be eligible to participate (determined via preliminary screening of the clinic's database). Once identified, these women will be sent a participant information sheet (PIS), a letter of invitation to participate and a reply slip.
2. Details of the study will be made available to the general public via social media advertisements and paper advertisements placed in relevant locations in the Midlands. Details of the study will also be shared by charities (Jo's Cervical Cancer Trust and Move Against Cancer). Potential participants who contact the research team regarding the study will be sent a PIS, a letter of invitation to participate and a reply slip.

Those who agree to continue with the study (by stating so on the reply slip) will receive a phone call from the study coordinator to check eligibility. If eligible, participants will then be invited to organise a baseline visit with the study coordinator.

Informed consent: At the baseline visit, participants will have the chance to ask the study coordinator any questions that they may have. After this, they will be asked to read the informed consent form and to demonstrate agreement by signing their initials beside each statement and by providing a full signature.

Demographic Information: At the baseline visit, participants will be asked to complete a demographic questionnaire which will ask them to provide the following details: age, date of birth, postcode, ethnicity, marital status, household composition, education level, cervical cancer treatment details and medical history. These pieces of information will be taken as they may provide further insight as to why participants engage with certain aspects of the intervention.

Baseline and follow- up assessment:
Participants will be asked to complete the following measurements at baseline, week 12 of the intervention and follow-up (6- months after starting the intervention).
1. A study questionnaire pack. This pack contains questionnaires to measure the following: quality of life; menopausal symptoms; depression and anxiety; fatigue; walking self-efficacy; motivation for physical activity; enjoyment of physical activity.
2. A physical measurement of participants' height and weight using scales. Participants' height will only be calculated once at the baseline visit.
3. An objective measure of physical activity. Participants will be asked to wear a research-grade accelerometer for 8 days.
*A measure of menopausal symptoms and objective physical activity will also be taken at week 6 of the intervention.

Intervention delivery
The 12-week multi-component intervention will consist of the following components: education, goal- setting, barrier identification, self-monitoring, group walking, physical activity prompts and health coaching.

These components will be offered to participants in the following order:

Day 1
Participants will be invited to an intervention launch session at either UHL or Loughborough University (LU) which will include:
1. An interactive education session on the benefits of walking and physical activity. Participants will also be given an education leaflet to take home
2. A goal setting session
3. Barrier Identification via a group discussion which is facilitated by the study coordinator
4. Participants will be given an activity monitor (e.g. a Fitbit) and instructions on how best to use it
5. Participants will be given a diary to help them to track trends in their physical activity and mood throughout the intervention and will be given instructions on how to complete the diary
6. Groups of participants will be added to a messaging group which will act as a platform whereby participants can keep in contact and organise group walks

Participants will be encouraged to utilise the resources that they receive at the intervention launch during the 12 weeks of the intervention.

Weeks 2, 4, 6, 8, 10 and 12:
Participants will receive fortnightly health coaching which will take place via telephone call with the study coordinator. These conversations will address any queries participants may have about the intervention at that point, evaluation and updating of the participant's physical activity goals and how the participant might overcome any barriers to physical activity that they are experiencing.

Process evaluation:
The process evaluation will be a mix of questionnaires and interviews which will aim to understand whether participants accept the intervention and its components.

Evaluation questionnaires:
Specific evaluation questionnaires will be administered to gauge how participants feel about the intervention launch, wearing the self- monitoring device and using the messaging group.

An evaluation interview:
A semi-structured interview with each participant will take place after the final visit (6 months) to gain insight into participants' overall perceptions of the intervention. Those participants who withdraw will also be invited to take part in an interview to discuss their reasons for withdrawing if they wish to do so.

Intervention Type
Behavioural

Primary outcome measure
The feasibility aspects of the trial, measured via:
1. Recruitment rate: the number of participants who are recruited, represented as a percentage of the number of women who show interest, measured at baseline

2. Attrition rate: the percentage of participants who withdraw after completing baseline measurements, measured at 6 months
3. Retention rate: the percentage of participants who complete all programme components and evaluation measurements, measured at 6 months
4. Compliance rates: represented by
4.1. Percentage of participants who fully comply with wearing the research-grade accelerometer, measured at 6 months
4.2. Percentage of participants who complete the study questionnaires at baseline, 6 weeks, 12 weeks and 6 months
4.3. Percentage of women who engage with the 6 health coaching sessions (telephone calls), measured at 6 months
4.4. Percentage of participants who complete diary entries, measured at 6 months
4.5. Percentage of participants who take part in group walks and the frequency of these, measured at 6 months

Secondary outcome measures
1. Minutes of physical activity, measured using accelerometer at baseline, 6 weeks, 12 weeks and 6 months
2. Minutes of moderate-intensity activity measured using accelerometer at baseline, 6 weeks, 12 weeks and 6 months
3. Menopausal symptoms measured using the Menopausal Rating Scale at baseline, 6 weeks, 12 weeks and 6 months
4. Quality of life measured using the European Organisation for Research and Treatment of Cancer QOL measure (EORTC QLQ-30) at baseline, 6 weeks, 12 weeks and 6 months
5. Symptoms of fatigue measured using the Multidimensional Fatigue Symptom Inventory- short form (MSFI- SF) at baseline, 6 weeks, 12 weeks and 6 months
6. Symptoms of anxiety and depression measured using the Hospital Anxiety and Depression scale (HADS) at baseline, 6 weeks, 12 weeks and 6 months
7. Belief in their ability to complete incremental 5-minute periods of walking, measured using the Self-Efficacy for Walking Scale at baseline, 6 weeks, 12 weeks and 6 months
8. Different types of motivation for physical activity measured using the Behavioural Regulation in Exercise Questionnaire-3 (BREQ-3) at baseline, 6 weeks, 12 weeks and 6 months
9. Enjoyment of physical activity measured using the Physical Activity Enjoyment Scale (PACES) at baseline, 6 weeks, 12 weeks and 6 months

Overall study start date
01/10/2019

Completion date
14/12/2021

Eligibility

Key inclusion criteria
1. Women who are at least 6 months post-treatment for cervical cancer
2. Women who are between the ages of 18-60 years
3. Women who do not meet the national guidelines for physical activity (150 minutes of moderate-intensity physical activity)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Female

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Total final enrolment
30

Key exclusion criteria
1. Women who have been treated for abnormal/pre-cancerous cells only
2. Women who are unable to be physically active for a medical reason which is unrelated to their cervical cancer diagnosis and treatment
3. Women under active follow up who do not have relevant approval from the consultant gynaecologist
4. Where a firm grasp of the English language is not evidenced

Date of first enrolment
15/10/2020

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
Loughborough University

Sponsor details
c/o Jen Fensome
Research and Enterprise Office
Loughborough
England
United Kingdom
LE11 3TU
+44 (0)1509228693
j.fensome@lboro.ac.uk

Sponsor type
University/education

Website
http://www.lboro.ac.uk/

ROR
https://ror.org/04vg4w365

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council (ESRC); Grant Codes: ES/P000711/1

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Loughborough University; Grant Codes: GS1020

Alternative Name(s)
Lboro

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Leicester Hospitals Charity

Results and Publications

Publication and dissemination plan
It is hoped that the study protocol will be published in BMJ Open and therefore will be available via open access. Planned publication in a high impact journal with the intent to publish in August 2022.

Intention to publish date
01/08/2022

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 (https://repository.lboro.ac.uk/category). All raw data will be shared when the study has finished and will be available for 5 years. Data will only be shared with those who have been granted access by the research team, for research which will further knowledge in this area. Consent will be obtained from participants. Data will be archived in with LU policy.

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 V1.3	30/06/2020	30/09/2020	No	Yes
Protocol article		03/01/2022	05/01/2022	Yes	No
Basic results		10/01/2023	10/01/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		05/04/2025	08/04/2025	Yes	No