

A multicomponent physical activity intervention for women who have been treated for cervical cancer: A feasibility study

Adult Participant Information Sheet

Hello! We would like to invite you to take part in our study. Before you decide whether to take part, we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study before making a decision if you wish.

What is the purpose of the study?

Physical activity has wide-ranging health and wellbeing benefits for cancer survivors. Little is known about what types of physical activity are most suitable after treatment for cervical cancer. So, our research team have designed a 12- week programme which aims to increase physical activity and you will learn more about what this programme involves in this information sheet. The aim of this study is to deliver the programme among a group of women who have been treated for cervical cancer. We would like to assess womens' experiences of the 12-week programme to help us decide if the programme is suitable for a larger study.

Who is doing this research and why?

This research is being undertaken by a research student (Miss Nessa Millet) for her PhD studies. She is based in the School of Sport, Exercise and Health Sciences (SSEHS) at Loughborough University. The physical activity programme has been designed by the research team listed at the end of this sheet. They would now like to deliver the programme to understand what women think of it and to assess whether it is enjoyable. Nessa's supervisors are Dr Hilary McDermott and Dr. Fehmidah Munir, both from Loughborough University. Nessa is also supervised by Dr. Esther Moss, a consultant gynaecologist and Dr. Charlotte Edwardson from the University of Leicester. This research is jointly funded by Loughborough university, the Economic and Social Research Council (ESRC) and Leicester's Hospital Charity.

Why have I been invited to participate?

You have been invited to participate as we think you may be eligible to take part.

you are eligible to take part if you.....

- have been treated for a diagnosis of cervical cancer more than 6- months ago (this does not include those who have been treated for abnormal cells / pre- cancerous cells only)
- are between the ages of 18-60 years
- do not take part in 150 minutes of physical activity per week
- can gain permission from your consultant gynaecologist to take part
- have a firm grasp of the English language

Do I have to take part?

No, you don't. You are under no obligation to take part in this study. If, after reading this information sheet and asking any additional questions, you do not feel comfortable taking part, you do not have to.

What is involved?

If you agree to doing this study, you will take part in a physical activity programme. This programme is quite simple, we will provide you with resources and education to help you to increase your physical activity. The extent to which you engage with these resources and the amount of physical activity that you do is up to you! The programme will include the following:

1. A programme launch

You will be invited to attend an interactive education session about physical activity with other women who are also participating. This session will take place at Loughborough university or virtually and will last around 2 hours. We hope to schedule this event on a date that suits you. The event will be a chance for you to meet other participants and to meet the research team. Light refreshments will be provided. Due to the evolving situation regarding covid-19, there will also be the option to attend this launch virtually if you are concerned about your safety. At the launch, you will:

- Learn more about the health benefits of physical activity and walking.
- Learn how to set goals to help you to be more physically active
- Take part in an interactive group session where you will have the chance to discuss ways to become more physically active

2. Wearing an activity monitor

You will be given this monitor on day 1 of the programme (see picture for an example). You will receive the monitor in person if you decide to attend the programme launch or else it will be sent to you in the post if you attend virtually. It is for your own use to help you to keep track of your daily step count and the amount of physical activity that you do. You will be asked to wear the monitor for the 12 weeks of the programme, and you will be permitted to keep the monitor after the study has ended. We will explain how to best use the monitor and will create an on-line community for all those participating. You will be encouraged to join the online community (accessed online through your phone, iPad or laptop/ computer) which is an easy to use forum where you can post about your progress and set activity challenges. You will only be given one activity monitor during the study. In the event of loss, a replacement will not be given. If the monitor is damaged, you will be asked to contact the study co-ordinator as soon as possible to organise a repairment where possible.



- If you do not own a smartphone that can download applications, please speak to the researcher for an alternative arrangement to be put in place.

3. A messaging group

- A messaging group will be created (e.g. Whatsapp) for you and other women who are participating. You will be encouraged to keep in touch with each other and you will be encouraged to organise times and places to walk together if you would like to. The research team will help you to organise walks with those who are living in close proximity to you. If you do decide to organise a walk with others and do not enjoy it, there is no obligation for you to continue walking in a group.
- The messaging group is a platform for support and is not intended to introduce any feelings of competition between you and other participants in the study.
- Please be aware that your phone number will be shared with other women who are taking part in the research. However, if you would like to remain anonymous to others, there will be an option for a username to be used instead of using your own name on the messaging group.

4. A programme diary

We will ask you to complete a written diary to monitor trends in your physical activity (e.g. steps) and mood throughout the programme. We will explain how to fill out the diary and which you will be asked to complete the on a daily and weekly basis, depending on the entry. Daily entries will be very short and should take no more than 1-minute. Weekly entries should take no more than 1- 2 minutes.

5. Fortnightly telephone calls with the study co-ordinator

During the 12- weeks of wearing the activity monitor, we will keep in touch with you by telephone every 2- weeks to discuss your physical activity levels, your goals for the following week, any barriers to physical activity and how they could be overcome. This will also be an opportunity for you to ask any questions that you may have.

To test whether the programme has been effective and to understand what you thought of it, we will also ask you to do the following:

6. Complete a series of questionnaires

You will be asked to complete the following questionnaires:

- a. A short questionnaire about yourself.* You will be asked for your date of birth, your contact details, postcode, your education, your ethnicity, marital status, household composition, some information about your medical history and details of your cervical cancer treatment (completion time= approximately 5 minutes).

b. A study questionnaire- You will be asked to answer some multiple-choice questions about physical and psychological aspects of your well-being and about your levels of physical activity (completion time= 20 minutes)

c. A questionnaire about the programme launch - You will be asked to fill out this short questionnaire once, after the launch, where you will be asked to rate aspects of the session.

d. A questionnaire about your experience of using the activity monitor and the messaging group.

*Questionnaires will be sent to you via post and you will be asked to complete these at home and to post them back to the research team.

7. Wear a physical activity measurement device

You will be sent this device in the post and will be asked to wear it before the start of the programme. The study co-ordinator will explain how to use it via video or telephone call. This device is different to the activity monitor as it is for research purposes only and provides a much more accurate and scientific measure of your physical activity levels. The research team will be using this device to see if there are any changes in your physical activity throughout the programme. The device looks like a sports watch (see picture) and you do not need to do anything with it apart from wear it. You will be asked to wear the device for 8 days continuously during the day and night and to complete a short sleep log every day whilst wearing it. The device does not have a screen so you will not see any of your data. You will then be asked to repeat this at the following 3 additional time points of the study:



- Mid- programme (alongside wearing the activity monitor) for 8 days
- Directly after the programme for 8 days
- 6- months after starting the programme for 8 days

Exact dates for these time points will be confirmed after recruitment has been completed.

In the event of loss or damage to the activity device, you will be asked to contact the study co-ordinator (by phone call or email) as soon as possible to organise a replacement.

8. Take part in an interview

You will be asked to take part in an interview during the study with the study coordinator. This interview can either take place face to face or over the phone. During the interview, the study coordinator will ask you about your experience of taking part in the research study and how you think certain aspects may be improved. The interview will be recorded

using an audio recording device. Data will then be transcribed (converted into a written version where you will not be identifiable) and stored securely on university password protected IT systems. After your audio recording has been transcribed, it will be deleted from the university's IT systems. The study coordinator will then analyse the data. Analysis will be a process of reading and re-reading the interview transcripts and identifying common and relevant themes through-out. Interviews will take place after your 6- month visit.

In total, how many sessions do I need to attend, how long will they be and where will they be held

You will have the option to attend one session, which will take place at Loughborough university.

We will invite you to take part in an interview which will take approximately 60 minutes.

- Your travel to this visit will be reimbursed as per the standard Loughborough university rate (45p/mile travelled) or direct cost of train/ bus ticket.

Once I take part, can I change my mind?

Yes. After you have read this information and asked any questions you may have, we will ask you to complete an informed consent form , however if at any time, before, during or after the study you wish to withdraw/ discontinue your participation, please just contact the study coordinator by email or telephone (details found at the end of this information sheet). You can withdraw at any time during the study. As this is a feasibility trial, you will be asked to give your reasons for withdrawing which will be used in the results of the study, however you are not obliged to provide a reason if you do not wish to. Any data collected from you until that point will not be withdrawn and will be used to inform the results of the study. If you withdraw, you will be asked to return your activity monitor.

Are there any disadvantages or risks in participating?

- Participation does not pose any immediate risk to you. It is likely that participating in the intervention will lead to increased physical activity levels which may result in some initial tiredness or muscle soreness. There are no risks associated with increased physical activity and side effects relating to treatment of cervical cancer.
- You may find that discussing your cancer diagnosis, treatment or treatment related side effects may be upsetting. The researcher will not ask you direct questions about these topics, but you may decide to discuss them in relation to how you evaluate the programme and any changes in your perceived quality of life.

If you do experience any **psychological distress** as a result of our research study, we will be happy to sign post you to the following relevant support:

Charity	Type of support and how to access this support
Jo's cervical cancer trust	<p>A telephone helpline which offers information and support from fully trained members of staff or volunteers who have experience of cervical cancer.</p> <p><u>Phone Number:</u> 0808 802 8000</p> <p><u>Website</u> (for information on helpline opening times): https://www.jostrust.org.uk/get-support/helpline</p>
Macmillan Cancer support	<p>Macmillan provides a free telephone support line with minimal waiting times. Support is offered from trained employees and Macmillan nurses. Waiting times may be slightly longer if you would like to speak to a nurse.</p> <p><u>Support line phone number:</u> 0808 808 00 00</p> <p>Macmillan also provide an online community where you can anonymously speak to others who have been affected by cancer. You can join this by selecting 'online community' on the Macmillan website: https://www.macmillan.org.uk/</p>
Mind Charity	<p>Mind is a charity that provides immediate online support for those who are experiencing poor mental health. This online support can be accessed at: https://www.mind.org.uk/information-support/</p>
<p>Or if you are still under follow-up with the University Hospitals of Leicester you may wish to contact the <u>Gynaecology Clinical Nurse Specialists</u>: 0116 258 4840</p>	

What are the possible benefits of participating?

- You will receive an activity monitor to keep (e.g. a fitbit). This monitor will provide insight and information about your physical activity levels, heart rate and daily step count. Fortnightly health coaching via telephone calls will also be provided for you to review your current physical activity levels and to help you to overcome barriers to physical activity that you may be experiencing.
- At the programme launch, you will receive education on the benefits of physical activity and walking specifically. You will also be given a leaflet to reinforce these points and to provide tips on how to increase step count. In addition, you 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, you 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.

How will I be made aware of the results of the study?

On completion of the full research study (estimated 2022), you and your family members will be invited to an event held by the main researcher, Miss Nessa Millet. This event will be a chance for the research team to give back to you by presenting the results of the study along with providing a chance for you to ask questions. Further details of this event will be sent to you. If you are unable to attend this even, results of the study (in paper form) will be sent you.

Data Protection Privacy Notice

Loughborough University will be using information/data from you in order to undertake this study and will act as the data controller for this study. This means that the University is responsible for looking after your information and using it properly.

How will we use personal information about you?

We will need to use information about you for this research project. We will keep all information about you safe and secure.

This information will include your name, contact details, postcode, your ethnicity, education level and treatment details.

- Contact details will be collected and used to keep contact with you throughout the duration of the study. Your phone number will be needed for the researcher to make fortnightly telephone calls and to send text reminders (if you have agreed to this on the informed consent form).
- Postcodes will be collected to help researchers provide walk location options which are convenient for you and other participants.
- Other personal information such as ethnicity, education and treatment details will be collected to gauge socio demographic and ethnic variations in the women who take part.

What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

How long will my anonymised data be retained?

We will keep anonymised information about you for 5 years after the study has finished.

Will my personal information be shared with others?

Storage of personal data will comply with current data Protection legislation and so will be stored securely for up to 10 years on the university's IT system.

Will my taking part in this study be kept confidential?

All personal data will be anonymised, including data from the activity monitor and the physical activity measurement device. You will receive an unidentifiable ID number which

your data will be listed under. When interviews are being analysed, your name will be anonymised throughout along with the names of anyone else mentioned.

How will the anonymised data/results collected from me be used?

Data collected will be analysed by the study coordinator and results will be written up as her PhD thesis and will be submitted for publication in manuscript form. The researcher must write the thesis in a way that no-one can work out that you took part in the study. The results will be used to further refine the development of a large-scale physical activity trial for women who have been treated for cervical cancer. Results from this research will be used for educational purposes and will be presented at relevant conferences.

Your anonymised data will be shared with researchers listed on this information sheet and their organisations (Loughborough university; The University hospitals of Leicester; The University of Leicester). You may get the choice to give your research data from this study for future research. If you agree to this, your data will be kept securely to be shared, in the future, with researchers who are working in a similar area. Doing this makes maximum use of the information you have provided and allows researchers to discover more.

If you would like to find out more about how your information is used, please visit the following website:

www.hra.nhs.uk/information-about-patients/

Who is providing insurance for this study?

Sponsorship and Indemnity for this study will be provided by Loughborough University.

I have some more questions; who should I contact?

If you have any further questions about the study or about how your information will be used, please do not hesitate to contact the study coordinator, Miss Nessa Millet by mobile (**07551460347**) or by email (Acceptance@lboro.ac.uk).

If you have any questions more generally regarding Data Protection at the University, then please do contact the Data Protection Officer on dp@lboro.ac.uk or write to The Data Protection Officer at Academic Registry, Loughborough University, Loughborough, Leics, UK LE11 3TU.

What if I am not happy with how the research was conducted?

If you are not happy with how the research was conducted, please contact the Secretary of the Ethics Approvals (Human Participants) Sub-Committee, Research Office, Hazlerigg Building, Loughborough University, Epinal Way, Loughborough, LE11 3TU. Tel: 01509 222423. Email: researchpolicy@lboro.ac.uk

The University also has policies relating to Research Misconduct and Whistle Blowing which are available online at <http://www.lboro.ac.uk/committees/ethics-approvals-human-participants/additionalinformation/codesofpractice/> .

If you require any further information regarding the General Data Protection Regulations, please see: <https://www.lboro.ac.uk/privacy/research-privacy/>.

If you are interested to take part in this study, please contact the study coordinator, Miss Nessa Millet by email or telephone:.

Study Address (For all study materials, please send to):

The School of Sport Exercise and Health Sciences,
Loughborough University,
Epinal Way,
Loughborough,
Leicestershire, Le11 3TU

Study phone number: **07551460347**

Study email: Acceptance@lboro.ac.uk

The research team:

Study co-ordinator

- **Ms Nessa Millet**

Study Investigators

- **Dr. Hilary McDermott**
- **Dr. Fehmidah Munir**
- **Dr. Esther Moss**
- **Dr. Charlotte Edwardson**