Endo-TECH

Patient Information Sheet

You have been invited to take part in a research study. Before you decide if you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information leaflet carefully and discuss it with friends, relatives or your GP. Ask us if there is anything that is not clear, or if you would like more information. Please take time to decide whether or not you wish to take part.

Why are we doing this research?

Endometriosis is a chronic and often debilitating condition that can cause pelvic pain, painful periods and painful sex. It may also lead to infertility, fatigue and bowel and bladder problems. Endometriosis can have a significant impact on a person's life in a number of ways, including sleep and physical activity. As endometriosis is a complex condition, it is important for us to gather as much information as possible so that we can tailor treatments to each individual. Until now, this type of information has been largely collected using paper (or online) questionnaires but this does not provide a full picture of the impact of the condition. In this exploratory study, we will ask women with endometriosis to record their daily pain and fatigue scores on an online form and ask them to wear a Smartwatch that will record their physical activity and sleep patterns throughout the day and night. We will send you a reminder on your phone with a link to the website where this form can be found. At the same time, we will ask women to complete questionnaires with specific questions about symptoms and quality of life. We will then analyse and compare the daily pain and fatigue scores and Smartwatch data with the information from the questionnaires. This will allow us to see if the online and Smartwatch technology might be useful in the future in assessing different aspects of pelvic pain that sometimes women with endometriosis themselves might not be reporting (or be aware of) e.g. perturbed sleep, immobility. We also plan to collect information on what it is like to wear a Smartwatch (how acceptable it is).

Why am I being invited to take part?

You have been invited to take part because you have endometriosis and pain related to this.

Do I have to take part?

No, it is up to you to decide whether or not you wish to take part.

If you decide to take part you can also still withdraw at any time and without giving a reason. Deciding not to take part, or withdrawing from the trial, will not affect the healthcare that you receive, nor your legal rights.

What happens if I take part?

If you decide to take part, a member of the research team will ask you to complete a consent form. This maybe during a video/telephone call with the research team.

You will then be asked some questions about your health, to complete some questionnaires and to tell us about the medications that you are taking. The questionnaires ask about pain and fatigue symptoms, and the impact that endometriosis is having on your quality of life. Some of the questionnaires contain questions that are of a sensitive nature but you can leave these blank if you are not comfortable answering them. You may complete the questionnaires on paper in private or online. The questionnaires should take no longer than 40 minutes to complete. If we are concerned about any of the answers you have given in the questionnaires, we will ask you if we can contact your GP to provide further support.

We will then ask you to wear a Smartwatch for six weeks at a time over three different timepoints ('cycles'). We will contact you by telephone/video call before the end of each cycle to ask you some questions about any painkillers or hormones that you may have taken and whether you have had to see a healthcare practitioner for your endometriosis. During this call, we will arrange for the Smartwatch to be returned so that it can be charged. We will also arrange the best time for you to wear this again. The only time that you will have to come into the hospital in person is to collect the Smartwatch at the start of each cycle.

During each six-week cycle, we will also ask you to fill in daily pain and fatigue scores online. We will send you a reminder text each day to complete this.

We will ask you to complete the same questionnaires that you completed before you started to wear the Smartwatch during the last week of each six-week cycle. After you have completed the trial we will ask you to complete a short acceptability questionnaire so that you can tell us about your experience in the trial.

The Smartwatch does not have any information that you can see but at the end of your participation we can send you a readout of the information that we get from the Smartwatch if you are interested. None of the information collected on the smartwatch will be able to identify you directly.

Here is an image of the Smartwatch:

It is waterproof but can be taken off to shower if you prefer.

Are there any risks involved?

We do not anticipate that there are any risks associated with this study. You may experience skin irritation from the Smartwatch but you can contact the research team at any point if this is an issue.

What are the possible benefits of taking part?

You may or may not get a direct benefit from taking part in this trial. This trial will generate information that will give us information about women with endometriosis and pain and how it affects their lives.

What will happen if I do not want to carry on with the trial?

You can withdraw from the trial at any time without having to give a reason. If you decide not to take part in the trial or withdraw at any time, the clinical care that you receive will not be affected and this will continue as normal. With your permission, we will use any information obtained up to the point of your withdrawal. All information will be anonymised.

What if there is a problem?

If you have a concern about any aspect of this trial, you should ask to speak with your clinical researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be found at the end of this information leaflet.

Will my taking part in this trial be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information will include your:

- Initials
- Date of birth
- CHI number
- Unique hospital number
- Address including postcode
- Telephone number
- Email address

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the trial, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the trial.

What are your choices about how your information is used?

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

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If data will be used for future research: If you agree to take part in this trial, you will have the option to take part in future research using your data saved from this trial.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from [**www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by sending an email or
- by ringing us details at the end of the sheet
- Data Protection Officer contact information:

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh
EH8 9YL
Tel: 0131 651 4114
dpo@ed.ac.uk

NHS Lothian
Data Protection Officer
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5444
Lothian.DPO@nhs.net

What will happen to the results of the current research trial?

The results of this trial will be published e.g. in medical journals, reports, textbooks and conference presentations. You will not be identifiable in any publication or report. You will be able to see the published results of the trial on our website www.exppectedinburgh.co.uk, on Endometriosis UK's website and on Endometriosis.org. We anticipate that the results of this trial will be available in 2024.

Who is organising and funding the research?

The study has been organised by Professor Andrew Horne (Consultant Gynaecologist) and Dr Lucy Whitaker (Clinical Lecturer in Gynaecology). The trial is co-sponsored by the University of Edinburgh and NHS Lothian. The study is funded by a charitable donation from Standard Life.

Who has reviewed the trial?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee (REC). A favourable opinion has been

obtained from the REC, which has responsibility for scrutinising all proposals for medical research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the University of Edinburgh and NHS Lothian, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected. The trial proposal has been peer-reviewed by researchers at University of Edinburgh. NHS management approval has also be given.

What if something goes wrong?

In the event that something does go wrong and resulting in you being harmed during the research and this is due to someone's negligence, then you may have grounds for legal action for compensation against the local NHS Board but you may have to pay your legal costs. The standard National Health Service complaints mechanisms will still be available to you (if appropriate).

Contact details

You may contact the clinical research team directly – details below. If you require any further information from a doctor who is not involved in this trial you can contact Professor Colin Duncan on 0131 242 1000.

PI name: Dr Lucy Whitaker
Research nurse: Sharon McPherson / Nicola Watson
Contact number: 07501 273 898 / 07884 115330

Complaint's telephone number: 0131 536 3370

Complaint's email: feedback@nhslothian.scot.nhs.uk

Thank you for reading this information sheet