

RoADPain



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PARTICIPANT INFORMATION SHEET

For participants under 16

RoADPain: Understanding the Importance of Period Pain in Teenagers

You are invited to take part in our research study. Our names are Lydia Coxon and Katy Vincent. We are scientists that work at the University of Oxford in the Department of Women's & Reproductive Health.

Before you decide if you would like to join in, it is important for you to know what the study is about and what we would ask you to do. Taking part will not help you personally, although you will receive vouchers for your time. Please read and think about this leaflet carefully. You can talk to your friends, family or us about it if you want.

If anything isn't clear or you have more questions you can ask your parent/carer to give us a call and we can talk with you and your parent/carer about it.

Why are we doing this research?

Everyone experiences pain at some point, but for some people this pain does not go away. We study why some people experience pain for a long time and how we can stop this from happening to other people. We already know that women are more likely than men to get pain that doesn't go away (we call this chronic pain). There are lots of different types of pain, one of which is period pain. We want to look at young people who have had periods who experience period pain or not. We will use questions, brain scans and tests of different body systems (nerves, bladder and heart).

Why have I been invited to take part?

We hope to have 120 young people taking part. We are looking for about 60 young people that have period pain. We want people who have been having periods for 1 year, 3 years and 5 years.

- You are a young person aged 11-20
- You have started your periods
- You do not take hormone medicines or contraceptives (such as the pill or the mini-pill) for any reason.

Do I have to take part?

No. It is up to you. We will ask you to sign your name on a form to say that you agree to take part (this is called an assent form). As you are under the age of 16, we will also ask your parent/guardian to sign a form to say they agree for you to take part (this is called a consent form). We will give you a copy of this sheet and your assent form to keep.

You are free to stop taking part at any time and you do not need to tell us why.

If you do not want to take part or if you stop taking part, it will not change any care you get from a doctor now or in the future.

What will happen to me if I take part?

There are 4 parts to this study and we ask you to take part in them all:

- 1) Questionnaires
- 2) Saliva (spit) collection
- 3) Testing of body systems
- 4) Brain scan

We will ask you to fill in some questionnaires at the start of the study. The testing of body systems and the brain scan we will do twice, at different parts of your menstrual cycle (your menstrual cycle is the time between one period and the next). We will do these visits once during your period and once about 10 days after a period.

We will ask your parent/guardian to come along to all the visits, although they may not be able to be in the room with you for all parts of the study (such as during the brain scan). This is because having someone in the room can change things we are testing.

1) Questionnaires

When you start the study, we will ask you to fill out a questionnaire. This will include questions about you, including information about your periods and your wellbeing. We expect this will take about 15 minutes to complete.

At each visit we will also ask you to fill out a short questionnaire about how you are feeling.

You will be asked to complete another questionnaire at the end of the study.

2) Saliva (spit) collection

We will ask you to collect spit during your study visits and at home. For these we will ask you to chew something and spit into a tube. We will explain how to do these during a visit. We will give you paper instructions for any you collect at home. All together we will ask you to collect 14 separate samples. One of your saliva samples will be used to look at genetics, there is more information about this in the section 'What will happen to the samples I give?'

3) Testing of body systems

The second part of the study will take part in the John Radcliffe Hospital. We will do these tests at two different times. The timings of these will be around your menstrual cycle, with one session during your period and the other around 10 days after a period. These visits will take about 4 hours, and you can take break times on top.

On the day a member of the team will meet you and take you to certain room. We will explain what we are going to do, show you any tools we will use and answer any questions you and your parent/guardian have. If you are happy to continue we will ask you to sign a form.

Your parent/guardian can be in the room whilst we explain what we will be doing but we will ask them to step outside the room for the tests. Ideally, we would like you to not drink caffeine (this is found in tea, coffee and fizzy drinks) or take painkillers on the day of the tests. It is okay if you cannot do this.

On our website you can find a video recording of these visits so you can see what these will be like (www.wrh.ox.ac.uk/research/roadpain).

Part 1 looks at your nerves and muscles and takes about 1 hour. We will use different tools to look at how you feel things on your skin, like touch, cold and warm. We will do this on the opposite hand and arm to the one you write with (if you are right-handed we will test on your left hand/arm). We will ask you what you felt. There are videos online showing these.

Part 2 looks at your heart and how fast or slow it is pumping as well getting some saliva (spit) from you to look at a hormone called cortisol. This part will take about 1 hour. First we will ask you to chew on something which will help us collect your saliva (spit). Then we will stick small pads to your chest which allow us to measure your heart. We will put a cuff on your arm (this is the same type of cuff that is used to measure your blood pressure at the doctors). We will then ask you to sit still and quietly for 20 minutes so we can measure your heart. Next we will test how you feel about some things which cause pain. These will be short and will not cause you any damage. Once we have finished these tests we will ask for some more saliva (spit) and measure your heart again for 20 minutes.

Part 3 looks at how your bladder works. This will take up to two hours. About an hour before the test we will ask you to drink plenty of fluid (like water) to ensure you are well hydrated. When we start, we will ask you to go for a wee and we can then start the test. You will need to sit quietly in a room for the duration of this visit, but we will give you some puzzles to occupy you. We will give you some water to drink and then, at regular times, ask you to rate sensations from your bladder. When you feel your bladder is at its maximum fullness and you can't hold it any longer, we will ask you to go to the toilet and wee in a bowl. Then we will measure the volume (amount). We will stop this part after two hours and ask you to go to the toilet then if you haven't already. This may be a bit uncomfortable if it puts pressure on your bladder but should not be painful.

At the end of the visit, we will give you 5 small bottles that we would like you to collect saliva (spit) in at certain times the day before your next visit. We will explain what to do.

4) Brain scan

The third part of the study will take part in the John Radcliffe Hospital. We will do these tests at two different times. The timings of these will be around your menstrual cycle, with one session during your period and the other around 10 days after a period. Your parent/guardian will not be able to be in the scanner with you, but they may be allowed into the scan room if it is safe.

On the day a member of the team will meet you and take you to certain room. We will explain what we are going to do, show you any tools we will use and answer any questions you and your parent/guardian have.

The brain scan is a fMRI. Before the brain scan, for safety reasons, we will ask you to change into a pyjama-style top and trousers (we have these in many sizes). We will ask you to remove any metal objects you may be carrying (such as earrings, or a watch) or wearing (such as a bra, as they often contain metal, although if you have a soft sports bra without clasps you may wear this if you would prefer).

A radiographer (the person who controls the scanner) will go through some questions with you. Your answers to these are confidential.

More information about fMRI including how it works can be found on our website (www.wrh.ox.ac.uk/research/roadpain).

You will then go to the scanner room. The scanner looks like a large box with a tube through the middle. You will lie on a bed and we will put a helmet around your head. The bed then moves into the middle of the scanner. There is a mirror on top of the helmet so you can see out. Brain scans can be noisy, but we will give you ear plugs to make it quieter for you. So that we can get nice clear pictures, we will ask you to keep still during the scans and try not to move your head. You will be given a call button to hold during the scan which you can press to get the attention of the researcher on the other side of a window just outside the scanner. There are three parts to the scan.

1. We will ask you to look at a cross on a screen for about 15 minutes.
2. A researcher will come in and poke your lower leg with a blunt pin-prick (as in part 2). During this stage, we will take pictures of your brain. These pictures will be used to create a movie to understand where blood is flowing in the brain.
3. We will take some detailed pictures of your brain structure.

You may also have your heart rate monitored while you are having scans to help us improve our images.

We will explain exactly what to do before each scan starts. You can speak to us in between and take breaks if you wish. If you want to stop and get out of the scanner, you can use the call button and we will take you out straight away. At the end of the scan, we will ask you for some saliva (spit). Overall, this visit will take about 1 hour and 30 minutes.



This is a photo of the scanner we will be using.

What should I consider?

You may not be able to participate:

- If you are taking or have taken hormonal therapies (such as the pill or mini-pill) you will not be able to participate as these will affect your hormone levels and can alter your menstrual cycle.

- If you have or have had in the past, any chronic pain condition (other than period pain), including migraines, you will not be able to participate as it might alter some of the measures we are collecting.
- If you have had a diagnosis of cancer, you will not be able to participate as it might alter some of the measures we are collecting.
- If you are pregnant or breast-feeding then you will not be able to participate as these both affect pelvic pain and also many of the measures we are collecting.
- There are additional specific reasons that may mean that you cannot take part in this study, but we will discuss these with you if you want to take part.

You can tell the researcher if any of these apply to you or you think they might, and we will keep it confidential.

Are there any possible disadvantages or risks from taking part?

We have designed the study with the input of people like you (patient representatives), however, there are still some disadvantages associated with being involved:

Time: the questionnaires and study visits will take time to complete and will require visits to the hospital.

Distress caused by the questionnaires: we are aware that some of the questions we ask may be embarrassing or even upsetting to answer. If this is the case, we can provide support for you through the clinical teams with whom we work (doctors for example). We will give you information about how to ask for this help when we give you the questionnaires.

Discomfort from testing pain-relevant systems: the tests that we carry out want to look at how you feel pain so parts will cause some short-lasting pain. Nothing will cause lasting damage and any pain will be as short as possible. If you want to stop at any point we will.

Brain scan (fMRI): these brain scans use large magnets to work, so some people are not able to be scanned. We will go through a few questions with you to check you are able to be scanned. If you are scared of small spaces (claustrophobia) then you can not be scanned. As the machine is noisy you will be given earplugs. We will also ask you to change in to pajama style clothes. We ask you to not wear any make-up to the scan. The images of your brain will be used for research and won't be looked at by a doctor. Occasionally we might see something in a scan which isn't normal and then we would pass it on to be looked at by a doctor who would contact you or your parent/carer if it was important for your health.

Heart rate measurement (ECG): The measurements of your heart rate will be used for research and won't be looked at by a doctor. Very occasionally we might see something in a measurement (ECG) which isn't normal and then we would pass it on to be looked at by a doctor who would contact you or your parent/carer if it was important for your health.

What are the possible advantages of taking part?

Taking part will not help you personally, but we hope you'll find the tests and brain scan interesting. Also, we hope the findings from this study will be beneficial for young people and adults who menstruate and experience period pain or other chronic pain conditions.

Will anyone else know I'm doing this?

We will keep your information private. This means we will only tell those who have a need or right to know, such as the research team and your parents/carer.

We will inform your GP if you are taking part in the study by sending them a letter. We will also write to them if we are worried about any answers in the questionnaire. If we detect anything not normal in your brain scan (which is very rare) we will also contact your GP.

People from the University of Oxford and the NHS may be allowed to see your data if they need to check that the research is following the rules (regulations). This is called monitoring and/or audit.

Will I get anything for taking part?

We will pay for your travel to attend study visits at the hospital. Additionally, you will receive vouchers for taking part, to say thank you for your time taking part in the study. A voucher of £25 will be given to you for each visit (there will be four visits in total), a £15 voucher will be given to you after you complete the first set of questionnaires and a final £25 voucher will be given to you if you complete the end of study questionnaire. If you participate in all aspects of the study, you will receive £140 worth of vouchers.

What will happen to the samples I give?

The saliva (spit) samples will be kept securely and confidentially (privately), and will be labelled with your unique study number. Samples will be referred to only by this study number, and your name will not be available to the laboratory scientists. Once we have collected samples from all the people in the study these will be stored until we are ready to analyse (look) them. Some of the analysis (experiments to look at what is in your spit) may be performed by other laboratories including within commercial companies and therefore samples will be transferred from Oxford to these laboratories, this includes laboratories outside of the UK.

We will look at different biological and genetic material in your saliva (spit). We will use this information in our analysis to see how hormones affect our measures. You can find more information about genetics on our website (www.wrh.ox.ac.uk/research/roadpain).

If you agree, part of the samples taken will be used for genetic studies, looking for variation across your entire genome (all of your genes). Genes provide instructions for processes in the body and for traits such as eye colour. Everyone's genes are a little different. Information about these differences among people can help researchers understand things, such as how to best use drugs to treat disease. The results of these tests will not have any implications for you personally. We cannot tell you the results from the genetic tests. These tests are not the same as those that are sometimes carried out by doctors looking at a gene that is related to a disease, which are called clinical genetic screens. All data including the genetic data will be coded before analysis so that researchers will not be able to link research results directly to individuals. However, your DNA is unique to you so it can never be completely anonymous. If you have any questions about this please let us know and we can talk to you about them.

What will happen to my data?

The information you provide during the study is the **research data**. Any research data from which you or your parent/guardian can be identified (name, date of birth, contact details of your parent/carer), is known as **personal data**.

Personal data will be stored in a locked filing cabinet and on password protected servers in the University. Your name and the contact details of your parent/carer will be kept for up to 3 years after the study has finished, we will then remove all copies of these details. We will only keep these longer if you and your parent/carer consent to us keeping your details to contact you about future research studies. If you both assent/consent to this, we will securely store this personal data in a

password-protected file. Your date of birth will be kept alongside an anonymous study number which will also label your brain scans, any samples and test results. This is because it is important to keep a record of your age for our research. We will store this information for a minimum of 3 years after publication or public release of the work, which may be 2 to 3 years from the end of the study. The assent/consent forms you and your parent/carer sign at the start of the study will be stored securely for 10 years.

Other **research data** will be stored securely at the University for 3 years after the youngest participant turns 18 years old, or for 5 years, whichever is longer. Different scientists in the study will look at this research data and all will be under the supervision of Prof Katy Vincent. This research data will also be shared with other researchers interested in pain but this would always be completely anonymous. We will not share any of the research data with your parent(s)/carer(s).

The coded genetic data and limited relevant details including, age, gender, information about your body type, biochemistry etc. can also be made available to collaborators and to the National Institute for Health Research (NIHR) Biobank (<http://biobank.nihr.ac.uk/>). This is a panel of thousands of volunteers, both with and without health problems, who are willing to be approached to participate in research studies investigating the links between genes, the environment, health and disease. You will be asked if you are happy to be re-contacted for future research studies either related to period pain or for other health studies approved by an ethics committee that access the NIHR Biobank.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights>.

You can find out more about how we use your information by contacting katy.vincent@wrh.ox.ac.uk.

What if I don't want to take part in the research anymore?

Just tell your parents/carer and the people carrying out the research that you don't want to take part. You don't have to give a reason and no one will be annoyed with you. It is YOUR choice.

What will happen to the results of this study?

The results and findings from this study will be written in scientific papers that will be published and shown at relevant conferences (big meetings), including meetings dedicated to gynaecology and pain. You will not be identifiable in any of these instances, and your details will remain strictly confidential (private). Some of the research being undertaken will also be a part of student projects (like coursework, such as writing a PhD project or dissertation).

We would also like to show our findings to you. Summaries of the findings and all associated publications (papers or posters) will be available on the project website:

<https://www.wrh.ox.ac.uk/research/roadpain/view> and will also be placed on the websites of the partnering patient organisations: <https://endometriosis-uk.org>.

What if we find something unexpected or surprising?

None of the genetic or sample analyses are useful for and therefore we will not be telling you, any results from these. However, although the brain scans are not normally looked at by a doctor, there is the possibility that something not normal (abnormality) might be detected. As described above, if such an abnormality were found we would have the scan checked by a doctor who would then contact you and your parent/carer to advise on the need for further tests. We will also write to your GP if we are concerned about any answers in the questionnaires.

What if there is a problem or something goes wrong?

Please tell us if you are worried about any part of this study, by contacting the researcher (EMAIL). You may also talk to your parent/carer who will let the researcher know. If you are still unhappy or wish to make a complaint, either you or your parent/carer can contact Prof Katy Vincent on katy.vincent@wrh.ox.ac.uk or you may contact the director of the University of Research Governance Ethics and Assurances (RGEA) office on 01865 (6)16480, or email rgea.complaints@admin.ox.ac.uk.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of any clinical treatment which is provided.

How have patients and the public been involved in this study?

We have worked with patient representatives (people like you) since we started designing this study and they are key partners in the project. More details about what they do are available on the project website: <https://www.wrh.ox.ac.uk/research/roadpain/view>

Who is organising and funding the study?

This study is being organised by a group of researchers from around the United Kingdom, led by Prof Katy Vincent, Nuffield Department of Women's and Reproductive Health, University of Oxford. It is funded by the Medical Research Foundation as part of the UKRI Strategic Priorities Fund (SPF) Advanced Pain Discovery Platform (APDP), a co-funded initiative by UKRI (MRC, BBSRC, ESRC), Versus Arthritis, the Medical Research Foundation and Eli Lilly and Company Ltd. Oxford University is the Sponsor of this study.

Who has reviewed the study?

Before any research involving people can start, it has to be checked by a Research Ethics Committee to make sure that it is OK for the research to go ahead. This study has been approved by London-Bloomsbury Research Ethics Committee.

Further information and contact details:

Before, during or after the study, if you have any questions, please contact Prof Katy Vincent, Consultant Gynaecologist, who is leading the study (email: katy.vincent@wrh.ox.ac.uk). If you would like to be involved or would like more information to help you make this decision, please contact roadpain@wrh.ox.ac.uk

Thank you for reading this – please ask any questions if you need to.