Living with Vulval Lichen Sclerosus (LS) Survey

Participant Information Leaflet

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Link to survey:
https://tinyurl.com/livingwithLS

Introduction

Thank you for taking the time to read the information about this survey study. This leaflet explains why the research is being done and what it would involve. Please read the information carefully before you decide if you would like to take part. Talk to others about the study if you wish. Please ask us if there is anything that is unclear or if you would like more information.

Who is organising and funding the study?

This research has been organised by Dr Sophie Rees at the University of Bristol. It has been funded by the Economic and Social Research Council (ESRC). The research is sponsored by the University of Bristol and is supported by staff at the University of Warwick.

What is the study about?

Vulval Lichen Sclerosus (LS) is a chronic condition which can have a major impact on everyday life

and self-identity, but there has been little research about the experience of living with vulval LS.

The aim of this study is to understand the experience of vulval LS from the perspective of those living with the condition. This will include topics like access to diagnosis and care, treatment and management of LS, the impact of LS on your quality of life and your thoughts on future research projects for vulval LS.

Our reason for doing this research is to understand care needs and to design future research and services to improve the lives of individuals living with LS.

Why have I been chosen to take part?

You have been invited to take part in this survey study because your GP surgery is taking part in this research. We are inviting people with a diagnosis of vulval LS registered at your GP practice to complete a survey. You have been selected as one of these people because you have a diagnosis of vulval LS.

What would taking part involve?

Taking part in this study will involve completing the survey which will take approximately 30 minutes. At the beginning of the survey, you will be asked to give your consent to take part.

How do I access the survey on-line?

Here is the link to the survey:

https://tinyurl.com/livingwithLS

Do I have to take part?

No. Participation is completely voluntary and choosing not to take part will not affect you in any way.

We are not collecting any personal identifiable data i.e., name or address, so all the data that we do collect will be totally anonymous. This means that it will not be possible for you to withdraw your data once you have completed and submitted the survey as we will not know which survey is yours.

What are the possible benefits of taking part in this study?

Whilst there may not be any direct benefits to you, we hope that the information we gather will help us find ways of improving the lives of those living with vulval LS.

What are the possible disadvantages or risks of taking part in this study?

We do not believe that there are any particular risks associated with taking part in this survey study although we do acknowledge the time commitment.

We also appreciate that some people may find it difficult to answer questions about some of the sensitive topics associated with LS. If any of the questions within the survey cause you any distress, we suggest you contact your GP for further advice and support. We have also enclosed details of where to access additional support at the end of this leaflet.

Will my taking part be kept confidential?

Yes. All information that is collected during the study will be kept confidential at all times and held in compliance with the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR).

Your GP surgery used your name and contact details to contact you about the study. The research team do not have access to this information, they only have access to your unique study ID which will be used to manage all of your data.

In the future we may use your anonymous survey data for other research. We might agree to share summaries with other, carefully selected researchers running studies in this organisation and in other organisations.

Any such sharing will be closely monitored by the University and will adhere to University policies. These organisations may be Universities or NHS organisations.

You can choose whether you wish to allow your anonymous survey data to be used in this way. This is entirely optional and answering no will not stop you from participating in the survey.

Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

What will happen to the data collected about me?

The only people who will have access to the data that you give us will be this study's research team.

As a publicly funded organisation, the University of Bristol have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research.

This means that when you agree to take part in a research study, such as this, we will only use your data in the ways needed to conduct and analyse the research.

The University of Bristol will be the data controller for this study and the University of Warwick will be data processor. We are committed to protecting the rights of individuals in line with data protection legislation.

If you choose to complete the survey online via a weblink, this will be through Qualtrics which is a third-party company. Qualtrics has legal agreements in place with the University of Warwick and has been through strict information security assessment.
For further information please see below the links to Qualtrics' privacy statement:
https://www.qualtrics.com/privacy-statement/
https://www.qualtrics.com/support/survey-platform/getting-started/data-protection-privacy/

The University of Warwick will archive your anonymised data on a secure server for at least 10 years. Paper copies of the survey will be destroyed once the results have been published.

This study is funded by the ESRC who ask that anonymous research data is made available for secondary research in the public interest. Data will, therefore, be deposited in the UK data service at the end of the study: https://reshare.ukdataservice.ac.uk/

For further information, please visit www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/

What will happen to the results of the study?

The results of this study will provide us with a lot more information about what it is like to live with vulval LS. This will enable us to develop more research ideas and try to improve the lives of those living with LS.

The findings of this study will be published in academic articles. We will also present the findings widely at conferences and to health professionals so that they can understand the perspectives of patients. Where relevant, we will use direct, anonymous quotes from the text boxes within the survey.

We plan to produce a creative resource (e.g. an animated video) using the findings which will be used to help healthcare professionals understand the experiences of patients. We will never use any information that might identify you in these publications.

You will be able to access the results of the study via our website: https://warwick.ac.uk/fac/sci/med/research/ctu/trials/lwvls

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick Biomedical Science and Research Ethics Committee (BSREC) (Ref: BSREC 02/20-21) and the Health Research Authority (HRA) Research Ethics Committee (Ref: 21/EM/0274)

Who should I contact if I want further information?

If you would like further information about this research project, please contact Dr Sophie Rees or Dr Susanne Arnold on **0117 455 9264** or email us: livingwithLS@warwick.ac.uk

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of

Bristol official entirely independent of this study:

Head of Research Governance:
Adam Taylor
Head of Research Governance
Research and Enterprise Development
University of Bristol, Senate House
Tyndall Ave
Bristol, BS8 1TH (UK)
Tel: 0117 42 83065
Email: research-governance@bristol.ac.uk

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter on 0117 394824 or at: data-protection@bristol.ac.uk

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) casework@ico.org.uk

Accessing Support for LS

This section provides some links to where you can access information and support to help you with your LS. Unfortunately there is not a LS-specific charity which offers formal counselling. Please remember that your GP can help and may refer you to counselling if you need it.

Online LS information and peer support

- Emma Norman and Claire Baumhauer are two patient advocates who run the LS Awareness pages and support groups. Their website contains information about LS, and their active Facebook page provides support to people with LS.
- The British Society for the Study of Vulval Disease (BSSVD) have information about LS on their website. You can also find the location of specialist clinics in the UK.

- The Vulval Pain Society offers advice and information on all vulval pain matters, and also has a list of support groups.
- Ask Eve is a confidential, nurse-led information service that can listen to all your questions, Ask Eve is run by the Eve Appeal.

Mental health charities

- The Samaritans offer telephone support 24 hours a day, 365 days a year. Call 116123 for free. You can also get in touch with them by email or sending a letter:

  Chris
  Freepost RSRB-KKBY-CYJK
  PO Box 9090
  STIRLING FK8 2SA

- Shout Crisis text line. If you're experiencing a personal crisis, are unable to cope and need support, text **Shout** to 85258

Thank you for taking the time to read this Participant Information Leaflet.

The consent form to take part in this study is not enclosed in this document but can be found at the beginning of the survey.

The link to the survey can be found at:

https://tinyurl.com/livingwithLS

or using the QR code below

Study contact details

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