Participant Information Sheet

You are being invited to take part in this research study. Before you decide it is important for you to read this leaflet so you understand why the study is being carried out and what it will involve.

Reading this leaflet, discussing it with others or asking any questions you might have will help you decide whether or not you would like to take part.

What is the Purpose of the Study

There has been very little research conducted that explores the impact that Sjögren's syndrome has on an individual's sexual functioning and intimate relationships with their partners. When we look at research conducted with patients with other autoimmune rheumatic diseases, for example, rheumatoid arthritis, or systemic lupus erythematosus, we find evidence to suggest that sexual functioning may be impaired in some individuals that are diagnosed with an autoimmune rheumatic disease. As Sjögren's syndrome is the second most common autoimmune rheumatic disease, it is imperative that we conduct research in this area to determine if this is an issue that individuals' with Sjögren's syndrome face.

To do this effectively, we need to distribute an in-depth questionnaire (Phase 1) that assesses numerous dimensions of sexuality, such as sexual function, relationship dynamics, emotional and psychological distress, treatment strategies, and social support, to a large number of both males and females diagnosed with Sjögren's syndrome. In addition to the questionnaire, we also need to discuss these topics in depth with a small number of individuals to understand the lived experience of this topic for people with Sjögren's syndrome (Phase 2). You have the option to participate in either phase independently, or both phases, should you wish too.

Therefore, we are inviting you to take part in this study, even if you do not think this is an issue for you, it would be great to hear your experiences with this topic.

Who can take part?

You can take part in this study if you:

- Have a diagnosis of Sjögren's syndrome – either primary (pSS) or secondary (sSS).
- Are aged 18 or over
- Are male or female and have the same genital composition as assigned at birth
- Are comfortable answering personal questions of a sexual nature
- Are an English Native Speaker or are fluent in reading, writing and speaking in English
- Have access to the Internet

If you are unsure about your eligibility, then please contact the research team and we can discuss any issues (contact details at the end of the information sheet).

What will happen if I take part?

Your participation in this study involves the completion of an online survey. There are five sections to the survey, outlining them below will help you to decide if you are comfortable answering questions on the following topics.

Phase 1
The first section of the survey will ask you some basic demographical questions (e.g. ethnicity, educational attainment, age), sexual identity, relationship status, sexual history, hormonal status (e.g. menopausal status, menstrual abnormalities and contraception use), and illness characteristics (diagnoses, symptom activity). The second section will ask you questions about your experience of symptoms of Sjögren's syndrome on sexual activity, intimate behaviours, sexual satisfaction, sexual comfort, sexual functioning and emotional distress. The third section will ask you about your current relationship with a partner, particularly, your relationship satisfaction, communication, and partner support. You will also be asked questions about your communications with healthcare professionals around the topic of sexuality. The fourth section will ask you questions about your experience and use of lubricants and other genital products. The final section of the survey will ask you about mental health and quality of life. You will have the option to skip questions that you prefer not to answer.

The survey takes around 20 to 40 minutes to complete. Please feel free to take a short break part-way through if you become tired.

Phase 2 (Optional)
You will have the option of participating in a one-to-one discussion with the researcher following completion of the questionnaire to talk about your experiences of the topic in further detail. The one-to-one discussion will last around 30 minutes and will take place over Microsoft teams (no account needed) or phone call at a time, date and contact method most appropriate for you. Should you chose to participate in the second study, you will be asked to provide your email address (at the end of the survey) so that the researcher can contact you with more information and to organise a suitable time for the discussion with you. Your email address will not be linked to the data you provided in the survey and or in any data you chose to provide in a discussion with the researcher.

Do I have to take part?

Your participation in this study is completely voluntary and you may choose to withdraw at any time without penalty by exiting the browser. Answers to any questions you complete before withdrawing will be recorded and securely stored, as outlined below. When the survey closes and the data is downloaded, your incomplete response will be removed, and your data will not be included in the dataset and will not be analysed. You are free to refuse to answer any of the questions without providing an explanation, you can either chose the "prefer not to respond" response option or skip the question and move on to the next question.

What are the possible benefits of taking part?

There are no direct benefits of participating in this study. The information gathered will potentially help increase our understanding of the impacts Sjögren's syndrome has on sexual functioning and intimate relationships.

What are the possible disadvantages of taking part?

There are no known physical, economic or social risks associated with participating in this study. However, some of the questions cover topics that may be sensitive (e.g. topics of a sexual nature). It is possible that you might experience some discomfort answering these questions. However, you are not in any way obligated to answer any material that makes you feel uncomfortable; you can either choose the "prefer not to respond" response option or leave the question blank and move on to the next question. If you experience any emotional distress from taking part in this study and would like more information and support, please utilise the following resources or speak to your GP or healthcare professional.

- "Sex and Sjögren's syndrome" information leaflet from the Sjögren's Foundation https://www.sjogrens.org/sites/default/files/inline-files/Sex%20and%20Sjogren%27s%20Patient%20Education%20Sheet.pdf
- Patient helpline hosted by the British Sjögren's Syndrome Association (BSSA) https://www.bssa.uk.net/contact.asp
- Sjögren's syndrome information booklet compiled by the charity Versus Arthritis https://www.versusarthritis.org/media/1326/sjoegrens-syndrome-information-booklet.pdf
- Relationship help and guidance information sheets from Relate https://www.relate.org.uk/relationship-help/help-relationships

How will my data be stored, and how long will it be stored for?

Your data will be held securely at all times. All paper records will be kept in a locked filing cabinet on university premises and will not be stored with any identifiable information (such as your email address or IP address). All electronic data will be stored securely on the University U drive, which is password protected and can only be accessed by the main researcher (Jemma McCready). Anonymised data will be stored for 7 years before being destroyed, or in accordance with any peer-review journal guidelines.

Will my taking part in this study be kept confidential and anonymous?

All questionnaire information obtained during the course of this study is strictly confidential and your privacy will be protected at all times. The data from this study is being collected using an online survey platform that complies with GDPR regulations. The server has an SSL Certificate providing encryption similar to those used by banks for online banking, thus ensuring the information you provide is secure. Your responses to the questionnaires (without any identifying information) will be stored on encrypted and password-protected drives that are GDPR compliant. Only the research team will have access to the data files.

When you register for the study, you will create your own personal participation code, which will be associated with your survey responses, so as to identify your data should you wish to withdraw for the study. No identifying information will be stored or associated with your responses. Moreover, no individual will be identified in any publication, report, or presentation of this research.

If you agree to participate in the follow up study, we will provide a separate link to a form where you will be asked to provide an email address on which the researcher can contact you with information about the next phase of the study. Your email address will not be linked to the data you provide. Your data and your identifying information will be saved in two different, secure databases.

What categories of personal data will be collected and processed in this study?

The following demographic data will be collected in the questionnaire - biological sex, gender, ethnic origin, sexual orientation and sexual status. The survey is also comprised of pre-validated questionnaires that explore various aspects of sexual functioning and sexual health. No indirectly collected identifiable information (e.g. IP addresses) will be collected, processed, or stored with any of your data. All data will be anonymised and it will not be possible for you to be identified from the data you provide.

What is the legal basis for processing personal data?

Processing personal data is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

Who are the recipients or categories of recipients of personal data, if any?

Only the researcher (Jemma McCready) and the research supervisor (Dr Kate Hackett) will have access to the information that you provide. Any data that leaves the site will be anonymised and it will not be possible for anybody outside of the investigational site to identify you.

What will happen to the results of the study and could personal data collected be used in future research?

It is intended that the overall results of the study will be published in peer-reviewed journals and presented at research conferences. The overall findings may be presented in a variety of formats (e.g., social media posts, media articles or in newsletters) and distributed to appropriate channels for dissemination to clinicians, patients and other academics. However, the data will be anonymized and you or the data you have provided will not be personally identifiable. We can provide you with a summary of the findings from the study if you email the researcher at the email address provided below.

Who is Organising and Funding the Study?

Northumbria University is the sole funder of this study. The organisers of this study are a PhD student (Jemma McCready) and an Associate Professor (Dr Kate Hackett) employed by Northumbria University.

Who has reviewed this study?

This study has been reviewed and approved by the Faculty of Health and Life Science Ethics Committee, Northumbria University. If you require confirmation of this please contact the Chair of this Committee, stating the title of the research project (Do individuals with Sjögren's syndrome experience issues with their sexual functioning and intimate relationships as a result of the disease?) and the name of the principal investigator (Jemma McCready):

Chair of Faculty of Health and Life Sciences Ethics Committee,
Northumberland Building,
Northumbria University,
Newcastle upon Tyne,
NE1 8ST

What are my rights as a participant in this study?

Under the GDPR act, you have a right of access to a copy of the information comprised in your personal data (to access the information you should submit a Subject Access Request). Additionally, you have a right in certain circumstances to have inaccurate personal data rectified; and a right to object to decisions being taken by automated means. If you are dissatisfied with the University's processing of personal data, you have the right to complain to the Information Commissioner's Office. For more information see the ICO website.

How do I take part?

If you have read the information sheet and would like to participate in this study, please click the following link (or paste it into your web browser) to be taken to the questionnaire:

https://nupsych.qualtrics.com/jfe/form/SV_6JOdd4vRdk2GWZT

If you need more information, would like to discuss your participation, or experience any problems as a consequence of taking part in the study you should contact Jemma McCready by email at jemma2.mccready@northumbria.ac.uk

Name and contact details of the Records and Information Officer at Northumbria University: Duncan James (dp.officer@northumbria.ac.uk).

You can find out more about how we use your information at:
www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/legal-services-team/gdpr/gdpr---privacy-notices/
or by contacting a member of the research team