



Participant Information Sheet: The LISTEN study (Listening: Involving SLE patients to empower and negotiate recognition)

Phase 1: Small group peer support and patient involvement in helping decide research questions

You are being invited to participate in the first phase of a study aimed at exploring ways to improve the lives of people with lupus, Undifferentiated or Mixed Connective Tissue Disease (UCTD, MCTD), discoid/cutaneous lupus, Sjögren's syndrome or overlap disease. We are hoping to do this by looking at the impact that these diseases, and different types of support, have on peoples' lives and what improvements patients and doctors would like to see.

Our earlier research shows that peer support is very important to many patients so we are looking to see if being in small email support groups with other people with lupus is an acceptable and helpful form of peer support.

We are also looking for your help in deciding what you, the patients, would like researched in more detail, including helping design questionnaires for patients and doctors; the responses to which should help us to identify common patient experiences and develop proposals for improving care and support.

If you decide to take part, your participation is entirely voluntary and your responses to the questionnaires will be anonymised. You are completely free to withdraw at any time from the small support group and/or the whole study without giving a reason and this would not affect the standard of care you receive. If you are randomly allocated to a small email support group, you can participate as much or as little as you like/are well enough to.

Who can take part in this study?

For this study you will need to:

- Be living in the UK
- Be aged 18 or over
- Have a diagnosis of lupus, UCTD, MCTD, discoid/cutaneous lupus, Sjögren's syndrome or Overlap disease

What will happen if I take part in this study?

- You will need to complete the online questionnaire please. This contains questions about your disease, quality of life and feelings.
- You will need to be willing to share your first name and an email address (or we can set one up for you for just this study) with the study researchers and with a small group (4-5) of other participants allocated to your email group.
- Once we receive the questionnaires, a computer programme will randomly allocate everyone into 3 equal groups, which will be labelled A, B and C. Each main group will contain approximately 60 people and be divided into smaller support groups for groups A and B, with Group C being the control group. The groups are explained below:
- **Group A.** If you are in group A, your email address and first name (but no other details) will be shared with 4-5 other people with lupus, UCTD, MCTD, discoid/cutaneous lupus, Sjögren's syndrome or overlap disease. Over the four months of the study you will be

invited to email your group to share your experiences and support each other. In addition, you will be invited to help with deciding what patients think is important in medical relationships and coping with the disease and for your advice on ways to improve quality of life and communication between doctors and patients. Research questions (for example: 'what do you think are the most important things for rheumatologists to ask in clinic appointments') will be sent to the group email chat by a researcher approximately weekly/ fortnightly. You can communicate as much or little as you want/ are able to about the research and within your group.

- **Group B.** If you are in group B, your email address and first name (but no other details) will be shared with 4-5 other people with lupus, UCTD, MCTD, discoid/cutaneous lupus, Sjögren's syndrome or overlap disease. Over the four months of the study, you will be invited to email your group to share your experiences and support each other. You can communicate as much or as little as you want/are able to within your group
- **Group C** will not be put into support groups initially as it will be the control group. This is a very important group in studies as it means we can compare with the group trying something new so we have scientific evidence to show if the support group helps. However, in order to ensure everyone has the chance of joining an email support group, everyone in Group C will be given the opportunity to be put in an email support group after the first four months of the study if they wish.
- People in all three groups will receive another questionnaire about their health, feelings and experiences at the end of the study (four months) and after 12 months.
- All groups will be free to continue with their email support group conversations for as long as they wish after the four-month period, but this will be outside of the research study.

What are the possible risks of taking part?

We do not foresee any direct risks to your physical health from participating in this study. For those who are randomly allocated to groups A or B, there are five small possible risks to consider:

- It is hoped that discussing your experiences in the group with other patients will be helpful to you, but some people may find some discussions in the group about health difficulties and medical experiences distressing. You will be given the contact details of LUPUS UK and the research team who can provide information about how to obtain further support.
- Although the support group contact will be by email, some relationships may be formed where you wish to meet face to face too. Please note this will be outside of the study, at your own risk and usual precautions should be followed for meeting online contacts.
- The only rule of the groups is that everyone be kind and supportive. It is most likely that this will be the case and anyone not following this rule will be asked to leave the group. The letter introducing you to your group will have the details of how to report any unkind emails.
- There is a very small risk of unwanted further contact from group members if you decide to withdraw or anyone has been withdrawn due to not following the rules of being kind and supportive. This risk can be removed by you setting up a separate email account for the email support groups or us setting one up for you. This could then be closed without affecting your main email account in the unlikely event of any problems of unwanted further contact from group members.
- Please remember that information shared and/or exchanged in these support groups is no substitute for medical advice. Always seek the advice of a qualified medical professional.

What are the possible benefits from taking part?

Forming a small group with other patients may be of benefit in providing a deeper level of understanding and support than can easily happen with friends and family without the disease. A

small group communicating privately may be more personal and comfortable for many people in addition to the support offered by larger public online forums. Being involved in helping with research into your own disease may be empowering and help to improve communication and medical support in the future.

We anticipate the information from the questionnaires will help inform doctors and researchers about the impacts of your disease and positive and negative medical experiences leading to greater understanding and support. Discussing your experiences and knowing they will be heard and used to try and make a difference in the future can be very helpful in coming to terms with any distress caused by any negative experiences and can help others in learning from positive experiences.

Everyone who signs up for the study and completes the questionnaires at the start and finish of the study will be entered into a prize draw to win £100 of 'love to shop' vouchers, exchangeable at many high street shops.

How confidential are my responses and how will you use my personal data?

- All data will be stored securely.
- The published results will not include any information that could identify individuals.
- We will analyse your experiences together with others and look for common patterns. We will use direct quotes from some peoples' questionnaires in the write-up of the study. These will be labelled with a participant number and no names will be included.
- We will be following the new data protection regulations, GDPR, May 2018.
- Cambridge University is the sponsor for this study. We will be using information from you in order to undertake this study and will act as data controller for this. This means that we are responsible for looking after your information and using it properly. Cambridge University will keep identifiable information about you for two years after the study and any follow-up study is completed, following which time any identifying material will be destroyed and the non-identifiable data will be archived for five years, then destroyed.
- Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
- Further information about how the University uses personal data can be found at: <http://www.information-compliance.admin.ac.uk/data-protection/research-participant-data>

Who is organising and funding the study?

The study is being led by the Behavioural Science Group at the University of Cambridge and funded by LUPUS UK.

If you wish to participate, please use the online link to complete the consent form and questionnaire. If you would like further information, please feel free to contact Melanie Sloan (researcher) on mas229@medschl.cam.ac.uk or 07975799052.

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