

## Participant Information Sheet: INSPIRE-Flare

### INSPIRE-Flare

#### Invitation and summary

You are being invited to take part in a survey aimed at investigating flares in patients with autoimmune diseases. The study aims to gather information about flares to raise awareness and develop plans to improve the case and lives of people with these diseases.

The questions in the survey have been decided by patients with input from researchers, charities, psychologists and a group of patient-centred clinicians who are all keen to hear your views, needs and ideas.

If you decide to take part, your participation is entirely voluntary and any decision about whether to participate will not affect your medical care. You can withdraw your participation at any time without giving a reason. Your doctors will not know whether you have participated in this study. Your responses to the survey will be anonymised and all identifiable information removed before analysis.

#### What's involved?

##### The background and purpose of the research

The INSPIRE-Flare study aims to investigate flares in autoimmune diseases terms of:

- Defining flares
- Triggers of flares
- Preventers of flares
- Progression of symptoms in the lead up to and during flares

Research into patient experiences of flares suggests a diverse range of flare triggers and preventers which may be unique to individual patients. Identification of patterns of symptoms in the lead up to and during flares could assist in earlier identification and treatment of impending flares.

#### What would taking part involve?

To take part in this study, you will need to complete the survey. The survey will take approximately 45 minutes to complete. This contains questions about your experience of factors which may trigger, worsen, prevent or reduce flares and your experience of symptoms which you experience in the lead up to or during a flare. It asks about both psychological and physical symptoms of your disease. To participate in this study, you will need to meet the following criteria:

- Be aged 18 or over
- Be diagnosed with an autoimmune disease. This includes systemic autoimmune rheumatic diseases such as lupus, Sjögren's, undifferentiated (UCTD) or mixed (MCTD) connective tissue

disease, systemic sclerosis, polymyalgia rheumatica (PMR), inflammatory (IA) (e.g. psoriatic arthritis, enteropathic arthritis) or rheumatic (RA) arthritis, and vasculitis. It also includes other autoimmune diseases such as multiple sclerosis, thyroid disease, autoimmune encephalitis, antiphospholipid syndrome, inflammatory bowel disease, inflammatory muscle disease, stiff person syndrome and type 1 diabetes.

### What are the possible benefits of taking part?

We anticipate the information from the survey will help inform doctors and researchers about flares in your disease. Knowing that your experiences will be heard and used to make a difference can be helpful in coming to terms with any distress caused by negative experiences with your disease. Being involved in helping with research into your own disease may be empowering and help to improve patient experiences and treatment of flares in the future.

If you participate, you can enter a prize draw to **win one of four £50 Amazon vouchers**.

### What are the possible risks of taking part?

We do not foresee any direct risks to your physical health from taking part in this study. However, some people may find it distressing to think about their physical and psychological experiences of flares. At the end of the survey, you will be given details about where to find support.

### 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' surveys in the write-up of the study for publication in journals, presentation in conferences and to inform future research. Quotes will be labelled with a participant number, and any identifiable information will be removed.
- We will be following the General Data Protection Regulations, UK-GDPR 2018.
- The University of Cambridge is the sponsor for this study. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Cambridge will keep identifiable information about you for two years after this study, and any follow-up study, is completed.
- 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. Once you have completed questions in the survey, this data cannot be withdrawn because it is immediately anonymised. You can withdraw from the study at any time by exiting the survey, however data already entered will still be collected. To safeguard your rights, we will use the minimum personally identifiable information possible.

- Only fully anonymised data will be shared between staff at different universities. You can find out more about how we use your information here: <https://www.information-compliance.admin.cam.ac.uk/data-protection/medical-research-participant-data>.

### **Ethical review of the study**

This project has been reviewed by the Cambridge Psychology Research Ethics Committee and the Health Research Authority. Please send any complaints regarding the conduct of the study to the lead researcher, Martha Piper, on [mp2196@cam.ac.uk](mailto:mp2196@cam.ac.uk) or the Patient Advice and Liaison Service on [cuh.pals@nhs.net](mailto:cuh.pals@nhs.net).

### **Who is organising and funding the study?**

The study is being led by the Department of Public Health at the University of Cambridge and funded by The Lupus Trust.

### **How can I take part?**

If you wish to participate, please use the online link or QR code to complete the consent form and survey. If you would like further information, please feel free to contact Martha Piper (study co-ordinator) on [mp2196@cam.ac.uk](mailto:mp2196@cam.ac.uk). Should you have problems with the conduct of the study, please contact Steve Morris on [sm2428@medschl.cam.ac.uk](mailto:sm2428@medschl.cam.ac.uk).

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