Gaining Insight into RheumAtic Fatigue (GIRAF)

This PIS should be read in conjunction with The University privacy notice,

We invite you to take part in a research study

- Before you decide whether you want to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish.
- Ask us if there is anything that is not clear or if you would like more information.

Important things that you need to know

- This research is being conducted by Dr Katie Druce at the University of Manchester and collaborators at Ulster University and uMotif, a digital health company who work with the NHS and Universities.
- We want to investigate how well a new method of data collection, called Dried Blood Spot Sampling (DBSS) works.
- As part of the study, we will ask people to used one DBSS kit per day on days 1-7, 14 and 30.
- We will also ask people to use a smartphone or tablet to report symptoms twice a day for 30 days.
- Lastly, we will ask people to wear a sleep monitor 24 hours a day and to complete a daily sleep diary for 30 days.
- You do not need to attend any meetings or appointments.
- To take part in this study you will need to register for an account with uMotif using your name, date of birth and email address. uMotif will not have access to any other personal information you provide during the study.
- You can stop taking part in the study at any time.
- This Project Has Been Approved by the University of Manchester's Research Ethics Committee 4, [UREC reference number 2018-5092-7436].

Contents

How to contact us

If you have any questions about this study, please contact Katie Druce by telephoning **0161 275 1604** or by emailing katie.druce@manchester.ac.uk

MANCHESTER 1824
The University of Manchester

Who will conduct the research?

- The research is being conducted by Dr Katie Druce at the University of Manchester and collaborators at Ulster University and a company called uMotif.
- The University of Manchester is the custodian of the data and will be responsible for data collection, analysis and the publication of study results in academic journals and scientific meetings.
- The research team at Ulster University will receive your completed DBSS kits and will be responsible for analysing the samples to extract information about inflammation.
- uMotif are a digital health company who work with the NHS and Universities and they have provided us with our study app and are responsible for providing technical support for participants if there are any problems with the app.

What is the purpose of the research?

- Fatigue is an overwhelming feeling of exhaustion, both physical and mental.
- Patients with rheumatic diseases, such as rheumatoid arthritis (RA), osteoarthritis (OA) and fibromyalgia (FMS), experience frequent fluctuations in fatigue.
- We think that these fluctuations may be caused by short-term changes in inflammation, but these changes are not regularly measured. A new method called Dried Blood Spot Sampling (DBSS) could be used to do so for the first time, but we are not sure how suitable the method is.
- We are conducting this study to determine how well the DBSS kits work in people with rheumatic diseases, including how many kits each participant is able to complete and return and the total number of kits from which we could extract inflammation data.

Who can take part?

We wish to recruit people who:

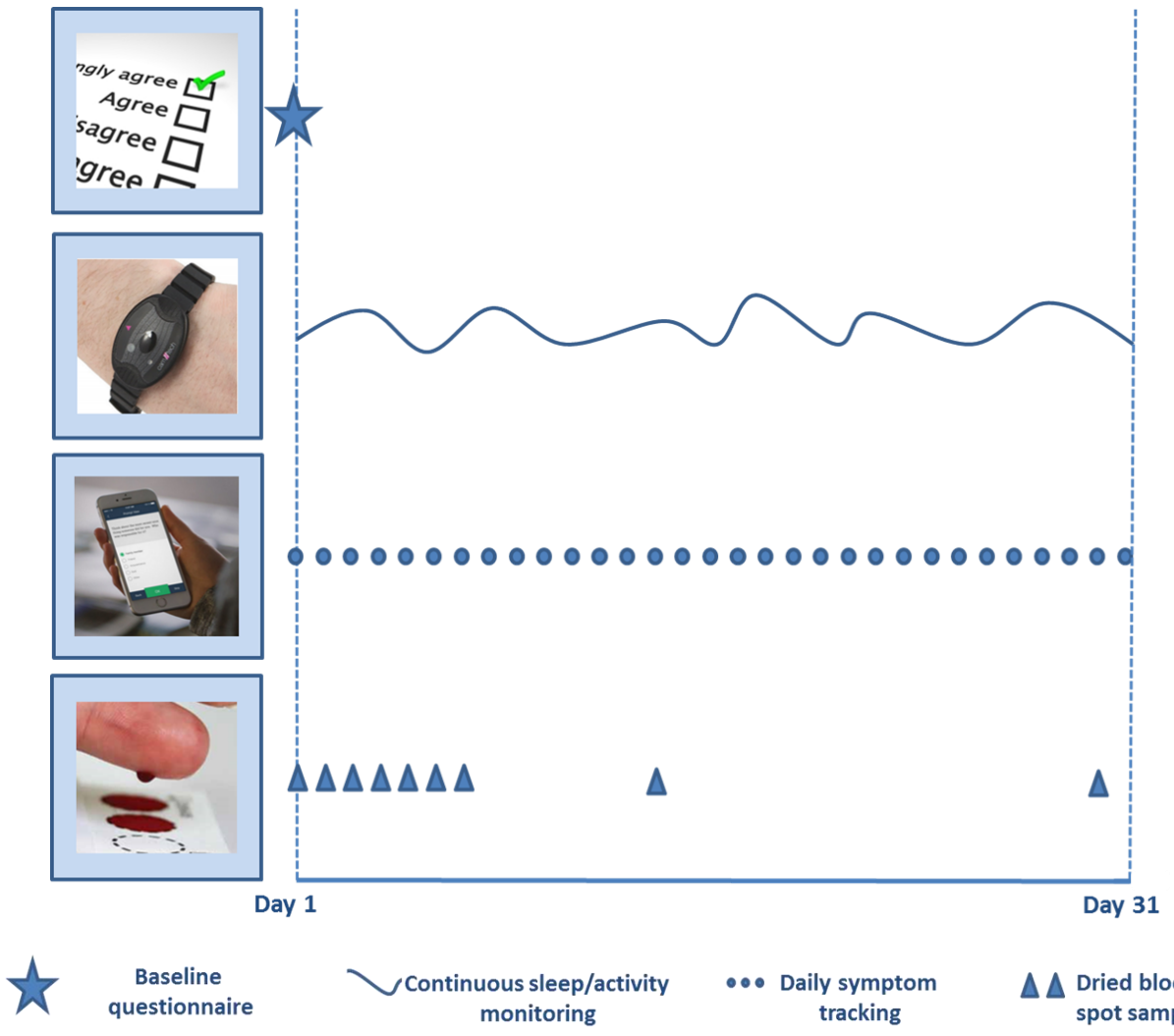
- are aged 18 or older
- have access to an Apple or Android smartphone or tablet
- have (primary) RA, OA or FMS
- are not currently employed in shift work

I have more than one rheumatic disease, am I still eligible?

- Many people have more than one rheumatic disease. For example, you may have rheumatoid arthritis and fibromyalgia. If this applies to you, you would still be eligible for this study, but we will ask you to indicate which disease is your "primary diagnosis". By primary diagnosis we mean the diagnosis which occurred first, or which you believe most affects you.

What would I need to do to take part?

- We would ask you to complete the study's screening questionnaire. If you meet the study inclusion criteria we will phone you at least 24 hours after we receive your questionnaire to discuss the project with you.
- If you agree to participate we will send you a study information pack, including a wrist-worn sleep monitor, dried blood spot sampling kits and instructions about how to download the study application (app). We will send you a reminder text on the day we expect you to start the study and will include a study password which you will need to enter in order to unlock the app.
- The study lasts 30 days in total and involves completion of a baseline questionnaire, continuous data collection using an app and a sleep monitor and use of dried blood spot sampling kits to collect finger-prick blood samples once a day for 7 days, then again on days 14, and 30.
- There should be no risks associated with the DBSS kits, though you may experience a small amount of pain and discomfort when using them. If using the kits becomes too uncomfortable you do not need to continue with the study.
- The study diagram below is designed to show you the information we will collect.



- You do not need to attend any meetings or appointments. We will however ask you to post the dried blood spot sampling kits to our team at Ulster University in the pre-paid envelopes provided. We will also ask you to use a separate pre-paid return envelope to return the sleep monitor and study documents to us after 30 days, by visiting your local post office.

- After you have completed the study, you may be given the opportunity to participate in some focus group studies to give us feedback about your experience of the study and the use of the DBSS kits, app and sleep monitor. There is no obligation to take part and we will specifically ask whether you agree to receive further information about the focus groups in the consent form. Consent to receive information does not guarantee that you will be invited to attend the focus groups.

What will by blood samples be used for?

- In this study we are interested in how well the DBSS kits work in people with rheumatic diseases, including how many kits each participant is able to complete and return. We are also interested in knowing how many DBSS kits we can extract inflammation data from. To answer this we will use your blood sample to measure a marker of inflammation called C-Reactive Protein (CRP).

- Samples collected by DBSS kits will be received, logged and securely stored by the research team at Ulster University for the duration of the analysis period. After this time, they will transfer the samples to the University of Manchester where they will be retained and securely archived for 10 years.

- If you consent, your anonymous research data and blood samples may be shared beyond the research team, for further analysis. Other analysis may include extraction of DNA (deoxyribonucleic acid), serum, RNA (ribonucleic acid), additional inflammatory markers and/or cells. We will specifically ask whether you agree to this in the consent form.

What does the sleep monitor measure?

- The sleep monitor measures physical movement and records this as activity. It is used to assess physical activity as well as sleep, but from the data we receive cannot tell whether you are washing the dishes, doing your shopping or having sex. There is no need to remove your monitor once you enter the study, unless it causes you discomfort.

What will happen to my personal information?

- In order to undertake the research project we will need to collect the following personal information about you:
    - Name
    - Sex
    - Date of birth
    - Mobile/landline telephone number
    - Delivery address (work or home)

- We will also ask you to complete a baseline questionnaire to tell us about you and your rheumatic disease, including information about your ethnicity, working status and the duration of your disease.

- We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information. The legal basis upon which we are using your personal information is "public interest task" and "for research purposes" if sensitive information is collected. For more information about the way we process your personal information and comply with data protection law please see our Privacy Notice for Research Participants.

- The University of Manchester, as Data Controller for this project takes responsibility for the protection of the personal information that this study is collecting about you. In order to comply with the legal obligations to protect your personal data the University has safeguards in place such as policies and procedures. All researchers are appropriately trained .

- Your personal details will kept separately from all other data collected during the study, including the baseline questionnaire, app and sleep monitor data. All data will be kept on secure databases within the Arthritis Research UK, Centre for Musculoskeletal Research. Your name, or any details that could identify you, will not be used in any publications resulting from this study. While the researchers will keep information confidential, due to the nature of a focus group confidentiality cannot be assured from fellow group members.

- For administrative purposes, your personal details will be stored securely for 5 years. Anonymised study data will be retained for 10 years after research is completed.

- You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings . This is known as a Subject Access Request. If you would like to know more about your different rights, please consult our Privacy Notice for Research Participants and if you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL. at the University and we will guide you through the process of exercising your rights.

  You also have a right to complain to the Information Commissioner's Office, Tel 0303 123 1113

Can I change my mind?

- It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

- If you do decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself.

- We will retain any data you have provided up until the point of withdrawal. This does not affect your data protection rights.

What if I want to make a complaint?

- It is important that you know who to contact if you wish to report any problems or to make a complaint. The details you need to do this are below:

Minor complaints

If you have a minor complaint then you need to contact the researcher(s) in the first instance. Please contact:

Katie Druce

Telephone: **0161 275 1604** or email: **katie.druce@manchester.ac.uk**

Formal complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact :

The Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL

Telephone: **0161 275 2674**

or email: **research.complaints@manchester.ac.uk**

This Project Has Been Approved by the University of Manchester's Research Ethics Committee 4, [UREC reference number 2018-5092-7436].