**Participant Information Sheet**

**Fatigue in Lupus Intervention Programmes (FLIP): A randomised controlled trial investigating the effectiveness of fatigue management in Systemic Lupus Erythematosus (SLE) Disease.**

You have been invited by a member of your Rheumatology Team or through Lupus UK to consider taking part in this research study. To help you decide whether or not 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. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

|  |
| --- |
| **What is the purpose of the study?** |
| Many patients with SLE experience high levels of fatigue, but we don’t know what kind of approach or intervention is most helpful. The majority of Rheumatology departments in the UK only have access to information booklets on how to manage fatigue.  Our main aim is to see if participation in a 4 week live online group fatigue management programme reduces the impact of fatigue in SLE patients more than standard care (access to fatigue booklets.)  NHS fatigue management groups mostly run at a hospital and are in person for a minimum of 6 weeks. This can be difficult for patients to attend. Our second aim is to demonstrate that a live online 4-week programme is as effective as the 7-week programme. |
| **Why have I been invited to take part?** |
| You have been invited to take part in this study because you have been diagnosed with SLE and have problems with fatigue. |
| **Do I have to take part?** |
| No, it is up to you to decide whether or not to take part. |
| **What do I have to do to take part ?**  **Enrolment**  If you do decide to take part in the study you can self-enrol onto the study by following this link. [https://redcap.link/flipscreening]  **Step 1** Click on the link which will take you to the secure database called REDCap. *This database is looked after by the University of Edinburgh and is used in lots of research studies. Only the research team at the university and the facilitators delivering the groups will have access to your information.*  **Step 2** Complete some screening questions to make sure you will be able to take part (this will take 5 minutes).  **Step 3** Read and sign the online consent form (a copy of this is at the end of this information sheet-this will take 10 minutes).  **Step 4** Once the consent form is signed you will be asked to complete some details about yourself (this will take 6 minutes).  **Step 5** Complete questionnaires about your sleep, the impact of fatigue on your quality of life and your disease activity. These should take no more than 30 minutes online. You can pause and come back to them if you wish.  *As part of the study, you will be asked to complete the same set of questionnaires a further three times over the following year. This is how we will measure the effectiveness of the three interventions. You will also be asked to complete an anonymous online patient satisfaction survey. There will also be a short additional survey about other factors that may contribute to fatigue and disease severity, for example sleep apnoea, vitamin deficiencies, and further demographics.*  **If you have any questions about the study, please feel free to contact the study team, their contact details are at the end of this information sheet.**  What happens after the questionnaires?  Once you have completed the questionnaires you will be randomly allocated by the REDCap software to one of the following interventions:  1.Standard care only (the fatigue booklets)  **OR**  2.Standard care plus a group  If you are allocated to the group intervention you will either attend a 4 week or a 7 week live online programme. This will be delivered using an online platform approved for patient use by the NHS.  *If you are not familiar with using an online platform, we can provide training to help you. These platforms are secure and no recording will be made. A member of the study team will contact you by telephone to discuss the day and time of the next available group. You will be provided with login details for the platform by email. You will join your other group members and facilitators live online for the duration of the sessions.*  We will write to your GP to let them know you are taking part in the study if you consent for us to do this.  What are the interventions?  **Standard Care**  All participants will receive a link to the Versus Arthritis and Lupus UK Booklets on Fatigue Management. These booklets provide information on fatigue, sleep, energy conservation, exercise and stress to help manage fatigue.  **Group Intervention**  Both the 4- and 7-week fatigue management programmes use a cognitive behavioural approach (CBA) to manage fatigue. This is a psychological approach used to explore unhelpful thinking styles which can impact emotions and behaviours and affect fatigue. Research has shown the ideal number for a group is 8-10.  The 4-week Fatigue Management Programme is three sessions run over consecutive weeks followed by a review session at 11 weeks. Each session explores a different theme, which can have an impact on fatigue and includes education, group cognitive exercises and discussion.  Each participant also has the opportunity to set a weekly goal and to share their experience with the group.  The schedule of the programme is as follows:   |  |  | | --- | --- | | **Week** | **Session Theme** | | Week 1 | Fatigue, Sleep and the REST™ programme | | Week 2 | Thoughts, emotions, behaviours | | Week 3 | Activity and the 4P’s (Prioritise, Plan, Pace, Posture) | | Week 11 | Review, Stress, Communication & Setbacks, the Future. |   The 7-week Fatigue Management Programme is six sessions run over consecutive weeks followed by a review session at 14 weeks It follows the same format as the 4-week programme.  The schedule of the programme is as follows:   |  |  | | --- | --- | | **Week** | **Session Theme** | | Week 1 | Fatigue and You | | Week 2 | Sleep and the REST™ programme | | Week 3 | Thoughts, emotions and behaviours | | Week 4 | Activity and the 4P’s (Prioritise, Plan, Pace, Posture) | | Week 5 | Stress and Communication | | Week 6 | Coping with setbacks | | Week 14 | Progress review and feedback | |
|  |
| **Is there anything else I need to do ?** |
| If you are allocated to the 4-week group intervention you will be asked to keep an activity diary for the week before the programme starts to get an idea of your daily routine and sleep patterns. This should take 5 minutes per day. |
| **What are the possible benefits of taking part?** |
| You may find the interventions you are allocated to in the trial will help to increase your confidence in managing your fatigue and improve your quality of life. If you are allocated to the group intervention you may meet people with the same symptoms and share  other people’s experiences. |
| **What are the possible disadvantages of taking part?** |
| If you are randomised to the live online group intervention you will have to commit to approximately 2 hours weekly for 3 or 6 consecutive weeks plus a review session (a total of either 4 or 7 weeks). |
| **What if there are any problems?** |
| If you have a concern about any aspect of this trial, please contact the trial manager:  Kathryn Berg, Email: [Kathryn.berg@ed.ac.uk](mailto:Kathryn.berg@ed.ac.uk). Phone number: 0131 6518755.  Kathryn will do her best to answer your questions. If something goes wrong and you are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). |
| **What will happen if I don’t want to carry on with the study** |
| You are free to withdraw from the trial at any time. If you decide to withdraw you don’t have to give us a reason why, and your decision to withdraw will not affect the standard of medical care that you receive. If you withdraw from the trial, 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. You will have the option to decide whether or not you would like to hear from us again with regard to the results of the trial or other research into fatigue and SLE. If you do decide to withdraw, a member of the research team will find out which option you would prefer. |
| **What happens when the study is finished?** |
| Following completion of the trial we would like to keep the electronic data we have collected from you for up to 3 years. The reason for this is that we will be recruiting participants for 1 year, with the last set of questionnaires collected a year after this. We will need to analyse the data and this could take up to another year. We may want to conduct some more research in the future and would like to have the opportunity to use your anonymised data if you are happy for us to do this. |
| **Will my taking part be kept confidential?** |
| Yes.  If you are allocated to the group intervention you will not need to disclose anything other than your first name if that’s what you wish. Additionally, all participants in the group intervention are asked to consent to not record or share confidential information outside the group.  All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. The University of Edinburgh will act as the data controller and access to your identifiable data will be restricted to the research at your hospital and those at the University of Edinburgh who have received appropriate training in the handling of personal data. The Sponsor(s) is/are responsible for overall management of the study and providing insurance and indemnity.  We will inform your GP that you are taking part in the trial provided that you consent to us doing so. All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.  **Where can you find out more about how your information is used?**  You can find out more about how we use your information  • at www.hra.nhs.uk/information-about-patients/  • our leaflet available from [www.hra.nhs.uk/patientdataandresearch  • by asking one of the research team  Dervil Dockrell [dervil.dockrell@ed.ac.uk](mailto:dervil.dockrell@ed.ac.uk)  Joanne Dobson [Joanne.dobson@ed.ac.uk](mailto:Joanne.dobson@ed.ac.uk)  Kathryn Berg [Kathryn.berg@ed.ac.uk](mailto:Kathryn.berg@ed.ac.uk)  Phone Number: 0131 537 3389  Mobile :07850 256666  • by sending an email to the data protection officer [dpo@ed.ac.uk](mailto:dpo@ed.ac.uk)  • by ringing the data protection team on 0131 650 2443 |
| **Why do you need my personal information and how will you use it?** |
| We need to have information from you in order to undertake this study. The reason that we need to store this information is so that we can perform the research that is described in this information leaflet.  The University of Edinburgh and NHS Lothian are co-sponsors of the trial and will act as what is called the data controller for this trial. The data controller is responsible for looking after your information and using it properly. The data we collect about you will be kept by storage on secure computer systems at the University of Edinburgh.  Access to YYourThe data will be restricted to members of the study team on secure computer systems which will be protected by usernames and passwords. Any paper records will be stored in locked cabinets within secure buildings to which only members of the study team have access. The Chief investigator, Dr Helen Harris will be responsible for ensuring that your data is held securely. |
| **Who is organising and funding the research?** |
| The research is being carried out by the University of Edinburgh and is funded by the BMA Foundation and Lupus UK. |
| **Who has reviewed the study?** |
| The study has also been reviewed by members of Lupus UK and patient focus groups from NHS Lothian and the SE Scotland Research Ethics Committee. |
| **Study Team Contact Details** |
| If you have any further questions about the trial please contact the chief investigator Dr Helen Harris by telephoning 0131 5371802 or by emailing [Helen.harris@nhslothian.scot.nhs.uk](mailto:Helen.harris@nhslothian.scot.nhs.uk).  You may also contact the other study team members by emailing [dervil.dockrell@ed.ac.uk](mailto:dervil.dockrell@ed.ac.uk), [Joanne.dobson@ed.ac.uk](mailto:Joanne.dobson@ed.ac.uk) or [Kathryn.berg@ed.ac.uk](mailto:Kathryn.berg@ed.ac.uk) or by phoning 0131 537 3389 / 0131 6518755 or Mobile 07850 256666. |
| **Independent Contact Details** |
| If you would like to discuss this trial with someone independent of the study please contact :Dr Anna Marie Horne Annamarie.horne@nhslothian.scot.nhs.uk  If you would like general advice about participating in research you can get in touch with:  NHS Lothian  Patient Experience Team  2 – 4 Waterloo Place, Edinburgh, EH1 3EG  [feedback@nhslothian.scot.nhs.uk](mailto:feedback@nhslothian.scot.nhs.uk)  0131 536 3370 |
| **Complaints** |

If you wish to make a complaint about the running of the trial please contact:

ACCORD

Usher Building

Edinburgh Bioquarter, Edinburgh, EH16 4UX

resgov@accord.scot 0131 242 6476

|  |  |  |
| --- | --- | --- |
| **Screening Questions** | **Yes** | **No** |
| 1. Have you a confirmed diagnosis of SLE? |  |  |
| 2. Are you over 18? |  |  |
| 3.Where do you rate your fatigue based on a scale of 1 ( **no fatigue** ) to  10( **severe fatigue**) |  |  |
| 4. Have you participated in a fatigue or pain management programme in the last 5 years? |  |  |
| 5. Are you happy to complete your consent and questionnaires online? |  |  |
| 6. Are you happy to be randomly allocated to one arm of the trial ? |  |  |
| 7. If you are allocated to a group intervention, are you happy to participate in a group programme? |  |  |
| 8. Have you access to a computer/Smartphone/Tablet for internet and audio/video access? |  |  |
| 9. Are you familiar with online platforms such as Microsoft Teams, zoom etc. to be able to take part in a live online group programme? |  |  |
| 10. If not, would you be willing to have an online tutorial to learn how to use the locally approved NHS platform? |  |  |
| 11. Are you able to read and converse in English well enough to take part in a group setting? |  |  |

|  |  |  |
| --- | --- | --- |
| **Online Consent Form** |  |  |
| **Fatigue in Lupus Intervention Programmes (FLIP): A randomised controlled trial investigating the effectiveness of fatigue management in Systemic Lupus Erythematosus (SLE).** | YES | NO |
| 1. I confirm that I have read and understand the information sheet (version 9, date 01/10/2024) for the above trial. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. |  |  |
| 1. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason and without my medical care and/or legal rights being affected. However should I wish to provide a reason for withdrawal I understand that this will be used by the research team when analysing the results and limitations of the study. |  |  |
| 1. I agree that any information collected prior to my withdrawal will be used in the analysis; however, no new information will be collected. |  |  |
| 1. I understand that data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian) where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data. |  |  |
| 1. I give permission for my consent form and questionnaires to be held on the REDCap secure server by the central study team for administrative and analytic purposes. |  |  |
| 1. I agree to provide my telephone number and postal address to be contacted about the study and for the group information to be sent to me. I agree that identifiable contact information will be kept until the end of this trial or such time that all questionnaires have been completed and this information will be held confidentially and securely in accordance with the data protection act. |  |  |
| 1. I agree to provide my email address to receive reminders to complete follow up questionnaires until the trial period is over. I agree that identifiable contact information will be kept until the end of this trial or such time that all questionnaires have been completed and this information will be held confidentially and securely in accordance with the data protection act. |  |  |
| 1. If allocated to the live online group I agree to participate via an NHS approved online platform. I agree not to make a recording of the group sessions or share confidential information about other participants. |  |  |
| 1. I give permission for the anonymised data collected during the study to be stored at the University of Edinburgh for use in this study and future ethically approved research studies into SLE. |  |  |
| 1. I agree to my GP being informed of my participation in this research. |  |  |
| 1. I agree to take part in the FLIP study. |  |  |

Thank you