**Psychological Factors in Chronic Pain & Fibromyalgia**

**Participant Information Sheet**

You have been invited to participate in a research study being conducted to fulfil a requirement of the Doctorate in Clinical Psychology at The University of Oxford. Before you decide whether to participate, it is important for you to understand why the research is being done and what the research will involve. Please take the time to read the following information carefully and discuss it with others if you wish. We encourage you to get in contact with us if anything is unclear or you would like further information. Thank you.

**What is the purpose of the study?**

The study aims to explore any similarities and differences in psychological factors between chronic pain, fibromyalgia and those without pain issues. This has not been researched before and we hope that it will help us understand chronic pain and fibromyalgia better.

**Why have I been chosen?**

You have been invited to participate in this study because you are either working with or on the waiting list for either the Integrated Pain and Spinal Services or Berkshire Talking Therapies. However, this research is separate to these services and participation will not affect your pain management treatment. We are hoping to recruit around 100 participants to take part in this study.

**Do I have to take part?**

Taking part in this study is voluntary and optional; it is up to you to decide to take part in the research or not. Your pain management treatment will not be affected by your choice to participate or not to participate in this research. If you decide to take part. you will be asked to complete a consent form (on the next screen). If you decide you wish to withdraw while completing the questionnaire, simply exit. You may withdraw from the study at any time but it will not be possible to remove your data once it has been submitted. This is because the responses are anonymous and we would not be able to connect your anonymous data to you.

**What will the study involve?**

Participants in this study will be asked to complete an online questionnaire that takes on average 30 minutes to complete. You will only need to complete this questionnaire once. The questionnaire will ask you a range of questions about your characteristics (e.g. age, ethnicity, gender, health conditions), pain experience and mental health. You will be able to complete the questionnaire on either a smartphone or a computer, but you will need access to the internet to be able to complete the questionnaire.

We appreciate that pain and fatigue can vary each day and would advise you to complete the questionnaire on a day where you feel able to complete a 30 minute questionnaire. The study will remain open for participants until October 2023. The link to the questionnaire will not work after this date.

**What will happen with my data?**

Your email address has been passed on by the Berkshire NHS Foundation Trust service you are working with. You were contacted via email with the link for this study. Once this email was sent, your email address was permanently deleted from the researcher's inbox and sent folder. We are not collecting any further data such as IP addresses or any other information that may identify you.

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is ‘a task in the public interest.’ The University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

The answers you provide to the questionnaire will be anonymous and confidential. This means that nobody will be able to identify you from the answers you give and that your answers are only accessible by the research team (listed at the bottom of this sheet). Responsible members of the University of Oxford and the NHS trust may also be given access to data for monitoring and/or audit of the study to ensure that the research is complying with the appropriate regulations.

Your anonymous data will be held securely for 5 years after the study has ended and then will be deleted.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at

https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting Holly.Risdon@hmc.ox.ac.uk.

**Will the study be published?**

We aim to write a paper reporting the results of the study and aim to publish this in an academic journal. As part of this paper, we will report some demographic information about the participant group (e.g. age, gender, ethnicity). The group data will be analysed and no identifiable information about participants will be published. A summary of the results of the study will be available here once the study has concluded: [INSERT WEBSITE ADDRESS]

**What are the risks of taking part in the study?**

The study questionnaire will ask you questions about your mental health and pain experience. There is potential for this to bring up a range of emotions. We would advise you to use your support network around you should you feel upset. You are also welcome to contact any of the research team (listed at the end of this information sheet).

The questionnaire takes between 30 minutes to complete. If you need to take a break from the questionnaire, please do, but we ask that you complete the questionnaire the same day, or you may be re-directed to the start of the questionnaire.

**What are the benefits of taking part in the study?**

Participation in this study is voluntary and optional. We value your participation as you will be helping to improve the understanding of chronic pain and fibromyalgia. We are hoping this will lead to more research into treatment and may help future patients living with chronic pain and fibromyalgia.

**What if something goes wrong?**

The University of Oxford, as Sponsor, has appropriate insurance in place in the very unlikely event that you suffer any harm as a direct consequence of your participation in this study

If there are any problems with the study questionnaire affecting your ability to participate or you wish to raise a concern, please contact the lead researcher (Holly Risdon; Holly.Risdon@hmc.ox.ac.uk) or the University of Oxford Research Governance, Ethics and Assurance (RGEA) office on rgea.complaints@admin.ox.ac.uk" rgea.complaints@admin.ox.ac.uk.

**KEY INFORMATION**

* Taking part in this research study is voluntary and optional.
* Choosing to take part or not will not affect your pain management treatment.
* The study involves completing one questionnaire lasting between up to30 minutes.
* You will only need to complete the questionnaire once.
* Please take a break during the study questionnaire if you need to but ensure you complete the questionnaire the same day.
* If you have any questions or concerns at any time during the study, please contact the lead researcher Holly Risdon (Holly.Risdon@hmc.ox.ac.uk).

**Research Team**

Lead Researcher – Holly Risdon (Trainee Clinical Psychologist; Holly.Risdon@hmc.ox.ac.uk)

Research Supervisor – Professor Paul Salkovskis (Paul.Salkovskis@hmc.ox.ac.uk)

Research Supervisor – Dr Abigail Wroe (Abigail.Wroe@Berkshire.nhs.uk)

You can visit our study page here: [INSERT WEBSITE LINK] to download a copy of this sheet.