PATIENT INFORMATION SHEET

for

The MIDAS-GP Study

"Real world" pain outcomes and experiences of care

Taking part in this research study – key things to know

- Researchers at Keele University are working with NHS health professionals to find out how to improve treatment for people with painful conditions like back pain and osteoarthritis ("musculoskeletal conditions"). We need accurate information from patients and the public to do this.
- You have been invited to take part in this study because it has been recorded that you recently had an appointment with your GP Practice about a back, neck, joint or muscle problem (even if it was not the only reason for your consultation).
- We hope to hear from as many people as possible because this will give a more reliable picture. Your participation is important, even if your symptoms are now better.
- If you take part, we will ask you questions about your condition, how it affects you, and the things you've tried to manage it.
- Taking part is completely voluntary. If you choose not to take part, this will **not** affect your treatment now or in the future.

Help and Support

If you need any help completing your paper or online questionnaire, please feel free to ask a friend or family member to help you. Alternatively, you can contact a member of the study team at Keele Clinical Trials Unit on FREEPHONE 0800 130 3252 or email nstccg.midas@nhs.net during office hours (09:00-17:00), who will be able to provide assistance completing the questionnaire or provide further information about the study.

If you have any concerns or complaints, you can contact Keele University's Head of Project Assurance, email: research.governance@keele.ac.uk.

Alternatively, you can contact NHS England on 0300 311 2233 or email: england.contactus@nhs.net.

What is the purpose of this study?

The purpose of this research study is to provide accurate information to help improve NHS services for people with common musculoskeletal problems such as back pain or osteoarthritis.

Many people are unaware that conditions like back pain and osteoarthritis cause more disability in the general population than any other health condition. The poorest communities are often the hardest hit.

To have a suitably 'joined up' public health and NHS response to this challenge we need accurate and meaningful joined up information on musculoskeletal health, risk, and care in local populations.

Why have I been invited to participate?

You have been invited to take part because you have recently had an appointment with a health professional at your GP practice for a back, neck, joint, or muscle problem (even if it was not the only reason for your consultation).

What do I have to do if I take part?

Tell us about your symptoms and your experiences of care by completing three questionnaires over the next 6 months

The questionnaires ask you about your condition, how it affects you, and the things you have tried to manage it. They can be completed online or by pen-and-paper. In addition, we'll ask you a short question each month about your pain level, either by text message or by post.

Tell us if you give permission for the research team to access and link information held in your GP medical record and information on investigations and treatments held by national databases

The GP medical record contains information on consultations, prescriptions, treatments, referrals. National databases, which include NHS Digital, out-of-hospital cardiac arrest outcome registry, Hospital Episode Statistics, the Intensive Care National Audit and Research Centre (ICNARC) case-mix programme, Health Data Research UK, National Institute for Cardiovascular Outcomes Research (NICOR), ONS mortality data, and the UK Transplant Registry (UKTR) holds data on hospital investigations and treatments. We are asking your permission to access and link this information so that we can get a better idea of how patterns of care vary between different GP practices and between groups of patients.

To do this, the study will use your NHS number to link your questionnaire answers with your medical record information and with information held by national databases. Your name and address and/or telephone number and email address will be retained so that we can send you questionnaires while you take part in the study. There may be other times during the

study when we need to contact you by post, telephone or email (for example, if your consent form has not been completed correctly or to remind you about a questionnaire). This personal identifiable information will not be available to the independent researchers analysing the data.

If you do not wish to take part, you do not need to do anything.

If you do agree to take part and then change your mind, you are free to withdraw at any time, without giving a reason. To stop receiving further invitations or to completely withdraw from the study please contact the study team at Keele Clinical Trials Unit using the contact details in the 'Help and Support' section on the front page. Any answers you have already provided up until this point will be anonymised and retained unless you ask to have your information deleted. Withdrawing from the study will not affect the usual care you receive from your GP and will not affect your legal rights.

What are the possible benefits of taking part?

The information we get from this study will help to support how doctors and physiotherapists treat people with musculoskeletal symptoms involving back, neck, joint or muscle pain. There may not be any immediate benefits for you, although some people find it rewarding to take part in health research. Your participation in this study will help to:

- improve NHS services that are provided for people with common musculoskeletal problems such as back pain or osteoarthritis
- understand the local need for treatment and which groups of people are most under-served by the NHS at present

What might the risks be of taking part?

There are no risks (in terms of safety or physical harm) involved in participating in this study. The care you receive from your general practice will not be affected whether you take part or not.

You will need to spend some time answering the questions. We think it will take about 10-15 minutes to complete each questionnaire. We appreciate the precious time given voluntarily to take part in this study and to recognise this we will donate £100, for every 100 questionnaires returned, between selected local charities. At the end of each questionnaire you complete, you can choose any one from a choice of four nominated local charities, which charity you would like us to donate to.

Who is funding and organising this study?

The study is funded by the Nuffield Foundation (www.nuffieldfoundation.org) and Versus Arthritis (www.versusarthritis.org) (Reference Number OBF/43990). This study is part of a programme of work funded by the Nuffield Foundation, which is being conducted by the School of Medicine at Keele University.

Who has reviewed this research?

To protect your interests, all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee who are part of the Health Research Authority (HRA). The Yorkshire & The Humber - Leeds West Research Ethics Committee has reviewed and approved this study (REC Number: 21/YH/0178).

What will happen to the results of the study?

The results of the study will be presented at conferences and published in scientific journals and on the MIDAS-GP study website (www.keele.ac.uk/midas). The study results will also be used to improve NHS services and public health policies.

DATA INFORMATION

What are we using the data for?

The information gained by this study has been designed to help decision makers in both public health and healthcare organisations locally to better understand the severity and impact of musculoskeletal symptoms within the population. We will gather information together from different GP practices, national databases for example NHS Digital (https://digital.nhs.uk) and many individual patients. We will look for differences in patterns of care and try to understand what might be driving them.

If you consent to your questionnaire information being linked to your medical record information, Keele University will request your medical record information from your GP practice and national database for example NHS Digital. Your information will be depersonalised before it is analysed by the research team at Keele University. It will not be possible to identify you from this information and it may be used in future research.

What will happen to the information collected about me during the research?

Keele University is the sponsor for this study, which is based in the United Kingdom. Keele University will be using information from you to undertake this research and will act as the data controller for the data collected during this study. Under the General Data Protection Regulation (GDPR), the lawful basis we rely on for processing this information is to perform a public task.

This means that we are responsible for looking after your information and using it properly. Keele University will keep the information you provide for 10 years after the research has finished. This is normal in research of this nature.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways to make sure the research is reliable and accurate.

If you withdraw from the research study after agreeing to take part, we will keep the information about you that you have already given unless you ask to have your information

deleted. To safeguard your rights, our study design only requires the minimum personally identifiable information possible.

You can find out more about how we use your information and read our privacy notice at: http://www.keele.ac.uk/informationgovernance/informationgovernanceforthepublic/ or you can contact Keele University's Data Protection Officer at: dpo@keele.ac.uk.

We are committed to protecting the privacy and security of the personal information of all participants in our research. If you respond to this invitation, Keele Clinical Trials Unit (CTU) will use your name and contact details to contact you about this research study. Authorised individuals from Keele University and regulatory organisations may look at your healthcare and research records to check the accuracy of the research.

The only people in Keele University who will have access to information that identifies you will be people who need to contact you about the research or who audit the data collection process.

The data you provide will be "depersonalised" this means that the people who analyse the data that you provide will not be able to identify you and will not be able to find out your name and contact details. Your identifiable data will be securely stored by Keele CTU and will not be used beyond these purposes. On consenting to take part in the study, your information will be securely stored under a unique study number. Depersonalised data held on this basis may be used in other research studies, subject to appropriate approvals.

Any information that you do provide which contains your personal identifiable details will be securely stored by Keele CTU at Keele University and consent forms will be stored separately to the other data that you provide.

Our procedures for managing your information (including how we delete the data when we no longer use it) are in line with relevant regulatory requirements. To ensure electronic data are stored securely, it will be held on networks approved by recognised security schemes. Paper records are stored securely within lockable filing cabinets and/or in strictly restricted access rooms. Offices within Keele CTU are managed with a lock and key system and the overall building is secured using ID card entry by authorised persons only.

In accordance with the Keele University, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoid duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is anonymised (so that you could not be identified). Any requests for access to the anonymised data from anyone outside of the study team will follow Keele University's Health and Social Care Research Quality Management System Standard Operating Procedure for data sharing.

Thank you for taking the time to read this information leaflet and for considering taking part in this research study.