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**D-MAPP: Development and evaluation of the Digital-My Arm Pain Programme for improving painful distal upper limb musculoskeletal disorders**

# **PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT**

A large-print version of this sheet is available on request.

You have been invited to take part in a research study called D-MAPP. Before you decide if you want to take part, we would like to explain why we are doing the research, how we will use the information we have about you, and what the study will involve.

Please read this information carefully and discuss it with others if you like. Ask us if anything is unclear, or if you would like more information.

**Once you have read this information, your Researcher will talk to you about the study again and you can ask any questions you like.**

Take time to decide whether or not you wish to take part.

**How to contact us**

If you have any questions about this study, please talk to your researcher at

<<Enter Researcher >>

<<Contact details for site>>

**Thank you for reading this information sheet.**

**Why have I been invited to take part?**

You have been invited to participate in this study as you been medically diagnosed with a distal upper limb-musculoskeletal disorder (DUL-MSD) and experience the symptoms of this. The distal upper limb is the part of your arm from your elbow to your fingers. Examples of DUL-MSDs include hand osteoarthritis, carpal tunnel syndrome and tennis elbow.

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

D-MAPP is a web app designed to support the self-management of upper limb-musculoskeletal disorders. The app can be used on a smartphone, tablet, computer or laptop. The app is a personalised physio programme with additional support to aid recovery*.* This study aims to determine whether using D-MAPP alongside usual care, compared to receiving usual care alone, can improve pain and function in people with distal upper limb-musculoskeletal disorders. Usual care will vary for each individual, but this could include any medications you have been prescribed or exercise you currently complete.

**Who is taking part in the study?**

People with DUL-MSDs across the UK will be invited, and we are aiming for 356 people to take part. Though you have been invited to participate, not everyone who is interested in taking part will be able to. You be required to complete an eligibility assessment with a member of the research team and if you do not meet the eligibility criteria, this study would not be suitable for you.

**Do I have to take part?**

No, your participation in D-MAPP is voluntary and you may withdraw your consent to take part at any time, without giving us a reason. If you decide to take part, you will be given this information sheet to keep. You will be asked to sign a consent form, but you are still free to withdraw at any time and without giving a reason. If you decide not to take part, your usual treatment and care will not be affected in any way.

**What will happen to me if I take part?**

After completing a consent form, you will be asked to complete a set of questionnaires before being allocated into a group. You will be asked questions about how your condition makes you feel and the impact it has on your life. If you are completing these questionnaires at home, we ask that they are completed within 5 days of receiving them. **It is extremely important that the questionnaires are completed within 5 days of receiving them**. If they are not completed within 5 days, it will delay your participation in the study. If we have not heard from you after 5 days, we will be in touch to confirm you still wish to take part in the study.

A computer will allocate you randomly (as if by the roll of dice) to receive either usual care or be asked to use D-MAPP in addition to usual care. Neither your healthcare provider nor you will be able to choose which treatment you receive to allow a fair comparison to be made.

You will be contacted at 3, 6, 9 and 12 months after joining the study to complete a questionnaire booklet. Questionnaires will be provided electronically, and you can choose to receive them via text or email. If you have any difficulties completing an electronic questionnaire paper questionnaires can be provided. The study question will be answered by your questionnaire responses, which makes it important for you to complete and return them to us. We will send you reminder text messages and a member of the research team may call you if we haven’t heard from you. The questionnaire will take approximately 20-25 minutes to complete.

We will collect your phone number, email address and postal address to be able to send you information for the study. Emails will be sent from CTRU.D-MAPP@leeds.ac.uk, please check your spam/junk folder for messages from us. Text messages will be sent from **‘D-MAPP’**. If you have any concerns about a text message or email you have received, please contact CTRU.D-MAPP@leeds.ac.uk.

**Please let us know if any of your contact details change whilst you are taking part**. You can let us know this by contacting the research team at CTRU.D-MAPP@leeds.ac.uk or through the study website <<link>>. If we lose touch with you, we will continue to send questionnaires and collect data from medical records, unless you indicate to us that you no longer wish to receive questionnaires and have data collected. Data collected from you would still be made available (anonymously) for future research unless you indicate to us that you do not wish for it to be shared.

You do not need to attend any hospital, GP or healthcare centre visits specifically for the study, but we will ask you to provide details of your GP or usual care team, in case we need to ask them for any information about you.

If you are allocated to the D-MAPP group you may also be selected to be interviewed on your experience of using the D-MAPP, if you agree.

If you are allocated to the usual care group, you will have the opportunity to access and use the D-MAPP app at the end of your study follow up.

**What does using the app involve?**

You will receive instructions on how to download the app at home which must be completed as soon as possible, and no more than 5 days after receiving the information. You will be able to use the app at your own pace and at times convenient to you. How much you use the D-MAPP app will be collected from data saved within the app and a tool called Google Analytics, a service offered by Google. This information will tell us which pages you have looked at on the app, and how many times. This will help us to understand how people interact with the app.

You must be connected to the internet to use D-MAPP as the app cannot be used offline. The app will use ‘Cookies’ which are small pieces of data stored on a user's device to help the app remember your preferences and activities. Cookies are not optional and must be accepted to use the app. Users will not be able to opt out of the push / in-app notifications during the trial. You will have the option to receive out-of-app notifications (email or text) containing a reminder to complete your daily exercise sessions.

You will be asked to use D-MAPP for at least 12 weeks and to continue using the app during the 12 month follow up (unless you are advised to stop by your usual care team, or unable to do so).

The exercise programme contains instructions and videos to teach you a series of exercises to help improve strength and function. These will be specifically tailored to your condition and ability. The exercises will take approximately 2-40 minutes to complete, although you do not need to do them all at once. The app will encourage you to progress the exercises based on your symptoms and if you feel able to do so. Depending on how you feel, this might involve introducing new exercises and/or doing the exercises for longer. This means that the time needed to the exercises is likely to increase over the 12-week period. You should try to do the exercises as frequently as you are able, ideally every day. It is very important that you are willing to try the different parts of the D-MAPP, including the exercise programme.

**How long does participation last?**

We are asking you to take part in the study for 12 months. However, if you wish to withdraw from the study, you may do so by notifying your researcher at any point during your participation without giving a reason, although it may be useful for us to understand the reasons you no longer want to take part if you are happy to share these. You may withdraw consent to taking part in the study, completion of questionnaires and collection of follow up data.

If you decide to stop taking part in the study the app will still be available for you to use until 3 months after the final participant taking part in the study has completed their 12 month follow up (known as the ‘end of trial’). The end of trial date will be available on our website <<link>>.

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

## The disadvantages and risks of entering this study are small. A possible disadvantage is giving up time to complete the questionnaire booklet and also to use D-MAPP if you are in this group. You could temporarily experience increased pain from the exercises, which is expected with a new exercise regimen. If this does occur, you can stop at any time and put this information in to the app and it will suggest that you reduce the amount and intensity of the exercises. If you experience a serious problem you believe to be due to taking part, you will be provided with guidance about what to report and how to report it.

## What are the possible benefits of taking part?

We cannot promise the study will directly benefit you, but the information we get from this study might help the treatment of future patients with DUL-MSDS using D-MAPP.

**Will I get back any travel or other costs?**

There are no expenses available for this study and no additional hospital or clinic attendances required nor additional travel.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If your condition worsens during the trial, the clinical research team may ask you to get in contact with your GP or usual care provider.

If you would like to report any general concerns or complaints to an independent contact, you will be able to get in touch with the Patient Advice and Liaison Service (PALS):

* <<Enter PALS details for site >>

In the unlikely event that you are injured as a result of the managing organisation (University of Leeds), compensation may be available and you may have to pay your related legal costs. The hospital/clinic that have confirmed you are eligible for the study has a duty of care to you whether or not you agree to participate in the trial and the University of Leeds accepts no liability for negligence on the part of your hospital’s employees. If you wish to complain about any aspect of the way you have been treated please contact your research doctor in the first instance. Any claims will be subject to UK law and must be brought in the UK.

If you have private medical insurance, you should tell your insurer that you are taking part in research. They will let you know if it affects your policy.

**What happens when the research study stops?**

Your access to healthcare and the treatment you receive will be no different during or after the study. All participants, including those who are randomised to the usual care group will be able to use the D-MAPP app after the 12-month follow-up period has been completed and until 3 months after the final participant taking part in the study has completed their 12 month follow up (known as the ‘end of trial’). The end of trial date will be available on our website <<link>>.

**How will we use information about you?**

We will need to use information from you, your medical records and/or your GP for this research project.

This information will include your initials NHS/CHI number, name and contact details (phone number, email address, postal address). People will use this information to do the research or to check your records to make sure that the research is being done properly. To comply with laws and other rules about research, we need to keep your identifiable information until at least 5 yearsafter the study has finished.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure at the University of Leeds Clinical Trials Research Unit (CTRU, <https://ctru.leeds.ac.uk/>). The University of Leeds will have overall responsibility for how your information is used in this study, including making sure that all information is kept secure. The content of the D-MAPP web application is stored and delivered from the nearest data centre geographically, which maybe outside the UK if using it abroad. Any information you enter in the app will be saved on a computer database in Amsterdam, further details about this are available in the appendix.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

If you are completing consent electronically (using an electronic form during a telephone or video call) we will ask for your permission to enter your email address, date of birth and initials into the eConsent system before you use it. This information is visible to the hospital research team and also members of staff at the CTRU, University of Leeds. If you agree to have your details added to the eConsent system but then decide you do not want to take part in the study, your details will be completely removed and securely destroyed within 30 days.

### **What are your choices about how your information is used?**

* You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
* If you choose to stop taking part in the study, we would like to continue collecting information about your health from your medical records and/or your GP. If you do not want this to happen, tell us and we will stop.
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.
* If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

You can find out more about how we use your information in the following ways;

* At www.hra.nhs.uk/patientdataandresearch (Please feel free to ask for a printed copy of this if you cannot access this online version.)
* by asking one of the research team
* in the appendix available at the end of this information sheet

**What will happen to the results of the research study?**

When the study is complete, the results will be published in medical journals including the National Institute for Health Research (NIHR) <https://www.journalslibrary.nihr.ac.uk/pgfar/#/>, but no individual participants will be identified. You will also be able to access a copy of the results via our website <<add link>>.

**Contact Details**

If you have any further questions about your condition or clinical studies, please discuss them with your researcher.

If you have any questions about this study, please contact the research team at

<<Enter PI, nurse name >>

<< Contact details for site>>

If you have any further questions about your illness or clinical studies, please discuss them with GP or usual care team.

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published various resources to help people learn more about clinical trials. Contact UKCRC: Tel: 0207 395 2271; email: info@ukcrc.org; website [www.ukcrc.org](http://www.ukcrc.org).

|  |  |
| --- | --- |
| Participant ID:  | Initials:  |
| Date of Birth:  | NHS/CHI Number:  |
| ISRCTN:13131384 | Principal Investigator: |



**D-MAPP – Development and evaluation of the Digital-My Arm Pain Programme for improving painful distal upper limb musculoskeletal disorders**

**PARTICIPANT CONSENT FORM**

Please initial each box

(participant initial)

***Please initial each box***

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.

1. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that even if I withdraw from the study, the data collected from me will be used in analysing the results of the study.
2. I understand that my healthcare records may be looked at by authorised individuals from the study team, regulatory bodies or Sponsor in order to check that the study is being carried out correctly.
3. I agree to have my research data electronically linked to Google Analytics and in-app data storage and I understand this data will be downloaded and used by CTRU if I am randomly allocated to use D-MAPP.
4. I understand that the app cookies are essential to the functioning and performance of the app and they must be accepted if I am randomly allocated to use D-MAPP.
5. I understand that the research team and CTRU will keep secure records which will allow me to be followed up (including name, NHS number, hospital number, address, email address and telephone number).
6. I agree to a copy of this Consent Form containing my name, date of birth and NHS number and the record of my verbal consent (if applicable) being sent to the CTRU.
7. I agree to provide details of my GP and any other healthcare professional treating me, and understand they will be notified of my participation in this study and will be contacted to collect data about me if required.
8. I agree to take part in the above study.

**The following points are optional;**

**10.**  I agree that the information collected during this study may be used

to support other research in the future and may be shared anonymously with

other researchers.

**11.** I agree to be contacted in the future to participate in an interview about

my experience of using D-MAPP, if I am selected.

Please initial

**No**

**Yes**

**Patient:**

Signature………………………………………………………………………………………………………….

Name (block capitals)……………………………………………….……………………………………………

Date………………………………………………….…………………………………………………………….

**Investigator:**

I have explained the study to the above named patient and they have indicated their willingness to participate.

Signature…………………………………………..……………………………………………………………...

Name (block capitals)……………………………………………….……………………………………………

Date………………………………………………….…………………………………………………………….

If consent was completed remotely/verbally, please tick this box

**(If used) Interpreter details:**

Signature (if in person)…………………………………………..……………………………………………….

Name (block capitals)……………………………………………….……………………………………………

Date………………………………………………….…………………………………………………………….

Company/reference (where available)…………………………………………………………………………

(1 copy for patient; 1 for the CTRU; 1 held in patient notes, original stored in Investigator Site File)

**Appendix: more about how your information will be used**

This optional extra section of this patient information sheet is about how your information will be used if you agree to take part in this study. If you still have questions after reading this appendix, or would like more detail about anything, you should look through our **comprehensive guide** to how your information is used. You do not have to read it before taking part in this study, but you might want to look at specific sections if you have particular concerns. It is available at <https://ctru.leeds.ac.uk/ctru-comprehensive-privacy-guide/> or you can ask for a printed copy from your study doctor or nurse. This can also be made available in large print or other formats, if you need them.

## Will my taking part be kept confidential?

## Yes. If you decide to participate in D-MAPP the information collected about you will be handled confidentially and strictly in accordance with the consent that you have given and relevant data protection laws, including the 2018 Data Protection Act.

There are a few things you should know about how your confidentiality will be affected if you agree to take part in this study.

* Your **GP, and the other healthcare professionals involved in your healthcare, will be kept informed** of your participation in this study. This is because they might need to know you took part when they treat you for anything in future.
* Your **healthcare records may be looked at by authorised individuals** from the research team, The University of Leeds (the study Sponsor), the regulatory authorities or other authorised bodies to check that the study is being carried out correctly. This will only be done in line with your hospital’s policies to ensure your records are secure.
* We will **collect a copy of your completed consent form** if you agree to take part in the study. This is so that we can check you have definitely agreed to take part. This means people in the study team at the CTRU, University of Leeds who are authorised to deal with consent forms will see your name, date of birth and NHS/CHI number. However, these people are trained to treat your information with care, and the consent form will be stored securely at all times. We would also collect contact details to send questionnaires so will have your address, phone number and email address.
* If you are randomised to use the app, we will collect **Google Analytic data** to collect informationsuch as time spent on the app and pages most frequently used to help monitor treatment adherence. This will not include any identifiable or confidential information about you, and all data downloaded will be stored securely at the CTRU, University of Leeds.
* The app has been developed by an animation and web specialist company called **Morph**, who’s **Privacy Statement** is available here <https://morph.co.uk/privacy-policy/>**.** The data you enter into the app (in-app data) is stored on the Strapi Cloud Content Management System which is hosted in Amsterdam in the EU. A user ID, specific to you, will be used to identify your in-app data which will include your physio programme, your exercise progress, and any action plans. Their **Privacy Policy** is available at <https://strapi.io/privacy>. The CTRU, University of Leeds, will download this via data Globus Auth, an Identity and Access Management platform service, which is password protected. All relevant confidentiality agreements are in place. The CTRU will not download individual responses to the symptoms journal or personal information such as phone numbers.
* The app will use **cookies** to personalise and save information about each user’s session. These are required to improve user experience and to track usage of the app, they must be accepted and there will be no option to reject them in order to use the app. These in-app cookies will collect data such as:
* User Preferences: Information about user settings, such as language preference or theme choices.
* Login Information: Data related to user credentials, including session tokens to keep users logged in.

Usage Behaviour: Tracking how users navigate through the app, including screens visited, time spent on each page, and interaction patterns.

**What information will be collected, and what will it be used for?**

If you agree to take part in this study, we will need to collect and use some information about you and your health. We will only use what we need to run the study, to produce the results of the study and to make sure you and other people taking part in the study are safe.

This research is in the public interest, which means our results will be used to improve the healthcare of patients in the future. Because of this, if you agree to take part in the study, we will be able to use information about you, including sensitive information about your health.

Specifically, the ways we will use information about you are:

* + We will use information from you and your medical notes to run the study, to produce the study results and to confirm it is safe and appropriate for you to join the study. We will also collect information about your health from your study doctor or nurse and your medical notes to help make sure you and others are safe.
	+ We will collect a copy of your signed consent form so that we can be sure you have agreed to take part in the study.
	+ We will collect information about you and your health directly from you on study questionnaires. We will use this information to produce the study results.
	+ If you join this study, we will send you study questionnaires and reminders to complete study questionnaires. To do this, we will need to collect your address, email address and phone number. We will only use this information for the purposes mentioned here.

If you want to find out more about any of these, please refer to the **comprehensive guide** to how your information is used.

**Who is collecting my information?**

Your information will be collected by the Clinical Trials Research Unit within the Leeds Institute of Clinical Trials Research, University of Leeds. You can find out more about our work at <https://ctru.leeds.ac.uk/>.

University of Leeds has overall responsibility for what information is collected, how it is collected, and making sure people’s information is used securely and correctly. If you want to contact someone within the University about how your information has been or will be used, details are provided below. Please see the **comprehensive guide** for more about what this means for you.

We will make sure we follow the principles of data protection in everything we do. This means we will keep your information secure, keep it only for as long as we need it, only use the minimum information we need for specific, necessary purposes, and we will be open, transparent and fair with you about how we use your information. You can find out more about how we follow the principles of data protection in the **comprehensive guide.**

**Will my information be kept secure?**

We will take all necessary measures to ensure that information about you is sent and stored securely by us or by anyone acting on our behalf.

The information about you that we need for the study will be sent to us by post or electronically or will be entered directly into our secure study database by your study researcher. Study forms only show your initials, date of birth and your unique study identification number. Your completed consent form will also be sent to us so that we can be sure you have agreed to take part in the study. This will be sent separately to rest of the study forms.

Sometimes we will also get information about you by email. Emails will never contain your name, only your trial identifying number and sometimes your initials and date of birth.

Finally, some particularly sensitive documents will be sent to us via a ‘secure file transfer’. This means information is sent by the internet in a very secure way.

Information stored in our databases or other electronic storage locations is held very securely, in a way that would make it very difficult for any unauthorised people to access it.

**Who will see my information in the research team?**

We will make sure that the only people at the University of Leeds who can see your information are people who need to run or analyse the study.

**Who else will see my information?**

There are some specific situations where we need to share information with other people or other organisations. We will always do this carefully and only when it’s really necessary. We will avoid sharing information that could identify you whenever possible. We will never sell your information or pass it on to people who will sell it. We will only share information when it is necessary for the study, necessary to protect your safety or the safety of others, or in the public interest. Information we share will not be used to make decisions about future services available to you, such as insurance.

We will share your information for the following reasons. You can find out more about these in the **comprehensive guide.**

* + To run and analyse parts of the study, we need to share your information with collaborators (such as doctors, statisticians or other experts) outside the University of Leeds.
	+ To keep you and other people safe, we will need to share some information about health-related events you may have with authorised organisations. None of these organisations will be able to identify you from this information.
	+ To report to authorised people about the progress of the study, we will need to share some basic information with some authorised organisations, including the Research Ethics Committee that has approved this study. None of these organisations will be able to identify you from this information.
	+ To allow other researchers to carry out future research in the public interest. We will only share your information for worthwhile research with all appropriate approvals. We will only share your information in such a way that researchers outside the University of Leeds will not be able to identify you. Your information will not be shared if you have explicitly said you did not want this to happen.
	+ We may also use study information for additional research projects within the University of Leeds. We will only agree to do this for worthwhile projects with all appropriate approvals, and we will not share any clearly identifiable information with researchers outside the original study team.
	+ Due to storage space limitations, we will store information securely away from the University of Leeds for a period after the main part of the study is over. The archiving companies we use to do this for us will only store your information and will not access it or see your details.

**Can I see my information, or ask you to correct it?**

Usually, when an organisation or a company has information about you, you can ask to have access to that information at any time, or ask them to correct it if it needs correcting. However, this does not apply in the same way to information used for research in the public interest, because allowing people to access or change their information could harm the quality of the research. You therefore cannot ask to access or correct information we have about you. However, most of the information we will collect will also be in your medical notes, which you can get access to if you want to. You should speak to your study doctor and nurse if you would like more information about care you have received.

You have provided us with contact details for use in the study (**address, email address, phone number**) and it is important that we find out about any changes to these. Please let your study doctor or nurse know about any changes so that they can let us know. Otherwise, we might lose contact with you or send messages for you to your previous contact details.

**How long will my information be stored for?**

If you agree to take part in this study, we will need to keep your information for at least **5 years** after the end of the study. We need to do this in order to comply with laws and other rules about research, which say it must be possible to check the results of the research for a period of time after it has finished. We will keep your information secure during all this time. For practical reasons, we may ask reputable archiving companies to store information securely on our behalf, away from the University of Leeds.

At the end of this period, we will securely destroy your information.

**What will happen if I stop taking part in the trial?**

If you decide you would like to stop all your study visits for any reason, we will need to keep the information we have about you to make sure the results of the study are reliable. You will continue to receive your usual care if you choose to stop taking part in the study.

Usually, when an organisation or a company has information about you, you can ask them to delete it, or not use it for a certain purpose. However, this does not apply in the same way to information used for research, because it would harm the quality of the research if people could delete or remove their information. We also need to comply with laws and other rules about research that say we need to keep all information used in research for a period of time after the research finishes. If you agree to take part in this study, it will therefore not be possible for us to remove or delete your information later on, although you can ask us to collect no further information after a given time.

Some other things you should know about what will happen to your information if you stop taking part:

* + If you stop all study visits, you should discuss with your study doctor and nurse. If you still occasionally go to your hospital for routine visits, we would like to hear from your study doctor or nurse about these visits, if they are relevant to this study. This way, you can still contribute to the study and help make the study results more reliable, without giving any more of your time. However, you can tell your study doctor or nurse that you do not want any more information sent to us, and they will make sure your wishes are respected.
	+ If you stop attending your study visits without telling anyone at your hospital, or you change your contact details or move house and do not tell your hospital, they will lose contact with you. If this happens, we may ask your study doctor or nurse to contact your GP to check if you are OK and still happy to take part in the study.

If you want to know more about what might happen to your information if you stop taking part in the study, including *why* we need to use your information in the ways we do, please see the **comprehensive guide.**

**What if I have concerns about how my information is being used?**

Your study doctor or nurse should be your first contact for any questions about your participation in this study. If you still have questions that they cannot answer, and which are not answered by any of these documents, you can contact the University of Leeds Data Protection Officer (the University’s main contact for anything to do with how your information is used). You can do this using any of the details below. If you do contact them, please mention the name of this study (D-MAPP) and the Clinical Trials Research Unit.

* + Email: DPO@leeds.ac.uk
	+ Telephone number: +44 (0)113 343 7641
	+ Postal address for data protection issues: University of Leeds, Room 11.72 EC Stoner Building, Leeds, LS2 9JT

If you are not happy with the response to any queries or complaints, or believe your information is being used incorrectly or unlawfully, you should contact the Information Commissioner’s Office:

* + General website: ico.org.uk
	+ ICO contact webpage: ico.org.uk/global/contact-us
	+ Telephone number: 0303 123 1113
	+ Postal address: Information Commissioner’s Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5A

If you have any independent complaints, you should contact the University of Leeds Sponsor Representative:

* Email: governance-ethics@leeds.ac.uk.

**Who is organising and funding the research?**

This is a research project of the Leeds Institute of Rheumatic and Musculoskeletal Medicine, in collaboration with the Clinical Trials Research Unit at the University of Leeds. It is being funded by NIHR Programme Grants for Applied Research (PGfAR) and Versus Arthritis. The study is being sponsored by The University of Leeds.

**Who has reviewed the study?**

The study has been reviewed and favourable opinion was given by the <<*insert details when known*>> Research Ethics Committee and by the Research and Development Office at the hospital who entered you into the study. More details can be provided, on request, by your study researcher.