**
PARTICIPANT INFORMATION SHEET**

**Study Title: Fracture Assessment, Management and Outcomes in Upper limb Study during Covid-19**

**We would like to invite you to take part in a research study.**

Your decision to take part in the study is entirely voluntary. Before you decide, we would like you to understand why the research study is being done and what it would involve from you. Please read this sheet carefully. If at any time you have any questions, feel free to ask a member of our research team. Please feel free to talk to others about this study if you wish.

**Why is the study being done?**

The Covid-19 pandemic has imposed considerable strain on global health systems. Hospitals in the United Kingdom (UK) that normally manage injured patients with fractures have had to adapt rapidly to these challenges. Many fractures that are normally treated by an operation were being treated non-operatively. There is an urgent need to define how the management of patients with fractures had changed and describe subsequent patient outcomes from commonly seen upper limb fractures around the time of the Covid-19 pandemic. This study has been designed to capture key information on how adults with common upper limb fractures were managed within orthopaedic trauma services in the UK around the time of the Covid-19 pandemic and its impact on patient outcomes.

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

You have been invited to take part in this study because you have presented to the orthopaedic trauma service at one of the participating NHS hospitals with an upper limb fracture between the 1st December 2019 to the 14th March 2020 (pre-pandemic phase) or between the 15th March 2020 and 30th June 2020 (pandemic phase). The pandemic phase is when all elective and planned care services, unless urgent, were suspended in order to divert resources towards managing the Covid-19 pandemic.

**What would taking part involve?**

If you wish to take part in this study, a member of the research team will contact you via telephone to obtain your consent. You can provide consent via an electronic link if you provide an email address. You will receive an email with a link to the participant information sheet and consent form. If you consent to participate, your digital consent will be recorded on the secure REDCap electronic data capture system and a copy of your digitally signed consent form will be emailed to you.

Alternatively the member of research team will be able to provide study details over the phone and record your verbal consent digitally on the electronic REDCap data capture system. We will then post a paper copy of the electronic verbal consent form signed by the researcher to yourself, along with a copy of the participant information sheet with the research team’s contact details for your records. Your contact details and some information about yourself, including information about any underlying health conditions; details of your injury, employment; and whether you had tested positive for Covid-19 will be recorded. Some of this data will be collected from your hospital records.

If you provide an email address, you will later receive a follow-up questionnaire at 12 and 24 months from the date of your injury via email. The follow-up questionnaires will collect information about your general health and how your arm is functioning after the fracture by asking you some standard questions that are used in research. We will also ask you whether you have subsequently tested positive for Covid-19; your experiences in accessing health care; satisfaction with treatment; and any loss of productivity (days off work, change of work status). The research team will also collect some additional data from your hospital records at 24 months (readmissions; complications; secondary interventions). If you do not have an email address, a member of the research team will complete the 12 and 24 month follow-up questionnaires on your behalf by asking you those questions either over the telephone or via a video call.

Depending on when the member of the research team first contacts you to ask you for the initial information, we might also be able to obtain the 12 month follow-up data from the time of your injury at the same time as your consent to minimise inconvenience.

**How long will I be in the study?**

You will be in the study for 24 months from your injury date.

**What are the possible benefits of taking part?**

The study will improve our understanding of the impact of the Covid-19 pandemic on upper limb fracture care. The results of this study are likely to generally help inform other research studies that have been suspended due to Covid-19, about the potential impact of the pandemic on participants of those studies and the impact on patient outcomes due to changes in treatment pathways during the pandemic. It may also help us design appropriate care pathways for patients with upper limb fractures if services are affected in the future as a result of a pandemic.

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

There are no identified disadvantages or risks from taking part in this research study due to the observational nature.

**What happens if I don’t want to be in the study?**

Your participation in this study is entirely voluntary. If you do not want to participate in this study or if you decide to withdraw before the end of the study, your decision to do so will have no negative impact on your current or future treatment or care. You can withdraw by contacting the study team using the details provided at the end of this information sheet. Any information collected prior to withdrawal will be retained. You will not be contacted for any further information after this. Researchers will continue to collect hospital data.

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

We will need to use information from you and from your medical records for this research study. South Tees Hospitals NHS Foundation Trust, as sponsor, is the data controller and is responsible for looking after your information and using it properly. We will keep identifiable information about you for maximum of 12 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the South Tees Hospitals NHS Foundation trust for 3 years after the publication of the results of the study.

Personal information will include your name; contact details (email address, telephone, mobile, address); date of birth and ethnicity. We will use your personal details to collect data from you and your hospital records or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure (see, “**How will my information be kept confidential?**”).

We will remove any details that would identify you personally (such as your name, date of birth, etc.) from your answers to our questions. The results of the study will be written in a way that no-one could identify you personally from the reports and publications. Any data collected will be anonymised and may be used to inform future research.

**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 hospital. 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.

**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/](https://www.hra.nhs.uk/information-about-patients/)
* by asking a member of the research team
* by contacting a member of the research team via email or telephone

**How will my information be kept confidential?**

Personal data will be handled in accordance with the GDPR and Data Protection Act (2018). All electronic patient-identifiable information will be held on a secure, password-protected database accessible only to essential personnel. Paper forms with patient-identifiable information will be held in secure, locked filing cabinets within a restricted area. Direct access to source data/documents will be required only for study related monitoring and query related resolution.

Personal contact details will be stored securely in REDCap data capture system hosted by the South Tees Hospitals NHS Foundation Trust within its password protected servers in order to complete follow-up questionnaires. Access will only be granted to essential study personnel within the central study team and local research team and the contact details will be deleted once the information is no longer required to contact you. Anonymised data will be entered to South Tees Hospital NHS Foundation Trust (sponsor), York University or local NHS computers and stored securely on password protected computers. Patients will be identified by a code number only for any analysis and cannot be identified from study reports or any other outputs.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants’ interests. This study has been reviewed and given favourable opinion by the East Midlands-Derby Research Ethics Committee (Reference: 21/EM/0014) and the Health Research Authority (HRA).

**Further supporting information**

If you have any concerns or questions about any aspect of the study, or complaint about the way you have been dealt with during this study, in the first instance you should speak to the local research team member who has approached you. If you remain unhappy, you can contact the National Health Service’s complaints mechanism by contacting the local hospital trust Patient Advice and Liaison Services (PALS).

If you want more information about this study, please contact a member of the research team below.

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