Information for patients

We would like to invite you to take part in our research study. We will compare two different types of treatment for your broken wrist.

Before you decide to join in, it is important that you understand why we are doing this research study and what it would involve for you. Please watch the video animation <add link> which explains the study and read this information carefully.

Feel free to talk about it with other people if you want. If there is anything that is not clear, or if you would like more information, please ask someone from the research or clinical team.

Treatments for broken wrists

When a person breaks their wrist, the treatment usually involves a support for the injured wrist. This support provides pain relief. It also protects the fracture (the break) whilst it heals.

In most hospitals in the UK, people with a broken wrist are given a plaster cast. After 4 to 6 weeks, they go back to hospital to have the cast taken off.

The results of a recent research study show that a removable wrist splint might provide the wrist with the same amount of support as a cast.

The benefit of this is that you can take it off yourself at home, so you don't need to have it removed at a hospital. This could be more convenient for you. Providing people with a splint instead of a cast might also save money for the NHS.

At the moment, doctors, physiotherapists and other healthcare professionals are not completely sure if having a splint gives the same level of pain relief and support as a cast.

In this study, we will directly compare people receiving a cast with people receiving a splint for treating broken wrists. We want to find out if levels of pain and the ability to do everyday tasks are similar between the two groups. We will also have a look at the cost of both treatment options to the NHS, and society as a whole.

Why are you asking me if I want to join this study?

We are asking you because you have a distal radius fracture (a particular type of break) in your wrist and you are over the age of 16.

We plan to recruit nearly 2000 people with a similar injury to yours from hospitals across the country.

Do I have to take part?

No. It is up to you. Even if you decide to take part now, you can stop at any time without giving a reason. Whatever you decide, it will not affect your normal clinical care.

What would taking part involve?

If you decide to take part, a member of the study team will discuss the study with you, answer any questions you may have, and ask you to fill in a consent form. This is to show that you agree to being in the study.

A researcher will then help you to fill in a number of short online questionnaires. There will be questions about you, your health, and your quality of life. There will also be questions that ask how well you could do everyday tasks before you broke your wrist, and how well you can do those now. This should take no more than 10 minutes of your time.

A computer program developed by the University of Oxford will then put you in one of the two treatment groups.

The two types of treatment in this study are:

(a) Cast: When you first go to the emergency department, you will probably get a temporary cast. The hospital staff will give you a date when you need to come back to get a full cast. They will then give you another date to go back in about 4-6 weeks, when someone will take off your cast.

<Image of Cast TBC>

(b) Removable wrist splint: You will get a splint when you are in the emergency department. The person who treats you will tell you when you can take off the splint. You will not have to go back to the hospital, unless you have a problem.

<Image of Splint TBC>

You will have the same chance of getting either the cast or the splint, rather like the toss of a coin. This is important because it means we can test the different treatments fairly.

The person who treats you will not be able to choose which treatment you get, and you will not be able to choose.

People from both groups will get a leaflet when they leave the emergency department. This will include:

- Some basic instructions on care for the injured arm.
- Recommended exercises to help with recovery.

- Contact details for someone you can talk to if you have any questions or worries about the injury.

What will happen as my injury gets better?

We will follow your recovery for 12 months. During this time, you will not need to make any additional visits to the hospital. At certain times, we will ask you to fill in questionnaires.

During the first two weeks:

On days 1, 3, 5 and 10 after your injury, we will ask you to give a pain score. On days 7 and 14, we will ask you to give a pain score and to answer a few more questions about your health and your injury.

The questions will take between 2 and 5 minutes to answer.

After the first two weeks:

At 7 weeks, and then 3, 6 and 12 months after your injury, we will ask you to complete a number of questionnaires so we can follow your recovery.

The questions will be very similar to those we asked at the start of the study. We will also ask you some questions about any complications (extra difficulties) you might have had and if you have been out of pocket due to the injury.

Completing the questionnaires at each of these time points will take about 10-15 minutes.

What format will these questionnaires be in?

We would prefer you, if possible, to complete these online. We will send you a web link to the online questionnaires via email or text message.

It is always best if you fill them in as soon as you get them.

If we haven't heard from you after a few days, we will send you a reminder message. We might phone you, to make sure you can access and fill in the questionnaires, and if you want, we may complete the questionnaires over the phone with you.

What if I don't have a smart phone or computer, or can't fill in questionnaires online?

If you are unable to complete the questionnaires online, someone from the central research team can ring you and you can answer the questions over the telephone. If that doesn't work for you then we can send out paper questionnaires for you to fill in and return to us.

A possible extra interview about your experience

We would like to understand more about people's experience of recovery from a broken wrist. We also want to understand more about what it is like to join in with this study.

To help us with this, we might ask if you would like to take part in an interview about your treatment, recovery, and your decision to take part or not in this study. These interviews will be digitally audio recorded, transcribed by a member of the research team and kept for 12 months after transcription before they are deleted. We can give you more information about this part of the study if you are interested.

What are the possible benefits and risks of taking part?

Both treatments in this study are used across the NHS at the moment. They are not new or experimental.

We do not know whether there is a difference in recovery for patients who get a cast or a splint. This is why we are doing the research.

If you join in, it will help us make treatment for future patients with similar injuries better. This study will also give us information about the best use of resources within the NHS.

There are some standard risks of having a plaster cast or splint, such as rubbing on the skin, feelings of pins and needles, or numbness (temporary loss of feeling) and stiffness.

These risks are the same for any patient having these treatments. They are not affected by whether patients join this research study or not.

Will you tell my General Practitioner (GP)/family doctor if I join in with this study?

If we need some more information after you have filled in questionnaires, and neither you nor the hospital can give us this extra information, the

study team might contact your GP (doctor). Otherwise we do not intend to notify your GP of your participation in this study.

Who is organising this study?

The study is being conducted by a research team led by the Chief Investigator Professor Matthew Costa at the University of Oxford. It involves Orthopaedic and Emergency Department doctors, nurses and physiotherapists across the UK.

There is research support from the University of Oxford, which is the lead centre for the study.

The Oxford Trauma and Emergency Care research team are responsible for the day-to-day running of the study as part of the Nuffield Department of Rheumatology, Orthopaedics and Musculoskeletal Sciences (NDORMS).

The research team is qualified to run this study because they have all the relevant training and skills. The team has a lot of experience in caring for patients with broken bones, and are active in health research.

The study is funded by the National Institute for Health and Care Research (NIHR).

How have patients and the public been involved in creating this study?

Patient and public perspective has been key in the development of this research.

Our patient representatives have helped us to develop the research plan. They have also reviewed this Information Sheet, and all other patient facing study documents.

Participants' views will continue to be represented throughout the study.

If you would like to know more about getting involved in research as a patient or member of the public, please visit this link: https://www.nihr.ac.uk/patients-and-public/

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect the interests of the patients who join it.

This study has been reviewed and approved by the <Insert research ethics committee>

What if new information becomes available during this study?

Sometimes during the course of a research study, new information becomes available about the treatments that are being studied.

If this happens, the research team will tell you about it, and talk to you about whether you want to continue in the study.

If you decide to leave the study, we will encourage you to discuss your continued care with your doctor.

If you decide to continue in the study, we might ask you to sign an updated consent form.

Will you pay me for taking part?

We will not pay you for taking part in this study, as we foresee no extra costs to you for taking part.

What will happen to my data?

UK Data protection regulation means that we have to 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. It is based in the United Kingdom, is the data controller, and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records in order to undertake this study and will use the minimum personally-identifiable information possible. Your personal details will be held by the research team at the University of Oxford. All information you will give us will be transferred to, and stored at, the University of Oxford, using a secure, encrypted web-based system which will be accessed only by limited members of the study team.

We will keep identifiable information about you, including research documents with personal information, such as consent forms, for 12 months after the end of the study.

The local study team will use your name, NHS/CHI/H&C number, home address including postcode, and contact details, to contact you about the research study and to oversee the quality of the study.

Your data from the questionnaires will be sent to your study team at the hospital where you were consented for the study. In this way, your doctor will have full oversight of the data about your participation in the study, to ensure there is transparency in the data that the University collects.

The local team will keep identifiable information about you from this study in accordance with local policy for retention of medical records.

UK 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.admin.ox.ac.uk/ research-data.

You can find out more about how we use your information by contacting the study team at draft3-casp@ndorms.ox.ac.uk

Will my details be kept confidential?

You will be given a unique study identification number which will be used for all of the information that we collect from you. This information will be accessed only by members of the DRAFT3 study team who are required to do so and will be kept strictly confidential.

Responsible members of the University of Oxford and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

In line with what happens in the NHS, the only situation in which confidentiality would need to be broken would be if you told a health professional or research team member about something that could result in harm to yourself or others.

What if there is a problem?

The University of Oxford, who takes overall responsibility for this study as the 'study sponsor', has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your

participation in this study. NHS indemnity is in place for any clinical treatment which is provided.

If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Matthew Costa who is the overall lead of this study on draft3-casp@ndorms.ox.ac.uk, or you may contact the University of Oxford Research Governance, Ethics & Assurance team (RGEA) office on 01865 616480 or email ctrg@admin.ox.ac.uk.

For independent advice, <PALS/PASS/ The Patient & Client Council> is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. <PALS/PASS/ The Patient & Client Council>is unable to provide information about this research study. If you wish to contact the <PALS/PASS/ The Patient & Client Council> team, please contact <Insert relevant NHS site phone number and email from PALS/PASS/The Patient & Client Council website>.

What will happen if I don't want to carry on with the study?

Participation in this study is voluntary and you can withdraw at any time or change your mind at a later stage. Withdrawal will not affect the care you receive from the NHS. Please be aware that if you do decide to withdraw, any data collected to the point of withdrawal will be retained for the study.

Should you wish to withdraw, simply contact the study office on 01865 223113 or email draft3-casp@ndorms.ox.ac.uk. Alternatively, you may wish to contact your local research lead <name of local research lead> on <local research lead contact number> who will assist you.

What happens at the end of the study?

This study is expected to last 4 years. We will publish the findings at the end of the study in medical journals and present them at medical conferences. We will take out any details that would identify you personally from your answers to our questions and no individual patient results will be published. You will not be identified from any report or publication in the public domain. The research findings will be available on the study website <insert study website link>. Study progress will also be available on this website and we might send you a newsletter through the post to keep you updated.

GET IN TOUCH

If, at any time, you would like further information about this study you may contact our Trial Management Team using the following details.

University of Oxford Trial Manager

01865 223113

Draft3-casp@ndorms.ox.ac.uk

Your Local Research Lead < Name of local researcher>

<Insert telephone number>

<Insert email>

Overall Lead of this study: Professor Matthew Costa

For further details of the study and our full privacy notice you can also refer to our study website

<insert study website url>