Participant Information Sheet
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IRAS Project ID: 279115

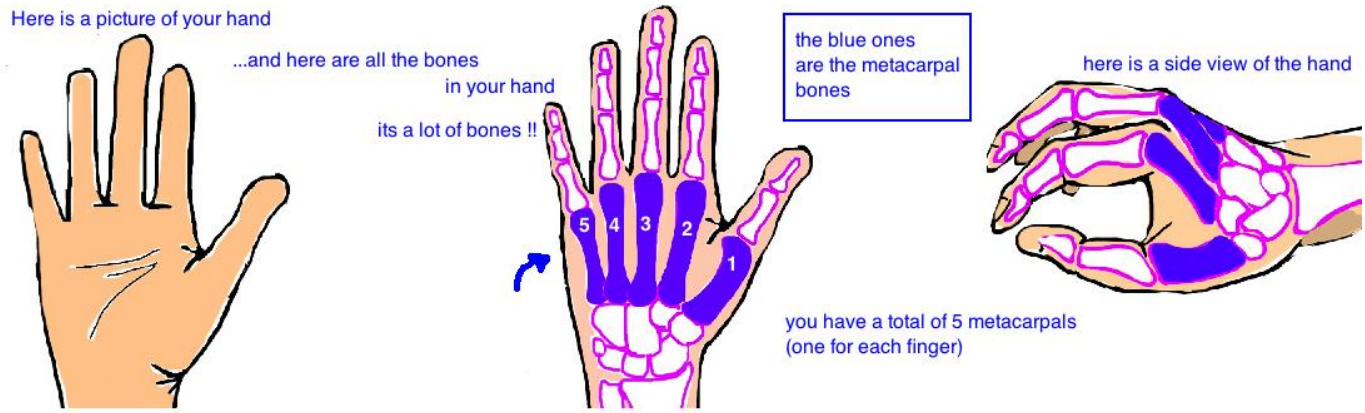
Surgical and non-surgical treatment for metacarpal shaft fractures in adults: an observational feasibility study (FACTS study)

Name of Chief Investigator: Clinical Associate Professor Alexia Karantana
Local Researcher(s): Miss Rowa Taha, Clinical Research Fellow in Hand Surgery, Professor Christopher Bainbridge and Anna Selby, Research and Postgraduate Manager Pulvertaft Hand Centre.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish and please ask us if there is anything that is not clear.

What is the purpose of the study?

Metacarpal shaft fractures, are breaks (also known as fractures) in the middle part of one of the bones in the hand. They are very common injuries in young, working-age people. They affect how your hand works and lead to pain, stiffness and time off work. As they affect people of working age, they can have a big impact on society.



www.bonetalks.com

At the moment, we do not know how best to treat them. This means patients get different care in different parts of the country. The best way of finding out is to do a study comparing treatments to see which is most effective. This research will help us to find out whether it is possible and how best to carry out a trial to tell us the best way of treating these injuries.

Why have I been invited?

You are being invited to take part because you have a break (fracture) in the middle part of the metacarpal bone (one of the small bones in the hand). We are inviting 70-84 participants like you to take part.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

You will be asked to complete some questionnaires about your hand and we will invite you to attend a research clinic in 6 weeks' time, where we will measure the range of movement in your hand and your grip strength. These measurements will take about 10-15 minutes and will not cause any discomfort or pain. During this clinic visit we will ask you some questions about your injury, its treatment and any extra costs you have incurred as a result of it. We will also review any Xrays that you have had and check your medical notes to see if you have had any problems in the 6 months following your injury.

You will be asked to complete some questionnaires about your hand and its recovery. These need to be filled in when you first enter the study, at the research clinic in 6 weeks and at 3 and 6 months' time, where we will send them out to you (either by email or post, depending on what's easiest for you) to be filled in from home.

You may also be invited to take part in interviews and focus groups linked to this study. Details about these are provided in a separate information sheet.

Summary of what will happen

It is important that you attend the 6week visit and complete all the questionnaires that we send you. This will help us to see how you and your hand are recovering.

To make things easier for you, we will help you with travel arrangements and reimburse all reasonable travel/parking costs. We will make sure to arrange the clinics so that it is possible for you to attend, at either Derby or Nottingham. We appreciate that you may be working so we can also hold the clinics at times to suit you, like after work or at the weekends.

Staying in contact with you

We would like to keep in touch with you by text message. If you have a mobile phone or smart device (and are happy to receive messages), we will send you text messages either fortnightly or monthly. You may be required to respond to some of the text messages to see how you are doing. This will help us find out how text messaging can best be used to help people in research studies.

You can opt out of receiving the messages at any time and you do not have to respond to them if you do not want to.

Expenses and payments

We will cover all your travel/parking costs for any visits you make as part of the study. You will not be paid an allowance for taking part in this study but vouchers will be offered if you take part in the interviews or focus groups linked to the study.

What are the possible disadvantages and risks of taking part?

Taking part in this study does not affect the usual care you will receive. We will just be monitoring how you and your hand are recovering, so there are no risks to taking part in this study.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help other people like you in the future. This research will help us to find out whether a trial to tell us the best way of treating these injuries is possible and how best to carry it out. This will ensure people like you receive the best care throughout the NHS, and that this represents value for money for the health service.

What happens when the research study stops?

If you would like, at the end of the study, we can update you with the results. We will also ask you if you would like to be contacted with information about any future research studies relevant to your problem. We would hold your contact details for 3 years after the end of the study, unless you tell us otherwise.

Your data is strictly confidential and will be held securely in accordance with regulations, at the University of Nottingham for 7 years after the study. Thereafter, it will be safely disposed of.

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. The researchers' contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service (PALS) on 0800 183 0204 or email PALS@nuh.nhs.uk.

In the very unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you and your medical records during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you which leaves the Queen's Medical Centre or the Pulvertaft Hand Centre will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth. We will also need this information if we need to follow up your medical records as part of the research, where we may need to ask the Government services that hold medical information about you (such as NHS Digital, the Office for National Statistics, among others) to provide this information to us. By signing the consent form you agree to the above.

Your contact information will be kept by the University of Nottingham for 7 years after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, 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 avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this (**before** it is shared) and ensure it is secure. You will be made aware if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

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

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?

The results of this study will be published in scientific journals and presented at conferences in the UK and abroad. This study will be included in the final PhD report of the lead researcher.

We will publish newsletters and summaries of the findings in local papers. We will also publish the findings online and via social media, so that we can reach as many people as possible.

You can get up-to-date information about the study on our website:

www.nottingham.ac.uk/research/groups/cebhs/projects/hand-wrist-fractures/facts-study.aspx

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the National Institute for Health Research (NIHR).

Who has reviewed the study?

All research in healthcare is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the (HRAapproval&PR) Research Ethics Committee

Further information and contact details

Lead Researcher	**Chief Investigator**
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Thank you