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PARTICIPANT INFORMATION SHEET

Physiotherapy RehabIlitation Managing Elbows – Post Trauma (PRIME-PT)

Invitation paragraph

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please ask us.

Purpose of the study

Physiotherapy rehabilitation is often used in the NHS to treat patients with traumatic elbow injury, but there are no specific guidelines and current physiotherapy practice is unclear.

The goal for physiotherapy treatment of traumatic elbow injuries is to improve elbow movement, improve function, reduce pain, and improve overall quality of life.

We want to improve the physiotherapy management of people with traumatic elbow injuries, reducing and addressing the development of stiffness post-injury. The purpose of this study is to find out whether it is possible to run a larger trial comparing two approaches to physiotherapy after a traumatic elbow injury. We want to understand how acceptable the treatments are to patients, how many people are willing to take part, and if people attend and complete their physiotherapy sessions.

The results of this study will help us design a future, larger study and improve rehabilitation for people recovering from elbow injuries.

Why have I been invited to take part?

You've been invited because we are recruiting patients aged 16 years and over who have recently sustained a bony elbow injury. This includes injuries such as elbow fractures or dislocations, seen and managed through the fracture clinic. We are aiming to include 30 patients in this study.

Do I have to take part?

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 free to withdraw at any time and without giving a reason. Withdrawing from the study will not affect the healthcare you receive or your legal rights.

What will happen to me if I take part in the research?

You will be randomised to either 2 sessions of usual care physiotherapy or the intervention group.

If you are allocated to the intervention group, you will attend **4-6 physiotherapy sessions over up to 3 months**. These sessions will focus on helping you safely improve movement, strength and confidence in using your elbow.

Kinesiophobia means a fear of movement. After an injury, some people worry that moving their arm might cause pain or damage the joint again. This can lead to avoiding movement, even when it is safe to do so. Avoiding movement can slow recovery and make the joint stiffer. In this group, physiotherapy includes support to help people feel more confident moving their elbow safely as part of their recovery.

At each session, the physiotherapist will:

- Check your progress and discuss any problems or concerns
- Measure your elbow movement using a simple measuring tool
- Guide you through exercises to improve movement and strength
- Answer questions and provide advice about safe movement and recovery

You will be asked to complete short questionnaires relating to your injury. You will also be given a **home exercise programme** to follow between sessions. This will be reviewed and adjusted at each visit.

If you are allocated to the usual care group, you will receive the **standard physiotherapy care normally provided** for people with a traumatic elbow injury.

This usually includes:

- An **initial physiotherapy appointment** to assess your elbow movement and discuss your symptoms
- Advice and education about your injury and recovery
- A **home exercise programme** to help improve movement and function
- One follow-up appointment

Your physiotherapist may measure your elbow movement using a simple measuring tool and ask you to complete short questionnaires, similar to routine care.

You will not receive the additional physiotherapy sessions offered in the intervention group, but your care will not be restricted, and you will continue to receive appropriate treatment as clinically required.

The physiotherapy sessions will be up to 45 minutes long and will take place at your usual physio setting, either at the John Radcliffe Hospital or Horton General Hospital.

Randomisation means that you will be assigned to one of the study groups by chance. This ensures that the groups are fair and that neither you nor the research team can influence which group you are placed in. After you agree to take part, you will be allocated to a group using a sealed envelope system that has been prepared in advance.

Regardless of which group you were allocated to, you will be invited for a follow-up 3 months after you have been randomised, so that we can find out if the treatment has helped or not. We will ask you to complete a questionnaire that is similar to the one you completed at the beginning of the study.

You may ask to pause or stop the research activities at any time.

What should I consider?

Who cannot take part:
You may not be able to take part if your elbow problem is not due to a recent injury, if you have a significant pre-existing elbow condition, or if another injury or medical condition makes physiotherapy unsuitable. The research team will confirm this with you.

Medication:
You can continue taking your usual prescribed and over-the-counter medications. Please let the research team know what you are taking.

Lifestyle or diet:
You do not need to change your normal diet or lifestyle. Any short-term instructions linked to study assessments will be explained in advance.

Other research studies:
If you are taking part in another research study, please tell the research team. This will usually not prevent you from taking part, but compatibility will be checked.

Are there any possible disadvantages and risks of taking part?

There is a small risk of doing too much too soon with exercises, which may lead to overexertion. During rehabilitation, you may also experience some temporary discomfort such as pain, swelling, bruising or redness.

Your physiotherapist will guide you to exercise at a safe level and adjust your programme if needed.

What are the possible benefits of taking part?

While there are no immediate benefits for those people participating in the research, it is hoped that this research will lead to improved management of patients with traumatic elbow injuries in the future.

Will my General Practitioner (GP) be informed of my participation?

Your GP will not be informed of your participation.

Will my taking part in the study be kept confidential?

Yes. All study records will be identified only by a code. We will only use NHS numbers where this is necessary to link to your NHS records. Information that can identify you will only be held securely by the study clinicians for the purposes of the study.

Confidentiality will be maintained as far as it is possible unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first.

Further information about how your personal data is used is provided in the section "What will happen to my data".

Will I be reimbursed for taking part?

Taking part in this study will not cost you anything. All physiotherapy appointments, assessments, and exercises provided as part of the study are part of routine NHS care and will be delivered during normal clinic visits. You will not be asked to pay for any treatment, equipment, or materials used in the study.

There are no additional costs to take part beyond what you would normally expect when attending NHS physiotherapy appointments.

Please note that travel expenses are not reimbursed for participation in this study.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), 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 and is responsible for looking after your information and using it properly.

We will need to use information from you from your medical records for this research project. We will share your information related to this research project with the following types of organisations, Oxford University Hospitals NHS Foundation Trust.

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data and we only allow them to process your data for the specific purposes we have stated in our instructions.

This information will include your NHS number, name, contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. Responsible members of the University of Oxford, regulatory authorities, and Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations

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 by:

- Using a unique study code instead of your name on all study documents and data
- Storing identifiable information separately from study data
- Keeping electronic data on password-protected, secure NHS or University systems
- Storing any paper records in locked cabinets within secure offices
- Limiting access to your information to authorised members of the research team only
- Handling and storing all data in line with data protection legislation (GDPR)

International Transfers
Your personal data will not be shared outside the UK.

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.

After the study ends, the retention period (this means the length of time we keep your data for) will begin and we will keep your data for a minimum of 3 years in line with the University Policy on Management of Data. Once the retention period has finished, the study data will be kept in a way that does not identify you.

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. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK by:
- asking one of the research team, via Georgina Wistow: Georgie.lucas@ndorms.ox.ac.uk or the Physiotherapy Research Unit: pru@ouh.nhs.uk
- sending an email to Georgie.lucas@ndorms.ox.ac.uk or pru@ouh.nhs.uk
- calling us on 01865 737526
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: How we use your personal data for research purposes | Compliance

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available athttps://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/.

The local study team will use your name, NHS number, and contact details, to contact you about the research study, and to oversee the quality of the study. A copy of the consent form from this study will be kept in your medical records for as long as those records are retained. They will keep any other identifiable information about you from this study for three years after the study has finished.

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

Taking part in this study is completely voluntary. You can change your mind and stop taking part at any time, without giving a reason. This will not affect your usual care or treatment in any way.

If you choose to withdraw, we would like to continue using the information already collected up to that point to support the research. However, if you prefer, you can ask for your data to be removed, and we will respect your wishes where possible.

What will happen to the results of this study?

At the end of the study, we plan to publish research findings and present at conferences, for example the Chartered Society of Physiotherapy Conference, to share what we have learnt. Participants will not be identifiable from any report or publication placed in the public domain. This study is part of an education project, with the principle investigator completing a Pre-doctoral Clinical Academic Fellowship funded by the NIHR.

A summary of the overall study results written in plain English will be made available to participants. This will be provided at the end of the study (within approximately 6 months of study completion) and can be shared via email or post on request.

What if we find something unexpected?

This study does not involve scans, genetic testing, or laboratory samples. However, during physiotherapy assessments or from questionnaire responses, we may identify information that could be relevant to your health or recovery.

If anything unexpected is found that may be important for your care, this will be discussed with you. With your permission, the information may be shared with your treating clinician so that appropriate follow-up can be arranged. Any findings will be managed in line with usual NHS clinical practice.

What if there is a problem?

If you have a concern about any aspect of this study, please speak with the clinical/research team. They will do their best to answer your questions.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, contact Georgina Wistow: Georgie.lucas@ndorms.ox.ac.uk or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, 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. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

NHS indemnity operates in respect of the clinical treatment provided.

The Patient Advisory Liaison Service (PALS) 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 is unable to provide information about this research study. If you wish to contact the PALS team please contact 01865 221473 or PALS@ouh.nhs.uk.

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

Patient and Public Involvement was involved to develop the research topic, study design and what research questions should be asked and will continue to be involved in the study.

Potential participants were involved in reviewing this Participant Information Sheet.

Potential participants were involved in describing the inclusion and exclusion criteria for this study. For more general information about taking part in research:

- https://www.nihr.ac.uk/get-involved/public-involvement
- https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/public-involvement-newsletter/

Who is organising and funding the study?

The University of Oxford is sponsoring the study. Mrs Georgina Wistow is an NIHR ICA Pre-doctoral Clinical and Practitioner Academic Fellowship awardee.

The collaborators include:

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Conflicts of Interest

There are no competing interests related to this study.

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 a favourable opinion by Yorkshire & The Humber - Leeds West Research Ethics Committee Research Ethics Committee.

Further information and contact details:

For further information please contact the Chief Investigator by telephone or email:
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Thank you for reading this information/for considering taking part.