

A study comparing two types of physiotherapy after traumatic elbow injury

Submission date 19/05/2026	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/06/2026	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/06/2026	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Traumatic elbow injuries can lead to pain, stiffness, weakness, and difficulty returning to everyday activities. Physiotherapy rehabilitation following elbow injury varies widely, and there is limited evidence to guide the best approach to treatment. Some patients may also develop fear of movement after injury, which may affect recovery and confidence using the arm. The aim of this study is to assess whether a structured physiotherapy rehabilitation programme can be delivered successfully within the NHS and whether a larger future trial would be feasible.

Who can participate?

Adults aged 16 years and over who have sustained a traumatic bony elbow injury within the past 4 weeks may be eligible to take part. Participants will be excluded if they are unable to adhere to study procedures or if they have previously had surgery on the affected elbow.

What does the study involve?

Participants will be randomly allocated to receive either an enhanced physiotherapy rehabilitation programme or usual physiotherapy care.

Participants in the enhanced rehabilitation group will attend 4-6 physiotherapy sessions over 3 months. Treatment may include exercises and support to improve confidence moving the elbow after injury.

Participants in the usual care group will receive standard physiotherapy care routinely provided within the NHS service.

All participants will complete questionnaires and elbow movement assessments at the start of the study and again at 3 months.

What are the possible benefits and risks of participating?

Participants may benefit from physiotherapy rehabilitation and additional monitoring during recovery. The information collected may also help improve rehabilitation following elbow injury in the future.

The risks of participating are low. Some participants may experience temporary discomfort or soreness during exercises or assessments, which is common during rehabilitation after injury.

Where is the study run from?

The study is being run from the John Radcliffe Hospital and Horton General Hospital, Oxford University Hospitals NHS Foundation Trust, Oxfordshire, UK.

When is the study starting and how long is it expected to run for?

The study is expected to begin recruitment in May 2026 and run for approximately 10 months. Each participant will take part in the study for approximately 3 months.

Who is funding the study?

The study is funded by the NIHR ICA Pre-doctoral Clinical and Practitioner Academic Fellowship programme.

Who is the main contact?

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Contact information

Type(s)

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Additional identifiers

Integrated Research Application System (IRAS)
366127

Protocol serial number
73083

Study information

Scientific Title
Physiotherapy Rehabilitation Intervention Managing Elbow - Post-Trauma

Acronym
PRIME-PT

Study objectives

1. To assess the willingness to be randomised - proportion of eligible patients approached who are randomised
2. To assess the recruitment rate - number of participants recruited per month per site
3. To assess the intervention adherence - proportion of participants allocated to "supervised rehabilitation" attending up to 6 physiotherapy sessions, completed patient exercise diary
4. To assess the retention - proportion of participants that complete Oxford Elbow Score at 3 months post randomisation

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/04/2026, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 207 104 8241; leedswest.rec@hra.nhs.uk), ref: 26/YH/0060

Study design
Feasibility study

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Traumatic elbow injuries

Interventions

Participants will be randomised in a 2:1 ratio to either an enhanced physiotherapy rehabilitation intervention or usual care using sequentially numbered, opaque, sealed envelopes prepared in advance according to a computer-generated randomisation sequence.

Intervention arm: Participants allocated to the intervention group will receive 4-6 physiotherapy sessions over a 3-month period. Treatment will include range-of-movement exercises, strengthening, functional rehabilitation, education and reassurance, and graded exposure to movement to address fear of movement following injury. Exercise programmes will be individualised according to the patient's presentation and stage of recovery.

Usual care arm: Participants allocated to the usual care group will receive standard physiotherapy management routinely delivered within the NHS service, typically consisting of an initial assessment and one follow-up appointment.

All participants will complete a follow-up assessment at 3 months post-randomisation, including questionnaires and elbow range-of-movement assessment.

Intervention Type

Behavioural

Primary outcome(s)

1. Recruitment rate measured using Screening and recruitment logs at During recruitment period
2. Participant retention and follow-up completion measured using Study follow-up records at 3 months post-randomisation
3. Intervention adherence measured using Physiotherapy attendance records and treatment documentation at Throughout intervention period

Key secondary outcome(s)

1. Elbow function measured using Oxford Elbow Score questionnaire at Baseline, 3 months post-randomisation
2. Upper limb disability measured using QuickDASH questionnaire at Baseline, 3 months post-randomisation
3. Health-related quality of life measured using EQ-5D-5L questionnaire at Baseline, 3 months post-randomisation
4. Pain severity measured using Visual Analogue Scale (VAS) at Baseline, 3 months post-randomisation
5. Elbow flexion, extension, pronation and supination range-of-movement measured using Goniometry at Baseline, 3 months post-randomisation
6. Fear of movement (kinesiophobia) measured using Tampa Scale of Kinesiophobia questionnaire at Baseline, 3 months post-randomisation

Completion date

01/03/2027

Eligibility

Key inclusion criteria

1. Aged 16 or older
2. Had a bony elbow injury (e.g. simple dislocation, fracture dislocation, olecranon fracture, radial head fracture, distal humeral fracture) within the past 4 weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

16 years

Upper age limit

110 years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Contraindication to participation in the study intervention
2. Previous surgery on the affected elbow
3. Unable to adhere to study procedures

Date of first enrolment

01/05/2026

Date of final enrolment

01/03/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

John Radcliffe Hospital

Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre**Horton General Hospital**

Oxford Rd
Banbury
England
OX16 9AL

Sponsor information

Organisation

University of Oxford

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Individual participant data will not be routinely shared but may be made available upon reasonable request, subject to appropriate approvals and data sharing agreements.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	01/05/2026	22/05/2026	No	Yes