

# Therapist-supervised exercise compared to usual care advice after distal radius fractures in people aged 50 years and over

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| <b>Submission date</b><br>21/09/2023   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>04/10/2023 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>08/07/2025       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Wrist fractures are an extremely common injury, representing about 1 in 5 of all broken bones seen in UK hospitals. After breaking their wrist, people are often provided with basic advice by the person who is treating them about how to get their wrist working again. We would like to find out if giving patients more detailed exercise advice will improve how quickly and how well they recover from a broken wrist. This study will compare two different ways of helping people recover from a broken wrist. The information we gather will provide scientific evidence about the effects of receiving additional sessions with a therapist. As therapy appointments aren't always convenient for patients, and it is important to make the best use of NHS time and resources, the WISE study aims to find out if the extra exercise advice helps with recovery.

### Who can participate?

People aged 50 years and over who have broken their wrist

### What does the study involve?

If the patient is happy to take part in this study, a researcher will ask some simple questions and check the patient's medical history to confirm that they are eligible. If the patient is eligible, the researcher will ask them to sign a consent form on a computer. If the patient is not at the hospital, a member of the research team will be able to document the patient's consent over the telephone. The researcher will also ask them to complete a short questionnaire that asks about health, level of activity, and injury. This questionnaire should take no more than 20 minutes to complete.

The researcher will then use a computer program to allocate participants to one of the two treatment groups. Participants will be randomised to either usual care or therapist-supervised exercise in addition to usual care.

Usual care is the normal advice that is provided by the hospital.

If participants are randomised to therapist-supervised exercise, they will receive three physiotherapy or occupational therapy sessions. These sessions may be face-to-face, by videoconference or telephone, depending on local policies. Participants will receive a detailed booklet containing advice and exercises, and will also have access to a website with the same information, which includes videos with instructions on how to do the exercises.

All participants will then be asked to complete a further questionnaire at three and six months post randomisation.

What are the possible benefits and risks of participating?

Fully qualified, registered health professionals will provide treatment. They will use widely recognised treatments in the NHS. We hope the information from this study will be used to help treat people with broken wrists more effectively.

Patients are unlikely to be harmed by this treatment. They may experience soreness after completing some of the exercises. This is normal, and patients will be given advice on how to manage this soreness. We are not able to pay travel expenses for attendance at therapy sessions as this part of patients treatment.

Where is the study run from?

University of Oxford (UK)

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

March 2023 to August 2025

Who is funding the study?

National Institute for Health and Care Research (NIHR) Research for Patient Benefit Programme (UK)

Who is the main contact?

Dr David Keene, wise@ndorms.ox.ac.uk

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr David Keene

### ORCID ID

<https://orcid.org/0000-0001-7249-6496>

### Contact details

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

329536

## Protocol serial number

CPMS 58092, NIHR205011, IRAS 329536

# Study information

## Scientific Title

Progressive resistance and flexibility exercises versus usual care advice for improving pain and function after distal radius fracture in adults aged 50 years or over: the WISE randomised superiority trial

## Acronym

WISE trial

## Study objectives

To compare the clinical effectiveness of a therapist-supervised exercise programme, to usual care advice, in improving pain and function after distal radius fractures in adults aged 50 years and over.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 09/10/2023, Yorkshire & The Humber - Leeds East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8012; leedseast.rec@hra.nhs.uk), ref: 23/YH/0201

## Study design

Interventional randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Distal radius fracture

## Interventions

Participants will be randomised to one of the following groups:

- Usual care advice: consisting of advice, and an information leaflet (if part of usual care)

- Therapist-Supervised exercise: usual care advice plus one session up to 60 minutes with a physio or occupational therapist to introduce a stretching and strengthening exercise programme. A further two sessions of up to 30 minutes over 12 weeks after the first session will provide guidance on progression of the exercise programme. If the hospital has pre-established practices for remote video or telephone consultations then the participant will be able to access this mode of delivery. Participants will be provided with a high-quality written and illustrated guide, and a website to support them with carrying out the exercises independently.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Wrist pain and function measured by the Patient-Rated Wrist Evaluation (PRWE) at six months post-randomisation

### **Key secondary outcome(s)**

1. Wrist pain and function measured by the PRWE at baseline and three months post-randomisation
2. Upper extremity function measured by the PROMIS Physical Function (Upper Extremity) at baseline, three and six months post-randomisation
3. Health related quality of life measured by EuroQol 5 Dimensions EQ-5D-5L at baseline, three and six months post-randomisation
4. Confidence in ability to exercise measured by the Self-Efficacy for Exercise scale (SEE) at baseline, three and six months post-randomisation
5. Exercise adherence measured by self-reported exercise frequency at three and six months post-randomisation
6. Health resource use measured by self-reported bespoke questionnaire at three and six months post-randomisation
7. Related complications measured by patient questionnaires and site complications reporting at three and six months post-randomisation
8. Upper limb muscle strength measured by Grip Strength (cylindrical grip) at six months post-randomisation

### **Completion date**

31/08/2025

## **Eligibility**

### **Key inclusion criteria**

1. Patient aged 50 years or over with a distal radius fracture treated surgically or non-surgically
2. Willing and able to give informed consent for participation in the study

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

50 years

**Sex**

All

**Key exclusion criteria**

1. Injury is more than two months old
2. There is evidence that the patient would be unable to participate in therapy or a self-guided exercise programme provided by a participating centre or adhere to trial procedures (including cognitive impairment and fracture/surgery complications such as Complex Regional Pain Syndrome)
3. Open fractures with a Gustilo & Anderson grading > 1

**Date of first enrolment**

30/11/2023

**Date of final enrolment**

31/01/2025

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****John Radcliffe Hospital**

Oxford University Hospitals NHS Foundation Trust

Headley Way

Headington

Oxford

United Kingdom

OX3 9DU

**Study participating centre****Southmead Hospital**

North Bristol NHS Trust

Southmead Road

Westbury-On-Trym

Bristol

United Kingdom

BS10 5NB

**Study participating centre**  
**Cheltenham General Hospital**  
Gloucestershire Hospitals NHS Foundation Trust  
Sandford Road  
Cheltenham  
United Kingdom  
GL53 7AN

**Study participating centre**  
**Royal United Hospital Bath**  
Royal United Hospitals Bath NHS Foundation Trust  
Combe Park  
Bath  
United Kingdom  
BA1 3NG

**Study participating centre**  
**Leicester Royal Infirmary**  
University Hospitals of Leicester NHS Trust  
Infirmary Square  
Leicester  
United Kingdom  
LE1 5WW

**Study participating centre**  
**Worthing Hospital**  
University Hospitals Sussex NHS Foundation Trust  
Lyndhurst Road  
Worthing  
United Kingdom  
BN11 2DH

**Study participating centre**  
**Airedale General Hospital**  
Airedale NHS Foundation Trust  
Skipton Road  
Steeton Keighley  
United Kingdom  
BD20 6TD

**Study participating centre**

**University Hospital of North Tees**

North Tees and Hartlepool NHS Foundation Trust  
Hardwick Road  
Hardwick  
Stockton-on-Tees  
United Kingdom  
TS19 8PE

**Study participating centre****Addenbrookes Hospital**

Cambridge University Hospitals NHS Foundation Trust  
Cambridge Biomedical Campus  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre****Musgrove Park Hospital**

Somerset NHS Foundation Trust  
Lydeard House  
Taunton  
United Kingdom  
TA1 5DA

**Study participating centre****Pinderfields Hospital**

Mid Yorkshire Hospitals NHS Trust  
Abeford Road  
Wakefield  
United Kingdom  
WF1 4DG

**Study participating centre****Royal Cornwall Hospital**

The Royal Cornwall Hospitals NHS Trust  
Treliske  
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United Kingdom  
TR1 3LJ

# Sponsor information

## Organisation

University of Oxford

## ROR

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

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Central Commissioning Facility (CCF)

# Results and Publications

## Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

| Output type                      | Details       | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> |               | 08/07/2025   | 08/07/2025 | Yes            | No              |
| <a href="#">Study website</a>    | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |