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

Submission date
21/09/2023

Recruitment status
No longer recruiting

Registration date
04/10/2023

Overall study status
Completed

Last Edited
08/07/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
329536

ClinicalTrials.gov (NCT)
Nil known

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
Truro
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?
Protocol article		08/07/2025	08/07/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes