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Wrist injury strengthening exercise for improving pain and function after distal radius fracture in adults aged 50 or over

Submission date
20/11/2020

Recruitment status
No longer recruiting

Registration date
28/01/2021

Overall study status
Completed

Last Edited
21/09/2023

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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. 1 in 10 women up to 90 years old will have a wrist fracture, with most occurring after a simple fall from standing height. Initial treatment for this fracture is either with an operation (for more severe breaks) or with a splint or cast.
After a wrist fracture, patients may experience long-term muscle weakness of the hand and arm, with an impact on their quality of life and wellbeing. There may also be long-lasting impacts on daily activities such as personal hygiene, domestic chores, and preparing meals.
Currently the care program offered to patients after the initial treatment varies between hospitals, but the majority of patients will be given some basic exercise instruction. This study will investigate whether adding in a programme of stretching and strengthening exercises for the hand and arm will help in the patient's recovery. These specific exercises are thought to improve wrist function and help with future activities of daily living.

Who can participate?
Patients aged over 50 who have a distal radius fracture.

What does the study involve?
Participants will be allocated at random to one of three groups:
1. Usual care consisting of advice and an advice leaflet
2. Independent exercise: usual care plus a single session with a physio or occupational therapist to introduce the stretching and strengthening exercise programme. Provision of a high-quality written and illustrated guide, and website to support participants with carrying out the exercises independently.
3. Supervised exercise: usual care, plus the guide and website available to the independent exercise group, but these participants would have three sessions with a therapist. The additional two sessions with the therapist will offer opportunities to discuss the progression of the exercises and resolve any problems.

What are the possible benefits and risks of participating?
The information from this study will be used to help treat people with broken wrists in the future. Exercises are already used in the NHS for people with broken bones. Participants are unlikely to be harmed by this treatment. The therapist will assess them to help make sure they are given exercises at the right level. Participants may experience some soreness in their wrist after completing exercises. They will be given advice on how to manage this soreness.
People sometimes feel uncomfortable answering certain questions about their health. If the researcher, physiotherapist, or follow-up questionnaire asks participants questions that they are uncomfortable with then they do not have to answer them.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
July 2020 to May 2022

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Kate Herbert
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
282917

Protocol serial number
IRAS 282917, CPMS 47701

Study information

Scientific Title
WISE - Wrist Injury Strengthening Exercise: a randomized multicentre feasibility study of flexibility and resistance exercises versus usual care for improving pain and function after distal radius fracture in adults aged 50 years or over

Acronym
WISE feasibility study

Study objectives
It is hypothesised that introducing structured flexibility and resistance exercise training has the potential to improve functional recovery by optimising recovery of muscle strength of the hand and upper limb.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/12/2020, South Central - Hampshire B Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8290; hampshireb.rec@hra.nhs.uk), REC ref: 20/SC/0433

Study design
Multicentre parallel three-group feasibility randomized controlled trial

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Distal radius fracture

Interventions
Randomisation will be completed online. The trial will employ 1:1:1 allocation, stratified by centre and initial fracture management (surgical vs non-surgical).

Participants will be allocated at random to one of three different study groups:
1. Usual care consisting of advice and an advice leaflet
2. Independent exercise: usual care plus a single session with a physio or occupational therapist to introduce the stretching and strengthening exercise programme. Provision of a high-quality written and illustrated guide, and website to support participants with carrying out the exercises independently.
3. Supervised exercise: usual care, plus the guide and website available to the independent exercise group, but these participants would have three sessions with a therapist. The additional two sessions with the therapist will offer opportunities to discuss progression of the exercises and resolve any problems.

The sessions will take place over a 12 week period, the first one lasting up to 60 minutes, and subsequent sessions up to 30 minutes. The participants will be followed up for 6 months post randomisation.

Intervention Type
Behavioural

Primary outcome(s)
The main aim of the feasibility randomised controlled trial is to determine whether a future definitive trial would be feasible. To determine the feasibility of a definitive RCT the success criteria are:
1. Patient engagement with the trial, measured by recruitment rate over 6 months of recruitment
2. Acceptability of the interventions, as measured by adherence (number and content of therapy appointments attended/website visits) and patient/staff interviews over 6 months of recruitment
3. Participant retention, as measured by the proportion of randomised patients providing outcome data at 6 months

Key secondary outcome(s))
The researchers will collect the proposed definitive trial outcome measures as part of this feasibility study to determine their viability in a future definitive trial.
1. Wrist pain and function measured using Patient Reported Wrist Evaluation (PRWE) at baseline, 3 and 6 months
2. Upper extremity function measured using PROMIS Upper Extremity at baseline, 3 and 6 months
3. Confidence in ability to do exercise measured using Self-efficacy Exercise Score (SEE) at baseline, 3 and 6 months

4. Self-reported exercise frequency measured using a trial-specific questionnaire at 3 and 6 months
5. Health-related quality of life measured using EQ-5D-5L at baseline, 3 and 6 months
6. Self-reported health resource use measured using a trial-specific questionnaire at 3 and 6 months
7. Reporting of adverse events using patient questionnaires and site complication at baseline, 3 and 6 months
8. Muscle strength measured using a dynamometer at 6 months
9. Balance and mobility measured using a trial-specific questionnaire at baseline, 3 and 6 months

Completion date
19/05/2022

Eligibility

Key inclusion criteria
1. Adult patients aged 50 years and older
2. Distal radius fracture treated surgically or non-surgically
3. Informed consent for participation in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
117

Key exclusion criteria
1. Injury is more than 2 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
01/11/2020

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
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Sponsor information

Organisation
University of Oxford

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr David Keene (david.keene@ndorms.ox.ac.uk) 3 years after the publication of the main trial results.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		07/03/2022	18/03/2022	Yes	No
HRA research summary			28/06/2023	No	No