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Physiotherapy in conservatively managed distal radius fractures

Submission date	Recruitment status	[ ] Prospectively registered
19/11/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/11/2015	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/05/2022	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
A distal radius fracture, commonly referred to as a broken wrist, is where bone running between the elbow and the thumb (radius) is broken. It can be extremely painful, making it difficult or even impossible to use the affected arm. If the break is “clean” and the broken pieces of bone are in the correct position, then they are usually treated by applying a plaster or fibreglass cast. This works by holding the broken sections of bone together so that they heal in the right position (immobilisation). The cast usually stays in place for at least 6 weeks, to give the bones a chance to heal. Once the cast is removed, many doctors recommend physiotherapy, to help restore strength in the arm muscles and to restore full movement. Physiotherapy is not always available and can be very expensive however, and many health professionals do not feel that it is a necessary part of recovery for those with a broken wrist. It can be argued that many patients could benefit equally well from managing their rehabilitation themselves, such as through self-directed exercises at home. The aim of this study is to compare the long-term effects of having physiotherapy to self-directed exercises on long-term recovery following a distal radius fracture.

Who can participate?
Adults who have had a broken wrist treated using a cast or splint for between 5-7 weeks.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group are given an advice sheet including information about the process of recovery. Those in the second group are given an outpatient appointment with a physiotherapist. Those in the third group are provided with a video that they can watch at home, and will instruct them how to perform rehabilitation exercises that may help their recovery. At the start of the study and then at 6, 12 and 52 weeks, participants complete a number of questionnaires in order to monitor their recovery.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Queens Medical Centre, Nottingham (UK)

When is the study starting and how long is it expected to run for?
October 2015 to August 2017

Who is funding the study?
AOUK (UK)

Who is the main contact?
Miss Jessica Nightingale

Contact information

Type(s)
Public

Contact name
Miss Jessica Nightingale

Contact details
Queens Medical Centre
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19314

Study information

Scientific Title
Outcomes and cost effectiveness of physiotherapy, self directed therapy and advice sheets following conservatively managed distal radius fractures: A prospective randomised controlled trial

Study objectives
The aim of this study is to investigate the effects of physiotherapy, self directed therapy and advice sheets on recovery following a distal radial fracture.

Ethics approval required
Old ethics approval format

Ethics approval(s)

East Midlands - Nottingham 2 Research Ethics Committee, 30/07/2015, ref: 15/EM/0297

Study design
Three-arm prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Musculoskeletal disorders; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
Participants are randomly allocated to one of three groups.

Group 1: Participants are given an advice sheet and a physiotherapy department leaflet (control group)
Group 2: Participants are provided with an outpatient appointment with physiotherapist
Group 3: Participants are provided with an instructional video that will help them to perform rehabilitation exercises at home.

Participants recovery is assessed at baseline, 6, 12 and 52 weeks for all groups.

Intervention Type
Other

Primary outcome measure
Symptoms and ability in the affected arm are measured using the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire at baseline, 6 , 12 and 52 weeks.

Secondary outcome measures
1. EQ5D at baseline, 6 , 12 and 52 weeks
2. Patient Evaluation Measure (PEM) at baseline, 6, 12 and 52 weeks
3. Routine Outcome Measures (ROM) at 6, 12 and 52 weeks

Overall study start date
12/10/2015

Completion date
01/08/2017

Eligibility

Key inclusion criteria
1. Aged between 18 and 70 years at the time of fracture
2. Able to give informed consent
3. Any fracture of the distal radius within 3cm of the radiocarpal joint will be considered for inclusion (including intraarticular fractures, fractures with comminution, associated ulnar styloid fracture, dorsal and volar displacement patterns) provided it has been deemed suitable for conservative management by the treating physician.
4. Fracture treated with immobilisation (plaster of paris / fibreglass cast / splint) worn constantly for between 5 and 7 weeks
5. English should be the patient's first language

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Total final enrolment
120

Key exclusion criteria
1. A fracture which extends beyond 3 cm of the radiocarpal joint
2. Any patient with bilateral fractures
3. A fracture which has been immobilised outside of the range of 5 and 7 weeks
4. Any patient who is deemed to be unlikely to be able to adhere to the trial procedure or complete the questionnaires (e.g. drug dependence or cognitive impairment)
5. Current participation in another ongoing study
6. Evidence of complex regional pain syndrome
7. Post plaster stiffness of the fingers which prevents the patient from being able to place their hand flat on a tabletop
8. Any previous fracture of the wrist or carpal bones whether treated operatively or conservatively

Date of first enrolment
12/10/2015

Date of final enrolment
01/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Queens Medical Centre
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Research organisation

Funder Name

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	13/05/2022	Yes	No
HRA research summary			28/06/2023	No	No