# A pilot study: a randomised controlled trial investigating the effect of therapeutic ultrasound and exercise on active digital flexion following phalangeal fractures

<b>Submission date</b> 25/01/2006	<b>Recruitment status</b> No longer recruiting	Prospectively registered
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
01/03/2006	Completed	☐ Results
Last Edited	Condition category	Individual participant data
27/01/2009	Injury, Occupational Diseases, Poisoning	Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

Mrs Sue Kennedy

#### Contact details

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# Additional identifiers

**Protocol serial number** N/A

# Study information

Scientific Title

#### Study objectives

Digits with fracture will have improved total active flexion following six weeks of ultrasound and a standard therapy programme when compared to digits exposed to placebo ultrasound or no ultrasound and the same programme of therapy care

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Added as of 18/06/2008: Nottingham Research Ethics Committee 1. Date of approval: 22/05/2007 (ref: 06/Q2403/42)

#### Study design

Randomised, double-blind, placebo-controlled

#### Primary study design

Interventional

## Study type(s)

Treatment

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

Proximal and middle phalangeal fractures in digits 2-5

#### **Interventions**

Therapeutic ultrasound and standard hand therapy programme of care (including exercise, oedema control, splints and advice) versus placebo ultrasound and standard hand therapy programme of care.

### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome(s)

Active digital flexion of metacarpophalangeal (MCP), interphalangeal (PIP) and distal interphalangeal (DIP) joints of the affected and contralateral finger.

#### Key secondary outcome(s))

Pain score and a measure of flexor tendon glide of affected and contralateral finger.

## Completion date

17/07/2006

# **Eligibility**

# Key inclusion criteria

- 1. Closed, extra-articular, proximal or middle phalangeal fractures involving digits 2-5
- 2. Immobilization with a zimmer splint for 14-21 days
- 3. Able to attend twice-weekly therapy for six weeks
- 4. Over 18 years of age

## Participant type(s)

Patient

## Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Compound fractures
- 2. Multiple fractures within the same digit
- 3. Intra-articular fractures and concomitant interphalangeal joint dislocations
- 4. Concomitant tendon injuries
- 5. Patients having undergone open reduction internal fixation of the fracture
- 6. Patients with mental impairment
- 7. Patients who are unable to read or understand English
- 8. Patients with inflammatory arthritis, significant digital osteoarthritic joint changes or diabetes
- 9. Patients with a pacemaker
- 10. Patients with carcinoma
- 11. Patients with previous injury to the fractured digit
- 12. Patients with osteoporosis
- 13. Patients presenting with adhered flexor tendons post-immobilization, requiring anaesthetic block

#### Date of first enrolment

27/02/2006

#### Date of final enrolment

17/07/2006

# Locations

#### Countries of recruitment

United Kingdom

England

Study participating centre
Physiotherapy Outpatient Department
Derby
United Kingdom
DE1 2QY

# Sponsor information

### Organisation

Derby University (UK)

#### **ROR**

https://ror.org/02yhrrk59

# Funder(s)

## Funder type

Government

#### **Funder Name**

Trent Workforce Confederation, Derby Hospitals NHS Foundation Trust (UK)

#### **Funder Name**

Chartered Society of Physiotherapy (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration