

Improving the Evidence for Effective Care of Hand Fractures and Joint Injuries

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Abstract

Background: Hand fractures and injuries impact considerably on patients and society. Hand injuries were prioritised by the recent James Lind Association Priority Setting Partnership on Common Conditions Affecting the Hand and Wrist, as currently there is little evidence to guide management. Clinical practice is mainly based on expert opinion leading to inevitable variation in management. Randomised controlled trials (RCTs) on hand injuries are rare and often poorly reported.

Aims: The overall aim of the thesis is to improve the evidence-base around the management of hand fractures and joint injuries. This will be achieved by informing the development of future RCTs in hand injuries.

This PhD thesis includes four projects: (1) a scoping review of the literature to highlight current research gaps and to identify common weaknesses in the design and reporting of hand surgery trials; (2) a multi-centre prospective cohort study of surgical patients presenting with proximal and middle phalangeal fractures (intra- and extra-articular), proximal interphalangeal joint (PIPj) bony volar plate injuries, and mallet finger injuries; (3) a Minimal Clinically Important Difference (MCID) study of the Patient Evaluation Measure (PEM) questionnaire; and (4) a nested qualitative study to explore patients' experiences of recovery and views about participating in hand surgery trials.

Scoping review: The aim of this study was to identify and assess all published randomised controlled clinical trials (RCTs) on treatment interventions for hand fractures and joint injuries. There were 78 published RCTs with trial interventions that were extremely heterogeneous, resulting in difficulty when trying to draw conclusions on the effectiveness and side-effects of individual treatments.

Conclusion: The published RCT evidence for hand fractures and joint injuries is narrow in scope and of generally low methodological quality. There is a need for high-quality, collaborative research.

Cohort study: Consecutive patients were recruited from fracture clinics in Nottingham and Cardiff (24/05/19 to 24/02/20) and asked to complete Patient Reported Outcome Measure (PROM) questionnaires. These were the PEM, the Patient-Reported Outcomes Measurement Information System Computerised Adaptive Test (PROMIS CAT) and EuroQol 5 dimensions (EQ-5D-5L) at baseline and then at 6, 12, and 24 weeks following presentation. Improvements in symptoms, function and quality of life were observed over the 6 months of follow-up, but patients' ratings generally did not return to pre-injury levels at 6 months. The PEM questionnaire was the most sensitive to change.

Conclusion: PEM is suitable for use as the primary outcome measure in trials, showing good sensitivity to change. Participants should be followed up for a minimum of 3 months, but might need follow-up for much longer as treatment response can be slow and was found to be still ongoing at 6 months in this study.

Minimal Clinically Important Difference (MCID) study: The aim of this study was to calculate the MCID of the PEM (range 11-77, lower score is better) at 24 weeks in order to inform the development and interpretation of future trials. The MCID for the PEM at 24 weeks was between 12-17 depending on the calculation method used. The MCID values were broadly consistent at different time points. The Minimal Detectable Change (MDC) was estimated to be 10.7 points.

Conclusion: The MCID calculations of the PEM will help in sample size calculations for future trials.

Qualitative study: Semi-structured interviews were conducted in 19 participants who were part of the cohort study. Though finger injuries were frequently seen as minor by the participants, their effects on them are greater than first anticipated. Experience of treatment and recovery varies significantly and is shaped by each patient's age, job, lifestyle and hobbies. Interviewees stated reluctance to accept randomisation in surgical trials, particularly if surgical and non-surgical interventions were to be compared. This was because they had a treatment preference and/or felt that there was a better treatment for their individual injury that the surgeon should know about.

Conclusion: People often coped by normalising the effect of these injuries by downplaying their effects in order to return to their daily lives. Because patients view their injury as

minor, they may be reluctant to take part in research. If the clinicians inform the patients that their injury can have major consequences, then patients might be more inclined to want to take part in research. Clinical equipoise and communication from researchers and the clinical team are essential to improve recruitment and retention.

Conclusions: Good quality RCTs for hand fractures are needed. The insight from this PhD project can help to plan future RCTs in this area.

Publications, presentations, conferences, courses, roles and awards

Publications
• Mousoulis C, Thomas K, Leighton P, Deshmukh S, Grindlay D, Karantana A. Treatment interventions for hand fractures and joint injuries: a scoping review of randomized controlled trials J Hand Surg Eur Vol. 2019; 45 (2): 111-118 https://journals.sagepub.com/doi/full/10.1177/1753193419865897 • Mousoulis, Christos; Thomas, Kim; Leighton, Dr Paul; Karantana, Alexia (2019): Study protocol. figshare. Preprint. https://doi.org/10.6084/m9.figshare.9677303.v1 • Deshmukh SR, Mousoulis C, Marson BA, Grindlay D, Karantana A. Developing a core outcome set for hand fractures and joint injuries in adults: a systematic review. J Hand Surg Eur Vol 2021; 46(5) : 488-95 https://journals.sagepub.com/doi/abs/10.1177/1753193420983719
Presentations
• Faculty Postgraduate Research Forum, Research Academy, as a 2min oral presentation and a e-poster, Wednesday, the 27th of June 2018 • Orthopaedics Monday lunchtime seminars on Monday, the 3rd of December 2018. • N-Trans Sandpit 1: Research presentations on Friday, the 8th of February 2019. • Presentation Skills For Researchers Graduate School course on Friday, the 25th of January 2019. • Research club presentation (Dermatology) – Wednesday, the 16th of October 2019

• Sue Watson presentation – compulsory for PhD completion – Tuesday, 29th of October 2019 (City Hospital) • Orthopaedics Monday lunchtime seminars on Monday, the 2nd of December 2019. • Further Presentation Skills For Researchers Graduate School course on Friday, the 25th of February 2020.
Conferences attended
• IDEAL International Conference in Bristol on the 13th and 14th of September 2018. • UK-RiME Annual Showcase in Nottingham on the 7th of September 2018.
Courses attended
• Nottingham Systematic Review course (June 2017) • Central Short courses by The Research Academy at the University of Nottingham over the 3 years of the PhD (compulsory) • Good Clinical Practice (December 2017 and December 2019) • Fundamentals of Clinical Trials by Nottingham Clinical Trials Unit (March 2018) • NIHR Valid informed consent (September 2018) • Qualitative Interviewing (February 2019) and Focus Groups (May 2019) by Social Research Association (SRA)
Roles and responsibilities
• Postgraduate Representative for Orthopaedics and Sports Medicine (March 2018-June 2020) • I represented the PG research students in various Departmental Staff meetings, Divisional teleconferences, Learning community forums, a Doctoral student consultation (June 2018) and an official Review of Education in the School of

Medicine about our student experience (Educational Enhancement and Assurance Reviews (EEARs)) (May 2019)

- I organised:
 - A Research club presentation for the Division (October 2018)
 - A PhD final Viva preparation training event (February 2020)

Grants and Awards

- Funding (£694.65) from the Nottingham Orthopaedic Walk (NUH charities) in order to purchase a Dictaphone

List of abbreviations

AUC	Area Under the Curve
BPSC	Between Patients Score Change
BSSH	The British Society for Surgery of the Hand
CONSORT	Consolidated Standards of Reporting Trials
COS	Core Outcome Set
COSMIN	COnsensus-based Standards for the selection of health Measurement INstruments
CRPS	Complex Regional Pain Syndrome
DASH	Disabilities of the Arm Shoulder and Hand
DRF	Distal Radius Fracture
EQ-5D-5L	Euro-QoL – 5 Dimensions – 5 Levels
GROC	Global Rating of Change
ICC	Intra-Class Correlation
ITT	Intention To Treat
K wires	Kirschner wires
MCID	Minimum Clinically Important Difference
MDC	Minimal Detectable Change
MHQ	Michigan Hand Outcomes Questionnaire
MyMOP	Measure Yourself Medical Outcome Profile
NICE	National Institute for Health and Care Excellence
PEM	Patient Evaluation Measure
PIPj	Proximal Interphalangeal joint
PROM	Patient Reported Outcome Measure
PROMIS CAT	Patient-Reported Outcomes Measurement Information System
PRWE	Patient-Related Wrist Evaluation
RCT	Randomised Controlled Trial
SD	Standard Deviation
SEM	Standard Error of Measurement
UK	United Kingdom
VAS	Visual Analogue Scale
WPSC	Within Patients Score Change

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Declaration

I certify that the work presented in this thesis was the result of original research primarily conducted by myself with the specified guidance and assistance of:

- The scoping review was developed by my supervisors and myself. Dr Douglas Grindlay (information specialist) helped with the search strategy and the screening using EndNote. Mr Sandeep Deshmukh was the second assessor of the quality appraisal of the included studies. The data extraction was done by myself. The analysis and write up was done by myself with the aid of my supervisors.
- Project conception of the cohort (and qualitative) study was done by my supervisors and myself, with some help from Professor Tim Davis. The cohort (and qualitative) study ethics approval was conducted by myself and my supervisors. Miss Jessica Nightingale, Mr Ben Marson and Mr Simon Craxford, who were working in the department and doing a PhD at the time, answered some questions for my cohort study development.
- I recruited 179 participants for the cohort study from fracture clinic in QMC, Nottingham. The rest of the patients were recruited at Cardiff (second site). Mr Ryan Trickett was the lead investigator in the Cardiff site. The statistical plan for the cohort study was aided by Dr Sonia Gran and Dr Laura Howells. Statistical analysis was done in STATA by myself with the help of Dr Richard Pearson. The cohort study data analysis and writing were conducted by myself under guidance from my supervisors and Mr Ryan Trickett.
- The interviews were conducted in person or over the phone by myself. The analysis was done in NVivo with the guidance by Dr Paul Leighton. The write up was conducted by myself under guidance of my supervisors and Mr Ryan Trickett.

Supervision of this thesis was undertaken by Miss Alexia Karantana, Professor Kim Thomas, and Dr Paul Leighton. Mr Ryan Trickett was an external supervisor to this PhD thesis.

- This study was NIHR CRN adopted
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Chapter 1: Introduction

1.1. Why is this topic of importance? Identification of research priorities

Hand fractures and joint injuries have a significant impact on patients and healthcare resources. They are common and are associated with significant morbidity (Haughton et al., 2012). As the hand has an important function in terms of manual dexterity and fine movements, a hand fracture or a joint injury can affect a person's capability to work, study, play sports and even carry out activities of daily living, particularly if both hands are affected, thus having an impact on the person's mental health and quality of life.

The priority of studying hand injuries and the gap in the literature was highlighted at the recent James Lind Alliance (JLA) Priority Setting Partnerships (PSP) on common hand and wrist conditions, which reported its findings in November (Karantana et al., 2021).

Clinicians, academics and patients decided by consensus on the ten most common research uncertainties of the common conditions affecting the hand and the wrist through a JLA PSP. The top ten priorities included "which hand/finger/thumb injuries would benefit from surgical intervention over hand therapy or no formal treatment, considering both functional outcome and societal cost?" and "which patients with acute ligament injuries to the wrist benefit from surgical treatment rather than from non-surgical methods?" with another 11 priorities identified concerning hand or wrist trauma. The work included in this thesis aims to help lay the foundations for addressing the JLA PSP research priorities concerning hand fractures and injuries for the future. This is an area lacking robust evidence and with variability in practice (Haughton et al., 2012). Further work is needed to inform clinical practice and help plan future high quality clinical trials for key injuries.

1.2. Definition of hand fractures/joint injuries for the purposes of this PhD project

A pragmatic approach to defining the scope of this project was required. The first step in this project was to define the range of conditions that are covered by the terms 'hand fractures and joint injuries'. For the purposes of this thesis, hand fractures and joint injuries have been defined as (1) carpal fractures, such as scaphoid, hamate, lunate, and pisiform and others, (2) metacarpal fractures, (3) phalangeal fractures, (4) fractures at the base of

the thumb, and (5) any joint injuries such as dislocations or fracture dislocation, (6) avulsion tendon and joint ligament injuries which can be associated with a small fracture, (7) other ligament injuries to the hand, carpus or wrist.

Distal radius fractures were excluded as part of this thesis. This was because they are a well-studied clinical entity in themselves for which there is an abundance of recent intervention trials (Lee et al., 2018) and guidelines (BSSH, 2018), as well as large scale ongoing multicentre randomised controlled trials (Nuffield Department of Orthopaedics, 2018). This is in contrast to the rest of the hand/carpus for which the evidence base covering treatments for a large number and variety of bony/joint injuries is extremely poor. Therefore, it was felt that pooling the distal radius fracture RCT literature with the other hand/joint injury would result in bias both in terms of numbers but also the quality of included trials.

1.3. Epidemiology of hand fractures/joint injuries

Fractures and ligament injuries are some of the most common injuries treated in emergency departments. Hand fractures account for 19% of all fractures (Van Onselen et al., 2003). Half of all hand injuries are fractures (Bernstein and Chung, 2006). The incidence of hand fractures has been reported as 3.7 per 1000 per year for men and 1.3 per 1000 per year for women (Anakwe et al., 2011). Most hand fractures involve the metacarpals, but as a group of bones, the phalanges of the fingers (proximal, middle and distal) are most commonly fractured (Van Onselen et al., 2003). Metacarpal and phalangeal fractures account for 75% of all hand fractures and carpal fractures account for 25% (Jindal et al., 2016). Scaphoid fractures account for 65% of all carpal fractures (Jindal et al., 2016). The right and left hand are equally involved in hand fractures (52% and 28% respectively), but 93% are right hand dominant (Van Onselen et al., 2003). The little finger sustains most of the fractures (38%) and then the ring finger (18%) (Van Onselen et al., 2003). Sporting activity accounts for 22.4% of all hand fractures (Aitken and Court-Brown, 2008). Patients with hand fractures are typically men aged between 15 and 35 years (Van Onselen et al., 2003). In the United States alone, there are around 18 million finger injuries per year severe enough to warrant a visit to a doctor or emergency department (Bernstein and Chung, 2006). This results in a loss of 3-4 million work days per year (Bernstein and Chung, 2006).

Characteristics of hand fracture and joint injury populations from the published literature are summarised in Table 1. Hand fractures and joint injuries are common in young men and they happen during sports activities, motor vehicle accidents and from getting into fights or punching a hard surface (AlMugren et al., 2016). Overall, males are more likely to have a hand fracture or a finger dislocation than females (AlMugren et al., 2016). Most hand fractures occur at home and are usually accidental (Chung and Spilson, 2001) (Ootes et al., 2012) where deprivation is a risk factor (Curtis et al., 2016). Finger dislocations usually occur during sports (especially basketball and football) (Golan et al., 2016) with an incidence rate of 11.11 per 100 000 person-years in the US (Golan et al., 2016). Young males are predominantly affected (Golan et al., 2016). Hand fractures and joint injuries result in work-days lost. In the elderly, they more often occur as a result of a fall from a standing height, presumably as a result of increasing osteoporosis.

Table 1: Population and injury characteristics for hand fractures and joint injuries

Seasonality	• The incidence of hand fractures remains relatively constant throughout the year, except for a decrease during the summer months (Van Onselen et al., 2003).
Age	• The average age of patients with hand fractures is 32 (Van Onselen et al., 2003). • The average age for men is 29.4 (SD 14.7) (Anakwe et al., 2011). • The average age for women is 44.1 (SD 22.8) (Anakwe et al., 2011). • Most hand fractures (45%) occur between the ages of 15 and 34 (Van Onselen et al., 2003). • For finger dislocations, the mean age of presentation 28.4 years. The highest rate is in 15-19 year-olds (Ootes et al., 2012).
Sex	• 73% of hand fractures are sustained by men (Anakwe et al., 2011). • The male to female ratio was 1.8:1 (Van Onselen et al., 2003). • The incidence rate for men was higher than that for women until the 6th decade of life (Van Onselen et al., 2003).

	• Men are more likely to have a metacarpal fracture (62% of men) (Anakwe et al., 2011). • Women are more likely to have a phalangeal fracture (58% of women) (Anakwe et al., 2011). • Men are more likely to have the injury after an assault/punch (32% of men) and sport (28% of men) (Anakwe et al., 2011). • Women are more likely to have the injury after a fall (40% of women) or sport (15% of women) (Anakwe et al., 2011). • For finger dislocations, males are more likely to be injured (78.7%) with a 17.8 per 100,000 person years rate in comparison to a 4.65 per 100,000 person years for females (Ootes et al., 2012)
Setting of injury	• Most fractures occur at home (30%) or in sports (14%) (Chung and Spilson, 2001) • Accidental falls are the cause of the majority of fractures (47%) (Chung and Spilson, 2001) • For finger dislocations, 35.9% occur in a sporting or recreational facility, in particular (Ootes et al., 2012). • 44.7% out of all finger dislocations are sport related and either happen in basketball (25.6%) or football (21.5%) (Ootes et al., 2012). • 24.1% of finger dislocations happen at home (Ootes et al., 2012)
Deprivation	• Metacarpal fractures are associated with deprivation in men ($p=0.017$) (Anakwe et al., 2011). • More affluent patients are more likely to receive operative treatment (men $p=0.020$ and women $p=0.019$) (Anakwe et al., 2011). • For men both deprivation rate (OR 1.12) and younger age (OR 1.036) independently predict operative treatment (Anakwe et al., 2011). • While only lower deprivation rate (OR 0.846) in women (Anakwe et al., 2011).

1.4. Common patterns of injury

The hand encompasses a range of bones and ligaments that could be injured.

Hand fractures

In a comminuted fracture, the bone is broken into many fragments. In an open fracture, there is a wound as a result of the injury. In an intra-articular fracture, a joint is involved. In an extra-articular fracture, there is no joint involvement. A fracture may be associated with a tendon, nerve or a blood vessel injury.

Carpal bone fracture: Carpal bones are frequently fractured after a fall on an outstretched hand. The most common one is the scaphoid bone. A broken scaphoid bone is difficult to diagnose clinically and may not appear as broken on hand X-ray initially. There needs to be a repeat X-ray or CT scan after immobilisation. The complications include non-union and avascular necrosis. Avascular necrosis is death to bone due to lack of blood supply. This is because the broken bone can lose access to the blood supply as the scaphoid is only supplied by two branches of the radial artery.

Metacarpal fractures: Fractures of the metacarpals account for up to 40% of hand fractures (Haughton et al., 2012). Fractures of the fifth metacarpal are known as 'boxer fractures'. Fractures of the first metacarpal are either type I injuries, which are known as Bennett's fractures, or type II, which are known as Rolando's fractures. Complication of fractures of the shaft of the metacarpals are that they tend to heal in a dorsal angulation and rotational deformity (Rommens, 1988).

Phalangeal fractures: Phalangeal fractures are common as phalanges are easily trapped or crushed (Figure 1). Phalangeal fractures account for approximately 26% of all missed fractures as they are difficult to spot and the clinician frequently does not request an X-ray (Haughton et al., 2012). Loss of productivity attributed to these fractures exceeds \$2 billion every year in the US (Carpenter and Rohde, 2013). The fractures of the distal phalanx mostly are stable and don't need a reduction (Rommens, 1988). In general, closed and minimally displaced fractures with good alignment can be treated conservatively (Eddy, 2012). Phalangeal fractures are fully immobilised for a maximum of 3 weeks followed by reduced immobilisation and active exercise (Eddy, 2012). Volar plate avulsion fracture

occurs after hyperextension injury to the PIP joint often during sports (Figure 1) (Eddy, 2012).

Joint/Ligament injury

Joint and ligament injuries are an important health problem. The incidence rate of finger dislocations, for example, is 11.11 per 100,000 person-years (Golan et al., 2016). A joint dislocation is when the two surfaces of the joint are no longer in contact with each other (BSSH, 2020a). A joint sprain is when an injury damages the tissues supporting a joint (e.g. the ligaments and the joint capsule) (BSSH, 2020b).

Carpometacarpal joint injuries: Carpometacarpal joint dislocation of the fingers are high-energy injuries following punching or forceful landing. Thumb carpometacarpal joint dislocation is associated with sports and motorcycle injuries. (Warwick et al., 2009).

Injuries of the thumb metacarpophalangeal (MCP) joint: Acute injuries of the thumb MCP joint are common (Warwick et al., 2009). There is consensus for the management of certain injuries, such as the Stener lesion. This lesion is where the ulnar collateral ligament (UCL) ruptures (or avulses a fragment from the thumb metacarpal base) and flips out from its position to lie superficial to the extensor hood. This means the ligament cannot heal (or the fracture fragment unite). Hence surgery is required to prevent instability. Skier's thumb is an injury to the ulnar collateral ligament of the MCP joint (BSSH, 2020f). It usually happens when one falls onto the outstretched thumb, especially if the thumb is gripping something at the same time, e.g. falling when skiing (BSSH, 2020f). There may be an associated fracture (BSSH, 2020f). Treatment consists of either a period of splintage or a repair of the ligament with an operation (BSSH, 2020f). Less often is a chronic stretching of the ligament (gamekeeper's thumb) without an acute injury, which leads to a loss of strength when pinching or gripping (BSSH, 2020f).

Dislocations of the proximal interphalangeal joint (PIP joint): Dislocations of the PIP joint are extremely common and appear with or without a fracture. Ball games are a particular hazard for these injuries. Dorsal dislocations of the PIP joint are the most common and occur due to hyperextension of the PIP, with volar plate disruption and may have a small avulsion fracture (Earp and Waters, 2007). The most common complication of this injury is a pseudo-Boutonnière deformity with PIP flexion contracture (Earp and Waters, 2007). The majority of PIP injuries have partial soft tissue tears and can best be treated with buddy taping, short-term splinting, and early range of motion (Earp and Waters, 2007).

Mallet finger: A mallet finger injury is a tear of the tendon that straightens the DIPj (Figure 1). Mallet finger follows a sudden flexion injury in sports (e.g. a ball hitting the end of an outstretched finger) or it can be very low energy (e.g. tucking in a bed sheet) (Warwick et al., 2009). The tendon may tear where it joins to the end bone of the finger, or it may pull off a small fragment of bone (mallet fracture). As part of treatment, the DIP joint is maintained in slight hyperextension via a splint for a minimum of 6 weeks (BSSH, 2020e). It is very important that the DIP does not bend during the splintage period even when the splint is temporarily removed for hygiene purposes (BSSH, 2020e). After this time, the splint is worn for one to two weeks at night or when it is at risk of injury (BSSH, 2020e). Most injuries treated with splintage will heal satisfactorily (BSSH, 2020e). If the tendon fails to repair itself, there may be additional period of splintage or a surgery (BSSH, 2020e).



Figure 1: A proximal phalanx fracture (top left), a middle phalanx fracture (top right), a volar plate injury (bottom left) and a mallet finger (bottom right)

1.5. Management of hand fractures/joint injuries

There is variability in practice in the management of hand fractures and joint injuries (Haughton et al., 2012). There is no consensus about the best management plans for these patients (Meals and Meals, 2013). Clinicians and patients make decisions based on individual preference, experience and availability of resources (Haughton et al., 2012). As it is not certain which treatments are best, evidence from research is needed.

The aim of the treatment for fractures is to restore function taking into account factors, such as handedness, occupation, hobbies, and co-morbidities (BSSH, 2020c). The treatment may be operative (e.g. by closed reduction/manipulation with K wires) inserted through the skin, open reduction and immobilisation with K wires, screws, or plates or open reduction with external fixation) or non-operative (Figure 2) (BSSH, 2020c). The patient may be given exercises by the hand therapists if there is stiffness (BSSH, 2020c). Fractures usually take 6 weeks to heal (BSSH, 2020c). The outcomes can be worse if there is an intra-articular fracture or a fracture causing damage to adjacent tendons or nerves (BSSH, 2020c). The treatment for finger dislocations and sprains aims to reduce the joint back into its position and restore movement in the injured joint (BSSH, 2020a).

Many injuries are managed by non-surgical options when possible. It is generally accepted that undisplaced or stable injuries recover well without surgery. For other injuries, operative techniques have been developed and their use increased with time. This trend has not been evidence-led. Surgery can help improve and maintain the position of fractures and/or allow quicker recovery in some cases, but has specific risks of scar-induced stiffness, infection, is generally more invasive and requires an anaesthetic. It is also potentially more expensive for the health service as it uses many resources, but studies to investigate this have not been done. For the same injury there are also often a multitude of different surgical techniques and non-surgical options that can be used for example different types of fixation (wires or plates) or different types of splints and exercise regimes.

The effects of these injuries can be compounded by complications such as malalignment, stiffness, non-union, avascular necrosis, complex regional pain syndrome (CRPS) and concurrent tendon or nerve injury (Markiewicz, 2013). Treatments can also have iatrogenic complications such as infection, nerve injury, sensitive scars, and stiffness (Markiewicz, 2013).

The diversity of hand injuries treated by different treatment modalities, as well as the lack of consistency in outcome reporting and research methodological standards make existing evidence difficult to interpret and apply to clinical practice. Further work is needed to inform clinical practice and help plan future high quality clinical trials (Karantana et al., 2021).



Figure 2: A proximal phalanx fracture (left), which was treated with an operation (screw fixation)

1.6. Introduction to Evidence based medicine (EBM)

1.6.1. What is EBM?

Clinical decisions in surgery should be based on evidence. “EBM is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients” (Hentz et al., 2005). EBM is the practice of individualised medicine. It uses the triad of (1) clinical expertise, (2) evidence from research studies and (3) patient ideas, values and expectations (Masic et al., 2008). It includes shared decision making with the patient.

There were traces of EBM in ancient Greece and ancient Chinese medicine (Masic et al., 2008). However, it was not until the 20th century that this had an impact in almost all fields of health care and policy. The idea of EBM appeared at McMaster University in Canada in 1988, but during the 1990s it became known throughout the world (Masic et al., 2008). Professor Archie Cochrane, a Scottish epidemiologist, was the founder of EBM and made EBM widely acceptable (Masic et al., 2008).

An example of evidence base is the Cochrane Library is a collection of databases in medicine and other healthcare specialities. The Cochrane Database of Systematic Reviews is a collection of systematic reviews. There are other databases, such as Cochrane CENTRAL (for controlled trials) (Masic et al., 2008).

1.6.2. Current trends in EBM

More recently, the value of EBM has been called into question on the basis that (1) statistically significant benefits may be marginal in clinical practice, (2) there is an overemphasis in following guidelines, and (3) EBM guidelines may map poorly to complex multi-morbidity (Greenhalgh et al., 2014). Other criticisms of EBM are: (1) EBM relies on reductionism of the scientific method, (2) EBM encourages formulaic ‘cookbook’ medicine, discouraging clinical reasoning, experiential and expert judgment, and (3) there is no high-quality evidence that its application has improved patient care (Djulbegovic and Guyatt, 2017). These issues are due to a poor-quality research conduct and reporting. Better quality research is needed. They are also due to a poor understanding of strengths and limitations of the approach, i.e. a focus on research evidence forgetting that clinical decisions are also

based on clinical expertise and the patient's ideas and expectations. It is unlikely that there will ever be a time when there will be research data for every single clinical decision.

In the future, EBM has to address the following challenges: (1) failure to publish and suppression of research results, and (2) evidence generated by so-called big data (Djulbegovic and Guyatt, 2017).

1.6.3. EBM in Hand Surgery

Surgeons have been slow to adopt EBM, possibly because designing and conducting high-quality surgical trials presents some unique challenges (Meshikhes, 2015). Potential solutions to improve EBM in surgery include: (1) educating surgeons at all levels, (2) the development of research projects by patients' needs, (3) encouragement of multi-centre trials, (4) encouraging patients to participate in clinical trials, (5) addressing ethical issues, (6) developing other studies in surgical areas where RCT is not feasible, and finally (7) emerging surgical technique should undergo a period of compulsory evaluation before general adoption is permitted (Meshikhes, 2015).

1.7. What is a scoping review?

A systematic review is 'a review of a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review' (Ham-Baloyi and Jordan, 2016).

A scoping review is a type of systematic review which identifies the nature and the extent of research evidence on a topic. It is the assessment of available published research with the aim of identifying the breadth of relevant evidence, as opposed to trying to answer a specific question (Grant and Booth, 2009). A scoping review can help to inform practice, policymaking and research (Colquhoun et al., 2014).

The stages of conducting a scoping review are: (1) identify the research question, (2) identify relevant studies using a systematic search, (3) study selection using inclusion and exclusion criteria, (4) charting the data using a data extraction form, and (5) collating,

summarizing, and reporting the results using an analytic framework or thematic construction. (Colquhoun et al., 2014)

The synthesis includes: a narrative around the quality and the quantity of the literature, perhaps by study design, and a map of the literature identifying key concepts, gaps (Colquhoun et al., 2014). An example, is the study by Takata et al. which looked at hand therapy interventions for issues such as osteoarthritis, tendon surgeries, and carpal tunnel syndrome (Takata et al., 2019). They organized interventions into 7 categories: education, exercise, activity, manual techniques, physical agent modalities, orthotics, and miscellaneous.

The strengths of a scoping review are that it shares some characteristics of a systematic review as it is systematic, transparent, and replicable and can inform whether a full systematic review is needed (Grant and Booth, 2009). The weaknesses include limitations in that it holds the potential for bias, if it does not include a quality assessment then the existence of studies rather than their intrinsic quality is the basis for conclusions which affects policy and practice recommendations (Grant and Booth, 2009).

1.8. Randomised controlled trials (RCTs)

RCTs are studies in which the intervention studied is compared to either an established intervention, no intervention or placebo. Patients are randomly allocated to either the intervention studied or the control arm. Table 2 shows the solutions to minimise bias in reporting of clinical trials.

Table 2: Solutions to minimise bias in clinical trials

Blinding
Good quality trials should be blinded whenever possible, i.e. there is concealment of group allocation from one or more individuals involved in the trial (Karanicolas et al., 2010). Surgical trials are difficult to blind, especially for the surgeon, who will know what operations he/she is performing, and for patients, who will know whether they had an operation or not. However, sometimes it is possible to achieve blinding in surgical trials. (Karanicolas et al., 2010). For example, outcome assessors can be blinded, unless the scar and the post-operative recovery makes it difficult. The trial team and people who do the analysis (e.g. the statisticians) can also be blinded.
Allocation concealment
Allocation concealment is different to blinding. Allocation concealment is the allocation of treatment conducted by someone who is blind to the treatment allocation schedule, so does not know what the next allocation will be. It aims to eliminate selection bias during the process of recruitment and randomization, whereas blinding seeks to reduce performance and ascertainment bias after randomization (Karanicolas et al., 2010).
Randomisation
Randomisation controls for known and unknown confounders which makes the patients in the two (or more) arms of the trial comparable (Suresh, 2011).
Intention-to-treat analysis
It is inevitable that some patients may change their treatment if this is not working. In intention to treat analysis (ITT) the results are analysed according to the treatment arm the patient was randomized to and not according to the treatment they received. ITT maintains the randomization and therefore confounders are not a problem (Losina et al., 2012). In per protocol analysis the results are analysed according to the treatment they received, but may be subject to the effect of confounders.

Investigators have suggested that doing RCTs in surgery is harder than other specialities (Ergina et al., 2013) (McCulloch et al., 2002). The issues with surgical trials are the resistance to randomization, the variability in management, the impact of surgeon's level of

experience and learning required to use new techniques, the issues with comparing operative and non-operative interventions, the implementation of blinding and the impact of crossovers from one trial arm to another (McCulloch et al., 2002) (Losina et al., 2012). This is a problem particularly if participants cross over from the non-surgical to the surgical treatments as it imbalances the trial, making interpretation difficult. This is unique to surgical trials as only the non-surgical group can cross over to the surgical and not the other way (the participants in the surgical group have already had the surgery), so contamination of the intervention is all 'one way'. Intention to treat analysis would only deal with a small amount of contamination. This is difficult to adjust for statistically. Furthermore, there is lack of equipoise on behalf of the surgeons; they think they know what is the best treatment for their patients.

Blinding in surgical RCTs is difficult to perform. A few examples are the following: (1) the type of scar displayed and the absence of scar in nonsurgical groups, (2) radiographs in orthopaedic implant cases, (3) the day of surgery or the surgeon's name, when a particular technique is performed only by one doctor, (4) different types postoperative care, (5) the surgeon as an observer for the assessment of the impact of an operation to the patient (Demange and Fregni, 2011). Blinding of personnel, statisticians, patients, doctors and outcome assessors should be done if possible.

Surgical studies show poor compliance with the CONSORT guidelines for trial reporting (Agha et al., 2007) (Balasubramanian et al., 2006) (Sinha et al., 2009) (Lewis and Warlow, 2004) (Ingram et al., 2010). These are a minimum set of recommendations for reporting of clinical trials in order to reduce bias in the assessment of results. Trials must be registered with a trial registry before patient enrolment so that there is transparency to performance and reporting of clinical trials (De Angelis et al., 2004).

There have been some studies which looked into issues with RCTs pertaining to hand surgery practice, such as publication bias (Sando et al., 2013), lacking outcomes that genuinely reflect real-world settings and concerns (Heneghan et al., 2017), and using outcomes that have not been validated for hand fractures/joint injuries (Valdes et al., 2016). Publication bias is when evidence from smaller trials and those with negative findings is less likely to be published.

1.8.1. Trial design

Pragmatic trials seek to determine the effectiveness of an intervention in a real-world setting to inform clinical decision making (Williams et al., 2015). Explanatory trials seek to determine the efficacy of an intervention under ideal conditions (Williams et al., 2015). The majority of the trials are neither entirely pragmatic nor entirely explanatory – they are part of a continuum (Williams et al., 2015). How pragmatic a trial is depends on the question that the study is trying to answer, i.e. is it about effectiveness or efficacy of the interventions for a particular clinical problem. The PRECIS tool is one method to assess where on the pragmatic-explanatory continuum a trial resides (Williams et al., 2015). The Readiness Assessment for Pragmatic Trials (RAPT) model enables interventionists to assess an intervention's readiness for a pragmatic randomised controlled trial (Baier et al., 2019). Even studies which claim to be pragmatic may deviate from usual care and pragmatism (Dal-Re et al., 2018).

1.9. Prospective cohort studies

Prospective cohort studies are defined as a study in which a group of participants are followed up in time to check their recovery and/or the development of complications or disease (Health Knowledge, 2017). In retrospective cohort studies both the exposure and outcome have already occurred at the outset of the study. This is less time consuming and less costly, but it is more susceptible to the effects of bias (e.g. adequate data on exposure and confounders may be unavailable) (Health Knowledge, 2017).

Well-designed observational cohort studies can play an important role in deriving evidence for surgical specialities if an RCT is difficult to conduct, e.g. for surgical procedures which have been used extensively and is widely accepted by surgeons (Song and Chung, 2010). In these, efforts have been made to reduce selection, information, non-respondent, and attrition bias, information on potential confounders has been collected and they have high internal and external validity. They have a duration of follow up that is enough for the information on outcomes (primary and secondary) to be collected and they maintain good levels of follow up (Table 3).

Table 3: Definitions of the different types of biases and validities in cohort studies

Bias	A systematic error in the design, conduct or analysis of a study (Hammoudeh et al., 2018).
Selection bias	When the sample obtained is not representative of the target population (Hammoudeh et al., 2018). Avoided by recruiting consecutive patients.
Healthy entrant effect	Comparing working individuals to the general population as workers are more likely to be healthier than the general population (Hammoudeh et al., 2018).
Information bias	Bias that arises in the collection, recall, recording or handling information in a study, including how missing data is dealt with (Hammoudeh et al., 2018). For example, misclassification, observer, recall and reporting bias.
Non-respondent bias	When those who respond are different to those that don't respond (Hammoudeh et al., 2018).
Attrition bias (losses to follow up)	Cohort participants may move to a different area, die or refuse to continue to participate in the study (Health Knowledge, 2017). Losses to follow up lead to missing data, reducing the study's internal validity (Song and Chung, 2010). They should not exceed 20% of the sample (Song and Chung, 2010). In order to minimize losses to follow-up, during enrolment one can exclude subjects likely to be lost and obtain information to allow future tracking (e.g. permission to use medical records) (Song and Chung, 2010). During follow-up, it is generally recommended that researchers maintain periodic contact by telephone or by mail (e.g. newsletters) (Song and Chung, 2010).
Confounder	A is a risk factor that is associated with the exposure and influences the outcome (Hammoudeh et al., 2018). Examples of a confounders in surgical trials are surgical performance and expertise, surgical complexity and pre-operative risk factors (comorbidities).
Validity	It refers to lack of systematic error (Hammoudeh et al., 2018).
Internal validity	Refers to the inferences made from the study that are related to the same source population as to whether or not the study

	has measured what it had originally planned on measuring (Hammoudeh et al., 2018).
External validity	Refers to the degree to which the study results can be generalised to other populations. If participants were not representative of the general population (or of the patients of interest) then the study results may not be generalisable to others (Hammoudeh et al., 2018)

1.10. Patient Reported Outcomes

A Patient Reported Outcome (PRO) is directly reported by the patient without interpretation of the patient's response by the clinician or anyone else and pertains to the patient's health, quality of life or functional status associated with health care or treatment (Weldring and Smith, 2013). Patient Reported Outcome Measures (PROMs) are tools to measure Patient Reported Outcomes (PROs). These are usually questionnaires that capture quality of life, functional status, and symptom burden, personal experience of care, and mental health and wellbeing (Weldring and Smith, 2013).

1.11. Minimal Clinically Important Change (MCID)

Traditionally, most hand surgery RCTs used objective clinical outcomes, such as grip strength and range of movement. PROMs are increasingly being used as outcomes in hand surgery RCTs. PROMs refer to the patient's evaluation of a health condition and its treatment.

The MCID is 'the smallest difference in a score that is considered to be worthwhile or important' (Beaton et al., 2002). Patients have a different view of when they have changed or when are better than the clinicians. A change should be clinically meaningful and not just statistically significant (Copay et al., 2007)

A clinically important difference represents a change that would be considered meaningful and worthwhile by the patient such that he/she would consider repeating the intervention if it were his/her choice to make again (Copay et al., 2007). The MCID is a threshold value for such a change (Copay et al., 2007).

Jaeschke et al. 1989 (Jaeschke et al., 1989) were the first to develop the MCID calculation using a method to compare the significance of changes in scores in quality of life instruments with global rating of change scales. This study highlighted that there is variability among individuals as a limitation of this type of research (See Chapter 4 for more detail in the methods to calculate MCID).

1.12. Qualitative research

Qualitative research seeks to explore social process and human experience, ask about what, why and how, and seek to explore and explain (Cristancho et al., 2018). It seeks to find out how people interact and to explore, explain and describe the experiences and meaning of people's behaviour, experience and events. Qualitative research explores attitudes, behaviour, text, words, meaning, process, exploration, and patterns. Qualitative research explores subjective experience, whereas quantitative research seeks to find objective measurement (Tavakol and Sandars, 2014). Qualitative research helps to understand and make sense the reality created by individuals in groups. It is used to discover the underlying meaning of events and activities.

A nested qualitative study can complement a quantitative study. Synthesized together these different forms of data can support clear recommendations about the nature and the form of future research (O'Cathain et al., 2013).

Analysis of qualitative data is frequently inductive (based on the data, i.e. grounded in the phenomenon it explains), but can also be deductive (looking at certain things in the data pre-specified *a priori*) (Moser and Korstjens, 2018). Qualitative research might be inductive to fully prioritise the voice of the participant or it might be structured to look for specific things in a more pragmatic fashion.

1.12.1. Interviews

Interviews are the most common method of generating qualitative data in applied health research. Interviews can be flexible, powerful and they can capture complexity any topic (Britten, 1995). Interviews can be structured, semi-structured or in-depth depending on whether the interviewer asks pre-specified questions or mainly responds to what the interviewee wants to talk about during the interview (Britten, 1995) (DiCicco-Bloom and Crabtree, 2006). The interviewer should always be open, neutral, sensitive and clear to the interviewee (Britten, 1995). They aim to understand the interviewee's point of view. One of the most important aspects of an interview is that the interviewee can ask clarification questions which can help them feel at ease (DiCicco-Bloom and Crabtree, 2006). An issue with interviews is that respondents want to give the 'right' answer or tell the interviewer what they think they want to hear (Britten, 1995). This can be managed by explaining to the interviewee at the start of the interview that there is no right or wrong answer and data will be anonymised so that the interviewee just discusses their own experience.

1.13. IDEAL framework for evaluation of surgical interventions

The IDEAL framework for evaluation of surgical interventions in the different stages of surgical innovation is the following (Barkun et al., 2009):

Stage 0 and stage 1: This stage is called innovation and relates to the first time a procedure is done either in the initial pre-human work and the first time it is used in human beings. Safety is the main concern. Evaluation at this stage is with the development of agreed reporting standards for key outcomes (McCulloch et al., 2013).

Stage 2a: This stage is called development. In this stage the technical details have not been completely worked out and only few surgeons carry the procedure. Evaluation at this stage is with prospective development studies with transparent reporting of changes in technique (McCulloch et al., 2013).

Stage 2b: This stage is called early dispersion and exploration. In this stage many technical details of the operation have been perfected and more surgeons perform the procedure. Evaluation studies at the exploration stage are usually prospective and observational, and investigate skill and learning (Ergina et al., 2013).

Stage 3: This stage is called assessment. The innovation is becoming the standard of care. A definitive (preferably randomised) evaluation is carried out at this stage (Ergina et al., 2013).

Stage 4: This stage is called long-term implementation and monitoring. In this stage the procedure is the standard of practice and perhaps has replaced a previously existing one. Late or rare outcomes are monitored. The typical evaluation study design is a registry (McCulloch et al., 2009).

1.14. Specific solutions for progress in surgical research

The solutions for progress in surgical research include detailed prospective audit data collection, a comprehensive continuous performance evaluation, a comprehensive review of the evidence base is needed to indicate areas warranting new trials of old techniques, surgeons' and patients' equipoise, and the need for study types other than RCTs should be recognized (McCulloch et al., 2002). Trauma registries that measure relevant outcomes in the trauma population must be identified and implemented (Gabbe et al., 2008). In the UK, the Royal College of Surgeons recently developed a network of centres with expertise to address these issues, and major funding bodies have made surgical trials a priority (Catto et al., 2017). This initiative is working well, and the number of funded and successfully run RCTs in surgery has dramatically increased (Catto et al., 2017). Trainee surgeons need protected time to participate in clinical trials to advance the specialty, even if this might increase the time they spend away from the operating theatre, where they learn their craft (Morton and Bicknell, 2015) (Balch et al., 2016).

1.15. Thesis plan

There is poor evidence around the management of hand fractures/joint injuries (Haughton et al., 2012). Clinical decisions are based on expert opinion. There is a lot of variation in practice (Haughton et al., 2012). This PhD aims to improve the evidence base for the effective care of hand fractures/joint injuries. This thesis aim to guide the development of future high quality RCTs. Table 4 shows the four inter-related projects that this thesis consists of. Figure 3 shows an overview of the PhD project with a focus on impact. Figure 4 shows the GANTT chart of the thesis.

Table 4: The four inter-related projects as part of this thesis

Scoping review (Chapter 2)
To understand the number, type and quality of published RCTs in hand fracture and ligament injury. This enabled us to understand the strengths and limitations of the existing trials and identify research gaps for future research. The included studies were appraised using the Cochrane risk of bias tool (Higgins et al., 2017). The aim of the scoping review was to look at what has been done before and making it more accessible to hand community.
Prospective cohort study (Chapter 3)
The aim of the cohort study was to collect prospective outcome data (PROMs) on key injuries that are areas of uncertainty and potential for future trials. The data was collected on key finger fractures and joint injuries. This helped identify suitable PROMS and facilitate sample size calculations. This study included some primary data collection on outcomes.
Minimal Clinically Important Change (MCID) study (Chapter 4)
The aim was to calculate the MDC, and the MCID of the PEM questionnaire at 24 weeks using a variety of distribution and anchor methods.
Nested qualitative study (Chapter 5)
The aim of the qualitative study was to investigate barriers and facilitators in the design and delivery of RCTs in hand fractures and joint injuries from the patients' point of view.

The strength of this PhD thesis is that it addressed a JLA priority (management of hand fractures and joint injuries) and laid the foundations to future projects doing the same. It is novel in that it includes work on outcomes for patients with hand fractures/joint injuries in a scoping review and a cohort study (especially in that it used the PROMIS CAT questionnaire), it calculates MCID for finger injuries and looks at patients' recovery and views on research from the patients' perspective in the interview study.

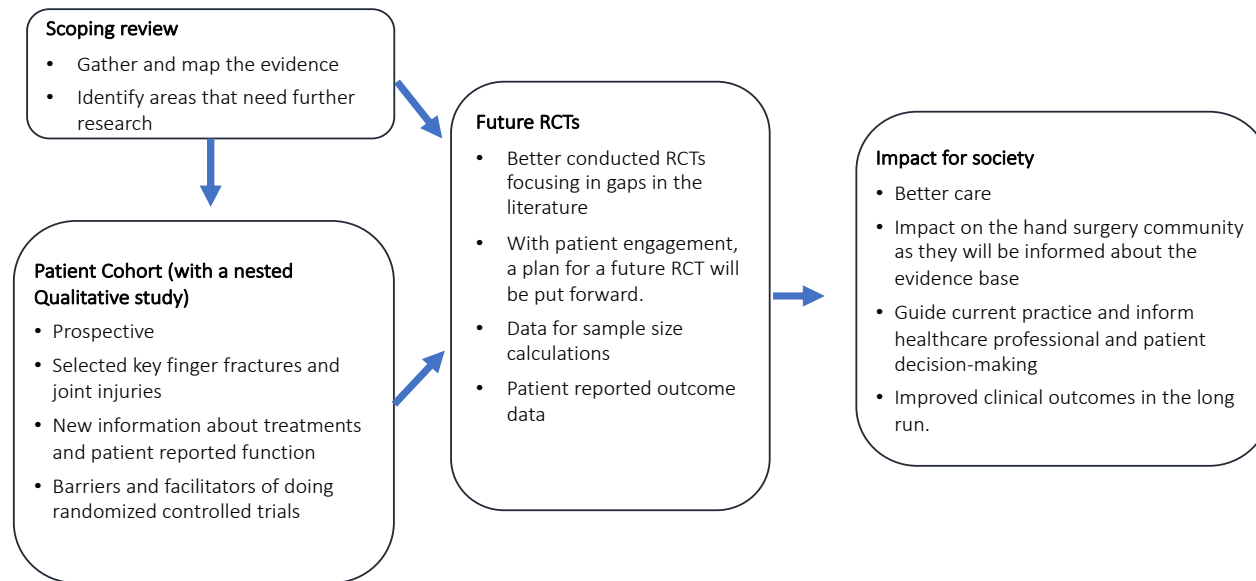


Figure 3: Overview of the PhD project

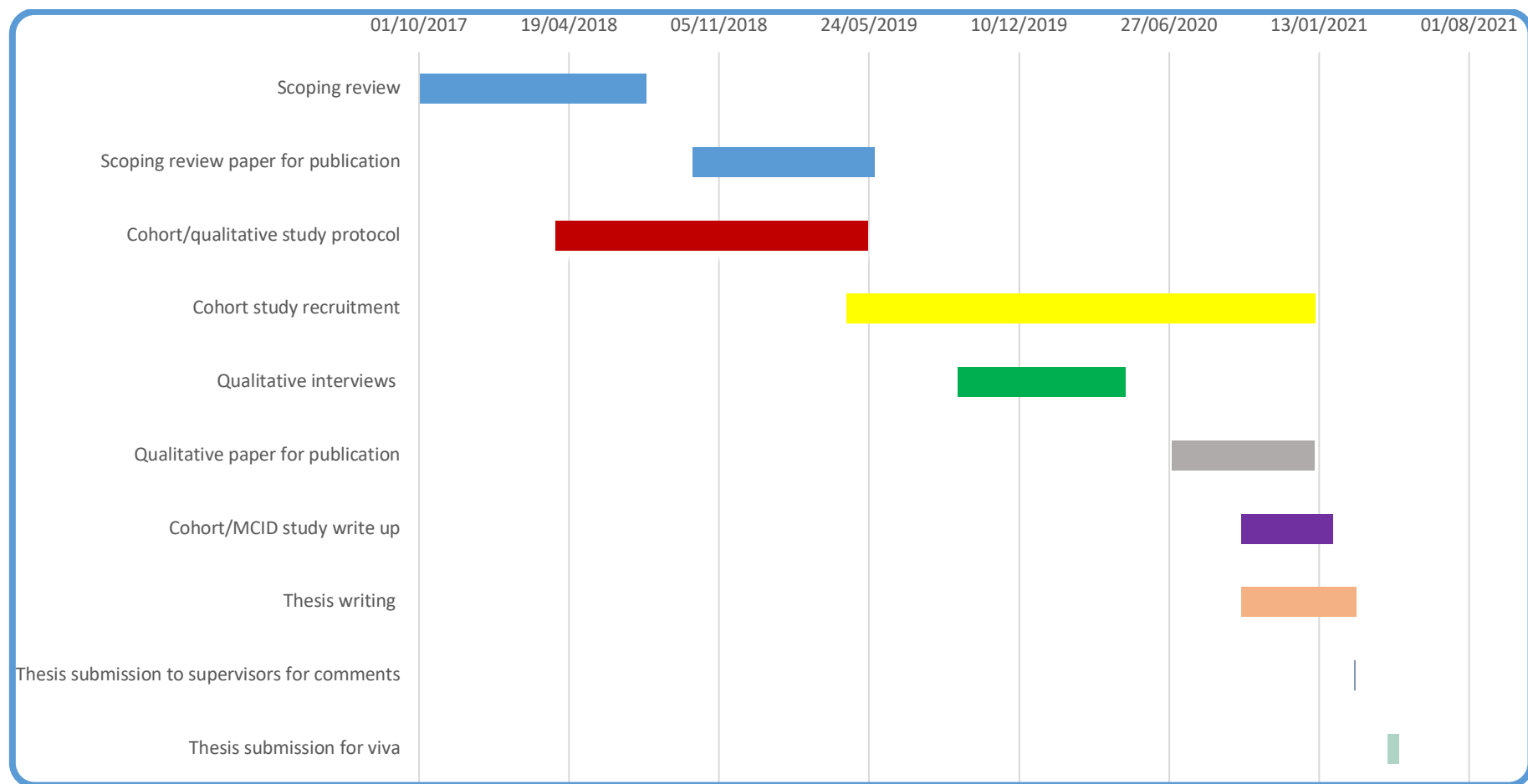


Figure 4: GANTT chart of the thesis

Aims of the PhD thesis

- To improve the evidence base for the management of hand fractures/joint injuries from a patient experience/wellbeing point of view
- To inform the development of future multi-centre randomised controlled trials on the treatment of common hand fractures/joint injuries.

Objectives

- To identify and assess existing randomized controlled trial (RCT) evidence on treatment interventions for hand fracture and joint injuries in order to inform practice and help plan future trials (via scoping review).
- To document recovery from finger injuries in terms of patient reported outcomes over six months from the time of injury, to describe the range of treatments received by injury type, health outcomes and to investigate losses to follow up over time (via cohort study).
- To inform future hand surgery trials by establishing the MCID for the PEM questionnaire for finger fractures. To calculate the MDC, to provide estimates of MCID for the PEM questionnaire using the different methods at 24 weeks compared to post-injury baseline and to assess whether timepoint of assessment influence the PEM MCID in finger fractures.
- To generate detailed, person-centred data about the experience of recovery from finger injury and experience of participating in clinical research, with a view to informing better designed future studies in hand injury (via qualitative study).

Chapter 2: Treatment interventions for hand fractures and joint injuries: a scoping review of randomised controlled trials

2.1. Summary

The aim of this study was to identify and assess all existing randomised studies on treatment interventions for hand fractures and joint injuries, to inform practice and plan future research. PubMed, Cochrane CENTRAL, MEDLINE and Embase were searched. There were 78 randomised controlled trials published over 35 years, covering seven anatomical areas of the hand. These were assessed and sample size, sources of bias, outcome measures and follow-up duration as well as retention are reported. In terms of interventions studied, the trials were extremely heterogeneous so it is difficult to draw conclusions on individual treatments. The published randomised controlled trial (RCT) evidence for hand fractures and joint injuries is narrow in scope and of generally low methodological quality. Mapping of these trials provides a useful resource and stepping-stone for planning further research. There is a need for high-quality, collaborative research to guide management of a much wider breadth of common hand injuries.

2.2. Introduction

The wide variety of hand injuries treated by different methods, and the lack of consistency in outcome reporting and research methodological standards make existing evidence difficult to interpret and apply to clinical decision making.

The importance of studying hand injuries and the gap in the evidence base was recently highlighted by the James Lind Alliance Priority Setting Partnership (Chapter 1) (Karantana et al., 2021). Further work is needed to inform clinical practice and help plan future high quality clinical trials (Karantana et al., 2021).

A scoping review is a type of systematic review that identifies the nature and extent of research evidence on a topic. It is the assessment of available published research with the aim of identifying the breadth of relevant evidence, as opposed to trying to answer a specific question (Grant and Booth, 2009) (see Chapter 1).

The aim of this scoping review was to identify and assess existing randomized controlled trial (RCT) evidence on treatment interventions for hand fracture and joint injuries in order to inform practice and help plan future trials. The objectives were to collate and map existing RCT evidence to the anatomical sites of hand fractures or joint injuries, appraise the quality of studies using a recognized risk of bias assessment tool, summarize outcomes used and assess the length of follow-up and retention rates in published RCTs.

2.3. Methods

The study was prospectively registered on PROSPERO (https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=102845). Preferred Reporting Items for Systematic Reviews and Meta-Analyses, Extension for Scoping Reviews (PRISMA-ScR) were followed (Tricco et al., 2018).

2.3.1. Scope and eligibility criteria

For the purposes of this review, hand fractures and joint injuries were defined as carpal fractures of the scaphoid, hamate, lunate and pisiform and others; metacarpal fractures; phalangeal fractures; fractures at the base of the thumb; any joint injuries, such as dislocations or fracture- dislocations; avulsion tendon and joint ligament injuries which can be associated with a small fracture; and other ligament injuries to the hand, carpus or wrist. Distal radial fractures were not included in this review which was focussed on the hand and carpus.

Inclusion and exclusion criteria are outlined in Table 5. Interventions included primary treatment (e.g. plaster or surgery for a scaphoid fracture), secondary treatment (e.g. treatment for scaphoid non-union or deformity secondary to the injury) and/or associated therapy interventions (e.g. physiotherapy). Trials were included without restrictions on publication time or language.

Table 5: Inclusion and exclusion criteria for the scoping review

Criteria
Inclusion criteria
Study design • Randomised controlled trials • Studies stated to be 'randomised' but for which there is inadequate information about sequence generation and/or allocation concealment • Quasi randomised studies Population • Adults with acute hand fracture(s) and/or joint injury(ies) of the hand • In studies of mixed populations (e.g. adults and children) a randomized controlled trial is included if 90% or more of the population meet the eligibility criteria Intervention • Any intervention for the treatment of hand fractures and joint injuries. This includes primary, secondary treatment and/or associated therapy interventions Comparator • Any other intervention for the treatment of hand fractures and joint injuries as described above • Placebo or no intervention Study report characteristics • Full study reports published in peer review journals • Abstracts of completed studies, if the full study report is not yet available • No timeframe restrictions for trial report publication • Studies in any language
Exclusion criteria
• Separate publications of economic evaluation of the primary trial • Studies of treatment for distal radial fractures • Studies where the primary injury is trauma of nerve, vessel, tendon and/or soft tissue deficits • Review articles, unpublished and ongoing trials

2.3.2. Search strategy

The search strategies were compiled with guidance from an information specialist with hand surgery expertise. The search strategy was constructed in four parts:

- (1) names of bones, joints and ligaments of the hand (e.g. phalanx, scaphoid, collateral),
- (2) general terms for fractures and joint injuries (e.g. fracture, dislocation),
- (3) specific terms about hand fractures and joint injuries (e.g. boxer's, Stener, gamekeeper's thumb), and
- (4) the sensitivity-maximizing version of the Cochrane RCT filter;

(1) and (2) were combined using the Boolean 'AND' which was then combined with (3) using the Boolean 'OR'. The findings were then combined with the RCT filter (4) using the Boolean 'AND'. The search terms are detailed in Appendix 1.

The databases searched were PubMed, Cochrane CENTRAL, Ovid MEDLINE, and Ovid Embase. The details of coverage and the interfaces used are shown in Table 6. The search was carried out on 27 of December 2017.

Table 6: Databases searched

Database	Interface	Coverage
PubMed	PubMed	1946-present
Cochrane Central Register of Controlled Trials (Cochrane CENTRAL)	Wiley	1999-present
Embase	OVID	1980-present
MEDLINE	OVID (In process and non-indexed)	1946-present

2.3.3. Data management, quality assessment and data extraction

Records identified via the searches were imported into EndNote X7 (Thompson Reuters, New York, NY) and duplicates removed. Two review authors (Dr Christos Mousoulis and Dr Douglas Grindlay) independently screened all titles and abstracts for potentially eligible

studies, for which full-text reports were obtained where appropriate. The quality (risk of bias) of included studies was assessed independently by two assessors (Dr Christos Mousoulis and Mr Sandeep Deshmukh) using the Cochrane Risk of Bias tool for randomised controlled trials and quasi-random studies (Higgins et al., 2017). Disagreements were resolved by consulting a third review author (Miss Alexia Karantana) and discussion. One review author (Dr Christos Mousoulis) extracted the data, using a pre-piloted standard data collection form (Appendix 2). Data extraction included details of the population, intervention, comparator and outcomes (PICO) for all included trials, external funding source, registration with a trial repository, sample size, sample size calculation, method of randomization, RCT study design (single or multi-centre), and whether intention-to-treat analysis was performed. Length of follow up, losses to follow-up and the outcomes (primary, secondary) were also extracted.

2.3.4. Mapping and data synthesis

The studies were mapped according to the anatomical site of the fracture or joint injury. A narrative descriptive synthesis of the findings, structured around the anatomical site of the hand fracture or joint injury, is presented. Descriptive statistics (proportions, median with range, mean with standard deviation) were used to report study characteristics. Linear regression was used to test the association between length of study follow-up and study retention rates.

2.4. Results

The study selection process is demonstrated via a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart (Moher et al., 2009) (Figure 5). Seventy eight RCTs fulfilled the eligibility criteria and were included. The authors of three studies were contacted as it was unclear whether they were randomised. One confirmed that the study was an RCT (Sourmelis et al., 1995), one that the study was a cohort study (Gabler et al., 2001) and no reply was received from the third (Toker et al., 2015), so the study was excluded. Details of the included studies, mapped by anatomical region, are presented in Appendix 3 (Tables 42-49), including report identifiers and the PICO outline for each trial.

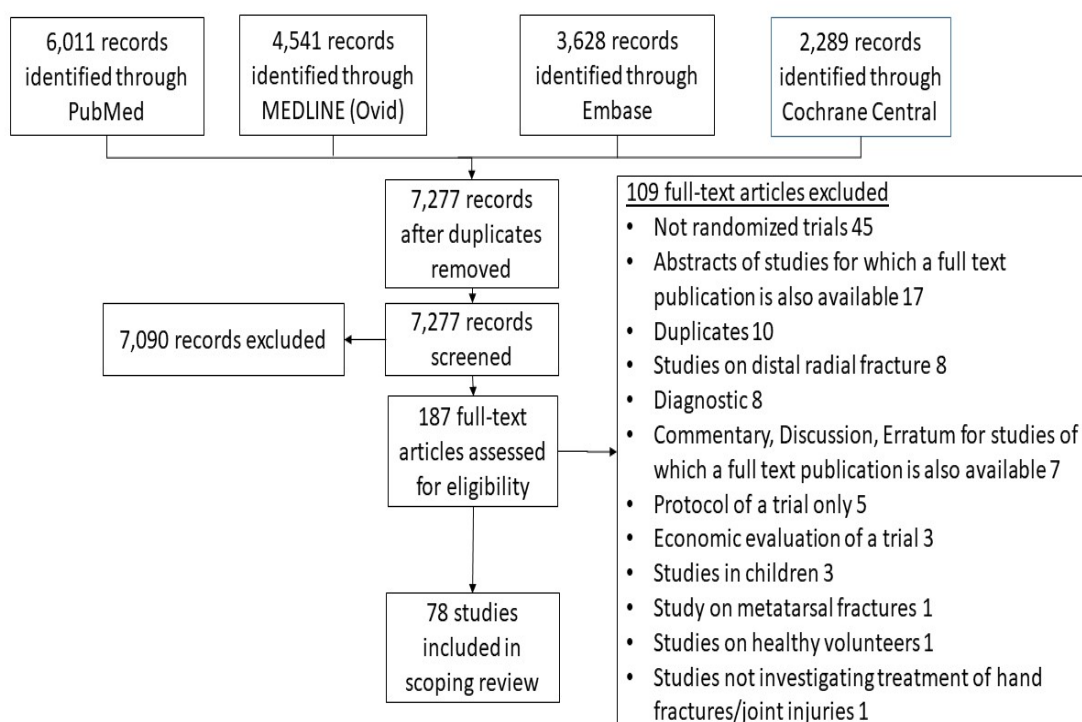


Figure 5: Review PRISMA flow diagram.

Trial publication dates ranged from 1982 to 2017 (Figure 6). Most trials were from European institutions [51/78, 65%], with fewer studies from North America (USA and Canada) [9/78 (12%)] and the rest from other parts of the world [18/78 (23%)]. The five countries which reported the highest number of trials were the United Kingdom [14/78 (18%)], the United States [8/78 (10%)], Denmark [7/78, (9%)], Netherlands [5/78 (6%)] and Sweden [6/78 (8%)]. Of the included trials, 46 (59%) were published after 1 July 2005, when the registration requirement for trials was implemented by the International Committee of Medical Journal Editors (ICMJE) (De Angelis et al., 2004); of those, only 8/46 (17%) indicated compliance by reporting registration in a clinical trial repository. Few trials reported a sample size calculation or intention-to-treat analysis, studies were generally small (under 100 participants) and single-centre (Table 7); median sample size was 54 (range 8-352). Only 14 of 33 (42%) trials that looked at operative treatment interventions reported the training/experience of surgeons.

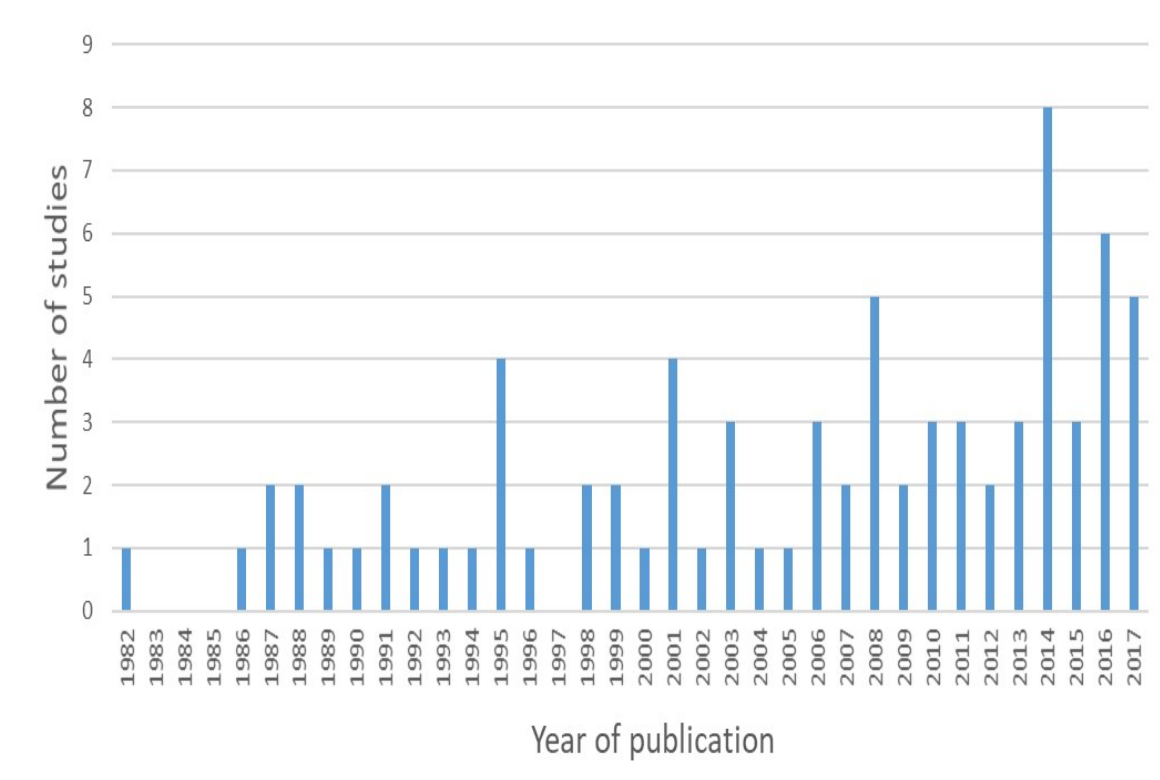


Figure 6: Distribution of trials per year of publication.

2.4.1. Mapping

The trials were mapped according to the anatomical site of injury treated; this is presented visually in Figure 7. The four most common injuries studied were scaphoid fractures (28 trials), followed by metacarpal (23 trials), mallet fingers (ten trials) and proximal phalangeal fracture (five trials). One trial reported a mixed population of 'closed hand bone fractures'.

RCTs investigated the effects of a wide range of treatments, including Kirschner-wires, different types of splints, casts, or orthoses and exercise/rehabilitation programmes. An equal number of studies compared two different types of surgical treatment, and a type of surgical treatment compared to a type of conservative treatment, with the remaining comparing two conservative treatments (Table 7). Table 8 shows the different types of non-operative treatment assessed. Of the conservative treatments compared, 35/78 (45%) studies assessed different splints/casts/orthoses, 2/78 (3%) studies compared rehabilitation regimes, 4/78 (5%) electrical stimulation to no treatment, 2/78 (3%) ultrasound therapy to no therapy, 1/78 (1%), laser therapy to no therapy, and 2/78 (3%) studies compared pharmacological interventions. Appendix 3 presents details of all included RCT intervention comparisons, mapped by anatomical site of injury.

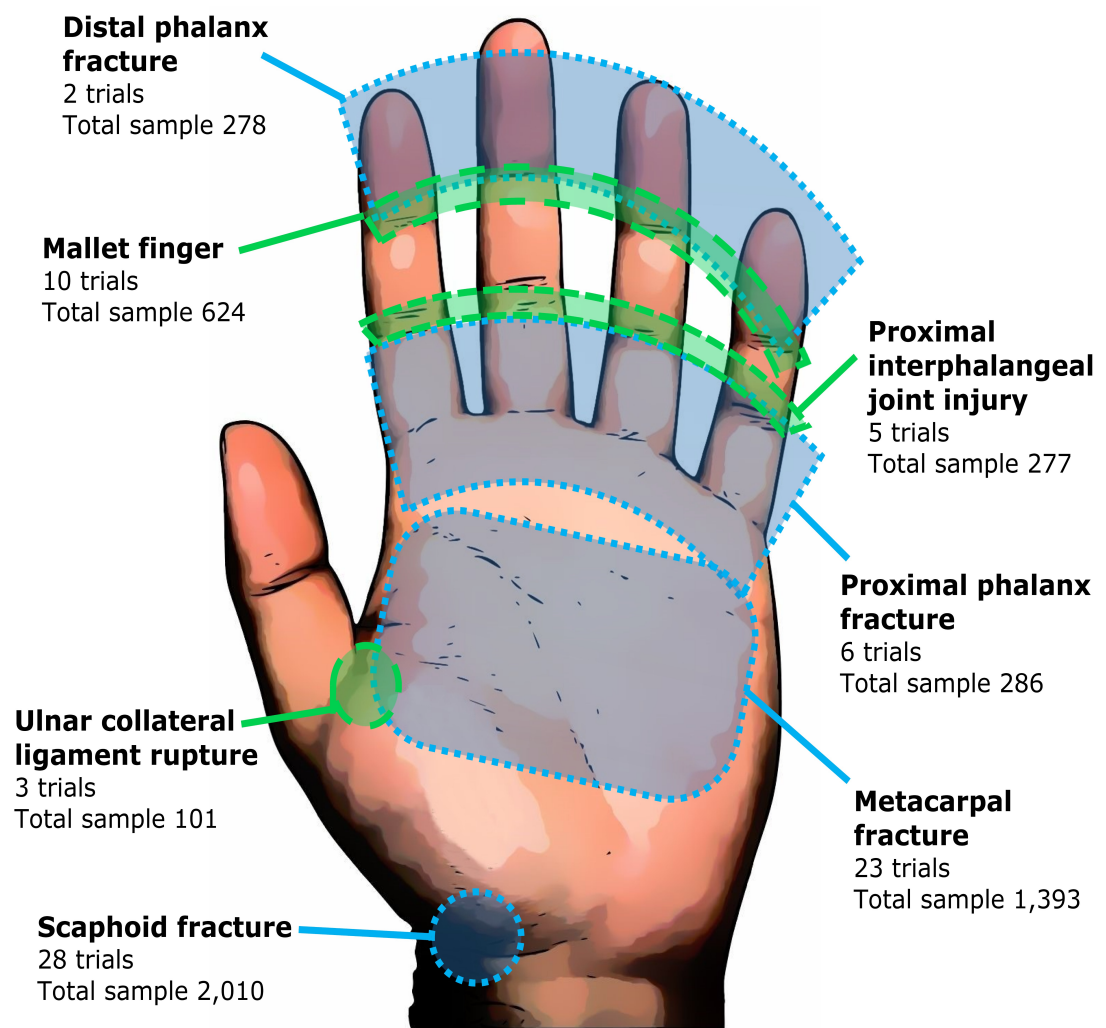


Figure 7: Mapping of the included randomised trials according to the anatomical site.

Table 7: Study characteristics

Study characteristics	n /N (%)
Studies published after 1 st July 2005	46/78 (59%)
Study report indicating registration in a trial repository	8/46 (17%)
Sample size > 100	12/78 (15%)
Studies reporting a sample size calculation	26/78 (33%)
Randomised controlled trial study design • Single-centre • Multi-centre • Inadequate information	49/78 (63%) 11/78 (14%) 18/78 (23%)
Randomisation • Randomised controlled trials • Quasi Randomised trials	73/78 (94%) 5/78 (6%)
Study report indicating intention-to-treat analysis	14/78 (18%)
External funding source	13/78 (17%)
Comparison type • Two different types of surgical treatment • A type of surgical treatment compared to a type of conservative treatment • Two different types of conservative treatment	16/78 (21%) 16/78 (21%) 46/78 (59%)

Table 8: Different types of non-operative treatments assessed in the included RCTs

RCTs for	Different types of non-operative management assessed
Scaphoid fractures	Plaster cast, below elbow cast including or excluding the thumb, Colles' cast, long and short thumb spica cast, munster thumb spica cast, pulsed electromagnetic field treatment, thermoplastic removable splint, supportive bandage
Metacarpal fractures	Immediate mobilisation, reduction and splint immobilisation, functional tape, ulnar gutter plaster cast, dorsal hood short arm cast, volar splint, home exercise program, traditional physical therapy program, ulnar plaster of Paris, functional brace made of Hexalite, elastic bandage, moulded metacarpal brace, neighbour strapping, short arm cast with volar outriggers, short arm cast

	extended to the proximal interphalangeal joint with a 3-point mould, functional cast (allowing the wrist and digits a free range of motion), compression glove and early mobilisation, Galveston metacarpal brace, dorsal/ulnar plaster cast, pressure bandage
Mallet finger	Pryor and Howard splint, aluminium orthotic device, night splint after 6-8 weeks of continuous splinting, perforated splint, 'stack' splint, dorsal/volar padded aluminium splint, custom made thermoplastic thimble splint, immobilisation using an orthosis, cast immobilisation using Quickcast, removable lever type thermoplastic orthosis, Abouna splint
Proximal phalangeal fracture	Functional forearm cast, Lucerne cast, wrist and finger exercises, static splinting
Fracture/dislocation of PIP joint	Dorsal block splinting of the proximal interphalangeal joint with daily exercises, closed reduction and immobilisation with a short arm cast, active range of motion, foam rubber covered aluminium splint, treatment with analgesics and no immobilisation, double finger bandage, Carstam splint, aluminium splint
Rupture of UCL	Percutaneous neuromuscular electrical stimulations which were superimposed to voluntary flexion, modified spica splint with freedom at the metacarpophalangeal joint, traditional spica splint, plaster cast, functional splint
Distal phalangeal fractures (open)	Short and long courses of antibiotics, no antibiotics
Closed bone fractures	Low level laser therapy, sham laser treatment

2.4.2. Quality assessment of trials

The quality assessment of included trials is visually summarized in the risk of bias graph (Figure 8). Appendix 4 details the quality assessment for each individual study. A common finding was that most of the studies which claimed to be "randomised" did not actually specify how the randomisation was done (i.e. coin toss, sealed envelopes, computer generated sequence or other) or whether or how the allocation sequence was concealed.

Only 24/78 (31%) scored “low risk of bias” for random sequence generation and 14/78 (18%) for allocation concealment.

Only a small proportion of studies reported blinding, with 8/78 (10%) studies blinding the participants and/or the study personnel and 20/78 (26%) blinding the outcome assessors. Most studies did not report on ‘blinding’ status. Very few studies [5/78 (6%)] referenced a study protocol. Studies published before 2003 generally tended to score “unclear” for many risk of bias domains, whereas those published after 2003 tended to report more of the information required for bias assessment, therefore scoring either “low” or “high” more often in the domains (Figure 8).

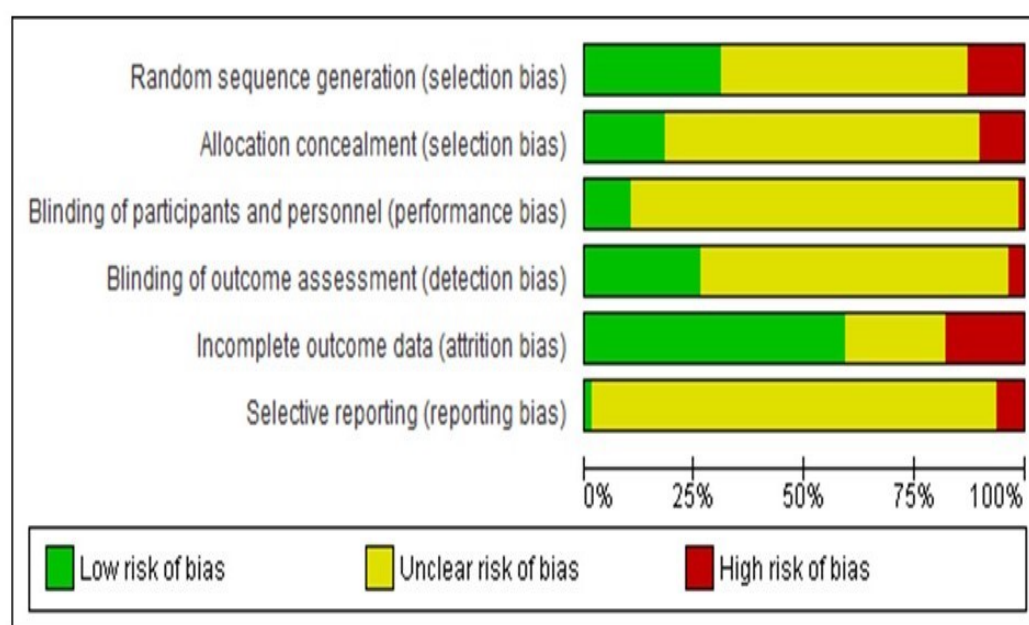


Figure 8: Risk of bias graph: authors' judgements about each risk of bias item presented as percentages across all included studies.

2.4.3. Outcomes and follow-up

Only 13/78 (17%) trials specified the primary outcome measure in full, including what was measured and when. The median time point for the assessment of the primary outcome out of 13 studies was 6 weeks (range 1-16). A further 4/78 (5%) trials specified the primary outcome, but this was incomplete, i.e. they did not report the time point of interest. The primary outcome was “blinded” in 10/78 (13%) trials. Only two trials selected a recognized standardized Patient Reported Outcome Measure (PROM) as primary outcome measure (the QuickDASH). Table 9 shows the outcomes assessed in included trials.

The maximum length of individual study follow-up was highly variable (median 24 weeks, range 1 to 624 weeks). Twenty-two studies (28%) had a maximum follow-up of 1 year or more. Follow-up (retention) data were reported in 50/78 (64%) of trials; in these trials retention was over 80% in 37/50 (74%) at the end of the study. This translates to reported follow-up over 80% for only 37/78 (47%) of trials. Retention rates of 70-80% were reported by 6/78 (8%) and 50-69% by 7/78 (9%) trials, with the rest providing no retention information at all. The median follow-up retention was 89% (range 55-100%) at the end of each study. Retention did not show an association with the maximum length of study follow-up (regression coefficient -0.008; $p=0.63$; 95% CI: -0.39 to 0.023).

Table 9: Outcome assessed in included trials

Outcomes	n/N (%)
Clinical measurements	64/78 (82%)
• Range of motion	45/78 (58%)
• Grip strength	33/78 (42%)
Radiological	32/78 (41%)
Pain	28/78 (36%)
Patient reported outcome measures (PROMs)	19/78 (24%)
• Disabilities of the Arm, Shoulder and Hand (DASH)	10/78 (13%)
• QuickDASH	7/78 (9%)
• Patient Evaluation Measure (PEM)	2/78 (3%)
• Patient-Related Wrist Evaluation questionnaire (PRWE)	2/78 (3%)
• Michigan Hand Outcomes questionnaire (MHQ)	1/78 (1%)
Return to previous occupation	15/78 (19%)
Overall satisfaction with the result	15/78 (19%)
Complications	12/78 (15%)
Physician-reported and/or composite outcome scores	5/78 (6%)
• Mayo Modified Risk score	2/78 (3%)
• Green/O'Brien score	2/78 (3%)
• Modified Scaphoid Outcome Scoring System	1/78 (1%)
Satisfaction with cosmetic appearance	4/78 (5%)
Quality of life (EQ-5D)	1/78 (1%)

2.5. Discussion

This comprehensive scoping review identified and assessed published RCTs on the treatment of hand fractures and joint injuries. It was guided by a search of publications developed with support from an experienced information specialist and used sound methodology informed by the PRISMA-SCR guidelines (Tricco et al., 2018). It has highlighted issues with design and reporting, informed by a recognised assessment tool (Cochrane Methods, 2018). It provides a reference for the planning of future studies as well a

repository of the included trials, mapped by topic (Appendix 3). It highlights the paucity of high-level evidence to guide the clinical management of people with hand injuries.

The review identified 78 trials published over a period of 35 years, which is a surprisingly small number. To put this number into context, a systematic review on the treatment of distal radial fractures identified 90 RCTs published over 5 years from 2010 to 2015 (Lee et al., 2018). The trials reviewed covered the minority of the anatomical areas of the hand susceptible to injury Figure 7. The commonest anatomical areas included represent either the common injury patterns, or those injuries with an unpredictable clinical course, contentious treatment strategies, or suboptimal outcomes. In terms of the interventions studied, the trials were extremely heterogeneous, and compared various types of operative and non-operative treatments, so it is difficult to draw any conclusions on individual treatments. There are further issues with the design, conduct and reporting of these trials, suggesting potential for bias.

Mandatory prospective trial registration came into effect in July 2005 (De Angelis et al., 2004). Of the RCTs published after this time, very few studies had been registered with a trial registry. Only a few studies referenced a study protocol and for the rest it is unknown whether a study protocol was available, but not reported. It was therefore not possible to assess for selective outcome reporting in studies without a protocol. In terms of quality assessment, most assessed bias domains were graded as unclear, reflecting the pressing need for greater clarity in trial reporting via the enforcement of adherence to CONSORT guidelines by researchers and journals (Nagendran et al., 2013).

Selection bias refers to systematic baseline differences between the two groups (Cochrane Methods, 2018). Randomization helps to control for known and unknown confounders and minimizes selection bias. Even though all studies were reported as randomised trials, the randomisation and allocation concealment methods were not described in many trials.

Very few studies were blinded, which introduces performance and detection biases.

Performance bias refers to the introduction of differences between the two groups other than the intervention (Cochrane Methods, 2018). Knowing which intervention a patient has received can affect the care provided by clinicians and the perception of recovery by the patients. Detection bias refers to systematic differences between groups in how outcomes are determined (Cochrane Methods, 2018). Knowing which intervention a patient has received can affect outcome assessment, especially of subjective outcomes such as pain. Though it is impossible to achieve blinding in many surgical trials, assessors should be

independent and blinded whenever possible. When it is not possible to blind, this should be stated. Most of the included trials did not discuss the blinding, or explained why they did not blind. Most studies also failed to report a sample size calculation and had a sample size of less than 100 participants, which is likely to be too low to draw meaningful conclusions with narrow confidence intervals (Corty and Corty, 2011).

Though most trials assessed outcomes likely to be reported directly by patients, such as pain and measures of satisfaction, only a small proportion of trials measured this in a standardised way that can be compared across studies, such as a standardised scale or patient-reported questionnaire. Only 24% used Patient Reported Outcome Measures (PROMs). The most frequently used PROMs were the DASH and QuickDASH, reflecting their prominence in orthopaedic publications. Furthermore, very few trials in this review specified their primary outcome, whereas they measured a wide range of heterogeneous secondary outcomes at differing time points (Table 9), precluding future meta-analysis in systematic reviews. This leads to research waste. This review indicates that more work on PROMs in hand injuries is needed. A core outcome set (COS) is the solution to this problem.

A core outcome set for trials relating to the treatment of hand injuries would substantially increase the transparency and consistency of reporting (Williamson et al., 2012). A core outcome set is a consensus minimum set of outcomes that should be measured and reported in all trials relating to a specific condition and is developed with the input of all relevant stakeholders, including patients, researchers, clinicians, and policy-makers (COMET, 2018). Furthermore, issues with poor design are important to highlight and address because a solution will require the endorsement and cooperation of researchers, funders, reviewers, journal editors, and the wider clinical community.

Length of follow-up was variable and participant retention at the final follow-up point was often not reported. Only 22/78 (28%) of trials had duration of follow-up of 1 year or more. Participant retention did not show an association with follow-up length, suggesting that either most studies reporting the percentages of follow-up at the last attendance were relatively short (median follow-up 24 weeks) or possibly that those which had high percentages of losses failed to report it.

Few trials of operative treatments reported the training/experience of surgeons (Giddins, 2015). Those that did said that the authors carried out the surgery. The authors were senior, likely to be enthusiasts with specialist knowledge, which would make the results less generalizable.

The low number of multi-centre studies and the lack of external funding shows that hand surgery needs to follow other specialties in conducting larger, collaborative studies.

The results of this review are compatible with other reports. Post et al. carried out an analysis of two major hand surgery journals for the level of evidence of RCTs (Post et al., 2013). They found that the lack of quality may be for a number of reasons, such as economic (i.e. trials in surgery lack comparable budgets to those trials funded by pharmaceutical companies), the relatively small and heterogeneous patient populations and the inability to blind surgeons and patients. They suggested that there is a need for high-quality publications, which could be achieved by the use of the CONSORT statement as a guideline to improve the quality of RCT reporting. A systematic review of all hand surgery articles published in six journals over a 20-year period found that the number of hand surgery articles has progressively increased over the last 20 years (Sugrue et al., 2016). Systematic reviews in hand surgery have found that there has been an increase in quantity of RCTs over time, but their methodological quality has remained low (Long et al., 2018). However, in terms of published systematic reviews, there has been an overall improvement in quality (Momeni et al., 2013). Furthermore, there has been an overall trend towards quality improvement of studies in hand surgery in the last 15 years (Barroso et al., 2017). There have to be efforts to improve quality of studies in hand surgery (Momeni et al., 2013) (Long et al., 2018). Future studies should measure health outcomes that patients consider important (Li et al., 2015). This was the first scoping review looking at interventions for the management of hand fractures/joint injuries. This scoping review added that future trials need to be well designed and focus on PROMs.

This is not a systematic review of the effectiveness of specific interventions, so clinically relevant conclusions about the effectiveness of treatments for a particular injury cannot be drawn. The comparatively low number of studies, heterogeneity of interventions, deficiencies in trial design and inconsistencies in outcome assessment make this very difficult, which is why so many systematic reviews in the field of hand surgery rely on lower levels of evidence by including non-randomized studies (Sugrue et al., 2016).

Chapter 3: Prospective cohort study for patient outcomes in the management of finger fractures and joint injuries

3.1. Summary

A prospective cohort study of participants with finger fractures and joint injuries with the aim of improving the development of future RCTs in the field was conducted. A total of 168 consecutive patients were recruited from fracture clinics in Nottingham and Cardiff (24/05/19 to 24/02/20) and asked to complete PROM questionnaires (Patient Evaluation Measure (PEM), the Patient-Reported Outcomes Measurement Information System Computerised Adaptive Test (PROMIS CAT) and EuroQol 5 dimensions Questionnaire (EQ-5D-5L) at baseline and then at 6, 12, and 24 weeks from presentation. The target recruitment of 30 participants per injury was met for three injury types (proximal phalanx extra-articular fracture, volar plate injuries and mallet finger injuries). Follow up rates were 70% at 6 weeks, 61% at 12 weeks and 68% at 24 weeks. PROMs showed improvement over the 6 months of follow-up, but generally did not return to pre-injury levels at 6 months. Based on this, we recommend that patients are followed up at least for 6 months in any future RCT. The PEM questionnaire was the most sensitive to change and should be set as the primary outcome measure in trials.

3.2. Background

A focus on finger fractures/joint injuries was chosen as this is more specific than the broad definition of hand fractures/joint injuries adopted for the scoping review (Chapter 2). There is a need for research in finger fractures and joint injuries as they are common and result in a heavy burden for patients and the NHS (Haughton et al., 2012) (Markiewicz, 2013). A study found that the incidence of finger fractures/joint injuries is 116 per 100,000 persons per year in US residents (Ootes et al., 2012). Another study found that phalangeal fractures account for 12.5 fractures per 10,000 persons and are more common in the 18-34 and the 35-49 year-old-groups (Karl et al., 2015). Phalangeal fractures are the most common type of fracture for males and that phalangeal fractures decrease with increasing socioeconomic status (Karl et al., 2015). According to a study using surveillance data, hand and wrist injuries annually account for \$740 million in the Netherlands with productivity costs

contributing more than direct health-care costs (de Putter et al., 2012). Hand and finger fractures were the most expensive group (\$278 million) largely due to high productivity costs in the age group of 20-64 years.

Though most finger injuries do well when treated, if untreated or suffering a serious complication, a patient may lose hand function permanently and this can have an impact on their activities and quality of life.

According to the scoping review (Chapter 2), there is minimal clinical research on finger injuries published and this has been of poor quality, but there is growth in the number of trials more recently. Even though finger fractures/joint injuries can happen at any age, they are more common in active young males, frequently in sports (Robertson and Wood, 2015). These are less likely to engage in research (Henderson et al., 2010) (Booker et al., 2011). The injuries require urgent attention and are treated conservatively and/or surgically (Eddy, 2012).

Finger fractures and joint injuries encompass a range of different injuries. For the purposes of this study the finger was considered as distal to the metacarpal bone of the index to little fingers. Thumb injuries were not included as the thumb is a distinct entity in hand surgery. It was decided to focus on proximal phalangeal fractures (intra and extra-articular), middle phalangeal fractures (intra and extra-articular), volar plate injuries, and mallet fingers (Figure 9). These finger injuries were selected because:

- (a) they are common,
- (b) there is variation in practice in their management,
- (c) there is no high-quality evidence to support clinical decision making,
- (d) they can be treated with or without surgery.

Distal phalangeal tuft fractures are not included as they are often not a substantial injury and are often self-limiting.

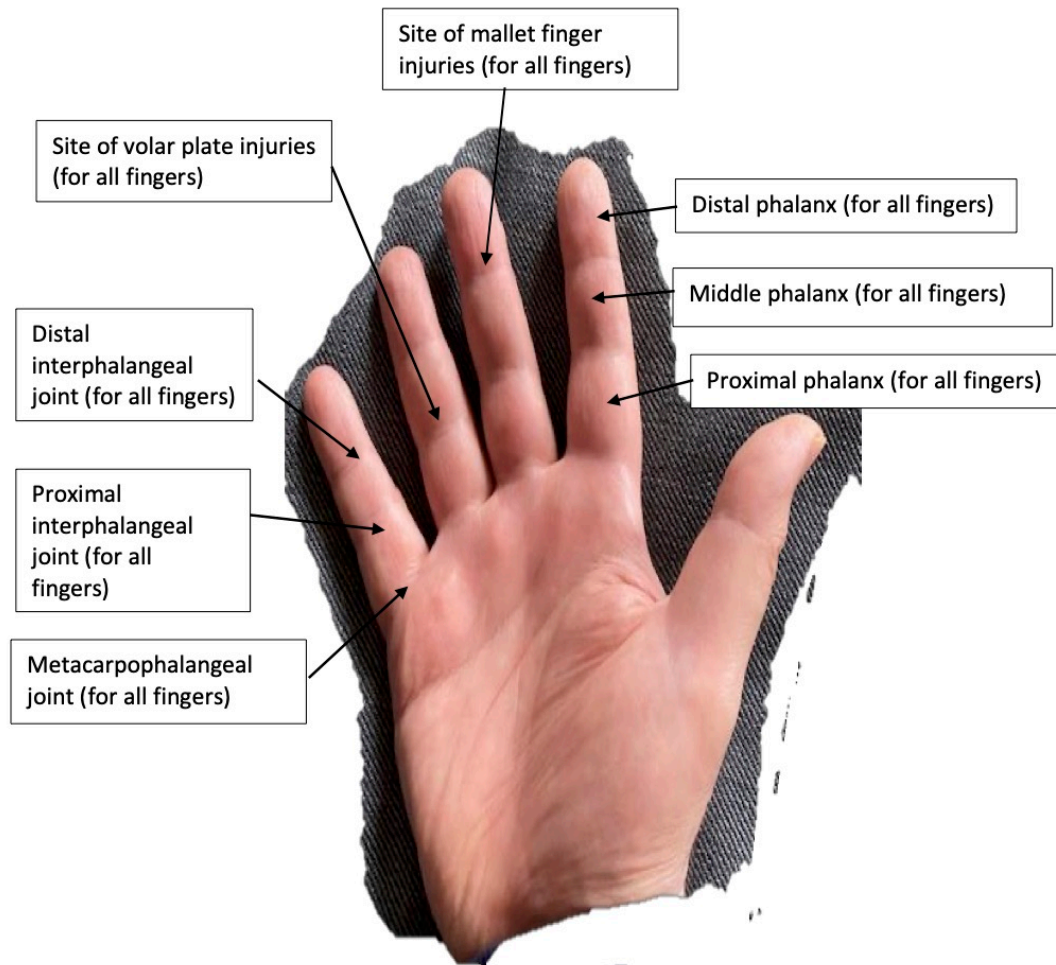


Figure 9: Infographic for finger nomenclature (bones, joints and injuries)

Proximal and middle phalanx fractures were of three different entities: (1) extra-articular fractures, i.e. shaft and metaphyseal, (2) intra-articular fractures of the phalanges, i.e. base proximal and middle condylar fractures, and (3) fracture dislocations of the proximal interphalangeal joint (PIPj).

A recent systematic review of the treatment of extra-articular proximal and middle phalangeal fractures recommended that closed displaced extra-articular phalangeal fractures can be treated non-operatively, provided that closed reduction is possible and maintained (Verver et al., 2017). No definite conclusion could be drawn upon which operative treatment is preferable if surgery is necessary (Verver et al., 2017).

Injuries to the hand vary in their treatments and outcomes, and all are treated by both non-surgical and surgical methods. Specific indications for varying treatment strategies vary but

in general volar plate injuries are generally benign and they are treated non-operatively unless a significant proportion of the articular surface is involved, leading to instability (Pattni et al., 2016). Non-operative treatment varies from doing nothing to therapy and/or dorsal blocking splints. Conservative management for closed, stable volar plate injury with splinting and hand therapy has good outcomes (Pattni et al., 2016). Mismanagements or delayed treatment can result in chronic PiPj problems, including stiffness, subluxation, and swan neck deformities, leading to weakness of grip and poor function (Pattni et al., 2016).

The vast majority of patients with mallet finger injuries are splinted for 6-8 weeks in the UK (BSSH, 2020d) with additional weeks of immobilization in cases of persistent lags (Valdes et al., 2015). A Cochrane systematic review found that there was insufficient evidence from RCTs to establish the effectiveness of interventions by a meta-analysis (Handoll and Vaghela, 2004). A systematic review suggested that outcomes for RCTs in mallet finger injuries should focus on activity, participation, environmental factors and quality of life. (Valdes et al., 2016).

Even though proximal interphalangeal (PIPj) fracture dislocations are not as common, results are generally poor for major injuries of this joint with regards to stiffness and deformity and there is great variation in treatments offered including different types of surgery and non-operative treatment (Freiberg, 2007).

This cohort study is needed to provide evidence for the development of future RCTs. The scoping review showed that there is lack of evidence to document recovery in terms of outcomes for these injuries, especially from the patient perspective (i.e. PROMs) and also lack of evidence of engagement and/or retention in research studies of these patients (Mousoulis et al., 2019). These are essential in developing and designing future studies such as RCTs. A cohort study is the most appropriate method to provide this evidence.

3.3. Methods

3.3.1. Aims and objectives

The aim of this study was to document recovery from finger injuries in terms of patient reported outcomes over six months from the time of injury.

The purpose of this cohort study was to inform the development of future multi-centre randomised controlled trials on the treatment of common hand fractures/joint injuries.

The secondary objectives were: (1) to describe the range of treatments received by injury type, (2) to characterise response in patient reported outcome measures, which will help facilitate sample size calculations for future trials and (3) to investigate losses to follow up over time.

3.3.2. Study design

A prospective cohort study was conducted. Approvals were sought by the University of Nottingham and NHS REC (Appendix 5). Ethical approval was given by NHS REC Coventry and Warwickshire (REC Reference 19/WM/0087).

The original protocol of this study has been published in Figshare.

https://figshare.com/articles/preprint/Study_protocol/9677303

3.3.3. Setting

This study took place in two UK hospitals (Nottingham and Cardiff). Consecutive patients with finger fractures/joint injuries coming through fracture clinics in Nottingham and Cardiff over a set period of time (24/05/19 -24/02/20) were approached as potential study participants.

3.3.4. Eligibility criteria

Inclusion criteria

- Skeletally mature adults (17 or over) attending hand fracture clinic as a new patient with any of the following finger injuries
 - proximal phalanx extra-articular,
 - proximal phalanx intra-articular,
 - middle phalanx extra-articular,
 - middle phalanx intra-articular fractures,
 - volar plate injury,
 - mallet finger

Exclusion criteria

- Injury older than 14 days at the time of presentation to hand fracture clinic
- Patient who would not be able to give consent, adhere to trial procedures or complete questionnaires.
- Non-English speakers

3.3.5. Recruitment

Recruitment took place in fracture clinic at Queens Medical Centre (QMC) in Nottingham and University Hospital of Wales and University Hospital of Wales and University Hospital Llandough in Cardiff. These were chosen because of availability of research team and different approaches to management of hand injuries. Non-operative management of finger injuries is favoured in Nottingham, whereas more operative interventions are used in Cardiff.

The direct clinical team screened new fracture clinic attendances for eligibility at both sites (Nottingham and Cardiff). Patients were approached by the direct clinical team and asked if they would be interested in taking part in the cohort study. If they agreed, a member of the research team (Dr Christos Mousoulis in Nottingham and NHS Trauma & Orthopaedics research staff in Cardiff) spoke to them about the study, provided the patient information sheets and answered any questions (Appendix 6 and 7). Patients were told that they could withdraw from the study at any point without giving any reason. The patient signed the

consent form (Appendix 8) and completed baseline questionnaires about demographics and the PROM questionnaires (Appendix 9 and 10).

3.3.6. Outcome assessment including specifics on each PROM used

Patients were further sent PROM questionnaires at 6, 12 and 24 weeks electronically or by post if they did not have access to email. These were the GROC, PEM, EQ-5D-5L, and the PROMIS CAT (Appendix 10). A core outcome set for hand surgery did not exist at the time of conducting the study. These PROMs were chosen because they are:

- In common use in UK research studies, short and specific for the hand (PEM), and preferred by patients in the PPI work (PEM) (see Section 3.3.12)
- established for quality of life and cost-effectiveness in the UK (EQ-5D-5L),
- and novel for finger injuries (PROMIS CAT).

The GROC, chosen for MCID calculations, is specific for patient assessment of improvement/deterioration recovery in their health state.

Patient Evaluation Measure (PEM)

This measures hand function. The patient scores their health on a scale from 1 to 7 on 11 outcomes such as the pain, movement, grip, appearance, and overall feeling of the injured hand. The range is 11 to 77. A low score represents improvement. PEM found to be comparable with other well-established questionnaires, such as Disabilities of the Arm, Shoulder and Hand (DASH) which is a 30-item self-rated upper extremity disability and symptoms questionnaire, in terms of validity and reliability in distal radius fractures and carpal tunnel syndrome (Hobby et al., 2005) (Henry, 2007) (Dias et al., 2008b). It is the primary outcome measure for the POINT proximal phalanx NIHR HTA trial in the UK and other NIHR HTA non-trauma studies of finger pathology such as DISC and Hand-2 Dupuytren's trials (NIHR National Institute for Health Research, 2019) (NIHR National Institute for Health Research, 2020). There is a 10 and 11 question version of the PEM, and the 11 question version was used in this cohort study (Hobby et al., 2005).

EQ-5D-5L

The measures quality of life at present moment. The EQ-5D-5L is a standardised instrument that has been validated in a diverse population in multiple countries in patients with a range of clinical conditions and normal health (EQ-5D, 2018). It provides health utilities for health economic analysis. Patients indicated their state of health (range 1-5) in five different dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). They also, indicated their overall health on the day of questionnaire completion on a scale from 0 to 100, with 0 meaning the worst health they can imagine and 100 meaning the best health they can imagine (EQ-VAS). A high score represents improvement.

The EQ-5D index is a single summary number which reflects how good or bad a health state is according to the preferences of the general population of a country or region. A high score represents improvement. The England standard EQ-5D valuation set from 2012 was used. A representative sample of the population in a country/region was asked to place a value on EQ-5D health states (EQ-5D, 2018).

PROMIS CAT

This measures function of the upper limb at present. It is a computerised adaptive test. For participants who do not engage with electronic means, a paper version is available. An observational cross-sectional study found a strong correlation between QDASH and PROMIS Physical Function-Upper Extremity Computer Adaptive Test (CAT), with shorter completion time for the latter (Beckmann et al., 2016). The PROMIS was thought to be valid, reliable and easy to use, with easy reference to population norms (Doring et al., 2014). A T score of 50 represents the norm in the United States and every 10 points represents a standard deviation from the norm. A high score represents improvement. The range was 18-61.

Global Rating of Change (GROC)

This is a global assessment of clinical change perceived by the patient (range -7 to +7, deterioration (-7 to -1), improvement (+1 to +7) or remained unchanged (0)) compared to a previous time point ("since they started treatment") (Jaeschke et al., 1989).

For this study, Global Rating of Change (GROC) was interpreted as follows

- <-3 deterioration
- -2 to +2 as unchanged
- >3 as improvement

The decision was between using (-1 to +1) or (-2 to +2) as unchanged. The latter was decided *a priori* because these were the cut-off points used in a previous PhD thesis in the department (Coughlin, 2018) and published data (Wright et al., 2012). Just to note that there are no universally agreed cut-off points.

Table 10 shows the data collection for the cohort study.

3.3.7. Outcomes

The primary outcome of interest was the PEM score at 6 months for all participants (and the individual injuries).

The secondary outcomes were the following:

- PEM scores (mean and SD, median and IQ range) at all time points (pre-injury, 6, 12, and 24 weeks) for all participants and for the individual injuries
- PROMIS CAT scores (mean and SD, median and IQ range) at all time points (pre-injury, 6, 12, and 24 weeks) for all participants and for the individual injuries
- EQ-5D-5L scores (including VAS and index) (mean and SD, median and IQ range) at all time points (pre-injury, 6, 12, and 24 weeks) for all participants and for the individual injuries
- Changes in the PEM from pre-injury to 6 months, for those patients with available pre-injury scores.
- GROC scores for each time point for all participants and for the individual injuries.
- Follow-up rates for each time point and overall

Table 10: Data collection for the cohort study

	Baseline (pre- injury)	Baseline (post injury)	6 weeks (online/ postal/ health records)	12 weeks (online/ postal/ health records)	24 weeks (online/ postal/ health records)
Demographics (age, sex, co- morbidities, dominant hand)	x				
Employment, occupation	x				
Injury (mechanism, type, date, severity)	x				
Details of primary treatment	x				x
Complications (from the hospital health records)					x
Hand Health Profile of the PEM	x	x	x	x	x
EQ- 5D – 5L	x		x	x	x
PROMIS CAT	x		x	x	x
GROC	x		x	x	x
Full recovery from injury Y/N			x	x	x

PEM: Patient Evaluation Measure, EQ-5D-5L: Quality of Life Questionnaire, PROMIS CAT: Patient-Reported Outcomes Measurement Information System Upper Extremity Computerised Adaptive Test, GROC: Global Rating of Change questionnaire

Complications were identified exclusively from medical notes, i.e. a patient would have to come back to fracture clinic with a complication to be picked up. There was no self-reported question of complications in the follow-up questionnaires. This was because it was thought to be an accurate and effective method of capturing complications as hand fracture care in both Nottingham and Cardiff is delivered in secondary care. The aim was to

reduce the burden of longer questionnaires on participants. Participants' perception of complications is not always clear and they will frequently say that they do not have a complication even if they might.

Patients were sent a total of three £5 thank you Amazon vouchers if they completed any of the follow up questionnaires, i.e. one at 6, 12 and 24 weeks.

3.3.8. Data management

Data collection and management complied with University of Nottingham and University of Cardiff internal protocols and NHS REC regulatory requirements. University of Nottingham was the sponsor of this study. University of Cardiff and NHS REC ethical approval was sought (Appendix 5). The data management plan for this study is in Appendix 11.

RedCAP was used (REDCap, 2019). This is a secure web-based application to capture data for clinical research and create databases. Personal identifiable information, such as name and address, was stored in a separate hard copy Masterfile.

Reporting of this study was using the STROBE guidelines (Song and Chung, 2010).

3.3.9. Sample size

The primary outcome was the mean PEM score and SD at 6 months. Sample size was based on precision, i.e. the width of confidence intervals for the PEM score at 6 months. The following formula was used: $N = (3.84 \times \sigma^2) / (w^2)$, where sigma = standard deviation of the PEM at 6 months from previous papers and w = width of the confidence interval of PEM at 6 months that would be narrow enough to be confident that the mean value calculated in this study is close to the true mean value of the population.

The SD of the PEM at 6 months sourced from the literature was 14 (Coughlin, 2018), and the confidence interval that was decided was 5. With sigma of 14 and w of 5, $(N = (3.84 \times (14)^2) / (5)^2 = (3.84 \times 196) / (25) = 753 / 25 = 30)$, the aim was for circa 30 patients for each injury (see Inclusion criteria) plus losses to follow up, making it a total of 210 patients for the 6 injuries.

3.3.10. Analysis

The data from questionnaires were analysed quantitatively using Excel (Version 16.47.1 for Mac, Microsoft Corporations, USA) and STATA (Version 13.1 for Mac, StataCorp, USA) software, using descriptive statistics with appropriate measures of spread (mean and standard deviation, median and interquartile range) for each data type. Data is presented in a study flow chart, tables and figures as appropriate.

Imputing of missing data was not appropriate for this study as this is not a comparative study. Imputing would increase the sample size and change the mean (and standard deviation). This will depend on the type of imputation and whether the data is missing at random or not. Imputation is likely to introduce bias in the analysis. Nevertheless, the characteristics of patients with follow up data and those with no follow up data were presented.

3.3.11. Modifications to study due to COVID-19 pandemic

The COVID-19 pandemic affected this study. Recruitment had to stop from February 2020 to July 2020 as the University of Nottingham and Nottingham University Hospitals NHS Trust halted the non-critical and non-COVID related research. However, remote follow up was continued. In Nottingham, follow up rates did not seem to be affected. Patients were reminded by email and by phone call to complete follow up questionnaires. On the other hand, the follow up rates in Cardiff were low during the pandemic as research staff locally had to prioritise COVID-19 research.

Recruitment resumed in Nottingham and Cardiff from July 2020. Recruitment rates were lower than before the pandemic as a result of lower numbers of these injuries in fracture clinic overall, indicating that patients mostly stayed at home and did not engage in high risk activity during the second and third national lockdown (for example contact sports) which would result in finger fractures.

Data lock for the purposes of the thesis was on the 15th of December 2020. For the cohort analysis only participants who had reached 6 months after injury were included, i.e. only those recruited before the pandemic. This is why the calculated sample size was not

achieved for this study. The research team will continue to follow-up all recruited patients to 6 months, and this data will be used in the final analysis prior to publication.

Learning points included the importance of maintaining contact with participants and sending reminders to improve follow up rates, and working with the researchers of the second site in order to support them to continue with recruitment as soon as they were able to.

3.3.12. Patient and public involvement (PPI) prior to cohort study and qualitative interviews

The cohort (and qualitative) study was informed by separate qualitative PPI work. Patients in the waiting area in fracture clinic were approached and provided feedback on study concepts, design and delivery. Participation was voluntary. 32/37 patient who were approached were happy to discuss and 5 declined. They were interviewed informally and asked questions about the aims of the study, how to optimise recruitment and retention, potential use of incentives, the study pathway and outcome measures.

For recruitment, patients discussed the importance of presenting the purpose of the study and how it will help patients and the service. If they can relate to this, they are more likely to agree to participate. Participation should be voluntary, and patients should be told that their treatment will not be altered in any way by this observational study. For retention, it is important to maintain contact with participants by regular newsletters and updates about the study. The questionnaires and patient information sheet were thought to be clear and concise. Interviews were thought to be useful and the interview guide was well received.

3.4. Results

3.4.1. Population

One hundred and sixty eight (168) participants were recruited in this cohort study from fracture clinic in Nottingham and Cardiff. The dates of recruitment were 24/05/19-

24/02/20 and after this recruitment was stopped because of lockdown due to the COVID-19 pandemic.

3.4.2. Flow chart

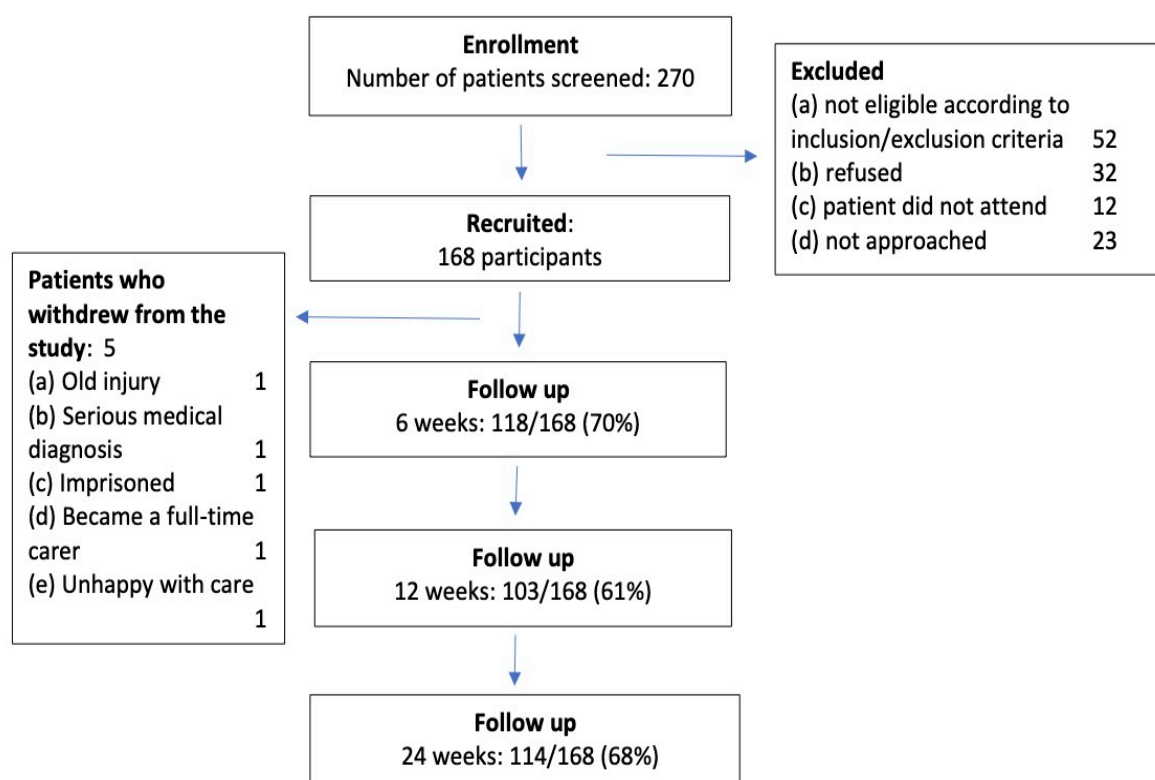


Figure 10: Flow chart of patients in the cohort study

The flow chart of the patients in the cohort study is shown in Figure 10. 12% of participants who were approached refused to take part in the study. Follow up rates around 60-70% at all time points. Some patients only completed the 12-week or the 24-week questionnaire and 20% gave no follow up data at all. Only 5 participants formally withdrew from the study after recruitment.

3.4.3. Demographics

Table 11: Demographics

	Proximal phalanx extra articular	Proximal phalanx intra articular	Middle phalanx extra articular	Middle phalanx intra articular	Volar plate injuries	Mallet finger injuries	Total
All	(n=48)	(n=17)	(n=12)	(n=11)	(n=41)	(n=39)	(n=168)
Age	40.8 (18.1)	31.9 (13.1)	36.3 (11.7)	31.8 (12.3)	37.2 (16.4)	48.9 (19.1)	40.0 (17.5)
Sex							
Women	23 (47.9%)	2 (11.8%)	4 (33.3%)	5 (45.5%)	22 (53.7%)	14 (35.9%)	70 (41.7%)
Men	25 (52.1%)	15 (88.2%)	8 (66.7%)	6 (54.5%)	19 (46.3%)	25 (64.1%)	98 (58.3%)
Employment							
Working	39 (81.2%)	12 (70.6%)	10 (83.3%)	9 (81.8%)	30 (73.2%)	29 (74.4%)	129 (76.8%)
Type of work							
Clerical	5 (10.4%)	1 (5.9%)	-	-	1 (2.4%)	3 (7.7%)	10 (6.0%)
Light manual	3 (6.2%)	1 (5.9%)	1 (8.3%)	2 (18.2%)	1 (2.4%)	1 (2.6%)	9 (5.4%)
Heavy manual	5 (10.4%)	1 (5.9%)	3 (25.0%)	1 (9.1%)	7 (17.1%)	6 (15.4%)	23 (13.7%)
Fine skill	2 (4.2%)	-	-	1 (9.1%)	1 (2.4%)	3 (7.7%)	7 (4.2%)
Other	24 (50.0%)	9 (52.9%)	6 (50.0%)	5 (45.5%)	20 (48.8%)	16 (41.0%)	80 (47.6%)
Self employed	4 (8.3%)	-	2 (16.7%)	2 (18.2%)	1 (2.4%)	4 (10.3%)	13 (7.7%)
Health							
Serious concomitant disease	3 (6.2%)	1 (5.9%)	-	-	4 (9.8%)	7 (17.9%)	15 (8.9%)
Taking regular medication	19 (39.6%)	4 (23.5%)	4 (33.3%)	5 (45.5%)	18 (43.9%)	21 (53.8%)	71 (42.3%)
Driving	37 (77.1%)	11 (64.7%)	9 (75.0%)	6 (54.5%)	24 (58.5%)	29 (74.4%)	116 (69.0%)

Demographics were summarised in Table 11. These are demographics of those willing to be recruited. Demographics of those screened were not recorded other than the reason for exclusion.

The target of 30 patients for each injury was achieved for proximal phalanx extra-articular fractures, volar plate and mallet finger injuries. As a result reporting of this study has

concentrated on these injuries, but other injuries are presented for information and transparency.

Overall for all injuries, more males than females were recruited, except only for volar plate injuries when more women were recruited. The participants had a wide age range (17-91 y), but mostly younger (Figure 11). Overall participants were very healthy with only a minority having a serious concomitant disease and taking medication. 13% of young people were students. Volar plate and mallet injuries were common and thus recruitment was stopped once there were about 40 participants. The average age of participants with mallet finger injuries was higher than for the other injuries.

With regards to PIPj fracture dislocations, 13 participants were recruited in this study (5 proximal phalanx intra-articular condylar fractures and 8 middle phalanx intra-articular base fractures). This was excluding volar plate injuries.

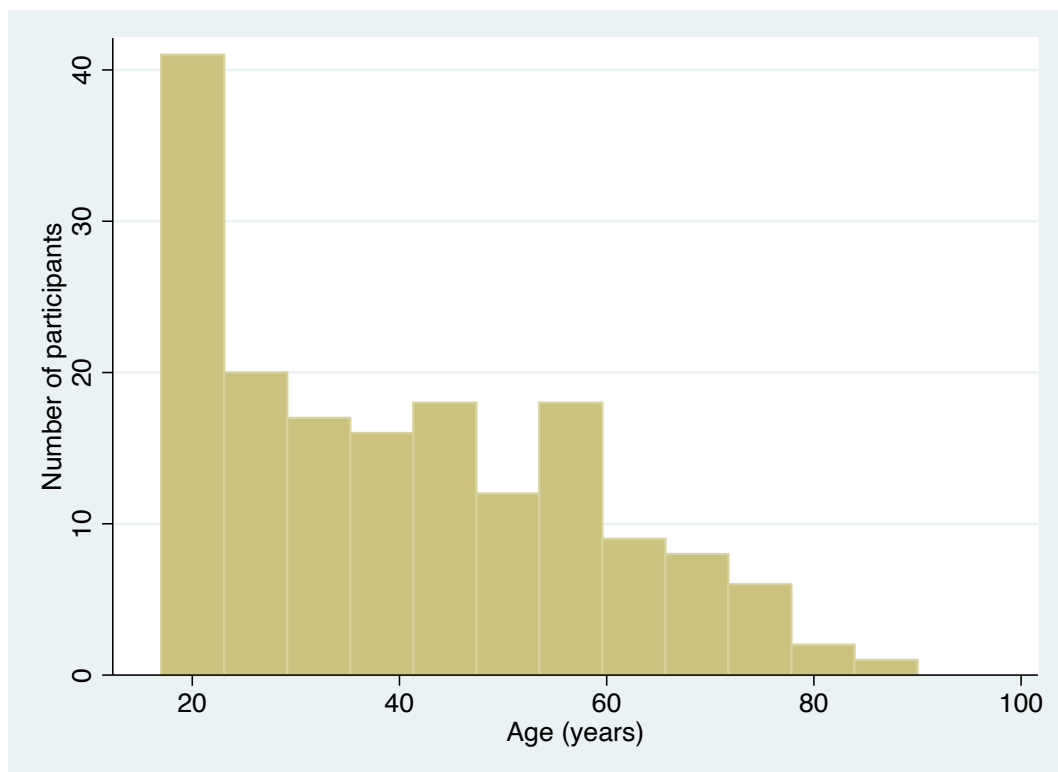


Figure 11: Age distribution for the whole cohort

3.4.4. Details of injury for patients in the cohort study

Table 12: Hand dominance and finger affected

	Proximal phalanx extra articular	Proximal phalanx intra articular	Middle phalanx extra articular	Middle phalanx intra articular	Volar plate injuries	Mallet finger injuries	Total
All	(n=48)	(n=17)	(n=12)	(n=11)	(n=41)	(n=39)	(n=168)
Injury in the dominant hand	24 (50%)	12 (70%)	5 (42%)	6 (55%)	21 (51%)	21 (54%)	89 (53%)
Finger affected							
Index	4 (8.3%)	4 (23.5%)	1 (8.3%)	1 (9.1%)	10 (24.4%)	2 (5.1%)	22 (13.1%)
Middle	4 (8.3%)	5 (29.4%)	2 (16.7%)	1 (9.1%)	10 (24.4%)	18 (46.2%)	40 (23.8%)
Ring	14 (29.2%)	3 (17.6%)	4 (33.3%)	3 (27.3%)	16 (39.0%)	10 (25.6%)	50 (29.8%)
Little	28 (58.3%)	4 (23.5%)	5 (41.7%)	6 (54.5%)	8 (19.5%)	11 (28.2%)	62 (36.9%)

Table 13: Mechanism of injury

	Proximal phalanx extra articular	Proximal phalanx intra articular	Middle phalanx extra articular	Middle phalanx intra articular	Volar plate injuries	Mallet finger injuries	Total
All	(n=48)	(n=17)	(n=12)	(n=11)	(n=41)	(n=39)	(n=168)
Mechanism of injury							
Fall	21 (43.8%)	7 (41.2%)	3 (25.0%)	2 (18.2%)	16 (39.0%)	12 (30.8%)	61 (36.3%)
Blow from an object	11 (22.9%)	5 (29.4%)	3 (25.0%)	4 (36.4%)	16 (39.0%)	8 (20.5%)	47 (28.0%)
Road traffic accident	1 (2.1%)	-	-	-	2 (4.9%)	-	3 (1.8%)
Crush	7 (14.6%)	1 (5.9%)	3 (25.0%)	1 (9.1%)	2 (4.9%)	5 (12.8%)	19 (11.3%)
Punch	2 (4.2%)	1 (5.9%)	1 (8.3%)	-	1 (2.4%)	1 (2.6%)	6 (3.6%)
Other	6 (12.5%)	3 (17.6%)	2 (16.7%)	4 (36.4%)	4 (9.8%)	13 (33.3%)	32 (19.0%)
Injury in sports	19 (39.6%)	9 (52.9%)	4 (33.3%)	6 (54.5%)	18 (43.9%)	13 (33.3%)	69 (41.1%)
Injury at work	5 (10.4%)	1 (5.9%)	3 (25.0%)	-	3 (7.3%)	3 (7.7%)	15 (8.9%)

Table 14: Fracture pattern and characteristics

	Proximal phalanx extra articular	Proximal phalanx intra articular	Middle phalanx extra articular	Middle phalanx intra articular	Volar plate injuries	Mallet finger injuries	Total
All	(n=48)	(n=17)	(n=12)	(n=11)	(n=41)	(n=39)	(n=168)
Fracture pattern							
Undisplaced	11 (22.9%)	5 (29.4%)	4 (33.3%)	1 (9.1%)	35 (85.4%)	36 (92.3%)	92 (54.8%)
Minimally displaced	20 (41.7%)	9 (52.9%)	6 (50.0%)	3 (27.3%)	5 (12.2%)	2 (5.1%)	45 (26.8%)
Displaced	17 (35.4%)	3 (17.6%)	2 (16.7%)	7 (63.6%)	1 (2.4%)	1 (2.6%)	31 (18.5%)
Open fracture	1 (2.1%)	1 (5.9%)	1 (8.3%)	-	1 (2.4%)	-	4 (2.4%)
Nerve injury	1 (2.1%)	-	-	-	-	-	1 (0.6%)
Tendon injury (other than mallet)	1 (2.1%)	-	-	-	-	1 (2.6%)	2 (1.2%)
Injury requiring local or distal soft tissue flap cover	1 (2.1%)	-	-	-	-	-	1 (0.6%)

For most injuries, more than half of the participants had an injury in the dominant hand. The most commonly affected fingers were the ring and little (Table 12). Mechanism of injury was frequently a fall, a blow from an object or hyperextension following impact to fingertip in mallet finger injuries. Mechanisms of injury were not exclusive, there was overlap. Sports injury was in about 40% of patients for all injuries. Very few participants were injured at work (Table 13). Most injuries were undisplaced or minimally displaced. There was no pathological fracture (Table 14).

3.4.5. To describe the range of treatments received by injury type

Table 15: Treatment by injury type

	Proximal phalanx extra articular	Proximal phalanx intra articular	Middle phalanx extra articular	Middle phalanx intra articular	Volar plate injuries	Mallet finger injuries	Total
All	(n=48)	(n=17)	(n=12)	(n=11)	(n=41)	(n=39)	(n=168)
Treatment							
Operative treatment	2 (4.2%)	1 (5.9%)	-	3 (27.3%)	-	-	6 (3.6%)
Non-operative treatment	46 (95.8%)	16 (94.1%)	12 (100.0%)	10 (90.9%)	40 (97.6%)	39 (100.0%)	163 (97.0%)
Physiotherapy	29 (60.4%)	9 (52.9%)	6 (50.0%)	6 (54.5%)	19 (46.3%)	8 (20.5%)	77 (45.8%)

Six participants had an operation and the rest had non-operative treatment (Table 15).

Twenty percent (20%) of patients who had non-operative treatment, had a manipulation.

45% of participants had physiotherapy.

Very few complications were reported through the medical notes, such as stiffness treated with physiotherapy, pain and extensor lag (Table 16). There were no reported instances of non-union, infection, nerve injury, tendon injury, malunion and removal of metalwork.

Three participants needed an operation after their initial treatment. A 34-year-old male patient who had an ORIF (screw fixation only) for a proximal phalanx extra-articular fracture later needed an extensor tenolysis for scarred tissue in the extensor hood. A 21-year-old male patient who had a Zimmer splint for a proximal phalangeal extra-articular fracture later had an ORIF. A 21-year-old male who had a resting splint for a proximal phalangeal intra-articular fracture later had an ORIF with K wires.

Table 16: Complications reported exclusively from medical notes

	Proximal phalanx extra articular	Proximal phalanx intra articular	Middle phalanx extra articular	Middle phalanx intra articular	Volar plate injuries	Mallet finger injuries	Total
All	(n=48)	(n=17)	(n=12)	(n=11)	(n=41)	(n=39)	(n=168)
Complications (reported through medical notes)							
Restricted movement	2 (4.2%)	-	-	1 (9.1%)	1 (2.4%)	-	4 (2.4%)
Hand weakness	-	-	-	-	-	1 (2.6%)	1 (0.6%)
Persistent pain	-	2 (11.8%)	-	1 (9.1%)	2 (4.9%)	1 (2.6%)	6 (3.6%)
Other	11 (22.9%)	2 (11.8%)	-	1 (9.1%)	3 (7.3%)	9 (23.1%)	26 (15.5%)

3.4.6. To characterise response in patient reported outcome measures, which will help facilitate sample size calculations for future trials

3.4.6.1. Response in terms of the Patient Evaluation Measure (PEM) questionnaire – Primary Outcome

The primary outcome was the PEM score at 6 months (mean and SD, median and IQ range) for all participants (and the individual injuries). The PEM questionnaire is in Appendix 10.

Table 17: PEM score at 6 months for all participants (and the individual injuries) in comparison to pre-injury scores

	Patient Evaluation Measure (PEM)							
	All participants		Proximal phalanx extra-articular fracture		Volar plate injuries		Mallet finger injuries	
Timepoint	Mean and SD	Median and IQ range (75-25)	Mean and SD	Median and IQ range (75-25)	Mean and SD	Median and IQ range (75-25)	Mean and SD	Median and IQ range (75-25)
Pre-injury baseline	11.8 (4.4) (n=168)	11 (11-11) (n=168)	12.6 (6.1) (n=48)	11 (11-11) (n=48)	11.1 (0.5) (n=41)	11 (11-11) (n=41)	12.3 (6.1) (n=39)	11 (11-11) (n=39)
24 weeks	24.7 (14.3) (n=114)	20.5 (33-14) (n=114)	24.9 (15.5) (n=32)	19.5 (34-13) (n=32)	25.0 (14.0) (n=30)	22.5 (36-14) (n=30)	22.6 (11.9) (n=28)	18.5 (28.5-14) (n=28)

PEM scores at 24 weeks were not back to normal pre-injury levels (Table 17). The levels of PEM at 24 weeks were similar between all participants and the individual injuries.

The three injuries were presented because the numbers for these have reached the target of 30 participants per injury.

3.4.7. Recovery in terms of Patient Reported Outcome Measures (PROM)

Pre-injury levels were normal for most participants. Overall, PROMs improved over time (6, 12 and 24 weeks) but did not reach pre-injury levels at 24 weeks (Table 18 and Figure 12). All PROMs are in Appendix 10.

PEM (Table 18, Figure 12)

Pre-injury scores were mostly 11, which is the highest score. Patients were saying they were normal before the injury. PEM decreased (improved) at 12 and 24 weeks but did not reach pre-injury levels.

EQ-5D-5L (Table 18 and Table 19, Figure 12)

VAS and index improved at 12 and 24 weeks and almost reached pre-injury levels. Most impact was seen in domains of pain, self-care and activity which is not surprising as they are mostly affected by injury.

PROMIS CAT (Table 18, and Figure 12)

Improved health over time, but not reached pre-injury levels.

PEM was the PROM that was the most sensitive to change. The PEM is specific for hand function, whereas PROMIS CAT is for the function of the whole upper limb and the EQ-5D-5L is a generic instrument for quality of life. The scores at 24 weeks for PEM were the furthest away from pre-injury levels. The results were similar for all participants and for the 3 injuries (Appendix 12).

Table 18: PEM, PROMIS CAT and EQ-5D-5L VAS results for all participants

Timepoint	PEM		PROMIS CAT		EQ-5D-5L (VAS)	
	Mean and SD	Median and IQ range (75-25)	Mean and SD	Median and IQ range (75-25)	Mean and SD	Median and IQ range (75-25)
Pre-injury baseline	11.8 (4.4) (n=168)	11 (11-11) (n=168)	56.7 (8.1) (n=156)	61 (61-54.9) (n=156)	84.0 (13.1) (n=168)	90 (93.5-80) (n=168)
Post-injury baseline	46.7 (14.4) (n=50)	48.5 (56-36) (n=50)	x	x	x	x
6 weeks	32.8 (15.7) (n=118)	30.5 (44-21) (n=118)	44.7 (10.6) (n=105)	42.4 (54.5-35.3) (n=105)	77.2 (20.0) (n=116)	85 (90-70) (n=116)
12 weeks	28.5 (14.9) (n=103)	25 (39-16) (n=103)	49.9 (11.3) (n=93)	53.5 (61-41.2) (n=93)	80.5 (17.3) (n=102)	85 (93-75) (n=102)
24 weeks	24.7 (14.3) (n=114)	20.5 (33-14) (n=114)	51.0 (11.3) (n=104)	55.4 (61-40)	83.7 (15.5) (n=113)	90 (95-80) (n=113)

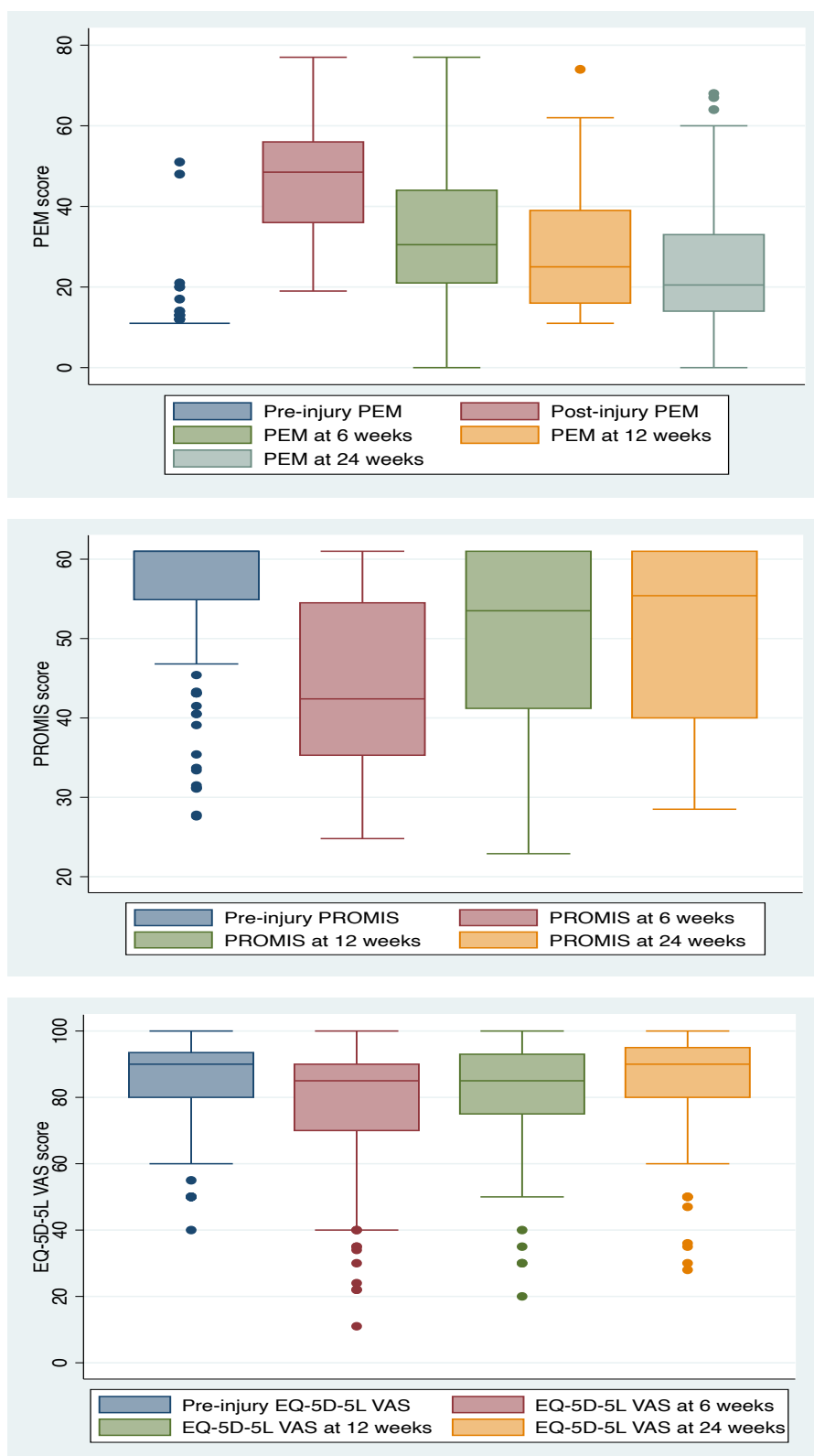


Figure 12: Box and whisker plots for PEM, PROMIS CAT and EQ-5D-5L Visual Analogue Scale (VAS) for all participants. A lower score indicates improvement on the PEM and a higher score indicates improvement on EQ-5D-5L and PROMIS CAT.

Table 19: EQ-5D-5L results for all participants (a higher score is worse for mobility/self-care/activity/pain/anxiety and better for mean Index and mean EQ_VAS)

	EQ-5D-5L						
	Mobility (range 1-5)	Self-care (range 1-5)	Activity (range 1-5)	Pain (range 1-5)	Anxiety (range 1-5)	Index (UK) (utility score)	EQ_VAS (range 0-100)
Pre-injury Baseline (n=168)	1.2	1.1	1.2	1.3	1.4	0.91	84.0
6 weeks (n=116)	1.3	1.4	1.9	2.0	1.6	0.75	77.2
12 weeks (n=102)	1.3	1.3	1.6	1.8	1.5	0.80	80.5
24 weeks (n=113)	1.2	1.2	1.4	1.7	1.5	0.82	83.7

Global rating of change (GROC) since the time that they began treatment for the injury

Table 20: GROC results for all participants

	Total		
	6 weeks	12 weeks	24 weeks
Total	118	103	114
Worsened (< or = -3)	7/118 (6%)	4/103 (4%)	5/114 (4%)
No change (-2 to 2)	24/118 (20%)	18/103 (18%)	18/114 (16%)
Improved (> or = 3)	87/118 (74%)	81/103 (78%)	91/114 (80%)

The majority of participants improved on the GROC, but 18-24 (16-20%) remained unchanged and 4-7 (4-6%) worsened (Table 20). The results were similar for the different injuries (Appendix 12). Most participants said they had improved, but as seen previously not reached a full recovery.

3.4.8. Return to function

Table 21: Full recovery at all time points

	Full recovery (according to the patient)	No full recovery (according to the patient)
6 weeks (n=118)	27/118 (23%)	91/118 (77%)
12 weeks (n=103)	32/103 (31%)	71/103 (69%)
24 weeks (n=114)	55/114 (48%)	59/114 (52%)

Table 22: Mean PEM scores at 24 weeks for patients who reported that they had fully recovered versus those who reported that they had not

	PEM score (mean (SD))
Patients who reported that they had fully recovered at 24 weeks (55/114)	17.02 (7.03)
Patients who reported that they had not fully recovered at 24 weeks (59/114)	32.29 (15.13)

Participants were asked to state whether they have achieved full recovery at all time points (6, 12 and 24 weeks) in a Yes or No question. This was a separate single question, not the results of a statistical comparison of the PEM scores. Only 48% of participants stated that they had reached a full recovery at 6 months (Table 21). Participants who reported that they had not fully recovered at 24 weeks had a higher mean PEM score than those who reported that they had fully recovered (Table 22).

3.4.9. Analysis of missing data

The characteristics of patients who completed a 6 month follow up were compared against those of patients who did not complete the 6 month follow up. Patients who completed a 6 month follow up may have missed either of the 6 or 12 week questionnaire and patients who did not complete the 6 month follow up may have completed either the 6 or 12 week questionnaire. No hypothesis test was done on this as the study was not powered to find statistically significant differences on these comparisons and because there are multiple comparisons. Due to chance alone, there would be 1 in 20 chance of finding a statistically significant difference in one of the comparisons.

Table 23: Characteristics of patients who completed a 6-month follow up against those who did not

	Patients who completed 6-month follow-up	Patients who did not complete 6-month follow up
All	(n=113)	(n=55)
Age	41.1 (17.3)	37.8 (18.0)
Sex		
Women	49 (43.4%)	21 (38.2%)
Men	64 (56.6%)	34 (61.8%)
Injury type		
Proximal phalanx extra-articular	31 (27.4%)	17 (30.9%)
Proximal phalanx intra-articular	8 (7.1%)	9 (16.4%)
Middle phalanx extra-articular	9 (8.0%)	3 (5.5%)
Middle phalanx intra-articular	7 (6.2%)	4 (7.3%)
Volar plate injury	30 (26.5%)	11 (20.0%)
Mallet finger injury	28 (24.8%)	11 (20.0%)
Treatment type		
Operative	2 (1.8%)	1 (1.8%)
Non-operative	110 (97.3%)	53 (96.4%)

Patients who did not complete 6-month follow up were slightly younger and male; 55/168 (33%) participants did not complete the 6-month questionnaires (Table 23)

The characteristics of patients who did not complete any follow up questionnaires at all were compared to those who completed part of the follow up and those who completed all follow up.

Table 24: Characteristics of those who did not complete any follow up questionnaires against those who completed part of the follow up and those who completed all follow up

	No follow up at all after baseline	Completed part of the follow up	Completed all follow up
All	(n=37)	(n=38)	(n=93)
Age	35.0 (16.3)	38.4 (17.8)	42.6 (17.5)
Sex			
Women	12 (32.4%)	15 (39.5%)	43 (46.2%)
Men	25 (67.6%)	23 (60.5%)	50 (53.8%)
Injury type			
Proximal phalanx extra-articular	11 (29.7%)	14 (36.8%)	23 (24.7%)
Proximal phalanx intra-articular	6 (16.2%)	4 (10.5%)	7 (7.5%)
Middle phalanx extra-articular	2 (5.4%)	4 (10.5%)	6 (6.5%)
Middle phalanx intra- articular	3 (8.1%)	3 (7.9%)	5 (5.4%)
Volar plate injury	8 (21.6%)	7 (18.4%)	26 (28.0%)
Mallet finger injury	7 (18.9%)	6 (15.8%)	26 (28.0%)
Treatment type			
Operative	-	1 (2.6%)	2 (2.2%)
Non-operative	36 (97.3%)	37 (97.4%)	90 (96.8%)

Patients who did not complete any follow up were slightly younger than patients who completed part or all follow up (Table 24). Treatment modality probably did not affect completion.

The characteristics of patients who did not complete the 6-week questionnaire at all were compared to those who stated that they worsened on the GROC at 6 weeks (in comparison to when started treatment for the injury) and those that improved on the GROC at 6 weeks. This analysis is presented in relation to GROC just at 6 weeks because it relates to worsened GROC in 7 patients. The aim was to investigate why 7 patients at 6 weeks, 4 patients at 12 weeks and 5 patients at 24 weeks worsened on the GROC. The 6 week was chosen as that was the timepoint with most patients who worsened.

Table 25: Characteristics of those who did not complete the 6-week questionnaire against those who stated that they worsened, those that remained unchanged and those that improved on the GROC since treatment began

	No follow up at 6 weeks	Worsened on the GROC at 6 weeks	Unchanged on the GROC at 6 weeks	Improved on the GROC at 6 weeks
All	(n=52)	(n=7)	(n=24)	(n=85)
Age	36.3 (17.7)	39.9 (11.6)	50.0 (16.5)	39.7 (17.2)
Sex				
Women	16 (30.8%)	3 (42.9%)	13 (54.2%)	37 (43.5%)
Men	36 (69.2%)	4 (57.1%)	11 (45.8%)	47 (55.3%)
Injury type				
Proximal phalanx extra-articular	19 (36.5%)	2 (28.6%)	6 (25.0%)	20 (23.5%)
Proximal phalanx intra-articular	7 (13.5%)	1 (14.3%)	1 (4.2%)	8 (9.4%)
Middle phalanx extra-articular	3 (5.8%)	1 (14.3%)	1 (4.2%)	7 (8.2%)
Middle phalanx intra-articular	4 (7.7%)	-	1 (4.2%)	6 (7.1%)
Volar plate injury	11 (21.2%)	2 (28.6%)	7 (29.2%)	21 (24.7%)
Mallet finger injury	8 (15.4%)	1 (14.3%)	8 (33.3%)	22 (25.9%)
Treatment type				
Operative	-	-	1 (4.2%)	2 (2.4%)
Non-operative	51 (98.1%)	6 (85.7%)	23 (95.8%)	83 (97.6%)

Table 25 showed that patients who remained unchanged on the GROC at 6-weeks were older than the other groups, more likely to be women, and more likely to have a mallet finger injury. Patients who improved were mostly men with either a proximal phalanx extra-articular, a volar plate or a mallet finger.

Only one patient from the seven who worsened on the GROC at 6 weeks returned to fracture clinic for a check. This was a 30-year-old male with volar plate injury, who complained of pain and restricted movement after 6 weeks and was treated with physiotherapy.

3.5. Discussion

3.5.1. Key findings

The aim of this cohort study was to inform the development of future multi-centre randomised controlled trials on the treatment of common hand fractures/joint injuries. The main findings of this cohort study were that it compared outcomes using different patient-reported outcome measurement instruments and it characterised mean (SD) and median (IQ range) response for different time points on the patient journey. These data help support choice and timing of primary outcome, duration of follow-up, and sample size estimates for future trials.

The patients' outcomes were not back to 'normal' (as stated at the pre-injury baseline) at 24 weeks. The recovery was incomplete. This is further explored in Chapter 5 (Qualitative study). For the majority of participants, health outcomes were poor at 6 weeks, suggesting that the hand injuries were still problematic and causing an impact on daily function at this time. Good functioning and quality of life had generally improved by 12 to 24 weeks, but for many participants outcomes were still not at the same level than prior to the injury after 24 weeks of recovery. This is in line with the Qualitative work (Chapter 5). Since 52% of participants reported, when asked directly, that they had still not achieved a full recovery by 24 weeks, further long-term follow-up could be useful to explore whether improvements continue beyond this point. However, little improvement was seen between 12 and 24 weeks, suggesting that there is likely only marginal gain from longer follow up.

Complications were only seen in 26/168 (15%) of patients. One limitation of this was that complications were captured exclusively through medical notes, so a patient would have to come back to fracture clinic in order for these to be picked up. Though this approach would capture all complications requiring treatment in secondary care where these injuries are managed, in large scale studies that involve multiple centres complications could also be patient reported to ensure none are missed.

This is a learning point for future trials. It is not useful to rely on the medical notes for collection of adverse event data. Furthermore, the Qualitative study (Chapter 5) found that patients are unlikely to state that they have a complication when asked directly so future trials would need to take this into account when designing questionnaires about complications.

In terms of PROMs, the PEM appears to be the most sensitive to change and, therefore, PEM could be considered as the primary outcome for an RCT in finger injuries. Patients in the qualitative study (Chapter 5) favoured the PEM above the PROMIS CAT and the EQ-5D-5L. They felt that the questions in those were not relevant to a finger injury.

The PROMIS CAT and the EQ-5D-5L did pick up change, but not as much as the PEM. This could be as the PROMIS CAT is generic for the upper limb and not specific for the hand, which decreases its granularity. For example, a patient may be able to change a light bulb without any difficulty even if a finger is not fully functional. Even though the EQ-5D-5L Visual analogue scale did pick up on the worsening due to the effects of the injury, it is a generic instrument (i.e. not condition specific) that tests overall quality of life.

Whether the PROMs used are sensitive enough to consider what patients thought and worried about is something that was further explored in the qualitative study (Chapter 5). For example, a musician can do activities of daily living, but may not be able to play the piano.

A very small number of participants indicated that the effect of their injury worsened compared to the time of injury. Their demographics do not suggest that this might be due to a particular injury or treatment. Only one of them returned to fracture clinic for a check, which suggests that the others suffered in silence. This could be further explored in a future study.

According to the results of this study most patients are likely to be fine pre-injury (highest possible score on PROMs), so the post-injury baseline is important to collect when assessing treatment response. The post-injury PEM can give a baseline for the interpretation of the scores in the follow up points. Furthermore, in a future trial, selection bias would be minimised through randomisation, which aims to ensure that relevant characteristics are balanced at baseline.

In this cohort study, 20% of those recruited gave no follow up data at all. This is a key message for future trials. This might be just an issue with this being an observational study. Participants are less invested in an observational remote study, in which no one assesses the effect of a treatment they have been allocated to. In an RCT it would be different as there would be more contact between the researchers and the patients and so the loss to follow up would be lower. It is worth highlighting that this may also be something that is enhanced by recruitment for acute trauma studies that have no cool off period, i.e. when someone says yes at baseline and then is immediately in, then later may lose interest to continue in the study.

Follow-up rates overall (67%) were better than most trials, though still well below the ideal of 85%. The overall follow-up did not majorly drop over time (70%, 61% 68%), as is the expected pattern for most studies. This means that the 20% percent that were straight after recruitment are a very important group to focus on and develop retention strategies for. At recruitment it has to be reinforced how important the follow-up data is and also if there is a primary outcome timepoint, also to flag to the patient that for example the 3-month or the 6-month questionnaire is the most important. A study should also have built-in incentives for completion of follow up questionnaires, such as payments, follow up calls and regular newsletters. The qualitative study has developed some insights into retention of participants in a trial (Chapter 5).

The BSSH national hand registry, which is an observation cohort for capturing PROMs after mainly elective surgery for audit purposes, has follow-up rates which are much lower than this cohort study (BSSH The British Society for Surgery of the Hand, 2021).

In terms of methods to reduce bias in this cohort study, consecutive patients with finger injuries in fracture clinic were recruited to minimise selection bias. Monetary incentives were given to improve recruitment and follow up rates. Patients were sent reminder emails and called on the phone to improve follow up rates. This would reduce attrition bias.

Information on potential confounders including age, sex, occupation, comorbidities, severity of injury, type of management was collected. Analysis consisted of mainly descriptive statistics.

3.5.2. Relevance to the wider literature

This cohort study is one of the first to study PROMs in finger fractures/joint injuries. The PROMs were selected because of the following reasons: The PEM is the PROM of choice for BSSH national Hand Registry and is easy to complete (Dias et al., 2008b). It has reasonable characteristics to assess hand function. PROMIS is novel and adaptive so this study included this to explore its potential (Alonso et al., 2013). The EQ-5D-5L was chosen as it is the standardised questionnaire for quality of life that is used by NICE. The PPI done before the study found that the questionnaires were acceptable to the participants (see Section 3.3.12). Just to note that there is no current core outcome set for hand fractures and joint injuries though one is currently under development (Deshmukh et al., 2021). None of these are well validated and none have evidence for this population (Wormald et al., 2019).

Recently, there has been work in PROMs in hand fractures/joint injuries. However, there has not been a lot of work for the PEM, PROMIS CAT and EQ-5D-5L in finger fractures/joint injuries. A systematic review of RCTs in hand and wrist trauma found that other PROM questionnaires, such as the Disabilities of the Arm, Shoulder and Hand (DASH) and the Patient Related Wrist Evaluation (PRWE) both have evidence of reliability, validity and responsiveness in hand and wrist trauma (Dacombe et al., 2016). Although there have been previous cohort studies in hand surgery which assessed quantitative outcomes, such as re-operation rates in patients with extra-articular fractures of the proximal and middle phalanx (von Kieseritzky et al., 2017), there have not been many cohort studies on PROMs in finger fractures/joint injuries. A cohort study of patients with hand fractures found that the DASH, Michigan Hand Outcomes Questionnaire (MHQ) and PRWE showed comparable responsiveness in assessing change in patients with hand fractures (Weinstock-Zlotnick et al., 2015).

In terms of clinicians' expectations, patients' recovery may continue after 6 months. Furthermore, the rate of improvement slowed down after 12 weeks. Studies have followed up patients e.g. with proximal phalanx fractures for 1 year, but it is not clear from their results whether the patients improve after 6 months (Singh et al., 2011). Intra-articular

fractures may result in long term function deficits of the injured joint (Oetgen and Dodds, 2008). If patients with finger fractures/joint injuries were to be followed up for longer than 6 months until they are better, perhaps the new normality would be when they accept the long-term problems (Chapter 5).

3.5.3. Strengths and limitations

The strengths of this cohort study were that it aimed to approach consecutive patients attending clinics (to avoid selection bias) and had broad eligibility criteria. This was a cohort study that gave us the opportunity to inform the design and conduct of future trials.

This study recruited in two surgical centres (Nottingham and Cardiff) and overwhelmingly recruited non-operative patients, which may not reflect practice in other UK surgical centres or practice around the world. Only very few patients who were treated operatively were recruited as Nottingham is generally known to favour a non-operative treatment for these injuries.

The target recruitment of 30 participants per injury was met for three injury types (proximal phalanx extra-articular fracture, volar plate injuries and mallet finger injuries). This is because they are more common, which is in line with the epidemiology of finger fractures overall. For the other injury types any conclusions should be guarded.

Another issue was that complications were exclusively picked up from the medical notes. Patients were not asked to report any complications.

Also, a limitation was the relatively small sample size for each of the multiple injuries considered. Hence there was no scope for direct comparison allowing the ability to interpret response rates for different injuries and treatments. Nevertheless, information on potential confounders was collected and presented.

There were some issues with the classification of type of work, concurrent injury and complications as a lot of participants classified their response in the 'other' category, resulting on free text data that is harder to interpret. Also, the definition of serious concomitant disease is vague and generally patients said that they did not have a serious medical problem. Perhaps a targeted question, i.e. does the patient have diabetes, osteoporosis or is a smoker might be more appropriate.

Information about the demographics of patients that were approached and said no was not collected. This was not part of the ethics application. In future studies screening logs will be important to give further information.

3.5.4. Implications for clinical practice

The information this study has provided on the recovery from these injuries up to 6 months will be useful in the clinical setting as it is novel and will allow both patients and clinicians to manage expectation about recovery rate and overall recovery, the importance of which has also been highlighted in the qualitative study (Chapter 5).

Patient expectations in a clinical setting should be managed better, i.e. whether patients are told that this injury may require 3-6 months to recover and perhaps may never fully recover. If patients are fairly stable between 12 and 24 weeks perhaps we would not expect further improvements beyond 24 weeks. However, this study did not provide evidence about whether patients continue to improve after 24 weeks or not.

3.5.4. Implications for future trials

The next step in the investigation of interventions in the management of finger fractures and joint injuries would be RCTs comparing surgical and non-surgical options. An RCT would be a stronger study in the hierarchy of evidence, but it would be narrower. It would only answer one particular research question, e.g. whether operative or non-operative treatment in proximal phalanx fractures is more appropriate.

Outcomes per injury were remarkably similar, which supports reporting "finger fractures" universally. This has implications for future and historical papers. Different finger injuries might be usefully studied together in a single RCT, however, intra-articular fractures and extra-articular fractures may be better studied separately as the outcomes are worse for the former.

One of the real clinically uncertain areas, the PIPj fracture dislocations are rare, so a trial for these would be difficult to perform.

3.5.5. Conclusions

This study provided evidence to support the PEM as a primary outcome measure in a trial for finger fractures/joint injuries. The PEM was the most responsive questionnaire for finger fractures and joint injuries amongst those investigated in this study. Six months would appear to be appropriate timing for a primary outcome as most participants would have improved by as much as they are going to by that time. In this study, participants showed continued improvement over 6 months, with the most improvement seen in the first 3 months. However, even after 6 months of follow-up, participants did not return to pre-injury levels and it is not clear whether continued improvement would be seen beyond this time.

Chapter 4: Minimal Clinically Important Difference (MCID) for the Patient Evaluation Measure (PEM)

4.1. Summary

The aim of this study was to calculate the Minimal Clinically Important Difference (MCID) of the Patient Evaluation Measure (PEM) at 24 weeks in order to aid the interpretation of trial findings and inform trial design. The secondary objectives of this study were to calculate the Minimal Detectable Change (MDC) for the PEM, and the MCID at different timepoints after presentation (6, 12 and 24 weeks). Data from the cohort study were used. Patients were given the PEM questionnaire to fill in at baseline, 6, 12 and 24 weeks and the Global Rating of Change (GROC) at 6, 12 and 24 weeks. The GROC was the anchor for the MCID calculations. The results of this study show that the MCID values for the PEM at 24 weeks was 12-17 depending on the calculation method used. The MCID values were slightly different at the different time points, but the range was the same suggesting that the MCID is likely to be broadly consistent at different time points. The MDC was estimated as 10-11.

4.2. Background

Minimal clinically important difference (MCID) is the smallest difference in a PROM, that the patient perceives as clinically important (Beaton et al., 2002). An improvement in a patient's assessment of a PROM should be statistically significant, but also clinically meaningful (Copay et al., 2007). Knowing the MCID can also help to interpret the effectiveness of a given treatment and patient satisfaction with regards to treatment (Copay et al., 2007). MCID helps to guide clinical decision making during the course of treatment (Beaton et al., 2002) (Wright et al., 2012). The MCID score is used in sample size calculations for adequately powering a study to minimise the false positives (type 1 errors) and the false negatives (type 2 errors) (Wright et al., 2012). The MCID score of a PROM allows us to pre-define what is clinically important and this aids in interpretation of trial findings.

A low MCID may result in overestimating the positive effects of treatment (Wright et al., 2012). A high MCID may incorrectly classify patients as failing to respond to treatment (Wright et al., 2012).

There are different methods to calculate the MCID: distribution and anchor methods. Distribution methods rely on statistical parameters, such as the spread of the data using standard deviation and effect size. Anchor based approaches compare the change in PROM score to some measure of change (anchor) (McCreary et al., 2018). The choice of the anchor is crucial as it determines the perspective of the patient which may differ from the clinician's point of view (de Vet et al., 2007). The strength of anchor methods is that using the patient perspective to guide the assessment of improvement in PROMs and thus clinical decision making during the course of treatment (Wright et al., 2012). The weakness of the anchor method is that changes are associated with baseline scores and they are dependent on the patients' ability to understand the context of improvement (Copay et al., 2007). It is, thus, subject to recall bias (Wright et al., 2012). Descriptive factors such as age, socioeconomic status or education can influence report of change (Cook, 2008).

Minimal detectable change (MDC) is a mathematical concept and it represents the smallest change in score in the PROM that is not likely to be due to measurement error (Copay et al., 2007). The calculation of the MDC enables researchers to be certain that the MCID is greater than the MDC (Terwee et al., 2009). In order to calculate the MDC, a calculation of the Intra-Class Correlation Coefficient (ICC) is required (Terwee et al., 2009). This is done by a test-retest study. Participants are given the PROM questionnaire twice: once at baseline and once again within one week. The patients' responses on the PROM would only vary by measurement error as the patients' clinical condition is unlikely to have changed in those days. The agreement between the completion of the PROM in the two time points is used to calculate the ICC.

The strength of the MCID is that it includes the calculation of a change bigger than random error (MDC) in order to find what is not only statistically significant, but clinically meaningful for the patients. (Wright et al., 2012). This helps guide management decisions in clinical practice. However, there are numerous methods of calculating the MCID, which can produce a range of MCID scores (Wright et al., 2012). The MCID score is a range or continuum rather than a fixed value and depends on the context (Wright et al., 2012). MCID is influenced by patient demographics, prior expectations, assessment time points,

analytical method, treatment modality and fracture classification Therefore, it cannot necessarily be transferred across patient populations (Wright et al., 2012).

The overarching aim of this study is to calculate the MCID for the PEM in patients with finger fractures. The choice to focus on MCID for the PEM was made in order to inform future trials in finger fractures/joint injuries. There is limited literature on the topic.

4.3. Methods

4.3.1. Aims and Objectives

The aim of the study was to establish the MCID for the PEM.

The objectives were: (1) to establish the MDC for the PEM, (2) to establish the MCID for the PEM at 24 weeks, (3) to establish whether timepoints of assessment following injury influenced the MCID.

4.3.2. Study design

Data was collected as part of my prospective cohort study (Chapter 3).

4.3.3. Data source

Patients were recruited from fracture clinic at Nottingham and Cardiff (Chapter 3). They were given questionnaires to fill in (demographics and PROMs). The PEM questionnaire (pre- and post-injury, 6, 12 and 24 weeks). The hand-health measure of the PEM is a PROM questionnaire that assesses hand function (Chapter 3). Scores range from 11 to 77. Higher score indicates worse hand function. The GROC questionnaire (completed at 6, 12 and 24 weeks) The Global rating of change (GROC) is a questionnaire that assesses how a patient feels they are in comparison to “when they started treatment”. There are different GROCs (11, 13, 15 and 17 point). A 15-point GROC was used in this study. The range is from -7 to +7. The range of deterioration is from -7 to -1, 0 is unchanged and improvement is from +1 to +7.

For the test-retest study, patients were asked to complete another PEM questionnaire within a week after baseline and within a week after the 6-week questionnaire. The aim was to get at least 30 test-retest responses in order to calculate the minimum detectable change.

4.3.4. Calculating the minimum detectable change for PEM

The aim was to recruit at least 30 participants into the test-retest study. The Intra-class correlation coefficient (ICC), SEM and the MDC were measured. ICC (one-way random effects model) is a statistic that describes how strongly responses in a questionnaire in the same group of patients resemble each other (Wright et al., 2012). Standard error of the measurement (SEM) is the amount of variation in the scores in a scale due to the measurement error (the unreliability of the scale) (Coppay et al., 2007). It represents the standard deviation of repeated measurements in one patient.

- $SEM = SD \text{ pooled} \times \sqrt{1 - ICC}$
- $SD \text{ pooled} = \sqrt{(SD \text{ baseline})^2 + (SD \text{ at 6 months})^2} / 2$
- The MDC was given with a confidence level of 90% (MDC90) or 95% (MDC95).
 - $MDC90 = 1.65 \times SEM \times \sqrt{2}$
 - $MDC95 = 1.96 \times SEM \times \sqrt{2}$

4.3.5. Calculating the minimum clinically important difference for PEM

A variety of both distribution and anchor-based methods were used to estimate MCID to provide a range of plausible values. The first step was to check that the GROCC change scores were correlated with PEM ($r \geq 0.3$). For an anchor to be useful it must at least moderately correlate with the PEM change score ($r \geq 0.3$) to meet the assumptions of Pearson's r correlations (Revicki et al., 2008). MCID and 95% confidence intervals were presented as the sample size is small (<50 participants). The primary timepoint for assessment of MCID was 24 weeks after injury. Secondary timepoints were 6 and 12 weeks. STATA was the software package used to calculate the MCID and the 95% confidence intervals (CIs) (Terluin et al., 2015).

4.3.6. Distribution methods

Effect size is a standardised measure of change obtained by defining the standard deviation of the difference in scores from baseline to post-treatment and multiplying it by 0.5 (or 0.2) (Wright et al., 2012). Effect size of 0.2 is considered small and 0.5 moderate (Copay et al., 2007). It has been found that the value of $0.5 \times \text{SD}$ provides values closest to the anchor-based estimates across a variety of studies (Beaton, 2003) (Howells et al., 2018).

4.3.7. Anchor methods

There are numerous methods to use an anchor in the calculation of the MCID. In this study the within patients score change, the between patients score change and the Receiver Operating Characteristics (ROC) analysis were used.

The GROC was used as the anchor. GROC is a flexible, quick and simple method of self-assessment of clinical progress on behalf of the patient (Kamper et al., 2009). It is sensitive to change and its open nature allows the patient to take into account their holistic recovery (Kamper et al., 2009). There is no clear consensus on what values on the GROC should be the 'unchanged' category (Norman et al., 2003) (Kamper et al., 2009) (Walenkamp et al., 2015). For the purposes of this study, -2 to +2 on the GROC was defined as 'unchanged'. It was thought that if unchanged was defined as 0 or (-1 to +1) on the GROC, then this might not capture all the patients who have remained unchanged. The range of -2 to +2 as unchanged has been used in other studies (Coughlin, 2018).

'Within persons' and 'between persons' anchor calculations were made. The within persons score change (WPSC) is the mean change in score in patients who were improved (Wright et al., 2012). The selection of the cut-off point on the anchor is arbitrary and can correspond to small, moderate or large change (Wright et al., 2012). The between persons score change (BPSC) is the mean change of score of patients who improved minus the mean change in score of those who did not (Wright et al., 2012). The selection of the two adjacent levels of the scale is arbitrary (Wright et al., 2012).

Receiver operating characteristics (ROC) curves

ROC curves are used to balance the sensitivity and specificity to determine the MCID. The MCID is the score with greatest sensitivity and specificity to discriminate between improved and unchanged patients (Copay et al., 2007). Sensitivity is the proportion of patients who report an improvement on the anchor out of all patients who have improved (Copay et al., 2007). A sensitivity of 1 indicates all true positives (TP) (people who have actually improved) are identified. Specificity is the proportion of patients who do not report an improvement on the anchor out of all those who did not improve (Copay et al., 2007). A specificity of 1 indicates that all true negatives (TN) (people who have not changed at all, no clinical benefit) are identified. Plotting the sensitivity (true positives) (Y axis) against 1-specificity (false positives) (x axis) can help calculate the MCID (Copay et al., 2007). The MCID is the change in score for which the sum of the sensitivity and specificity were the greatest. This was the score with the smallest amount of misclassification. The AUC represents the probability that scores will correctly discriminate between improved and unimproved patients (Copay et al., 2007). Probabilities range from 0.5 to 1 with 0.5 representing the ability to discriminate because of chance and 1 representing the ability to correctly discriminate all the patients (Copay et al., 2007). An area of 0.7 to 0.8 is considered acceptable and an area of 0.8 to 0.9 excellent (Copay et al., 2007). If the area under the curve was below 0.6, this was discounted (Copay et al., 2007).

4.3.8. Defining the baseline for change scores

There are specific issues with PROMs in trauma surgery. The baseline in the PROM needs to be established. Is it the pre- or post-injury PROM? The injury will affect the patient's physical and mental condition and thus their responses to the PROMs. Post injury PROM will be subject to the effect of the injury and the pre-injury PROM will be subject to recall bias. This is unique to trauma. In chronic relapsing conditions, baseline may be when the condition is in remission and then a relapse would be compared to this. Also, the appropriate time points for assessing meaningful change need also be established.

For the purposes of the MCID, the baseline measurement depends on how the GROC question is set. If the GROC asks to compare to the time that treatment began, then the baseline is the post-injury PROM rather than the pre-injury PEM that is collected at baseline retrospectively. During interim analysis it became apparent that the post-injury PEM was

also essential for the calculation of the MCID, this unfortunately had not been collected for the first 117 patients. However, the post-injury PEM was immediately added to the dataset following an ethical substantial amendment and collected for the remaining patients for the purposes of this analysis. Only complete PROM data was used. There was no data imputation.

4.3.9. Sample size

The sample size for the cohort study is outlined in Chapter 3. Secondary to the COVID-19 restrictions and difficulties in defining baseline scores at the start of the study, there has been a reduction in the sample size. The COSMIN group recommend having more than 100 participants for the calculation of MCID and more than 50 participants for MDC calculation (de Vet et al., 2011).

Pragmatically, the sample size here is smaller than intended, with a goal of achieving 30 for the test-retest and at least 50 for the MCID calculation. Recruitment is ongoing, and the results presented here will be updated with additional data prior to publication in a peer reviewed journal.

4.3.10. Impact of COVID-19 pandemic on the MCID study

The COVID-19 pandemic had an impact on this study (Chapter 3). The patient recruitment had to stop in the first lockdown (between March and July 2020). Recruitment resumed in July 2020 in Cardiff and September 2020 in Nottingham but was slower than expected at both sites. This was secondary to redeployment of research and clinical staff, as well as the perceived lower rate of eligible injuries by recruiting clinicians. This was unavoidable and as a direct result of the COVID-19 pandemic. This meant that the sample size of the MCID study is smaller than planned.

4.4. Results

4.4.1. Population

One hundred and seventeen patients were excluded from the MCID calculation as they did not complete a post-injury PEM at baseline. Eighty-nine patients completed a post-injury PEM at baseline with complete follow up data available for 60. Demographics of the subset of patients from the cohort study who were included in the MCID study are presented in Table 26.

Table 26: Demographics of the 89 patients who had a baseline post-injury PEM and were included in the MCID study

	Patients with post injury PEM who have completed part or all follow up	Patients with post injury PEM who have not provided follow up data
All	(n=60)	(n=29)
Age	39.5 (16.9)	35.4 (16.2)
Sex		
Women	35 (58.3%)	7 (24.1%)
Men	25 (41.7%)	22 (75.9%)
Injury type		
Proximal phalanx extra-articular	23 (38.3%)	17 (58.6%)
Proximal phalanx intra-articular	8 (13.3%)	3 (10.3%)
Middle phalanx extra-articular	5 (8.3%)	1 (3.4%)
Middle phalanx intra-articular	7 (11.7%)	3 (10.3%)
Volar plate injury	12 (20.0%)	2 (6.9%)
Mallet finger injury	5 (8.3%)	3 (10.3%)
Treatment type		
Operative	2 (3.3%)	-
Non-operative	60 (100.0%)	28 (96.6%)

Pre-injury and post-injury PEM scores for the subset of patients from the cohort study who were included in the MCID study (Figure 10).

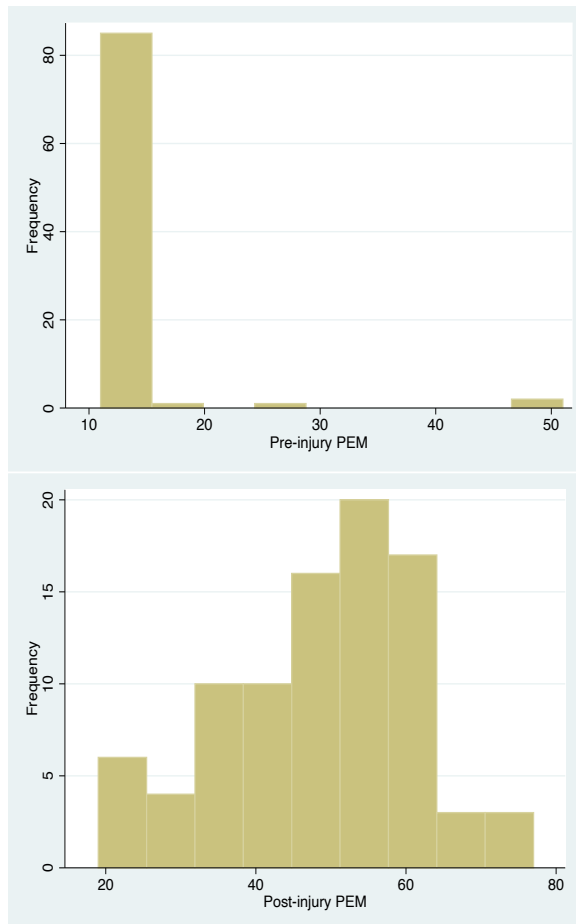


Figure 13: Histograms of pre- and post-injury PEM scores in the patients who were included in the MCID study

Figure 13 shows that the majority of the participants scored 11 (highest possible score) on the pre-injury PEM. They said that their hand was normal before the injury. For the post-injury PEM, there was a range of responses. Therefore, the post-injury PEM for baseline assessment is preferable.

4.4.2. GROC and PEM scores at different time points compared to immediate post injury PEM

Table 27: Post-injury GROC and PEM scores (mean (SD), frequency) at 6, 12 and 24 weeks.

	PEM at 6 weeks		PEM at 12 weeks		PEM at 24 weeks	
GROC score	Mean (SD)	Frequency N (%)	Mean (SD)	Frequency N (%)	Mean (SD)	Frequency N (%)
Total	35.3	52	30.8	43	23.5	35
-7		0		0		0
-6	77	1/52 (2%)		0		0
-5		0		0		0
-4		0	68	1/43 (2%)	64	1/35 (3%)
-3		0		0		0
-2	37 (13)	3/52 (6%)	25	1/43 (2%)		0
-1		0		0		0
0		0	52	1/43 (2%)	67	1/35 (3%)
1	49.3 (12.4)	4/52 (8%)	74	1/43 (2%)	33 (10.6)	3/35 (9%)
2	50.8 (10.8)	5/52 (10%)	50.3 (14.6)	4/43 (9%)		0
3	57.0 (7.8)	4/52 (8%)	32 (4.5)	6/43 (14%)		0
4	37.3 (13.0)	4/52 (8%)	48 (18.4)	2/43 (5%)	33.3 (21.2)	3/35 (9%)
5	33.6 (16.1)	9/52 (17%)	39 (15.6)	2/43 (5%)	26.2 (11)	5/35 (14%)
6	24.2 (9.6)	16/52 (31%)	24.5 (12.7)	18/43 (42%)	16.4 (4.7)	12/35 (34%)
7	21.2 (12.5)	6/52 (12%)	13.7 (3.7)	7/43 (16%)	12.6 (2.5)	10/35 (29%)

Dark grey is worsened, light blue is unchanged and light green is improved on the GROC

Table 28: Frequencies of worsened, unchanged and improved on the GROC at the different time points (6, 12, and 24 weeks)

GROC score	6 weeks N (%)	12 weeks N (%)	24 weeks N (%)
Worsened (-7 to -3)	1/52 (2%)	1/43 (2%)	1/35 (3%)
Unchanged (-2 to +2)	12/52 (24%)	7/43 (15%)	4/35 (11%)
Improved (+3 to +7)	39/52 (74%)	35/43 (82%)	30/35 (86%)

Table 27 showed the post-injury GROC and PEM scores at all timepoints. Table 28 showed the frequencies of the different GROC scores at all timepoints. As the GROC increases from deterioration to unchanged and to improvement, the PEM scores decrease (also showing improvement) for all time points.

4.4.3. Correlation between the GROC change scores with PEM scores

Table 29: Correlation between GROC and PEM scores at 6, 12 and 24 weeks

	Correlation between GROC and PEM scores (r)
6 weeks	-0.61
12 weeks	-0.65
24 weeks	-0.81

The correlation (r) needs to be equal to or higher than 0.3 or -0.3 if the direction of the correlation is negative (Howells et al., 2018). In this situation it is higher than -0.3, so there is a high correlation between GROC and PEM (Table 29). This means the data can be used for MCID calculation. The correlation is negative as a lower score on the PEM and a higher score on the GROC represent an improvement.

4.4.4. Objective 1 - MDC for PEM for patients with finger fractures

Test-retest data from 37 patients were used.

- ICC (one-way random effects model) = 0.84
- $SD \text{ pooled} = (\sqrt{(SD \text{ baseline})^2 + (SD \text{ at 6 months})^2})/2 = (\sqrt{(12.9)^2 + (14.4)^2})/2 = (\sqrt{((166.4) + (207.4))})/2 = (\sqrt{373.8})/2 = 19.3/2 = 9.65$
- $SEM = SD \text{ pooled} \times (\sqrt{1 - ICC}) = 9.65 \times (\sqrt{1 - 0.84}) = 9.65 \times (\sqrt{0.16}) = 9.65 \times 0.4 = 3.86$
- The MDC was given with a confidence level of 90% (MDC90) or 95% (MDC95).
 - $MDC90 = 1.65 \times SEM \times \sqrt{2} = 1.65 \times 3.86 \times 1.41 = 9.0$
 - $MDC95 = 1.96 \times SEM \times \sqrt{2} = 1.96 \times 3.86 \times 1.41 = 10.7$

The calculated MDC is 10.7. The value for the calculated MCID from the different methods should be above 10.7 so that it is higher than the measurement error.

4.4.5. Objective 2 - To provide estimates of MCID for the PEM questionnaire that can inform future hand surgery trials using the different methods at 24 weeks

4.4.5.1. Minimum clinically important difference for PEM

Table 30: MCID results of the different distribution and anchor methods at 24 weeks (primary endpoint)

	Distribution 0.2x SD (95% CI)	Distribution 0.5 x SD (95% CI)	Within person anchor (95% CI)	Between person anchor (95% CI)	ROC (95% CI)
24 weeks (n=34)	4.9 (3.9 to 5.9)	12.3 (9.7 to 14.8)	17 (-7.8 to 41.8)	8.5 (0.8 to 16.2)	15.1 (-2.8 to 33.0)

4.4.5.2. MCID results summarised for all different methods at primary timepoint

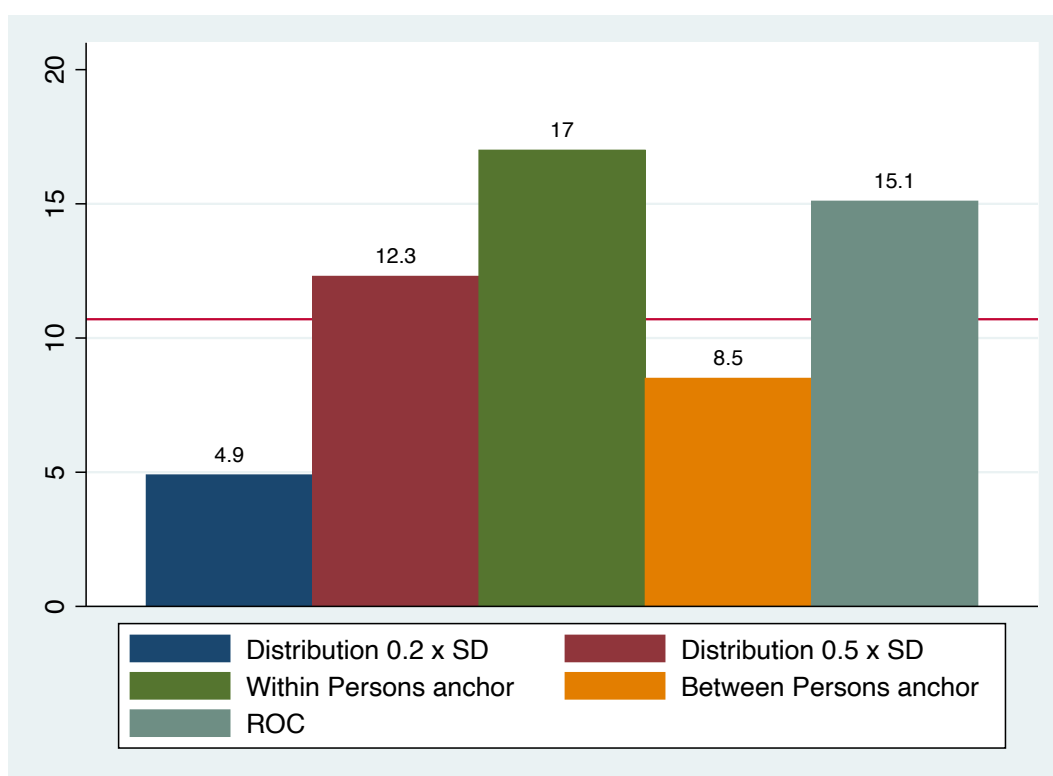


Figure 14: Graphical representation of the MCID scores from the different distribution and anchor methods (Reference line is the MDC95 of 10.7)

The MCID for the PEM at 24 weeks were in the range of 12-17 depending on the method (Table 30 and Figure 14). The 0.2 x SD and the Between persons anchor were dismissed because they are below the MDC. The confidence intervals are high because of the small

sample size and the negative confidence intervals indicate that there may have been deterioration in the PEM when there was improvement in the GROC.

The MCID values calculated for the distribution (0.5 x SD), the within persons anchor, and the ROC were higher than the MDC and thus higher than the measurement error.

The MCID values calculated for the distribution (0.2 x SD) and between persons anchor were below the calculated MDC, so were not higher than the measurement error.

4.4.6. Objective 3 – to assess whether timepoint of assessment influence the PEM MCID in hand fractures

Table 31: PEM MCID results of the different distribution and anchor methods at the different time points (6, 12 and 24 weeks)

	MCID method				
	Distribution 0.2 x SD (95% CI)	Distribution 0.5 x SD (95% CI)	Within person anchor (95% CI)	Between person anchor (95% CI)	ROC (95% CI)
6 weeks (n=51)	3.1 (2.3 to 4.0)	7.8 (5.7 to 10)	2.8 (-6.8 to 12.5)	16.5 (13.9 to 19.1)	14.1 (7.5 to 20.7)
12 weeks (n=42)	4.1 (3.2 to 5.0)	10.3 (8.1 to 12.5)	13.5 (-2.1 to 29.1)	8.3 (3.4 to 13.2)	17.1 (6.3 to 27.9)
24 weeks (n=34)	4.9 (3.9 to 5.9)	12.3 (9.7 to 14.8)	17.0 (-7.8 to 41.8)	8.5 (0.8 to 16.2)	15.1 (-2.8 to 33.0)

The calculated MCID was different at the different time points, but generally in the range of 12-17 (Table 31). For the distribution methods, the low effect size (0.2 x SD) for all time points and the moderate effect size (0.5 x SD) for the 6 and 12 weeks calculated MCID values below the MDC. For the anchor methods, the within persons anchor only for 6 weeks and the between persons anchor only for 12 and 24 weeks, the MCID value calculated was below the MDC.

The values for between persons anchor were lower than the within persons anchor and frequently lower than MDC.

The values for ROC were the highest amongst all calculated MCID values.

- At 6 weeks, 33/52 (64%) of participants achieved an MCID of 12 points or above.
- At 12 weeks, 33/43 (77%) of participants achieved an MCID of 12 points or above.
- At 24 weeks, 26/35 (74%) of participants achieved an MCID of 12 points or above.

4.5. Discussion

4.5.1. Main findings

All methods of calculating the MCID demonstrated a similar range of values. The range of MCID values calculated for PEM at 24 weeks was between 12 and 17 depending on the method used to calculate the MCID. MCID values were slightly different at each time point (6, 12 and 24 weeks), but the range of MCID values was broadly the same between 12 and 17. The $0.2 \times \text{SD}$ and the Between persons anchor at 6 months were dismissed because they were below the MDC. The distribution method with low effect size ($0.2 \times \text{SD}$) always calculated MCID value less than the MDC, so this method is not recommended for MCID calculations.

MCID can be calculated using a variety of methods that give slightly different results. Each of them has advantages and disadvantages, so it is difficult to choose one over the others. It is, thus, advisable for future trials to use a range of methods to calculate a MCID. The distribution method does not take into account what is meaningful for the patients, so its results should be taken with caution. However, from the results of this study the distribution method with the moderate effect size ($0.5 \times \text{SD}$) was consistent with the anchor methods although more likely to slightly under-estimate the MCID. Qualitative work is required to supplement the MCID calculations in order to offer ideas and solutions on which method to use.

The calculated ICC 0.88 from test retest which is good; the agreement was good. However, the MDC that was calculated using test retest was high (10.7). This is probably because of the small sample size and the fact that these assessments were done within a week apart, so might be higher than the true MDC. MDC for the PEM in previous studies was 7.38 (Coughlin, 2018).

The majority of participants from the subset of patients who have not provided follow up data were men with proximal phalangeal fracture. There is quite a difference in follow up

rates for men and women. This has implications for future trial development. Not only men are harder to recruit, but they are also harder to keep in the study.

4.5.2. Relevance to the published literature

This study was novel in that it calculated the MCID for the PEM for finger injuries.

In the literature, there is no consensus on the best method to determine the MCID of PROMs as there is large variation in MCID values calculated from the different methods. There has been one previous study that calculated the MCID for the PEM. They found that the MCID for PEM in Dupuytren's contracture was 3 points (Dias et al., 2015). This is much smaller than the MCID for the PEM for finger fractures/joint injuries calculated from this study. It is also much lower than the calculated MDC in this study, which should not be different between pathologies. The PEM improved by 9.1 points over 3 years in 103 patients who did not have surgery and by 13 points in the 343 patients who had surgery (Dias et al., 2015). The MCID for the PEM in patients with distal radius fractures was calculated as 9.5 (Coughlin, 2018). Again this is lower than both the MDC and the MCID calculated in this study. This might indicate that perhaps the MDC calculated in this study was too high. This could be because of limitations of the sample size and methods. There have been studies that calculated the MCID for other questionnaires, such as the PROMIS Physical function for distal radius fractures (Sandvall et al., 2019), PRWE for distal radius fractures (Walenkamp et al., 2015), QDASH for distal radius fractures, lateral epicondylitis and surgical carpal tunnel release (Smith-Forbes et al., 2016), and DASH for upper limb musculoskeletal condition having physical therapy (Franchignoni et al., 2014). There is minimal literature on MCID for hand fractures/joint injuries, especially for the PEM questionnaire. More importantly, there is lack of evidence specifically for finger injuries.

4.5.3. Implications for research

The calculated MCID will help determine what is clinically meaningful for patients with finger injuries in future hand injury RCTs. The calculated MCID can be used for sample size calculations for future RCTs. The MCID range was between 12 and 17 which is quite high in comparison to previous calculations. The higher MCID may incorrectly classify patients as

failing to respond to treatment. So, the higher MCID for the PEM calculated in this PhD project would result in lower sample size calculation in future RCTs. This would risk missing important differences that really exist.

4.5.4. Strengths and limitations

The sample size for this study was adversely affected by the COVID-19 pandemic and the subsequent break in recruitment. This study is ongoing and at the end it should provide results to be published in a peer reviewed journal. Due to problems with recruitment and missing post-injury data, this study will continue beyond the publication of this thesis. A larger sample size is likely to narrow the confidence intervals of both the MDC and MCID and provide a more accurate estimation of their true values. It is anticipated that this will lead to peer reviewed publication once the sample size exceeds the originally planned 50 patients for the test-retest calculation and 100 patients for the anchor-based approach. There is a current plan and resources in place for the study to continue at least until February 2022.

A strength of this study was that a calculation of the MDC using a test-retest sub-study was done, which is novel for finger injuries. Furthermore, a range of different methods were used to calculate the MCID (both distribution and anchor methods), which will help to determine which ones are more appropriate to use in hand injury RCTs in the future. One of the limitations of this study was that post injury PEM was not completed for the first 117 patients. This happened because of confusion of what the baseline PROM should be. The post injury PEM was needed for MCID calculations. Nothing could be done about the first 117 patients, so it was decided to recruit more patients and do the analyses only for the 60 participants for who we had a post injury PEM and who completed follow up questionnaires. Another limitation was that in the cohort study mainly non-operative patients with mixed injury types were recruited. One issue is whether the results of the mixed injury types and mixed treatment modalities could be used together to calculate a MCID (as it has been done in this study) or whether there would need to be calculation of MCID for the individual injuries and different treatment modalities.

4.5.5. Conclusions

The range of MCID values for the PEM at 24 weeks was between 12 and 17 depending on the method used to calculate MCID. The MCID values were slightly different in the different time points, but the range was the same suggesting that the MCID is likely to be broadly consistent at different time points. Pending additional studies from further datasets, these results can be used to inform the design and interpretation of future hand injury trials. Collection of pre- and post-injury baseline is essential for such cohort studies, especially if they aim to calculate MCID.

Chapter 5: “It’s just a finger, isn’t it...”: A patient perspective of recovery following finger fractures and participation in surgical trials

5.1. Summary

The aim of this qualitative study was to generate detailed, person-centred data about the experience and treatment of finger injury and to support the design of future research in hand injury. Semi-structured interviews were conducted in 19 participants who were part of the Cohort study of Patients’ Outcomes for Finger Fractures and Joint Injuries (OFFJI) study (Chapter 3). Results showed that although finger injuries were frequently seen as minor by the participants, their effects on them were greater than first anticipated. Experience of treatment and recovery varied significantly and was shaped by each patient’s age, job, lifestyle and hobbies. People often coped by normalising the effect of these injuries in order to return to their daily lives by downplaying the effects of the injury. The functional importance of the hand impacts upon how individuals viewed hand research. Interviewees showed reluctance to accept randomisation in surgical trials and thus may decline to take part in a trial. Clinical equipoise and clear communication are fundamental to improve recruitment rates. Pain, hand function and cosmesis were considered important, meaningful outcomes.

5.2. Introduction

The cohort study and MCID calculations have answered some of the questions identified in the scoping review. However, uncertainties remain: (1) how do patients experience treatment and recovery, (2) how do patients feel about taking part in research, (3) and about outcomes, such as the PEM questionnaire.

Finger injuries are common, presenting a significant burden to the NHS (Ootes et al., 2012) (Haughton et al., 2012) (Markiewitz, 2013). The hands are important in expressing emotion and communicating thoughts and feelings through touch (Herenstein et al., 2009). Finger fractures can incapacitate an individual affecting all aspects of life (Altizer, 2003). These injuries may affect activities of daily living leading to dependence, which may affect relationships. Body image may be affected. They can lead to issues in patients’ jobs and

hobbies. All of these may impact on wellbeing and have a consequence for psychological health.

Existing evidence on the optimal treatment of finger injuries is often of poor quality, making interpretation to inform clinical practice difficult (Mousoulis et al., 2019). Researching finger injuries presents challenges. Injuries are more common in active young males (Robertson and Wood, 2015). Young men don't participate in research (Henderson et al., 2010) (Booker et al., 2011). They are economically active. They are in transition phase from going to school and living with parents to going to University, having a job and living independently. They are in the process of establishing relationships. Young men are more likely to engage in risky behaviour and may not seek medical attention. A finger injury is a traumatic injury and need immediate care attention (Eddy, 2012), making recruitment to surgical trials in emergency settings difficult due to time constraints.

Qualitative research can help with the challenges associated with hand research by understanding experience, recovery, treatment, and patients' opinion of how to design studies better in terms of acceptability of design, interventions, choice of outcomes and communications. Interviews are a good method to investigate the patients' personal experience and opinion as they allow the patients to talk freely about their thoughts and feelings (Britten, 1995). A focus on experience of recovery will be a phenomenological assessment of the impact of the recovery from injury and understanding individuals' experience to inform better research. The added value of nested qualitative work in quantitative research has attracted the interest of investigators recently (O'Cathain et al., 2013) (O'Cathain et al., 2014). A review found that the qualitative research in trials mainly focused on the design, process and conduct of the trial; the target clinical condition for the trial (e.g. how it is perceived); the intervention being tested (e.g. its acceptability) and the outcomes of the trial (O'Cathain et al., 2013). Qualitative work can have benefits to support quantitative research at all stages of research (design, approvals, conduct, analysis, write-up and communications). It can also provide insight that can help understand individual experience of disease and treatment. Qualitative research might illuminate the specific characteristics of young men identified above by offering them a chance to talk about these issues in interviews. Interviews can capture the young men's experience and attitudes.

Prior qualitative research offers some insight (Schier and Chan, 2007) (O'Brien and Presnell, 2010) (Chan and Spencer, 2004) (Ammann et al., 2012) (Fitzpatrick and Finlay, 2008) (Bialocerkowski, 2002) (Watson et al., 2018) (Bamford and Walker, 2010). Nevertheless, the qualitative literature on hand fractures and joint injuries is not extensive. The investigators talked about the impact of the injury, e.g. at work, at home and in leisure activities. Patients may need to rely on others at work or at home, which can affect their confidence and make them feel anxious or even depressed (Schier and Chan, 2007). The need for psychological therapy for these patients has been discussed (Chan and Spencer, 2004). There is an issue about the perception of treatment and recovery as the lack of information on the recovery can make patients anxious (Watson et al., 2018). Patients frequently see the injury as minor and the operative treatment as complicated. This uncertainty in the recovery can affect satisfaction with the treatment (Bamford and Walker, 2010). The SWIFFT study talked about practical limitations, psychosocial impact, and treatment preference for patients with scaphoid fractures (Dias et al., 2020b). Qualitative studies in hand surgery also showed that if healthcare professionals empathise with patients and give them more information in fracture clinic then this will improve their overall experience of recovery (Bamford and Walker, 2010) (O'Brien and Presnell, 2010) (Huetteman et al., 2018) (Watson et al., 2018).

For research processes, this interview study aimed to investigate how patients feel about randomisation, how to improve recruitment and retention rates and how to choose outcomes in future trials. Randomisation is generally a concept that is difficult to communicate to patients. Patients need to be told that the risk in an RCT is not greater than standard care as they being are offered everyday treatments, unless it is a placebo-controlled trial. A systematic review, however, showed that placebo-controlled surgical trials are feasible, but recruitment is difficult (Wartolowska et al., 2016).

Recruitment to RCTs can be an issue because of preference for particular treatments (Leighton et al., 2012). A systematic review showed that engaging participants in the learning process of the trial and its potential benefits can help to improve recruitment rates (Caldwell et al., 2010). Even though there is no clear evidence that surgical trials differ from medical trials in terms of recruitment activity, an RCT comparing surgical and medical treatments might be difficult to recruit participants as both the patients and the surgeons may have a preference over which treatment they prefer (Whybrow et al., 2017) (Ollivere, 2018). They may not be in equipoise. A qualitative synthesis study has showed that

clinicians' personal views can affect the communication of equipoise to patients in trials and this needs to be addressed before recruitment (Rooshenas et al., 2016).

Participants may be lost to follow up as they may disengage once they have fully recovered from their injury. Engaging participants in the study by getting them to understand its value increases retention rates (Leighton et al., 2018).

It is also difficult to choose appropriate outcome measures for such studies. More recently there is an interest in Patient Reported Outcome Measures (Dacombe et al., 2016), but there is no Core Outcome Set for finger injuries.

More research in finger injuries is needed. They are traumatic injuries which are difficult to get patients to engage with research. Furthermore, these injuries happen more frequently in young men who are a challenging population. The aims of this interview study were to get a more detailed understanding of how the injury is viewed/experienced and how this population view research. This might support better designed future studies, better communication about research to this population and might generate more acceptable research processes.

5.3 Methods

The aim of this qualitative study is to generate detailed, person-centred data about the experience of finger injury and treatment, with a view to informing better designed future studies in hand injury.

The objectives of the qualitative study are: to explore patients' experience of finger injury and its treatment, to explore patients' experience of participating in clinical research, to gain insight about specific barriers and facilitators to participating in research, and to seek recommendation on the nature and design of future clinical studies in finger injury. This insight will help researchers to consider the appropriateness and acceptability of future hand studies and will help researchers to think about recruitment/retention strategies as well as outcomes which are meaningful to participants.

This interview study was nested within a prospective, longitudinal cohort study on finger fractures and joint Injuries (Chapter 3) (Table 32).

Table 32: PICO table for OFFJI study

	OFFJI study – Cohort study of patient outcomes in the management of finger fractures and joint injuries
Population (P)	Patients with finger injury presenting in fracture clinic within 14 days of injury • proximal phalangeal fracture (intra and extra-articular) • middle phalangeal fracture (intra and extra-articular) • volar plate • mallet finger
Intervention (I)	Operative
Comparator (C)	Non-operative
Outcomes (O)	Patient Reported Outcome Measures (PROMs) • Patient Evaluation Measure (PEM) • EQ-5D-5L • PROMIS Computerized Adaptive Test (CAT) • Global Rating of Change (GROC)

5.3.1. Study design

This is a semi-structured interview study exploring the lived experience of finger injury and treatment, and which considers attitudes about taking part in research. Ethical approval was obtained from NHS REC West Midlands - Coventry and Warwickshire (REC Reference 19/WM/0087) (Appendix 5). The Patient Information Sheet and the consent form for the Qualitative study are in Appendices 13 and 14.

5.3.2. Participants

OFFJI participants indicating a willingness to be interviewed were purposively sampled to build a study population representing a spectrum of injury, occupation, treatment modality and clinical course/outcome. To better reflect the usual clinical population the ideal sample would include participants with patient and treatment characteristics as described in Table 33 (Aitken and Court-Brown, 2008) (Anakwe et al., 2011). Patients with an attribute, such as male sex, a particular injury, young age, treatment modality were approached.

Table 33: Ideal sample within the interview study

	Gender		Age		Occupation	
	Male	Female	Under 30	Over 30	Manual	Non-manual
Operative	7	3	7	3	5	5
Non-operative	7	3	7	3	5	5
Total	14	6	14	6	10	10

5.3.3. Interviews

Interviews were semi-structured to explore injury, recovery, and opinion about research processes. The interview guide was developed to include questions around the experience of injury, treatment and recovery as well as attitudes to participation in research (Table 34). The aim was to create open-ended questions that would cover the totality of the experience and attitudes. Participants were encouraged to introduce any additional topic they thought relevant to researching hand injuries.

Interviews were conducted face-to-face or by telephone by CM. To capture potentially differing attitudes during recovery, interviews were conducted between 3 and 10 months post-injury.

Table 34: Interview guide

Themes and questions
Finger fracture/joint injury
• Please remind us of your injury? Did you seek help straight away? What made you seek medical help? How did you feel? What were you worried about? • How has the injury affected you? • How have you coped with work, at home and in leisure activities? How did that make you feel? • Have you needed help with activities of daily living and at work? What sort of help have you needed? Who has been able to help in these things? [If no one] how have you coped with this? How do you feel about this?
Experience of patient pathway for hand fractures/joint injuries
• What did the HCP tell you in the initial appointment in fracture clinic? What was the treatment you received? • What did you think of the treatment? How did you feel about the splint/operation? • Are you satisfied with the treatment? • Was it what you expected? • Was there anything that surprised you? • Would you rather a different course of action if you had this injury again? • Given your experiences what information would you give to new patients? What information would you give to the doctors treating them?
Recruitment and participation in a research study
• Why did you agree take part in this study? How did you feel when you were approached? • What sort of things did you think about when you decided to take part in the study? Was there anything that you were uncertain about? Is there anything else that we could of told you / given you to help you make the decision? • What would you say to anyone that wasn't certain about taking part? • What did you know about research before you were approached? How did you feel about research? • Do you think that there are any benefits to taking part in this type of research?

Study
• How have you found our study? How have you found the forms that we have given you? And the questions that we have asked you? How do you feel about taking part in this study? • How do you think we should collect data? (e.g. by questionnaires, interviews, of discussion groups) • If we asked you to stay involved in our study for a longer period, would you? What sort of things would influence your decision? Is there a maximum time you would stay involved for? • Is there anything that we can do to keep participants in the study? • How could we approach groups who are less likely to take part and remain in a study?
Randomization
• Do you understand what is meant by randomisation in research? • Do you think that you would you be willing to be randomised to a particular treatment in a research study? What would influence your decision? Would you accept that the doctor will not be deciding on their treatment? It will be by chance/toss of a coin. • Would you be happy to have surgery/conservative treatment if randomised to it?
Final questions
• How do you think that studies could be improved in the future both from the clinician's, researcher's and patient's point of view?

5.3.4. Analysis of the interview data

Interviews were digitally recorded and transcribed in full. Personal identifiers were removed. Data were analysed in NVivo software (version 12) by a single author (Dr Christos Mousoulis) and later verified by the remaining research team.

Framework analysis was used (Smith and Firth, 2011) (Srivastava and Thomson, 2009). Framework analysis is a pragmatic approach to studying an applied health problem, and it is structured and systematic. Using this approach, a set of themes are identified *a priori*, which help the development of the interview guide and help give focus to the interviews.

The data analysis is then based on these themes even though they are modified based on the interview data. The five stages of data analysis in the framework approach are: (1) familiarisation of the data, (2) identifying a thematic framework (key issues, concepts, etc.), (3) indexing (applying numerical codes), (4) charting (rearranging the data to the appropriate part of the thematic framework to which they relate to, and forming charts), and (5) mapping and interpretation (using the charts to define concepts, create typologies and find associations) (Pope et al., 2000).

Table 35 shows the two proposed themes and codes for the analysis. This was a starting point for the analytic process. These were further developed as part of the analysis of the interview data. Themes were identified *a priori*, informed by the study aims and previous literature (O'Brien and Presnell, 2010) (Dias et al., 2016) (Mousoulis et al., 2019), and then combined with other themes identified *de novo* during analysis (Dixon-Woods, 2011).

Framework analysis is preferable to other theoretical and exploratory approaches as it is more focussed and time efficient (Gale et al., 2013). An awareness of issues pertinent to this population from previous research mean that an inductive / exploratory approach was not required. A framework approach was decided because the goal of this research was clearly defined at the beginning. This was to help the development of future trials in the topic. The thematic framework was developed to address the research objectives. Each interview was considered independently helping to revise and build the thematic framework. Given the pragmatic nature of this nested study this approach seems sensible providing insight about injury and future research rooted in the responses of cohort participants. The framework approach helps to consider the study objectives explicitly and analyse data efficiently.

This was a pragmatic, nested study that did not formally test for thematic saturation. Framework analysis does not rest in ideas of thematic saturation as other analytic methods do.

Table 35: Themes for proposed framework analysis

Framework 1 - Patients' experience of injury and treatment
• Inconvenience - Bothersome symptoms and activities restricted • Psychological and Social impact • Speed of recovery • Complications • Experience of treatments (conservative or surgical)
Framework 2 - Research process for patients
• Appeal of research • Research process • Outcomes • Recruitment and Retention • Study burden • Equipoise • Randomization/Blinding

5.4. Results

The details of recruitment of participants for interviews are in Table 36. Twenty-eight participants were approached. These were selected purposively prioritising whether they were male, under 30 and whether they were operated or had a complication. The email was sent twice (once as a reminder) and the patient was called twice on two different occasions. For example, there were 9 patients who were operated in the cohort study and only 3 of them had consented to being approached for an interview. Of these 2 were interviewed and 1 was non-contactable. There were 30 manual workers in the cohort, 17 of those consented to be approached to be interviewed. Two were approached and interviewed. Patients who expressed an interest in taking part in the interviews after all patients were sent a newsletter were also invited to take part because of the difficulties with the COVID situation.

Table 36: Details of recruitment of participants for interviews

Participants who:	Number
Consented to being approached for an interview	112/161 (in Nottingham)
Approached to take part in an interview	28
Declined to take part in an interview	0
Approached to take part in an interview, but who were not contactable	9 did not answer phone or email (one of them after re-arranging the interview twice)

Nineteen interviews, each lasting between 30 and 60 minutes were conducted between 19/09/2019 and 30/04/2020. Demographics and injury of the participants are presented in Tables 37 and 38. The age range was between 21 and 78 years, and there were 10 women and 9 men. Two participants were treated operatively and 17 non-operatively.

Table 37: Demographics of patients who were interviewed

	Gender		Age		Occupation	
	Male	Female	Under 30	Over 30	Manual	Non-manual
Operative	2	0	1	1	1	1
Non-operative	7	10	3	14	1	16
Total	9	10	4	15	2	17

A-priori themes were added to during analysis and the final coding framework included 12 codes and themes (Table 35). Data is organised here to illustrate: A) the experience of injury/treatment, and B) the experience of research. Themes (from the framework analysis) were reviewed as part of the analysis and some 'informal' version of saturation was achieved around patient 12 or 13 when the interviews changed slightly into being more direct about how the development of future trials could be improved. Within 19 interviews, data was achieved to address each objective of the framework.

Table 38: Details of participants who were interviewed

Participant	Age	Occupation	Injury	Time from injury (months)	Type of treatment and complications
1 (F)	45	Agency employee	Proximal phalanx fracture extra-articular shaft	3.5	Non-operative (Bedford gaiter)
2 (M)	21	Student	Proximal phalanx extra-articular shaft	6.5	Operative (ORIF, had minimal extension lag 6 weeks later)
3 (F)	50	Receptionist	Proximal phalanx extra-articular shaft	8	Non-operative (Zimmer splint, had stiffness and fixed flexion deformity)
4 (M)	47	IT	Proximal phalanx extra-articular shaft	6	Non-operative (Zimmer splint, had stiffness treated with physiotherapy)
5 (F)	50	Education manager	Proximal phalanx fracture extra-articular base metaphyseal	3.5	Non-operative (Zimmer splint)
6 (M)	60	Engineer	Proximal phalanx extra-articular base metaphyseal	4	Non-operative (Bedford gaiter)
7 (F)	44	Not currently working	Proximal phalanx base fracture	10	Non-operative (Zimmer splint)
8 (M)	39	Student	Proximal phalanx fracture intra-articular base	4	Non-operative (Zimmer splint)
9 (M)	31	Clerical	Proximal phalanx intra-articular base	4	Non-operative (Mobilisation freely)

10 (F)	24	Banker	Middle phalanx intra-articular base – pilon fracture	4	Non-operative (Resting splint)
11 (M)	23	Student	Middle phalanx intra-articular base	5	Non-operative (Zimmer splint, had extensor lag at 3 weeks)
12 (M)	40	Driver	Middle phalanx intra-articular base	7	Operative (K wire fixation)
13 (F)	40	Not currently working	Volar plate	3.5	Non-operative (Resting splint)
14 (M)	58	Healthcare professional	Volar plate	10	Non-operative (Bedford gaiter)
15 (F)	28	Scientist	Bony mallet	4.5	Non-operative (mallet splint)
16 (F)	78	Retired	Bony mallet	4	Non-operative (mallet splint, had extension lag treated with physiotherapy)
17 (M)	68	Lecturer	Bony mallet	4	Non-operative (mallet splint)
18 (F)	55	Music teacher	Bony mallet	6.5	Non-operative (mallet splint, had reduced function of the affected finger)
19 (F)	55	Clerical	Bony mallet	9	Non-operative (mallet splint)

5.4.1. Participants' experience of injury and treatment

In this participants described the initial impact of the injury, misconceptions about its severity, and the inconvenient nature of sustaining a finger injury.

5.4.1.1. Inconvenience

A finger injury is often initially considered minor. Some participants continued playing sport believing the injury to be inconsequential.

“my friend’s son and my son they were playing with each other... and by accident, they kicked my little finger” (participant 13, 40y female, volar plate)

“It happened playing football. I was hit by a ball. I carried on playing for an hour” (participant 14, 58y male, volar plate)

The look of the finger made the patients realise that there was something wrong and not the pain.

“Yes, from the way that the finger looked, it wasn’t necessarily painful. It was more the look that made me realise it was broke” (participant 10, 24y female, pilon fracture)

A quick recovery to normality was predicted.

“I thought, maybe it was just potentially a dislocation and they might be able to put the finger back in” (participant 4, 47y male, proximal phalanx extra-articular shaft fracture)

“I knew I’d hurt myself but I didn’t think it was serious” (participant 6, 60y male, proximal phalanx extra-articular base fracture).

If they had multiple injuries the finger injury was the least of their worries.

“I’ve gone out from a newish road bike and had an injury... But, it wasn’t until I looked down at my fingers that I actually realised it was either dislocated or broken because it was the position of the little finger really... I had more focus on my head really than in my hand” (participant 1, 45 y female, who had a proximal phalanx extra-articular fracture and head injury)

However, any initial assumption was often replaced by a recognition of wider impact; once treatment started many participants recognised practical limitations associated with their injury.

“Well obviously I’m a university student, so I was unable to type my assignments or take notes in lectures” (participant 11, 23y male, middle phalanx intra-articular base fracture)

The importance of finger function is taken for granted in the population and thus finger injuries as thought as inconsequential. The following two quotes summarise this.

"You take everything for granted, but your hands are fantastic machines... the hands are key to being able to manipulate and express and... just generally interact... So being able to understand the effect of when something goes wrong I think is really important. And people need to have that explained to them" (participant 19, 55y female, bony mallet)

"The other thing is, that also explaining to people, when you say "I've broken a finger" they also have that expectation like "Well it's only a finger. Why aren't you at work?" you know that sort of thing. So I think the whole perception is probably not as it should be" (participant 3, 50y female, proximal phalanx extra-articular fracture)

The issues that patients had immediately after the time of their injury meant that their work would be affected. The impact in work for people is not just about the injury, but about how work treat them and that this will vary markedly between individuals, organisations and occupations. Workplaces sometimes allowed a phased return or offer reduced pay.

"Work are brilliant with any injuries any employee has, they give us back on a phased return, so they tend to work with employees more than anything" (participant 1, 45 y female, proximal phalanx extra-articular fracture)

"They gave me the time off but our policy, I did lose money because they didn't pay me the full sickness" (participant 3, 50 y female, proximal phalanx extra-articular fracture)

Some participants were able to return to work straight away.

"the bosses was good with me and they put somebody with me all the time, a driver's mate with me all the time to start with... And they was doing all the securing and what have you and basically I was just doing the driving" (participant 12, 40y male, middle phalanx intra-articular fracture)

Hand function is important in housework and some participants had issues with this. Participants also had issues with grocery shopping.

"But, it is quite difficult, for example, when I do groceries... I now bring my backpack with me, I still have to bring the plastic bag" (participant 13, 40y female, volar plate)

In addition to the practical limitations described above, participants had issues with hobbies, which sometimes affected them.

"I couldn't horse ride. That was out of the question" (participant 3, 50y female, proximal phalanx extra-articular fracture)

"well I did play obviously five a side on a weekly basis, so I didn't do that. Got kids so we go out like on bikes and stuff, so I didn't do that" (participant 4, 47y male, proximal phalanx extra-articular shaft fracture)

"A bit gutted... I am not proper massive on sports anyway... but obviously...., because I'd only just started rugby really this year and it happened after about four games" (participant 11, 23y male, middle phalanx intra-articular base fracture)

In the longer-term participants identified that full function had not returned, despite being back to their previous employment or hobbies.

"Fully back at work... The only thing ... if I don't focus on forming a fist properly, I will pick small things up, like tablets, I might drop some if they're in my hand" (participant 3, 50y female, proximal phalanx extra-articular shaft fracture)

"well it's like my finger still won't quite bend, from that joint it doesn't bend all the way, but I think that is going to be probably it for now" (participant 15, 28y female, bony mallet)

"I don't use my hand in the same way...I think it's probably slightly weakened by the experience. And it doesn't work in quite the same way as it used to, or my right hand works" (participant 14, 58y male, volar plate)

The impact of injury and on-going functional limitations differed between participants, influenced by both the injury itself and their prior employment or lifestyle. Table 39 illustrates some of these general points about the impact of a hand injury with two exemplars.

Table 39: Exemplars of the effects of injury and recovery

Exemplars of the effects of injury and recovery:
Participant 10 was a 24 year-old female, who was a banker, and had a pilon fracture. She had the injury at home. It was a fall when having a shower. It was not painful, but she went to the A&E because of the appearance of the finger. She had issues with picking heavy objects and doing housework initially and she still had issues opening jars and going to the gym at the interview 4 months post injury. The finger did flex at 4 months post injury, but it looked deformed. She did not have issues with her work as she works with a computer. In hindsight, she would have gone for the operation rather than the non-operative treatment.
Participant 6 was a 60 year-old male, who had a proximal phalangeal extra-articular base fracture and was interviewed 4 months post injury. He is an engineer. He fell off the bike in motorcycle training. He continued the course for another hour and then noticed the injury when he took off his gloves and the pain started. He was still getting pain and doing the physiotherapy exercises when he was interviewed. He had issues with grip when interviewed, which would affect childcare, but he reported he was fine as he could use the other hand. He was not working temporarily after a particular project finished. He had various hobbies, such as wood turning, going on a motorcycle, playing golf, doing DIY projects. He said he could still do all of them, but had to adjust due to the pain he was getting.

Patients cope by 'normalising' the fact that their fingers may never be 100% back to normal. People are saying to themselves that a finger is a small bone and this is minor and part of life. They get on with their lives. They say that no-one notices.

"the little finger, it is only a small bone" (participant 17, 68y male, bony mallet)

"initially I was upset but I'm not really too concerned because it's just life, it's just what happens" (participant 2, 21y male, proximal phalanx extra-articular fracture)

They accept the situation as part of life. The quicker they accept the situation and they adapt the quicker they can resume their lives. Some were happy to accept that their fingers may never be 100% back to normal.

“Well it’s not a huge problem because it’s my little finger. I mean if it was my other fingers, I guess it would be more of a problem”
(participant 10, 24y female, pilon fracture)

“Am I upset – um, no, not really, you know, I’ve broken a few bones over the years. I’m 59 years old and I’ve done a lot of sports so I break things. And, you know, it doesn’t bother me that it’s slightly bent. I suppose the one thing I wonder is if splint, had a splint on it of some sort, whether it would be straighter, but I’ve no way of knowing that” (participant 14, 58y male, volar plate)

“No, everything seems to be OK. I mean it may be a little bit swollen still, but, who notices it! Phew. Yeah. I only notice it cause I am aware of it and my girlfriend, she notices it. But, anybody else, no. Nobody has said anything” (participant 17, 68y male, bony mallet)

There is a difference in the impact of the injury. For example, for a health care professional who talks to people it is less of an issue

“Interviewer: What about with your job – what job do you do again?”

Respondent: Psychotherapist. Yeah, inpatient... so it doesn’t move at all because I sit and talk to people” (participant 14, 58y male, volar plate injury)

For others the consequences were considered much more significant. They cannot ‘normalise’.

“Also I’m a music tutor... I still cannot play to my standard... Yeah, it does affect me... it’s what I do” (participant 18, 55y female, bony mallet injury)

“Not happy with the outcome but is that – you don’t know if it’s normal or not”
(participant 18, 55y female, bony mallet)

Recovery was frequently longer than expected, despite no participants reporting any complications. Even with physiotherapy exercises the length of recovery was slow. Participants are time poor, they need to get back to their busy lives as soon as possible. Patients would have to do the physiotherapy exercises long term. Patients normalise their situation and accept it.

“I did not think it would be anything like as long as it took.

Interviewer: So, that was a surprise that it took so long?

Respondent: Yes, it was” (patient 16, 78y female, bony mallet)

“I was surprised that I was very determined with my physiotherapy, that it took a lot longer than I expected to get the

use of my fingers, to a more acceptable level. I mean it is pretty good now but I am still surprised I am having to work on it"
(participant 3, 50y female, proximal phalanx extra-articular shaft fracture)

In hindsight, participants felt that they should have sought treatment earlier. This reflects the patient perspective that it is minor and can wait.

"I would have sought treatment earlier. We were on holiday for a week before we got back home" (participant 16, 78y female, bony mallet)

5.4.1.2. Experience of treatments

Participants generally expressed positive feelings about their care when asked directly. They did not express any complaints. However, in discussion a number of criticisms or concerns were identified. Inefficiencies in fracture clinic and the need for improved communication, especially when discussing prognosis were highlighted.

"the input from the doctor in fracture clinic was very minimal"
(participant 14, 58y male, volar plate)

"Occupational therapy... Some of the devices weren't always that well-fitting, and could be quite uncomfortable" (participant 3, 50y female, proximal phalanx extra-articular shaft fracture)

"the person who put the splint was OK, there was no pain, but I don't think had much experience of putting splints on... this person does not know what they are doing" (participant 17, 68y male, bony mallet)

This was particularly apparent for participants undergoing non-operative treatment, when functional recovery 'feels slow'.

"There was one point when I was worried.... Because the swelling wasn't going down, and I went to see them and they said: this is normal. It would take time" (participant 15, 28y female, bony mallet)

A participant who was not 100% back to normal at 9 months said that she would still have chosen the conservative treatment if she had a choice.

“Yeah, I think personally I prefer the splint... I suppose you might have a little bit more control yourself as an individual over the splint” (participant 19, 55y, female, bony mallet)

One participant indicated a retrospective preference for surgery due to lack of functional return. This patient claims that the advantages and disadvantages of the options of operative and non-operative treatments were not fully explained to her at the baseline appointment in fracture clinic by the surgeon.

“My finger has healed weird so the top of the finger is bent and you can’t straighten it. I’d probably have gone with the operation. It would have been nice to have the option to fully understand the treatment” (participant 10, 24y female, pilon fracture)

In contrast, a participant who had undergone surgery expressed disappointment at the time taken to recover. It took 12 weeks after surgery to get back to living normally.

“I think that was what I was most upset about, that I just couldn’t go back to living normally for a prolonged period of time... It was just more of an inconvenience” (participant 2, 21y male, proximal phalanx extra-articular shaft injury)

The other participant who had surgery, knew it was going to be painful, but was reassured by the fact that he had a previous finger operation by the same surgeon which went well.

“Interviewer: What was it like having an operation?”

Respondent: Obviously no-one wants to have an operation, but I wasn’t scared or anything... It’s the second time I’ve broken the same finger as well and I worked with that same doctor obviously before, so I knew he was good... It was painful, first couple of days... Yeah, I knew it was going to be painful” (participant 12, 40y male, middle phalanx intra-articular base fracture)

Table 40 illustrates some exemplars of treatment experience of participants, one who was satisfied and one not satisfied with the care provided.

Table 40: Exemplars of treatment experience

Exemplars of treatment experience:
Participant 17 was a 68 year-old male, who was a lecturer, and had a bony mallet injury. He noticed that his finger was swollen but did not recall his injury. The pain was minimal initially. He was treated with a mallet splint and was satisfied with the care provided. He felt that because the injury was in his little finger, this was not as important as it is a small bone. Even though his finger was still swollen 4 months after the presentation he still felt it was OK as only himself and his girlfriend noticed it. He expressed some concern about one of the healthcare professionals who put on one of the splints as he/she was very inexperienced. He was not very concerned though as he felt this injury was not serious.
Participant 18 was a 55 year-old female, who was a music teacher and had a bony mallet injury. She had the injury when taking the dogs for a walk and tripped on the pavement. She was interviewed 6.5 months after the injury. Her finger was still painful and stiff. She was upset because she could still not play music to her standards, only to kid's standards. She was unhappy because the surgeon in fracture clinic told her that he was certain that she would reach a full recovery within 6 months. In hindsight, she would have rather had the mallet splint for longer.

5.4.2. Participant involvement in research

In terms of involvement in research, participants demonstrated a generally positive attitude towards research and offered insight about the OFFJI processes that they had experienced.

5.4.2.1. Recruitment/Appeal of research

Overall, participants were very happy to take part in research. Wanting to advance the overall care that the NHS provides they acknowledged that the benefit of research would impact upon others, rather than benefiting themselves directly.

"I think obviously future patients will benefit, but also, I'm sure research has been done before my own injury, so we all benefit for it overall. And also for the clinicians, the doctors, the trainees, I would have thought it would be a benefit for everybody overall"

(participant 3, 50y female, proximal phalanx extra-articular shaft fracture)

“I think it is good to have a dialogue between patients and the NHS” (participant 9, 31y male, proximal phalanx intra-articular base fracture)

“And I think it’s very important for you to do these research studies. How do we move forward any other way? I did a little bit of nurse training back in my younger days and I know it’s important to follow up on these things, so that’s why I said yes” (participant 18, 55y female, bony mallet injury)

Participants thought that this cohort study was straightforward and not time consuming.

“I’ve got no problems with it whatsoever. At the end of the day, if you don’t talk to your patients, then you don’t learn, and we all need to carry on learning” (participant 1, 45y female, proximal phalanx extra-articular shaft fracture)

“Any research that you can support... that will aid the knowledge bank is important..., because this is... likely to affect many people with these small injuries” (participant 19, 55y female, bony mallet)

In this cohort study, participants liked that the follow up questionnaires were short and were sent to them as an email and they could do it in their own time. They also liked the flexibility of arranging interviews and doing them over the phone.

“emails are by far away my preferential choice of receiving these sorts of things, because I can then answer in my own time, when I am free and I am happy to think about something” (participant 9, 31y male, proximal phalanx intra-articular base fracture)

Participants indicated that they felt that they might be less inclined to join a research study if they were in physical, or emotional, distress at the time of recruitment. In this circumstance research might be perceived to be an unwanted burden.

“...because if it is very painful, my main concern will be me, getting better first..., like I don’t care about your research now, maybe in the second visit after

*a few weeks when I feel less painful, probably I would be more willing”
(participant 13, 40y female, volar plate injury)*

With regards to when and where should patients be recruited, patients said:

“probably in Fracture Clinic... because in A&E like you’re a bit more anxious and you... ’re looking at the time and stuff depending on how long you’ve been there, and sort of in a rush when you get to A&E. You can’t wait to get out of A&E” (participant 7, 44y female, proximal phalanx base fracture)

However, participants reported that an earlier appreciation of the consequence of a hand injury and the time taken to recover might encourage them to engage with a research study, rather than presuming that research is unnecessary in such a “minor” injury.

“Interviewer: Why do you think that patients might not want to take part (to a research study)?

Respondent: With it being a little finger, they probably don’t realise how much it’s going to affect them” (participant 7, 44y female, proximal phalanx base fracture)

In order to improve recruitment rates (as participants said), the surgeon in fracture clinic, who is recruiting patients in the study, should be a good communicator. The surgeon does not have to be a consultant.

“Interviewer: do you think that we need a surgeon who is a good communicator to talk about all aspects of the study?

Respondent: Yes, and give people, if you like, the understanding and the confidence really. Yes. Get them on board” (participant 3, 50y female, proximal phalanx extra-articular fracture)

“Interviewer: do you think that it should be the consultant who talks to the patient about the study?

Respondent: I think it could be any doctor” (participant 19, 55y female, bony mallet)

When deciding on participation in a trial, participants felt that being told about the scope and value of the study is important.

“I suppose you’d want to know what the study was about, what it was trying to achieve... the time involved... what was physically involved...what the risks would be involved... what sort of study size ... whether it was just based locally or is it something that’s going off nationally or internationally” (participant 19, 55y female, bony mallet injury)

The doctors should present all the evidence and discuss the pros and cons of each treatment. Then it would be up to the patient to decide. The patient should be able to decide quickly.

"I'd be able to make a decision immediately, I might then reflect and change my mind, but you'd give them that option wouldn't you..." (participant 14, 58y male, volar plate)

Monetary incentives were important for some participants, but not others.

"Which your Amazon vouchers are a very good incentive for that. But, other than that... maybe their fingers have healed and they're fine and think why should I carry on with this" (participant 18, 55y female, bony mallet)

"It's not something that would instantly attract me to... this survey... It's more about the service kind of thing" (participant 8, 39y male, proximal phalanx intra-articular base fracture)

Regular contact from the research team, detailing study progress and impact was described as good for ongoing engagement.

"Whether it would be a newsletter or email, I think it's probably the best way to keep people engaged" (participant 9, 31y male, proximal phalanx intra-articular base fracture)

"Again, I think it's keeping things fairly simple, because people do lose interest, if they don't feel they're immediately gaining from something, which is a bit selfish, but that's human nature. I think the incentive for people is reiterating how they are helping, how the research will help towards improvements for their own treatment and other people's treatment, just gently remind them" (participant 3, 50y female, proximal phalanx extra-articular shaft fracture)

One patient suggested that there should be a website with information for patients with finger fractures/join injuries to help patients understand the role of research. This would help patients understand the importance of these injuries and get a feel of what the recovery is like for the average patient and how their recovery is different to that.

5.4.2.2. Outcomes

Pain

Participants reported pain as important following finger injury.

“I was in quite a lot of pain, and the finger was very bruised and they were very swollen and very painful, yes, it was a lot of pain to start with” (participant 1, 45 y female, proximal phalanx extra-articular fracture)

Participants may still feel pain months after the injury, but they may be reluctant to seek medical advice.

“I still feel pain, but I just don’t feel it’s enough to go back to the hospital. Will the pain ever go away, or how... I don’t know anything about it” (participant 13, 40y female, volar plate)

The pain can significantly affect on patients.

“it has affected me quite a lot, because even now it’s painful, I can feel it now and because I’m right handed, it was my little finger on the right hand, like, if I’m chopping vegetables, tying shoelaces, you tend to use that little finger and it is – it’s crooked now, it’s painful” (participant 18, 55y female, bony mallet)

Pain can be associated with limited function.

“Weightlifting or using the kettle bell, I seem to notice pain around my middle joint and since it’s got colder as well it’s painful” (participant 10, 24y female, pilon fracture)

Participants feel that pain is worse than limited finger function.

“Interviewer: ...long term, which one do you think is worse? Having pain or difficulty moving the finger? Or are they both equally bad?

Respondent: Probably having pain” (participant 7, 44y female, proximal phalanx base fracture)

Function

Participants reported function as important following finger injury. They complained that their hand was not working as well as before.

“It doesn’t work in quite the same way as it used to, or my right-hand works” (participant 14, 58y male, volar plate)

They had to rely on the other hand for carrying anything heavy.

"I'm a little bit more hesitant to carry anything too heavy on it, like shopping bags. I tend to shift that over to my left hand if I'm carrying anything too heavy" (participant 19, 55 y female, bony mallet)

Cosmetic appearance

The impact of cosmetic differences was also noted as impactful. It was thought that cosmetic appearance of their fingers was linked to their pride.

"I suppose appearance is a very personal preference, you know, some people are very proud of their fingers and their hands" (participant 19, 55 y female, bony mallet)

This meant that participants were embarrassed to show their fingers if they were affected.

"It's embarrassing, yes. I try to keep my hand like, not showing my hand, because everybody will go "Oh look at your finger" or "What have you done to your finger?" (participant 7, 44 y female, proximal phalanx base fracture)

Some participants were over 6 months post injury and were still experiencing issues with cosmetic appearance.

"It's still crooked. It looks disgusting" (participant 7, 44y female, proximal phalanx base fracture)

Patient-Reported Outcome Measures

Participants completed various Patient Reported Outcome Measure (PROM) and quality of life questionnaires as part of the OFFJI study (Patient Evaluation Measure (PEM), Global Rating of Change (GROC), EQ-5D-5L, PROMIS CAT); interviews reflected on these and the process of completing them. With regard to acceptability, participants liked that the follow up questionnaires were short and were sent to them as an email and they could do it in their own time. They felt that access to previous responses (for repeated measures) would enable them to be more accurate in their scoring.

"I'd say the only thing is to... maybe give the answers from the previous time because I want to make sure that I've not answered differently to avoid confusion for the person that's reading the answers" (participant 2, 21y male, proximal phalanx extra-articular fracture)

Specific items within these instruments were however highlighted as inappropriate or irrelevant, items such as the ability to 'change a light bulb' in the PROMIS CAT and 'anxiety

and depression' in the EQ-5D-5L. Participants noted that whilst they may experience issues in these domains, this was not as a result of their finger injury.

"I can't do, but it's not got anything to do with my finger, that's to do with the fact that I've lost my hearing and I've got no balance!"
(participant 18, 55y female, bony mallet)

"I think some of them (questions) were... not linked to the hand... it was something like... do you feel depressed?... Some people may be unhappy for other reasons, other than the injury" (participant 4, 47y male, proximal phalanx extra-articular shaft fracture)

An individualised approach to outcome questioning was considered a better way of capturing outcomes, and interviews were also recognised as a possible way of generating meaningful data.

"If I am very honest, some of the questions, I found were too broad and probably irrelevant to the injury I had... maybe try to have a specific sheet to insert with your questionnaire that is targeted towards an individual's injury"
(participant 6, 60y male, proximal phalanx extra-articular base fracture)

"Certainly, because when you've got a conversation you can express and have that dialogue, whereas when you are answering on a paper or an email format, you can't have that conversation" (participant 5, 50y female, proximal phalanx extra-articular base fracture)

5.4.2.3. Study burden

Participants recognised that research is separate to NHS care and that it requires additional time. Some participants took part in this study because they were not working and they had more free time.

"I just moved to the city, I am not working and I have time, so I thought why not help people, that is all. I mean I have time" (participant 13, 40y female, volar plate)

Participants generally felt that 6-month follow-up for involvement in any finger fracture research is sufficient.

"Interviewer: Do you think that six months is long enough or do you feel we should be sending another questionnaire after a year after the injury?"

Respondent: I don't think there'd be much point in that. I don't think my hand's going to change any more than it has done now, so I couldn't see the point of that, to be honest" (participant 14, 58y male, volar plate)

5.4.2.4. Equipoise, randomisation and blinding

Participants were asked whether they would take part in a hypothetical RCT on the treatment of a hand injury. A minority of participants (3/19) understood equipoise and said they would be happy to take part.

"Obviously it's clear that if the doctor doesn't know which way to go, that means obviously there's still more learning to be done" (participant 3, 50y female, proximal phalanx extra-articular shaft fracture)

"You've got the added benefit that both treatments will have an effect" (participant 15, 28y female, bony mallet)

A minority of participants (3/19) trusted the healthcare professionals' expertise and would say yes to participating in a hypothetical hand injury RCT if asked because of this.

"well, the doctors know a lot more than me so I would trust them" (participant 2, 21y male, proximal phalanx extra-articular shaft fracture)

Equipoise was a concept that was difficult to convey to participants. Equipoise in the eye of the patient depends on the surgeon's description of the treatment options. There is also the assessment of risk by the patient, i.e. is this injury serious enough. Participants who would be happy to take part in an RCT would have done so if they saw the finger injury as minimal risk.

"If it's uncertainty that means there's some evidence for this and some evidence for that, so you choose to be randomised into one or the other. You've got to make a decision somehow and I would have gone for that because, you know, minimal risk, it's a little finger" (participant 14, 58y male, volar plate)

Some found it difficult to accept that there was genuine uncertainty in what treatment was the best, and others wanted their surgeon to decide their treatment.

"If you weren't sure then I would expect you to refer back to any studies that you've done in the past, maybe look at a second opinion, talk it over with other people, and then come back to me and say well this is the best choice for you, let's go with this and

see what happens” (participant 1, 45y female, proximal phalanx extra-articular fracture)

“that’s a hard one really because obviously as a patient, you want to receive the most appropriate intervention” (participant 19, 55y female, bony mallet)

Randomisation and blinding were sometimes seen as a gamble. This was because they did not accept equipoise and randomisation. Participants wanted the surgeon to decide on the most appropriate treatment for their injury.

“I want obviously full range of movement, and it is a little bit like a gamble, isn’t it?” (participant 5, 50y female, proximal phalanx extra-articular base fracture)

“For me, as a patient, I’d feel a little bit, not let down, I’d feel a bit dubious really... that, that you are taking a little bit of a gamble” (participant 5, 50y female, proximal phalanx extra-articular base metaphyseal fracture)

“That would be extremely dangerous. If something goes wrong with the treatment and then the patient queries this. Well, why did you give me that particular type of treatment? People need to be informed about what they are having” (participant 17, 68y male, bony mallet)

Participants frequently had a treatment preference. Most perceived surgery as something major and unnecessary and were happy that they did not require it.

“I’m glad surgery didn’t take place and if someone had suggested it then I probably would have said “does it really need to happen”” (participant 4, 47y male, proximal phalanx extra-articular shaft fracture)

“I don’t know, it’s a tricky one isn’t it, because I said I didn’t want – ideally I wanted to avoid surgery” (participant 4, 47y male, proximal phalanx extra-articular shaft fracture)

“for most people a surgery is going to be a more daunting and, yeah, experience and it’s going to take more effort as well, whereas a splint seems to be a quicker process” (participant 2, 21y male, proximal phalanx extra-articular fracture)

Participants were more likely to participate in a study testing two variants of the same treatment modality, i.e. surgery versus surgery, rather than a study comparing two different modalities i.e. surgery versus splint.

“A different kind of splint, then that’s a little bit different, but if it’s between a splint, which is non-invasive, to something that’s invasive, you’ve got to be very careful with that” (participant 18, 55y female, bony mallet injury)

5.5. Discussion

Finger injuries are generally considered minor by participants but can have major consequences, they are often a greater burden to the individual than initially expected. This is particularly a problem as finger injuries are impacting on a young, economically active predominantly male population for who return to function is a priority. It is important for healthcare professionals to communicate well with these patients. The impact of course varies according to the severity of the injury and the individual’s personal circumstances (their job, hobbies, familial circumstances, etc.) but accepting that ‘normality’ might not be regained was not uncommon in this sample. Improved communication in health care was considered important for patient satisfaction in recovery.

Participants here recognised that a “minor” injury might not be an obvious candidate for conducting research, but the long-term consequences of a finger injury can make it worthy of consideration. These injuries happen in a predominantly young male population who might not engage in research as they want to get back to normality as quickly as possible. Many patients would be willing to take part in trials of finger injury, but they would prefer those studies to be low risk, straightforward and with minimal commitments outside normal clinical care. They felt that individuals who understand the scope and value of any research are more likely to take part and stay in a study. A website with information for patients to help patients understand the importance of these injuries, the recovery and the role of research would be beneficial.

To maximise recruitment and retention for a finger fracture trial, therefore, communication at recruitment is crucial. Empathy is likely to improve overall engagement in their treatment pathway and research process, e.g.in improving recruitment and retention strategies. Participants should be told the longer-term natural history of the injury and its treatments without scaremongering. Honesty about uncertainty, equipoise and risk is essential during the research consent process, and akin to the discussion occurring for surgical consent. Where potential participants do not accept treatment uncertainty or

clinicians are not in true equipoise, recruitment will be lower (Rooshenas et al., 2016). Trials of interventions which are very different from a participants' perspective, such as surgery vs non-surgical treatment, are the hardest to recruit to (Donovan et al., 2016) and this is supported by the findings of this study. Participants in this study demonstrated two conflicting stances regarding equipoise – those who view the injury as minor and consider surgery as an inappropriate treatment, and those in acute pain who regard their personal circumstance inappropriate for participation in research, wanting treatment as a priority. A preference for a particular treatment as influenced by participants' perception of risk is recognised as a factor in successful recruitment to research trials (Whybrow et al., 2017). Patients with finger injuries usually have a preference for a particular treatment, which is influenced by their perception of risk, e.g. between an operative and a non-operative treatment. This is what has been found in previous studies (Dias et al., 2020a).

Similar obstacles to recruitment occur at randomisation and may be exaggerated by the perceived differences between two treatment modalities rather than the actual treatment techniques. The hand injury is traumatic and requires urgent care and thus a young economically active predominantly male patient population whose priority is to return to function may not understand the concept of equipoise and randomisation in the acute setting when they are in pain. Randomisation is generally a concept that is difficult to communicate to participants due to misconceptions around equipoise (Whybrow et al., 2017) and participants in this study were less likely to agree to take part in a hypothetical RCT. Studies perceived to have a greater risk or involve more invasive interventions are more difficult to recruit to (Trewick et al., 2018). Specifically for finger injuries, the temporary incapacity and longer-term functional recovery are important factors to consider when determining patient willingness to participate.

Furthermore, this study did not interfere with routine care, hence interviews occurred after participants were offered and underwent a specific treatment by their clinical team. Hence, clinician equipoise was often absent, this being a key factor in influencing participant views regarding theoretical willingness to be randomised. To optimise recruitment, effective communication of equipoise, randomisation and blinding are required (Fletcher et al., 2012). Furthermore, an honest discussion detailing the potential importance of the study and how it may benefit future patients will improve recruitment (Caldwell et al., 2010) (Leighton et al., 2018).

The data on outcomes showed that pain, hand function and appearance were thought to be most important. With regards to the PROMs completed during the OFFJI study, interviewees perceived that they may be inadequate in delineating their true outcome. The PROM questionnaires used in the OFFJI study (PEM, EQ-5D-5L, GROG and PROMIS CAT) were seen as being less relevant to them by some participants. A suggested solution was to use individualised questionnaires, targeted to a specific injury and patient circumstance. Patient specific tools, such as MyMOP which allows the participant to specify what is important to them, could be considered as outcomes in future trials, and perhaps clinical practice (Ishaque et al., 2019), but there are practical issues with their administration.

This study added to the limited literature of hand injury exploring the lived experience of finger fracture injury, treatment and attitudes regarding research. It has provided a unique opportunity for participants to inform future hand surgery research design and implementation. However, the study also has some limitations. To better reflect the usual clinical population the ideal sample would have included more young males and under 30-year-olds treated operatively. Due to restrictions in terms of who was willing to be interviewed the ideal sample was not achieved. The interviewees were mainly participants undergoing non-surgical treatments due to the nature of the source population. The OFFJI study recruited mainly participants treated non-surgically and thus the inferences for recruitment to a purely surgical trial may be less robust. Nevertheless, most finger injuries, overall, do not require surgery. Most participants of the few that were treated operatively were not willing to be interviewed. Due to the COVID situation, time pressures and in prioritising young men, and patients who were operated on and/or had a complication, in retrospect it is recognised that there is an absence of manual workers. In a subsequent study, it is sensible that manual workers would become a priority.

The participants who were interviewed were not young males and manual workers. They had a range of different injuries. An issue was that there were five participants with mallet finger injury. Furthermore, as with any such study, participants who agree to participate in interviews may not have fully reflected the views of people less motivated, engaging fully in both the research and clinical pathways. We do not have data from participants who declined to join or failed to complete follow-up in the observational study. Finally, participants were treated in a single tertiary centre.

Key recommendations for future research in finger injury

- 1) The research importance and aims need to be highlighted and explained (as a perception of this being a minor injury might not motivate involvement in a study)
- 2) Clinician equipoise is paramount as participants showed a reluctance, in theory, to accept randomisation and blinding
- 3) Pain, hand function and cosmetic appearance were considered important outcomes for future hand surgery research.

Key recommendations for clinical practice in finger injury

- 1) Participants with a finger fracture and/or joint injury may often cope by accepting and 'normalising' the effects of the injury, as they are time poor and need to get back to their normal life.
- 2) Patients are likely to experience long term effects from this injury and express feelings of lack of reassurance/support/input by healthcare staff.
- 3) The perception of this being a minor injury, in spite of the functional importance of the hand, might not motivate reattendance in fracture clinic for ongoing symptoms

At the beginning of the chapter, the current gaps in understanding were (1) how do patients experience treatment and recovery, (2) how do patients feel about taking part in research, (3) and about outcomes, such as the PEM questionnaire. The interview study addressed these and found that the experience of treatment and recovery varies depending on the individual's job, lifestyle and hobbies, patients want to give back to the NHS so they are happy to take part in research, but they feel that some PROM questionnaires are not fit for purpose. This interview study supports and enhances prior writing on hand injuries, especially in terms of practical and psychosocial impact and it is more focussed on finger injuries.

5.5.1. Conclusions

The interview data showed that the participants with a finger fracture and/or joint injury may often cope by accepting and 'normalising' the effects of the injury, as they are time poor and need to get back to their normal life. A perception of this being a minor injury might not motivate involvement in a study, so the research importance and aims need to be highlighted and explained. The functional importance of the hand impacts upon how individuals view hand research. Participants showed a reluctance, in theory, to accept randomisation and blinding, which may reflect absence of clinician equipoise, the presentation of these injuries in the emergency setting, but also the differing nature of proposed interventions. Pain, hand function and cosmetic appearance were considered important outcomes for future hand surgery research.

6. Overall discussion and conclusions of the thesis

6.1. Main findings

Hand injuries have been poorly researched to date with many commonly used interventions having little formal evaluation and lacking high quality evidence of effectiveness. Surgery trials present unique difficulties for conducting clinical trials and this series of linked studies was designed to support people planning future RCTs in hand injury. This work included a range of hand injuries, but conclusions are based mainly on data from proximal phalanx extra-articular fractures, volar plate injuries and mallet finger injuries due to the numbers recruited for each type. This is helpful for future trials to know that these three injuries are likely to present and people willing to take part in research.

This PhD work provides data to support trial design decisions around recruitment strategies, eligibility criteria, likely treatment responses at different time periods, performance of outcome instruments and ability to collect follow-up data. This work also explored patients' attitudes to coping with hand injury, expectations of treatment response and experience of taking part in research.

6.1.1. Recruitment strategies

Participants were generally reluctant to accept equipoise and randomisation in trials (Chapter 5). They were more likely to participate in a trial comparing two different types of operative or non-operative treatment rather than one comparing operative versus a non-operative treatment. Designing an RCT to minimise the perceived breadth of risk to potential participants, for example comparing two types of splints, treatment duration, or two types of operation may result in improved recruitment. Where a trial compared a splint to an operation or placebo, then careful recruitment and discussion around equipoise in the trial is essential in order to engage the potential participant.

If patients understand the value of research studies and how they can give back to the NHS this will improve recruitment rates. A review concluded that recruitment still remains a significant challenge and adoption of innovative methods to implement recruitment interventions, such as training site staff and communication with patients are required

(Bower et al., 2014). The PRioRiTy study found that a collective focus on normalising trials as part of clinical care exploring greater public involvement in the research process can help improve recruitment in trials (Healy et al., 2018). A national campaign to increase public awareness and the valued contribution of participation in clinical trials should be implemented (Probstfield and Frye, 2011). Also making participation in any study as convenient and hassle free to patients as possible helps (Bower et al., 2014).

6.1.2. Eligibility criteria

Future RCTs could include either extra or intra-articular fractures of the fingers as these vary in severity (Lotgers et al., 2018) (Oetgen and Dodds, 2008). Intra-articular fractures are less frequent and more severe as they involve the articular surface and synovial joint. The results of this cohort study generally showed that the response to PROMs was similar in all finger injuries, however, the cohort study did not have enough evidence on individual injuries in terms of the response to treatment and the impact on daily living. An RCT for only intra-articular fractures, however, would need to be multi-centre and of long duration.

Proximal inter-phalangeal Joint (PIPj) fracture dislocations were rare in this study (Chapter 3), so an RCT evaluating treatments for PIPj injuries is also likely to require a multi-centre approach.

6.1.3. Likely treatment responses at different time periods

Future RCTs on the treatment of finger fractures and joint injuries could assess patients' recovery for at least for 6 months and beyond. In practice, this needs to be considered alongside retention in studies longer than six months, especially in studies of a hand fracture population. In this study, it was found that patients improve mostly from 6 to 12 weeks and then even more from 12 to 24 weeks (Chapter 3). However, the results of this PhD project showed that participants are not generally back to pre-injury levels at 6 months (Chapter 3) and beyond (Chapter 5) irrespective of whether they return to fracture clinic with or without a complication. They accept to new normality in order to get back to their busy lives.

6.1.4. Performance of outcome instruments

This PhD project included a cohort study which prospectively collected outcome data over 6 months for a range of injury types and a range of outcomes, checked the responsiveness of the instruments, calculated the MCID for PEM questionnaire and offered views of participants with regards to relevance and problems in the outcomes (qualitative study).

The cohort study found that the PEM is a suitable outcome instrument for use as the primary outcome in hand injury RCTs amongst those considered. The end point should be pre-specified. This study suggests it could be at 6 months. Participants who were interviewed suggested that pain, function and cosmetic appearance as secondary outcomes. Participants in the qualitative study did not raise concerns about the PEM questionnaire. It was felt appropriate and meaningful. Some participants said that the other two PROMs used in the cohort study (PROMIS CAT and EQ-5D-5L) may be too broad or irrelevant (Chapter 5) to their particular injury and/or personal circumstances. It was hypothesized that the PROMIS, as an adaptive questionnaire could be more appropriate, however, this was not found to be the case.

A Core Outcome Set for hand fractures/joint injuries would be useful. There is work currently under way (Deshmukh et al., 2021).

The MCID for a change in PEM at different time intervals was calculated as a range of 12-17 at all time points when correlated with the GROOC (anchor). The MDC was calculated as 10.7. This means that between two time points a change in PEM score of less than 10.7 is not clinically important and due to random error. A change of about 12-17 points is not only statistically significant, but clinically meaningful for patients.

6.1.5. Ability to collect follow-up data

Follow up long should be enough for full recovery and identification of long-term complications. The cohort study suggested that an RCT should follow patients for at least 6 months (Chapter 3). In order to keep participants in a trial, communication with a regular newsletter to maintain interest was advised by participants in the interview study (Chapter 5). As part of the SWIFFT trial, which was a multi-centre study comparing treatments for the fracture of the waist of the scaphoid bone in adults, stakeholders identified that (i) how

well a study is understood and (ii) how much it is valued are important factors in an individual's willingness to maintain their involvement (Leighton et al., 2018). Strategies to prevent losses to follow up include positive relationships with trial participants and support of trial staff (Daykin et al., 2018).

Financial incentives might increase the chances of keeping participants in the study for some people than others.

6.1.6. Experience of recovery from injury and taking part in research

Even though the injury is frequently initially seen as minor, its effects are greater than expected. The experience varies with age, job, lifestyle, and hobbies (Chapter 5). Patients cope by 'normalising' the effects of the injury as they are time poor and need to return back to their lives.

A perception of a finger injury being minor might not motivate involvement in a study, so the research importance and aims need to be highlighted and explained by the clinicians and researchers in the initial meeting in fracture clinic. There is a need to stress the importance of giving back to the NHS to improve the appeal of research and that the study burden would be minimal. Email communications and telephone interviews working around the patients' schedule will be well received.

6.1.7. Patient and public involvement

As part of this PhD project, a small scale Patient and Public Involvement (PPI) was done during the development phase of the cohort/qualitative study (see Section 3.3.12). This was a very positive experience that helped the refinement of the study. Generally, PPI is well received. RCTs should be developed with patients and not for patients taking into account the patients' needs. This will improve recruitment and retention rates.

6.1.8. Sample size calculations

Sample size calculations for future RCTs can be made based on the results of this PhD project using the prospectively collected mean (SD) data (Chapter 3) and clinical relevance and meaningful change estimated based on the MCID results reported in Chapter 4. The use of the MCID will reduce type I error (False Positives) and type II errors (False Negatives). Sample size powered and large enough to detect a pre-determined effect size. Sample size calculation should be well described and justified in the protocol and final report of future RCTs.

6.1.9. General points about future RCTs

In this PhD project, there has been a focus on large pragmatic RCTs. This is because the interventions assessed are established, i.e. they are at Stage 4 of the IDEAL framework for the evaluation of surgical intervention (long term implementation). However, a lot of these interventions have not been formally evaluated. This is the reason why a cohort study was conducted in this PhD project which will help to inform future RCTs. This project was an assessment of current practice, which does vary in different centres. An evaluation of a new surgical technique (Stage 2a (development) or Stage 2b (exploration)), for example, does not need to be a large-scale pragmatic RCT.

Future UK trials should be multi-centre, allowing centres with differing treatment rationales to contribute. This will cover both operative and non-operative treatment modalities. International trials could provide benefits, but they can be challenging with different healthcare systems and approaches to care and also logistical challenges (Huamani and Gonzalez-Alcaide, 2013). Countries differ not only in approach to surgical scenarios, but different outcome measures for different procedures. Outcomes would need to be unified to assess procedures in different countries. A core outcome set is needed.

A large scale RCT should be pragmatic; it should resemble daily clinical practice. Pragmatic clinical trials try to test an intervention in a study environment that is closer to real life in terms of study population, intervention, comparator and outcomes, but must still adhere to the stringent trial methods for minimizing selection, performance, information, attrition, selective outcome reporting, and publication bias (Williams et al., 2015).

6.2. Clinical application

This PhD project does not have the data to advise on clinical uncertainties in the management of hand fractures/joint injuries. For example, between two different types of operation for a particular hand injury. An RCT for the specific clinical situation would be necessary to give an answer to this. There are pros and cons for the different operative and non-operative interventions. Surgeons should use an Evidence Based Medicine (EBM) approach clinically, especially if they see patients with complex problems and multi-morbidity.

The information about the recovery that has been generated from this PhD project can help inform patient and clinician conversations and expectations surrounding recovery. Patients should be aware that this injury may require 3-6 months to recover and perhaps may never fully recover. If patients are fairly stable between 12 and 24 weeks perhaps further improvements beyond 24 weeks are not expected.

6.3. Impact of this PhD

The impact of this PhD is that it will help researchers in the field to design better quality RCTs that can address important unanswered questions that patients and healthcare professionals have about managing hand injuries. In the long run, this will lead to the development of policies and guidelines for the management of hand fractures/joint injuries which will help the shared decision making between the clinicians and patients. This will result in better care of these patients.

POINT is a multi-centre NIHR pragmatic RCT that has been developed to investigate the surgical versus splint treatment for proximal phalangeal shaft fractures (NIHR National Institute for Health Research, 2019). More RCTs like this are needed.

6.4. Strengths and limitations

This series of linked projects has mapped the existing trial evidence for informing clinical practice in hand fractures and provides unique, prospectively collected data to characterise outcomes and inform future trial design. This study is unique in providing prospectively collected data to inform future trials and characterise the impact of hand injuries over 6 months.

Recruitment was restricted to two recruiting centres due to resource limitations and this could impact the generalisability of these findings. From the two included recruiting centres we identified considerable variation in practice, especially in deciding whether to manage the injury conservatively or not. The study was also impacted by the COVID-19 pandemic which meant that fewer participants were enrolled than originally intended, thus limiting confidence in some of the conclusions. In particular, further data are required to confirm the proposed MCID estimates and their applicability in different injury types. An issue unique to studying trauma injuries is the difficulty of assessing baseline health status. It is likely that assessment of hand function both prior to injury and immediately post-injury are both useful to collect as baseline outcome assessments.

Table 41 outlines the key messages of this PhD project.

Table 41: Key messages of this PhD project

Key messages of this PhD project
Previous trials have been limited by poor methodology and reporting, particularly around sources of bias, sample size, follow up length and retention, outcome measures, reporting and heterogeneity in interventions studied.
Recruitment into hand injury trials is likely to be challenging because recruiting after acute trauma – so likely to be in pain and shock. Participants also demonstrated lack of equipoise around choice of treatments and recruitment is likely to be particularly challenging if comparing surgical and non-surgical interventions in the same trial.
Retention in trials can be improved if patients understand the value of taking part in a research study to themselves and others and by monetary incentives only for some patients.
Improvements in hand function and symptoms likely to be seen by 3 months, then gradual improvement through to 6 months (but still not back to normal). Unclear whether improvement continues beyond this time. This has implications for both trial design and clinical practice.
Most commonly presenting injuries were proximal phalanx extra-articular fractures, volar plate injuries and mallet finger injuries. There results of this study showed that data from different injuries were similar so they could be combined. However, since finger injuries differ in terms of severity, it would be advised to analyse separately if possible.
PEM was preferred patient-reported outcome by study participants and was more sensitive to change than PROMIS CAT and EQ-5D-5L. MCID values for PEM (12-17 points) were reported for people with hand injury for the first time.

6.5. Conclusions

Good quality RCTs for hand fractures are needed.

The insight from this PhD project can help to plan the RCT. Communication from the researcher and the clinical team can help to improve recruitment and retention. PEM could be the primary outcome at 6 months. Patients could be followed up at least for 6 months. An improvement of 12-17 points in the PEM, when the patients states that they have improved in the GROG, was found to be clinically meaningful. The MCID calculations and the mean (SD) of the PEM can help in sample size calculations for future trials.

APPENDICES

Appendix 1: Search strategies for the scoping review

Hand terms

("Hand bones"[MeSH] OR "Hand joints"[MeSH]

OR "Carpal bones"[MeSH] OR carpals OR carpo OR carpus[tw] OR carpocarpal OR intracarpal OR mediocarpal OR mesocarpal OR midcarpal OR transcarpal

OR carpometacarpal OR CMC

OR "Metacarpal bones"[MeSH] OR metacarpus OR metacarpal OR metacarpals OR metacarpo* OR midmetacarpal OR transmetacarpal

OR thumb OR thumbs OR thenar

OR "Scaphoid bone"[MeSH] OR scaphoid OR scaphoids OR scaphoidal OR hemiscaphoid OR medioscaphoid OR mesoscaphoid OR midscaphoid OR periscaphoid OR transscaphoid OR transscaphoidal

OR "Lunate bone"[MeSH] OR lunate OR lunates OR hemilunate OR mediolunate OR mesolunate OR midlunate OR perilunate OR perilunar OR "semilunar bone" OR translunate

OR "Pisiform bone"[MeSH] OR pisiform OR hemipisiform OR mediopisiform OR mesopisiform OR midpisiform OR peripisiform OR transpisiform

OR "Triquetrum bone"[MeSH] OR triquetrum OR triquetral OR hemitriquetral OR mediotriquetral OR mesotriquetral OR midtriquetral OR peritriquetral OR transtriquetrum OR transtriquetral

OR "Trapezium bone"[MeSH] OR trapezium OR trapeziums OR trapezial OR hemitrapezium OR mediotrapezium OR mesotrapezium OR midtrapezium OR pantrapezial OR peritrapezium OR peritrapezial OR transtrapezium OR transtrapezial

OR "Trapezoid bone"[MeSH] OR trapezoid OR trapezoids OR hemitrapezoid OR mediotrapezoid OR mesotrapezoid OR midtrapezoid OR pantrapezoid OR peritrapezoid OR peritrapezoidal OR transtrapezoid

OR "Capitate bone"[MeSH] OR capitate OR hemicapitate OR mediocapitate OR
mesocapitate OR midcapitate OR pericapitate OR transcapitate

OR "Hamate bone"[MeSH] OR hamate OR hamates OR hemihamate OR mediohamate OR
mesohamate OR midhamate OR perihamate OR transhamate

OR sesamoid OR sesamoids OR sesamoidal

OR "Finger phalanges"[MeSH] OR finger OR fingers OR phalanx OR phalangeal OR phalanxes
OR phalanges OR midphalangeal OR transphalangeal

OR ((Joints[MeSH] OR joint OR joints) AND (carpometacarpal OR metacarpophalangeal OR
interphalangeal))

OR ((Ligaments[MeSH] Or ligament OR ligaments) AND (beak OR capitoamate OR
capitolunate OR "central slip" OR "central slips" OR "extensor expansion" OR "extensor
expansions" OR "extensor hood" OR "expansion hood" OR "extensor retinaculum" OR
"deep transverse metacarpal" OR "dorsal intercarpal" OR "lateral band" OR "lateral bands"
" OR lunotriquetral OR "lunotriquetral interosseous" OR natatory OR pisohamate OR
pisometacarpal OR radiocapitate OR radiocarpal OR radiolunate OR radiolunotriquetral OR
radioscaphoid OR radioscaphocapitate OR radioscapholunate OR radiotriquetral OR "radial
collateral" OR retinacular " OR "ulnar collateral" OR radiopalmar OR "sagittal band" OR
"sagittal bands" OR scaphocapitate OR scapholunate OR "scapholunate interosseous" OR
scaphotrapezial OR scaphotrapezoid OR scaphotrapezotrapezoid OR "superficial transverse
metacarpal" OR trapeziocapitate OR trapezotrapezoid OR triquetralcapitate OR
triquetralhamate OR triquetrocipitate OR ulnocarpal OR ulnocapitate OR ulnolunate OR
ulnotriquetral))

OR "Collateral ligament, ulnar" [MeSH]

OR Testut[tw] OR Kuentz[tw] OR "Space of Poirier" OR "volar plate"

OR Barton[tw] OR Barton's OR Bennett[tw] or Bennett's OR Boxer OR Boxer's OR
Chauffeur[tw] OR Chauffeur's OR Colles[tw] OR Colles' OR Colles's OR diepunch OR "die-
punch" OR FOOSH OR "Jersey finger" OR Mallet OR Rolando[tw] OR Rolando's OR Smith[tw]
OR Smith's)

Fracture and ligament injury terms

(dislocation OR dislocations OR extraarticular OR "extra-articular" OR fracture[tw] OR
fractures[tw] OR "Fractures, bone" [MeSH] OR "Fractures, cartilage" [MeSH] OR "Fracture

healing" [MeSH] OR injury OR injuries OR injuries[subheading] OR intraarticular OR "intra-articular" OR rupture OR ruptures OR sprain OR sprains)

Specific hand fracture/injury terms.

("wrist fracture" OR "wrist fractures" OR "hand fracture" OR "hand fractures" OR (carpometacarpal AND dislocation) OR "digital fracture" OR "digital fractures" OR "carpal fractures" OR "carpal fractures" OR "carpal dislocation" OR "carpal dislocations" OR "gamekeepers thumb" OR "gamekeeper's thumb" OR ("proximal interphalangeal" AND dislocation) OR (("radius fracture" OR "radial fracture" OR "radius fractures" OR "radial fractures") AND distal) OR "skier's injury" OR "skier's thumb" OR "stener's lesion" OR "stener lesion" OR (stener AND lesion))

1 AND 2

3 OR 4

Appendix 2: Data extraction form (scoping review)

Study identifier	(number)
First author	(free text field)
Year of publication	(number)
Country of corresponding author	(free text field)
Does the publication state if the RCT was registered on a trial's repository, e.g. WHO?	Y/N
If so, was the trial registration number given?	Y/N/NA
Trial registration number	(number)
Did the publication state an external funding source?	Independent Industry/pharmaceutical Combination Unclear No
Sample size recruited	(number)
Sample size calculation	Non-reported Reported, but inadequate Adequate
RCT study design as reported by authors	Open Single blind Double blind Pragmatic None of the above
Setting	Single centre Multi-centre Inadequate information
Population	
Type of injury	(free text field)
Timing of treatment	Primary Secondary

Targeted age range	(free text field)
Population Inclusion criteria	(free text field)
Population Exclusion criteria	(free text field)
Intervention	(free text field)
Comparator	(free text field)
Difficulties in recruitment	(free text field)
Randomization	
Random sequence generation (selection bias)	Risk of bias Low/Unclear/High Quote:
Allocation concealment (selection bias)	Risk of bias Low/Unclear/High Quote:
Blinding	
Of participants?	Y/N
Of study personnel?	Y/N
Of assessors?	Y/N
Of analysis (e.g. statistician)?	Y/N
Blinding reported but unclear	Y/N/NA
Blinding of participants and personnel (detection bias)	Risk of bias Low/Unclear/High Quote:
Intention to treat analysis performed	Y/N
Age range of patients analysed in results	Mean Median Range
Post randomization exclusions (people who were randomized, but never got the intervention)	Yes (number and percentage) No exclusions Not reported

Training/experience/quality control of the surgeons	(free text field) Not stated
Did the publication specify the primary outcome?	Y/N
If there was a primary outcome, what was it?	(free text field), (include scale)
Was the primary outcome blinded?	Y/N
Did the publication report a time point for the primary outcome?	Y/N/NA
If so, what was it?	(number)
What were the (secondary) outcomes? (Only include if reported in methods or results)	(free text field) – in Methods (free text field) – in Results
PROM collected	Y/N
Blinding of outcome assessment (patient reported outcome)	Risk of bias Low/Unclear/High Quote:
Incomplete outcome data (attrition bias)	Risk of bias Low/Unclear/High Quote:
Selective reporting (reporting bias) Only looked at study protocol if referenced in the paper.	Risk of bias Low/Unclear/High Quote:
Is the follow up rate reported?	Y/N

What was the follow up rate at primary outcome measure time point?	(number and percentage)
What was the follow up rate at final follow up?	(number and percentage)
Time points they followed the patients for (e.g. 6 weeks, 3months, 1 year)	(free text field)
Maximum length of follow up (in weeks)	(number)
Average length of follow up (mean, SD or range)	(number)
Author's conclusion from the abstract	(free text field)
Comments	(free text field)

Appendix 3: Randomised Controlled trials (RCTs) included in the scoping review

Table 42: Table of RCTs for interventions for the treatment of scaphoid fractures

Study identifier	Population	Intervention and comparator	Outcomes	Follow up at	Sample size	Conclusion
Scaphoid fractures						
(Adolfsson et al., 2001) Sweden	Adults (mean age 31, range 15-75) with undisplaced fracture of the waist of the scaphoid.	Percutaneous Acutrak screw fixation was compared to immobilisation in a below elbow plaster cast for 10 weeks	ROM, Grip strength, Active flexion/extension, Radial/ulnar deviation, time to union.	16 and 24 weeks	53	No statistically significant differences with regard to the time to union. Patients who underwent surgery had a significantly better range of movement (ROM), but there were no significant differences for grip strength at 16 weeks.
(Bond et al., 2001) USA	Adults (mean age 24, range 18-44) with an acute nondisplaced fracture of the scaphoid waist	Percutaneous cannulated screw fixation was compared to cast immobilization	Grip strength, ROM, Radiographic union, Snuffbox tenderness, complications,	1 week and then at 2-week intervals until union. Every 12	25	Percutaneous cannulated screw fixation of nondisplaced scaphoid fractures resulted in faster radiographic union and return to military duty compared with cast immobilization.

			Patient satisfaction, time to return to military duty	weeks up to 104 weeks		
(Bilic et al., 2006) Croatia	Adults (average age 21, standard deviation 5) with symptomatic scaphoid non-union with no evidence of progressive healing	There were three treatment groups: (1) autologous iliac graft, (2) autologous iliac graft and osteogenic protein-1, and (3) allogenic iliac graft	Pain (VAS), Movements, Grip strength, Radiographic union.	4, 8, 12, 16, 28, 52 weeks	17	Osteogenic protein-1 resulted in an accelerated radiological and clinical repair of scaphoid avascular and necrotic proximal pole non-unions.
(Braga-Silva et al., 2008) Brazil	Adults (mean age 31, range 17-52) with symptomatic scaphoid non-union of a single wrist	Surgery including distal radius vascularised bone grafting compared to surgery including non-vascularised iliac crest bone grafting.	Wrist ROM, Grip strength, Radiographic union	145 weeks	80	Similar functional results were obtained with the two techniques
(Buijze et al., 2014) Netherlands	Adults (mean age 37.5, standard deviation 16) with acute nondisplaced	Treatment in a below-elbow cast including the thumb was compared to treatment in a	Wrist motion, Grip strength, The Mayo Modified Wrist	10 and 24 weeks	62	There was a significant difference in the average extent of union on CT at 10 weeks favouring treatment with a cast excluding the thumb

	or minimally displaced fracture of the scaphoid waist	below-elbow cast excluding the thumb	Score, DASH, Pain (VAS), Radiographic union			
(Caporrino et al., 2014) Brazil	Adults (mean age 27.7, range 18-56) with lack of scaphoid union for 3 months of conservative treatment.	Vascularised bone grafting (VBG) using the 1,2 intercompartmental suprareticular artery was compared to distal radius nonvascularised bone graft.	Union rate, Functional outcomes (pain, functional status, ROM, wrist strength)	Every two weeks until bone healing and at discharge.	27	Although the VBG group attained earlier union, this may not be clinically meaningful, nor justify the greater technical difficulty and use of resources associated with this intervention.
(Clay et al., 1991) UK	Adults (mean age 29.7, range 16-71) with radiologically proven scaphoid fractures	A forearm gauntlet (Colles') cast, leaving the thumb free was compared to a conventional 'scaphoid' plaster incorporating the thumb as far as its interphalangeal joint.	Radiological union, Tolerance of casts, Functional recovery	2, 4, 8 24 weeks	352	For acute, undisplaced fractures of the waist of the scaphoid, the simpler Colles' plaster appears to be equally effective.

(Clementson et al., 2015b) Sweden	Adults (median age 30, range 16-63) with acute scaphoid fracture	Surgical treatment consisted of wrist arthroscopy and percutaneous antegrade screw fixation compared to conservative treatment consisted of a below-elbow thumb spica cast until radiological signs of union appeared	DASH, VAS score, ROM, grip strength, Radiographic (CT scan)	6, 10, 14, 26, 52 weeks and then every 52 weeks	31	Non- and minimally displaced scaphoid waist fractures are best treated conservatively. Operative treatment may provide an improved functional outcome in the short term but at the price of a possible increased risk of arthritis in the long term
(Clementson et al., 2015a) Sweden	Adults (median age 30, range 16-63) with scaphoid waist fracture	Arthroscopically assisted screw fixation was compared to conservative treatment	Time to union	10, 14, 24 and 52 weeks	35	Screw fixation does not reduce time to fracture union compared with conservative treatment
(Dias et al., 2005) UK	Adults (mean age 29.5, range 16-61) with a fracture of the waist of the scaphoid	Early fixation was compared to non-operative treatment.	Clinical assessment: pain, swelling, tenderness, ROM, Grip strength, PEM	2, 8, 12, 26, 52 weeks.	88	This study did not demonstrate a clear overall, benefit of early fixation of acute scaphoid fractures.

(Dias et al., 2008a) UK	Adults (mean age 30, standard deviation 16-61) with a scaphoid fracture	Operative treatment (open reduction and internal fixation through the volar approach using a Herbert screw or a cannulated Whipple screw, with an additional Kirschner wire, or two Kirschner wires only) was compared to non-operative treatment (immobilisation of the wrist in a below-elbow cast for eight weeks with the thumb left free).	PRWE, Grip strength, Pinch strength, ROM, Radiological union	Seen 416 weeks after treatment	88	Our study revealed that the outcome of early fixation is comparable to that of initial non-operative treatment.
(Drac et al., 2014) Czech Republic	Adults (mean age 30) with acute nondisplaced or minimally displaced scaphoid waist fracture	Palmar percutaneous approach (surgical) was compared to dorsal limited approach (surgical).	Flexion, Extension, Radial deviation, Ulnar deviation, Grip strength, Pain, Complaints,	4, 8, 12 weeks	76	We found no advantage to the palmar percutaneous approach in the treatment of nondisplaced and minimally displaced scaphoid fractures compared to dorsal limited approach.

			DASH score, Patient satisfaction			
(Gaebler et al., 2002) Austria	Adults (age of participants not reported) with acute undisplaced scaphoid fractures	Percutaneous screw fixation was compared to non-operative treatment.	Radiological union, ROM, Grip strength, Pinch grip, Green/O'Brien score, Time to return to work and sports	8, 12, 16, 26, 52 weeks.	41	This study suggests that percutaneous stabilisation of scaphoid fractures is a safe and reasonable approach, especially in younger patients who want and need to get back to work and sports early.
(Gellman et al., 1989) USA	Adults (age of participants not reported) with acute non-displaced fractures of the carpal scaphoid	Long thumb-spica cast for 6 weeks, followed by application of a short thumb-spica cast until union was compared to short thumb-spica cast as a sole form of treatment.	Radiographs (Time to union, Delayed union, Non-union)	Every 3-4 weeks, until union.	51	We recommend an initial period of six weeks of immobilisation in a long thumb-spica cast, followed by use of a short thumb-spica cast.
(Goyal et al., 2013) India	Adults (mean age 34.7) with scaphoid non-union	Iliac crest bone graft compared to distal radius bone graft in surgery of	Residual pain, Complications, Pinch strength,	Minimum 156 weeks	100	The results of our study show that the fusion rates and functional

		nonunion of scaphoid fractures	Grip strength, ROM. QDASH, Mayo' scoring system, Pain (VAS)			results of the two techniques are equivalent.
(Hambidge et al., 1995) UK	Adults (age of participants not reported) with acute scaphoid fracture	Plaster immobilisation in 20 degrees of flexion was compared to immobilisation in 20 degrees of extension.	Comfort in plaster, ROM, Union	24 weeks	146	The authors recommend that a colles' type cast in slight extension be used for immobilization of the acute un-displaced scaphoid fracture.
(Hanneman et al., 2012) Netherlands	Adults (mean age 41, range 16-84) with acute scaphoid fracture	Pulsed electromagnetic field treatment compared to placebo	Grip strength, range of active extension, flexion, radial and ulnar deviation, Radiological healing, Tenderness, Pain	4,6,9, 12, 24 and 52 weeks after diagnosis of the fracture	53	We conclude that stimulation of bone growth by PEMF has no additional value in the conservative treatment of acute scaphoid fractures

(Hanneman et al., 2014) Netherlands	Adults (mean age 35, range 18-77) with acute scaphoid fracture	Active PEMF (pulsed electromagnetic fields) compared to placebo. All fractures were treated with immobilisation in a forearm cast with the first metacarpal and both phalanges immobilised	Range of active extension, flexion, radial and ulnar deviation, Grip strength, Tenderness in the anatomical snuffbox, Radiological healing, Pain	6, 9, 12, 24 and 52 weeks	102	We concluded that the addition of PEMF bone growth stimulation to the conservative treatment of acute scaphoid fractures does not accelerate bone healing
(Lawton et al., 2007) USA	Adults (age range 24-35) with acute non displaced scaphoid fracture	Munster thumb-spica cast was compared to a long arm thumb-spica cast	Forearm pronation and supination, elbow ROM.	Not reported	10	A Munster thumb-spica cast may play a role in the conservative treatment of non-displaced scaphoid fractures by allowing some elbow motion during the long immobilization period.
(Lyons et al., 2017) UK	Adults (age of participants not reported) with	Standard fiberglass resin cast was compared to	Union of fracture, Patient	Not reported	25	Treatment with a thermoplastic polymer based removable splint resulted in comparable outcomes

	acute non-displaced scaphoid fractures	thermoplastic removable splint	satisfaction, QDASH			and patient satisfaction compared to the use of traditional resin casts.
(Mayr et al., 2000) Germany	Adults (mean age 37, standard deviation 14) with fresh, stable scaphoid fractures	Low intensity, pulsed ultrasound with immobilisation was compared to immobilisation only.	Not reported.	CT scan every 2 weeks	28	The low-intensity, pulsed ultrasound therapy is suitable for accelerating the healing of fresh scaphoid fractures
(McQueen et al., 2008) UK	Adults (mean age 29.4, range 17-65) with acute scaphoid fracture	Percutaneous fixation with a cannulated Acutrak was compared to immobilisation in a cast	ROM, Grip and pinch strength, Modified Green/O'Brien functional score, Return to work and sports, Radiological evidence of union	8, 12, 26, 52 weeks	60	We recommend that all active patients should be offered percutaneous stabilisation for fractures of the waist of the scaphoid.

(Raju and Kini, 2011) Singapore	Adults (mean age 28, range 20-48) with non-union of the scaphoid involving the proximal pole, waist, and distal pole.	The Herbert screw fixation, the Matti Russe bone grafting, or the Kohlman modification of vascularised muscle pedicle graft procedure.	Scapholunate and radiolunate angles, ROM, Functional outcomes, Modified scaphoid outcome scoring system, Hardware failure or any iatrogenic fracture during pedicle dissection	24 weeks	33	The time to union was earliest in the Kohlman modification of vascularised muscle pedicle graft procedure, which is recommended for patients with old non-union (>1 year) or proximal pole fractures.
(Ribak et al., 2010) Brazil	Adults (age of participants not reported) with scaphoid non-union	Treatment using a vascularised bone graft from the dorsal and distal aspect of the radius was compared to treatment with a conventional	Radiographic evaluation, Active range of flexion, extension, radial	Not reported	86	We conclude that vascularised bone grafting yields superior results and is more efficient in patients in scaphoid nonunion.

		non-vascularised bone graft from the distal radius.	deviation, ulnar deviation, scaphoid-lunate angle, Pain, Grip strength, Joint mobility, Global outcome score			
(Ricardo, 2006) Cuba	Adults (mean age 26.7, range 17-62) with fractures of the scaphoid with established non-unions treated with vascularised pedicle bone graft	Low-intensity ultrasound was compared to placebo. The placebo units were adjusted to give no ultrasound signal output across the transducer.	Pain, Active range of motion of the wrist, carpal height index, and scapholunate-capitolunate angles, Radiographic evidence of union, Time to healed non-union	Not reported	21	Our data analysis suggests that ultrasound therapy may be beneficial to the healing of non-union of the scaphoid after treatment by vascularised pedicle bone graft.

(Saeden et al., 2001) Sweden	Adults (mean age 33, standard deviation 17) with acute scaphoid fracture visible at the first radiological examination.	Operatively using a Herbert screw was compared to conservatively by a short-arm cast	Tenderness, ROM, strength, Radiological union, Duration of sick leave, Symptoms (VAS), Grip strength, Range of flexion/extension	Not reported	61	Operative treatment of an acute fracture of the scaphoid allows early return of function and should be regarded as an alternative to conservative treatment in patients in whom immobilisation in a cast for three months is not acceptable for reasons related to sports, social life or work.
(Sjolin and Andersen, 1988) Denmark	Adults (mean age 27, range 9-75) with symptoms of a fractured carpal scaphoid, but without radiological evidence of fracture	Dorsal plaster cast was compared to supportive bandage	Radiographs (fractures, avulsion), Sick leave	Not reported	108	We conclude that patients presenting with the clinical picture of a fracture of the carpal scaphoid should be treated as having a soft-tissue injury if the four standard radiographs do not show a fracture. A cast may still be offered to patients with much pain.

(Vinnars et al., 2008) Sweden	Adults (mean age 31, standard deviation 12) with an isolated scaphoid fracture that was nondisplaced or minimally displaced	Immobilization in a below-the-elbow scaphoid cast with the thumb held in palmar abduction, the interphalangeal joint free, and the wrist in neutral or slight extension for a planned period of six weeks was compared to a standard Herbert screw or a cannulated Herbert-Whipple stabilisation.	DASH, PRWE, Radiographic, Complications	520 weeks	83	This study did not demonstrate a true long-term benefit of internal fixation, compared with nonoperative treatment.
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Table 43: Table of RCTs for interventions for the treatment metacarpal fractures

Study identifier	Population	Intervention and comparator	Outcomes	Follow up at	Sample size	Conclusion
Metacarpal fractures						
(Anand et al., 1999) USA	Adults (mean age 24, range 11-48) with Boxer's fracture (fracture of the neck of the fifth metacarpal)	Immediate mobilisation was compared to attempted reduction and splint immobilization.	Cosmetic satisfaction, Return to pre-injury status, Radiological union, Dorsal and ulnar angulation, Extensor lag, Grip strength, ROM.	1, 3, 6, and 12 weeks	60	The results of our study would suggest that these fractures could be treated with immediate mobilization with good functional results. We feel that reduction and splintage seem unnecessary for these fractures
(Braakman et al., 1998) Netherlands	Adults (mean age 26, range 14-44)	Functional tape for four weeks was compared to ulnar gutter plaster-cast for four weeks.	Power grip, static pulling strength of little	1, 4, 12, and 24 weeks	50	We advise treating fractures of the 5th metacarpal with a functional

	with fracture of the 5th metacarpal.		finger, maximum torque force, fracture angulation, power grip, Radiographic union, Residual symptoms at 6 months			tape rather than with cast immobilisation
(Cepni et al., 2016) Turkey	Adults (mean age 28, range 18-46) with an acute (0–15 days), closed, and simple fracture of the fifth metacarpal neck	Operative treatment was compared to splinting (U-shaped ulnar gutter)	Palmar angulation, ROM, Metacarpal shortening, QDASH, Return to work, Radiological union	4 and 7 weeks	24	We recommend antegrade intramedullary K-wire fixation as a reliable method, which minimizes the functional loss and allows for early return to daily activities in office workers who sustained a fracture of the fifth metacarpal neck.

(Galal and Safwat, 2017) Egypt	Adults (mean age 32, standard deviation 6) with a closed 5th metacarpal fracture with angulation more than 30	Surgical treatment using transverse pinning was compared to surgical treatment using intramedullary pinning.	Total Active ROM, Total Active Range of Flexion, QDASH, Radiological union	2, 6, 12, and 24 weeks	80	Both techniques are equally safe and effective. The only difference was shorter operative time & less incidence of complications in transverse pinning group.
(Garrazone, 1996) USA	Adults (age of participants not reported) with small finger metacarpal neck fractures.	Volar splint was compared to dorsal hood short arm cast	Grip strength, ROM, Subjective patient satisfaction	8-10 weeks	33	Volar splinting was shown to provide significantly increased grip strength along with improved range of motion, and decreased complaints of post treatment pain
(Gulke et al., 2017) Germany	Adults (mean age 32, range 18-60) with postoperative management of metacarpal fractures	A home exercise (HE) program was compared to a traditional physical therapy (PT) program.	ROM, Grip strength, DASH	2, 6, 12 weeks	60	Study results show that both HE program and traditional PT are effective in the postoperative management of metacarpal fractures

(Hansen and Hansen, 1998) Denmark	Adults (age of participants not reported) with fractures of the necks of the ring or little metacarpals.	Ulnar plaster-of-Paris from proximal interphalangeal joint to the ring and little finger was compared to a functional brace made of Hexalite and to an elastic bandage alone.	Fracture tenderness, ROM, Patient satisfaction	4, and 12 weeks	105	We recommend the functional brace for treatment of fractures of the neck of the ring and little metacarpals.
(Harding et al., 2001) UK	Adults (mean age 27, range 12-57) with fractures of the neck of the little finger metacarpal	Treatment with a moulded metacarpal brace was compared to treatment with neighbour strapping.	ROM, Tenderness, Overall satisfaction, Back to work	3 weeks	73	Patients treated with the metacarpal brace had significantly less pain than those treated with neighbour strapping, and this facilitated an early return to work.
(Hofmeister et al., 2008) USA	Adults (age of participants not reported) with isolated fracture of the fifth metacarpal neck.	Short-arm cast with volar outriggers (SAC-VOR) was compared to a short-arm cast extended to the proximal interphalangeal joint with a 3-point mold (MCP-ext).	Radiographic union, cast durability, complications. DASH. ROM, grip strengths	1, 4 and 12 weeks	81	Advantages of the MCP-ext cast include quicker application and, to a much lesser degree, better tolerability, range of motion, and final grip strength
(Kim and Kim, 2015) South Korea	Adults (mean age 27, range 18-53) with a surgical	An antegrade intramedullary K-wire was compared to a	DASH, Pain (VAS),	3, 24 weeks	46	Antegrade intramedullary pinning has some clinical advantages during the early recovery period, but the

	indication for a fifth metacarpal neck fracture	percutaneous retrograde intramedullary K-wire	Radiographic union, ROM			advantages are not evident at 6 months postoperatively.
(Konradsen et al., 1990) Denmark	Adults (age of participants not reported) with a shaft or neck fracture of the second through the fifth meta-carpal bone	Immobilization by a plaster cast (immobilizing the wrist and the joints of the involved digits) was compared to immobilisation by a functional cast (allowing the wrist and the digits a free range of motion)	Pain, Cast inconvenience, Time to return to work, Rotation, Ulnar/radial angulation, ROM, Grip strength, Radiographic union	1, 3, and 12 weeks.	100	Functional casting reduced volar angulation by two thirds for metacarpal shaft fractures and by one third for metacarpal neck fractures when compared with plaster cast immobilization. Sick leave was reduced by two thirds after functional casting compared with the plaster cast group.
(Kuokkanen et al., 1999) Finland	Adults (median age 28, range 11-68) with subcapital fractures of the fifth metacarpal bone	Closed reduction and splinting was compared to functional treatment	ROM, Grip force, Hand grip strength	4, and 12 weeks	29	Subcapital fractures of the fifth metacarpal bone can successfully be treated without closed reduction and splinting.

(McMahon et al., 1994) UK	Adults (mean age 31) with a unilateral fresh closed stable fracture of the shaft of a single finger metacarpal.	Compression glove and early mobilization was compared to immobilization in a plaster splint.	Hand volume, Finger circumference, ROM, Loss of flexion, Pain and functional limitations.	Not reported	42	Use of a compression glove relieved pain and avoided the loss of function imposed by splintage and was associated with a greater range of movement during the second and third weeks.
(Rafique et al., 2006) Pakistan	Adults (age of participants not reported) with isolated hand fractures (of metacarpals and phalanges). Both open and closed fractures were included.	Percutaneous K wires were compared to a buried placement of K wires.	Infection rate, Time to remove K wires	Not reported	60	Percutaneous K wires had significantly greater infection rate than wires which were buried deep to skin.
(Randall et al., 1992) USA	Adults (mean age 29, range 19-46) following treatment	Traction and palmar/dorsal glide techniques were used to perform the joint mobilization	Active ROM, Torque ROM, Excursion.	Three appointments over a 1	18	The joint mobilization treatment given to the subjects in this study resulted in a significant gain in

	of a metacarpal fracture and whose hand had been immobilized for least 2 weeks.	treatment and they were compared to no treatment.		week period		AROM and decrease in joint stiffness within a treatment session when compared to the control group.
(Sletten et al., 2015) Norway	Adults (mean age 27, range 18-68) with little finger metacarpal neck fractures.	Operative treatment (closed reduction and internal fixation) was compared to conservative treatment (no attempt of reduction, plaster-of-Paris for 1 week, buddy strapping and active exercises)	QDASH, Pain (VAS), Patient satisfaction, QoL EQ-5D-3L, Active flexion/extension, Flexion/extension deficit, TAM, Grip strength	1, 6, 12 and 52 week	85	We recommend conservative treatment with early mobilization for fractures up to 45–50° palmar angulation in the lateral view.
(Sorensen et al., 1993) Denmark	Adults (age of participants not reported) with fractures of the second through the	A functional brace (the Galveston metacarpal brace) was compared to a dorsal/ulnar plaster cast	Complications, Fracture angulation, Satisfaction with bandage	1, 4 and 12 weeks	113	We found that the benefits did not outweigh the risks of the functional fracture bracing, and we cannot recommend the tested version of the Galveston metacarpal brace.

	fifth metacarpal bones					
(Stattius Muller et al., 2003) Netherlands	Adults (mean age 29, range 15-74) with a fracture of the subcapital 5 th metacarpal	Treatment with an ulnar gutter plaster cast for a period of 3 weeks followed by mobilization was compared to pressure bandage for 1 week and immediate mobilization within limits imposed by pain	ROM, Patient satisfaction, Pain perception, Return to work and hobby, Need for physiotherapy.	6 and 12 weeks	40	A pressure bandage for 1 week and immediate mobilization is a sufficient alternative treatment of a boxer's fracture, if this is not angulated greater than 70° and not rotated.
(Strub et al., 2010) Switzerland	Adults (mean age 30, range 20-70) with acute, closed fractures of the little finger metacarpal neck with a palmar displacement of between 30° and 70°.	Closed reduction and intramedullary splinting was compared to conservative treatment without reduction	Flexion / extension of the MCP joint, Grip strength, Radiological union, Pain (VAS), Patient satisfaction, Time off work, Complications	2, 6, 12, 24, and 52 weeks	40	We conclude that intramedullary splinting for displaced fractures of the little finger metacarpal neck offers an aesthetic, but not a functional advantage.

(van Aaken et al., 2016) Switzerland	Adults (mean age 29, standard deviation 12) with fifth metacarpal (MC) neck fractures (Boxer's fracture)	Soft wrap and buddy taping (SW) was compared to reduction and cast (RC)	Pain (VAS), Patient Satisfaction, ROM, Power grip, Radiographic union	1, 4 and 16 weeks	68	This study supports the use of soft wrap and buddy taping for treatment of boxer's fracture with palmar angulation ≤ 70 degrees and no rotational deformity.
(Winter et al., 2007) France	Adults (mean age 32, range 18-65) with fractures of the little finger metacarpal neck, or "Boxer's" fractures.	Transverse pinning (operative) was compared to intramedullary pinning (operative). A palmar splint was applied for 1 week. Patients began physiotherapy three times per week for 30 days	Pain (VAS), Patient satisfaction, ROM, Grip strength, Radiographic union, Complications	Evaluated clinically six times after surgery, up to the 12 weeks	36	Intramedullary pinning gave better functional outcomes than transverse pinning, although the former was more technically demanding
(Xia, 2015) China	Adults (mean age 27.5, range 18-50) with metacarpal or phalangeal fracture	Mini-plate fixation was compared to Kirschner wire	TAFS score for hand function, total active flexion degree, length of	Not reported	76	The mini-plate fixation for metacarpal and phalangeal fractures can obviously improve hand function, shorten length of hospital stay and healing time

			hospital stay, delayed healing of bone, incidence of infection, healing time			
(Zyluk and Budzynski, 2009) Poland	Adults (mean age 34, range 16-75) with isolated, displaced and extra- articular metacarpal fractures.	Operative (by fixation with K- wires) treatment was compared to conservative treatment.	Active ROM, Grip strength, Radiological union, DASH	8 and 24 weeks	74	The results of this study indicate the equal effectiveness of both the operative by K-wiring, and conservative treatment of fractures of the metacarpals.

Table 44: Table of RCTs for interventions for the treatment of mallet finger

Study identifier	Population	Intervention and comparator	Outcomes	Follow up at	Sample size	Conclusion
Mallet finger						
(Auchincloss , 1982) UK	Adults (mean age 41, range 17-82) with mallet finger. Both open and closed injuries were included.	Percutaneous fixation of the distal interphalangeal joint using a K wire was compared to a Pryor and Howard splint for 6 weeks without radiographic control.	Subjective results (treatment acceptable good result, normal function), Objective results (Good, improved, unchanged), ROM	56, 72 weeks	50	After a mallet finger injury treated within two weeks by either method few patients have significant persistent disability. Both groups of patients were generally satisfied with their treatment and its outcome.
(Batibay et al., 2017) Turkey	Adults (mean age 36, range 17-61) with mallet finger	The new suture anchor technique (operative) compared to conservative management (aluminium orthotic device)	ROM, Extension lag/deficit DIP flexion, VAS score, Return to work, Radiologic	12, 24, 52 weeks	29	Our study suggests that the new suture anchor technique is not superior to conservative treatment

			union, DIP joint degeneration			
(Gruber et al., 2014) USA	Adults (mean age 50, range 24-78) with mallet finger with or without fracture and treatment with a period of continuous splint or cast immobilization for 6 weeks or greater	A night splint for an additional month after 6 to 8 weeks of continuous splinting was compared to no night splint.	DASH	Not reported	51	Supplemental night splinting does not improve the outcome of mallet finger.
(Kinninmonth and Holburn, 1986) UK	Adults (age of participants not reported) with mallet finger	Perforated splint and told to keep it on without restricting their activities compared to standard 'stack' splint with instructions on daily removal for hygiene purpose.	Skin status, Lag, Ability to change splint	2, 6, 52 weeks	54	The perforated mallet finger splint can produce consistently good results even in those patients who would not tolerate a conventional splint.

(O'Brien and Bailey, 2011) Australia	Adults (mean age 38, range 11-86) with mallet finger	A prefabricated stack splint (control), was compared to a dorsal padded aluminum splint, and a custom-made thermoplastic thimble splint. All were worn for 8 weeks continuously, with a 4 week graduated withdrawal and exercise program.	ROM, Compliance, Treatment failure and complications, Pain (VAS), Patient satisfaction	1, 6, 8, 10, 12, 20 weeks	64	In this study, no extensor lag difference was found between the 3 splint types, but custom-made thermoplastic splints were significantly less likely to result in treatment failure.
(Pike et al., 2010) Canada	Adults (mean age 43) with acute mallet finger	3 splint types were compared: volar padded aluminum splint, dorsal padded aluminum splint, and custom thermoplastic. Splints were continued for 6 weeks full-time.	Clinical lag, Radiographic lag, Complications, MHQ scores	7, 12, 24 weeks.	87	No lag difference was demonstrated between custom thermoplastic, dorsal padded aluminum splint, and volar padded aluminum splinting for Doyle I acute mallet fingers.
(Saito and Kihara, 2016) Japan	Adults (mean age 42, range 18-72) with mallet finger.	The 2-step immobilization group underwent initial immobilization using an orthosis, followed by the use	Not reported.	3 and 16 week	44	Our study thus suggested that the initial immobilization involved in new 2-step orthosis and is thus a good immobilization technique.

		of a second orthosis. This was compared to the figure of eight-type orthosis (control) group, which underwent conventional immobilization using an orthosis.				
(Tocco et al., 2013) Italy	Adults (mean age 45, standard deviation 12) with mallet finger	Cast immobilization of closed mallet fingers using Quickcast (QC) was compared to a removable, lever-type thermoplastic orthosis.	Edema, Hand function, Subjective evaluation of the orthosis, Satisfaction with outcome, Grip strength	Once during 3-4, 6-8, 7-9, 8-10, 10-12, 12-14, 24-28 and weeks	57	Cast immobilization seems to be slightly more effective than the traditional approach probably for its greater capacity to reduce edema.
(Warren et al., 1988) UK	Adults (mean age 46.1, range 10-77) with mallet finger	Stack splint was compared to Abouna splint	Extension loss, Success of treatment, Patient satisfaction	Regularly until 10 weeks	116	The Stack splint is more acceptable to the patient than the Abouna splint.

(Zhou et al., 2008) China	Adults (mean age: 27.5, standard deviation 9.5) with mallet finger	Percutaneous pinning with plaster splint was compared to open reduction and pulling out wire	Total active movement (TAM) functional assessment, operation time, flap necrosis and infection, skin ulcer, bone union, pseudoarthrosis	Regularly until 104 weeks	72	Percutaneous pinning with plaster splint is simple in operation and has smaller incisions and fewer complications compared with open reduction and pulling out wires.
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Table 45: Table of RCTs for interventions for the treatment of proximal phalangeal fracture

Study identifier	Population	Intervention and comparator	Outcomes	Follow up at	Sample size	Conclusion
Proximal phalangeal fracture						
(Abubeih et al., 2016) Egypt	Adults (mean age 31, range 14-56) with extra-articular proximal phalangeal fractures.	An extensor tendon splitting approach fixed with a nonlocking titanium miniplates and screws was compared to an extensor tendon sparing approach	QDASH, Total active ROM, Grip strength	Not reported	40	Meticulous surgical dissection, anatomical closure of layers, and early active mobilization are the keys to success in fixation of phalangeal fractures, regardless of the approach chosen.
(Franz et al., 2012) Switzerland	Adults (mean age 49, range 16-93) with extra-Articular Fractures of the Proximal Phalanges of the Fingers	Treatment using a functional forearm cast was compared to treatment with LuCa	Clinical and radiographic assessments, ROM	1, 2, 4, 6, and 12 weeks	66	The clinical and radiological results achieved with the Lucerne cast are comparable to those of established treatment.
(Horton et al., 2003) UK	Adults (mean age 26, range 14-79) with an isolated spiral or long	Closed reduction and Kirschner wire group was compared to open reduction and lag screw	Pain (VAS), Functional recovery, Tip-palm distance,	12, 24 and 52 weeks	32	We feel that surgeons treating displaced spiral and long oblique fractures of the proximal phalanx should favour the method with

	oblique fracture of the proximal phalanx		loss of extension/flexion grip strength, Radiographic union, Failure of fixation			which they are most familiar and competent, or the technique that utilizes the least health care resources.
(Kappos et al., 2016) Switzerland	Adults (age of participants not reported) with an isolated, closed proximal phalangeal fracture needing plate osteosynthesis	Open reduction and internal fixation with a plate and screws via a dorsal approach with adhesive barrier was compared to no adhesion barrier.	ROM. DASH, ability to work, Need for secondary surgery.	6 and 24 weeks	42	At 6 weeks there was a trend favouring the adhesion barrier that disappeared at 6 months. Overall the results do not support the use of this device
(Miller et al., 2016) Australia	Adults (mean age 34, standard deviation 11) following 1 week of open reduction and internal fixation of	6 weeks of synergistic wrist and finger exercises with the metacarpophalangeal joint constrained were compared to finger exercises with the metacarpophalangeal joint	Pain, Difficulty with specific and usual hand activity	1, 6 and 12 weeks.	66	Constrained and unconstrained exercises has similar effects after open reduction and internal fixation of proximal phalangeal fracture.

	proximal phalangeal fractures	unconstrained, as part of a comprehensive rehabilitation program				
(Sourmelis et al., 1995) Greece	Adults (age of participants not reported) with proximal phalangeal fracture	Functional treatment was compared to static splinting	Fracture union	4 and 6 weeks	40	We conclude that functional treatment is a safe method for the conservative treatment of the proximal phalangeal fractures

Table 46: Table of RCTs for interventions for the treatment PIP joint injuries

Study identifier	Population	Intervention and comparator	Outcomes	Follow up at	Sample size	Conclusion
Fracture/dislocation of PIP joint						
(Arora et al., 2004) Austria	Adults (age of participants not reported) with isolated, acute, closed dorsolateral dislocation of the PIP joint	Dorsal block splinting of the PIP joint following reduction with daily exercises was compared to a closed reduction and immobilisation with a short-arm cast including both interphalangeal joints for 4 weeks	Pain, Radiological (looking for arthritis and bony healing), Active ROM, Pinch power, Circumference of the finger, Stability of the collateral ligament	Not reported	65	Early active motion after dorsolateral dislocation of the PIP joint produces significantly superior results regarding the active range of motion and pinch power than static splinting.
(Boisgontier et al., 2009) France	Adults (mean age 36, standard deviation 12) with sprain of proximal	The techniques of both active range of motion (AROM) and of NMES superimposed (superimposed technique [ST]:	ROM	Not reported	20	These findings highlighted the superimposed technique as an effective method, which could be integrated in rehabilitation protocols

	interphalangeal joint	application of electrical stimulus during a voluntary muscle action) compared to active range of motion (AROM) treatment on its own				for recovering the proximal interphalangeal joint range of motion following sprain
(Norregaard et al., 1987) Denmark	Adults (mean age 24, standard deviation 11) with hyperextension trauma to the PIP joints of any of the four ulnar fingers	3 weeks of immobilization with a foam-rubber-covered aluminum splint applied to the volar surface with the injured joint flexed was compared to treatment with analgesics and no immobilization. They were advised to start active movements a few days after the trauma.	Pain, Thickened joint, Flexion/extension defect, Swan-neck or Button-hole deformity, Volar-plate tenderness, Stiffness and coldness	24 and 160 weeks	112	We concluded that comfort of the patient and the economic advantages of early motion are obvious.
(Pedersen et al., 1995) Denmark	Adults (mean age 37, range 18-79) with dislocation of the PIP joint (volar plate injuries)	Double finger bandage was compared to a Carstam splint	Clinical examination according to Benke and	2 and 24 weeks.	40	The two methods were equally good as treatment for volar plate injuries to the PIP-joint. The advantage of DFB may be a quicker return to full ROM.

			Stableforth, ROM			
(Thomsen et al., 1995) Denmark	Adults (mean age 37, range 18-79) with type I hyperextension injuries to PIP joint, involving avulsion of the volar plate or a minor avulsion fracture	Treatment with an aluminium splint for 2 weeks was compared to treatment conservatively by an elastic double-finger bandage for 2 weeks	ROM, Clinical (joint stiffness, hyperextension) . Satisfaction with treatment, Return to work.	2 and 24 weeks.	40	We find that type 1 hyperextension injuries to the PIP joint are well-treated with an aluminium splint or with DFB for 2 weeks.

Table 47: Table of RCTs for interventions for the treatment of rupture of UCL

Study identifier	Population	Intervention and comparator	Outcomes	Follow up at	Sample size	Conclusion
Rupture of UCL						
(Moineau and Boisgontier, 2014) France	Adults (mean age 43, standard deviation 12) with pre-stiff thumbs after operative repair for rupture of the ulnar collateral ligament	In the superimposed electrical stimulation session, they performed 20 min of percutaneous neuromuscular electrical stimulations which were superimposed to voluntary flexion. In the voluntary contraction session, they performed 20 min of repeated active flexions of the impaired metacarpophalangeal joint.	Not reported.	Not reported	8	Superimposing electrical stimulation to voluntary contractions is an efficient technique to improve active range of motion of the pre-stiff metacarpophalangeal joint of the thumb
(Rocchi et al., 2014) Italy	Adults (mean age 39, range 16-64) with an acute tear	Patients received modified spica splint with freedom of motion at the MCP joint, but prevention of the radial and	ROM, Pinch strength, Stability, Time off work,	Weekly in the first 4 weeks, and then 8, 24	30	Surgical repair, combined with active metacarpophalangeal motion allowed by the new functional splint,

	of the UCL (0-7 days)	ulnar joint deviation. This was compared to the operated thumb being immobilised for a month using a traditional spica splint.	Physiotherapy, Complications	and 52 weeks.		was effective, safe and well tolerated.
(Sollerman et al., 1991) Sweden	Adults (mean age 32, range 11-62) with fresh rupture of the ulnar collateral ligament of the MCP joint of the thumb.	Immobilization in a plaster cast was compared to a functional splint	Clinical examination, Stability tests, ROM, Pinch grip test, Comfort of the bandage, Length of sick leave.	60 weeks	63	We conclude that immobilization of the thumb after a ligamentous injury with a movable splint is strongly preferred by the patients and that the functional results of this technique are equal to plaster cast immobilization after both surgical and nonsurgical treatment.

Table 48: Table of RCTs for the interventions for treatment of distal phalangeal fractures

Study identifier	Population	Intervention and comparator	Outcomes	Follow up at	Sample size	Conclusion
Distal phalangeal fractures (open)						
(Sloan et al., 1987) UK	Adults (mean age 37, standard deviation 16) with open fractures of the distal phalanges of less than 6 hours duration treated by conventional surgery.	Short or long courses of antibiotics compared to no antibiotics.	Infection rate	1 week	85	Three different antibiotic regimes were compared, with no difference in the infection rate.
(Stevenson et al., 2003) UK	Adults (range 16-88) with open fractures of the distal phalanges of less than 12 hours old.	Prophylactic flucloxacillin compared to placebo (in addition to meticulous wound toilet)	Infection rate (superficial, deep)	1, 2, and 8 weeks.	193	It is concluded that the addition of prophylactic flucloxacillin to thorough wound toilet and careful soft-tissue repair of open fracture of the distal phalanx confers no benefit

Table 49: Table of RCTs for interventions for the treatment of closed bone fractures

Study identifier	Population	Intervention and comparator	Outcomes	Follow up at	Sample size	Conclusion
Closed bone fractures						
(Chang et al., 2014) Taiwan	Adults (mean age 33, standard deviation 8) with closed bone fracture (CBF) of wrist and hand. The fracture was in the phalanges, or the metacarpal, carpal, distal ulna, or distal radial bones. The patients had not been treated.	Low level laser therapy (LLLT) for the healing of CBF five times per week for 2 weeks compared to sham laser treatment	Pain (VAS), Functional disability, QDASH, Grip strength, Radiographic union	2 weeks	50	LLLT can relieve pain and improve the healing process of CBF in the human wrist and hand.

Appendix 4: Risk of bias summary for each included study (Scoping review)

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
1982 Auchincloss et al.	?	?	?	?	?	?
1986 Kinnimondy et al.	?	?	?	?	?	?
1987 Norregaard et al.	?	?	?	?	?	?
1987 Slocan et al.	?	?	?	?	?	?
1988 Sjolin et al.	?	?	?	?	?	?
1988 Warren et al.	?	?	?	?	?	?
1989 Gellman et al.	?	?	?	?	?	?
1990 Konradsen et al.	?	?	?	?	?	?
1991 Clay et al.	?	?	?	?	?	?
1991 Sollemann et al.	?	?	?	?	?	?
1992 Randall et al.	?	?	?	?	?	?
1993 Sorensen et al.	?	?	?	?	?	?
1994 McMahon et al.	?	?	?	?	?	?
1995 Hambridge et al.	?	?	?	?	?	?
1995 Pedersen et al.	?	?	?	?	?	?
1995 Soumleis et al.	?	?	?	?	?	?
1995 Thomsen et al.	?	?	?	?	?	?
1996 Oasamone et al.	?	?	?	?	?	?
1998 Braakman et al.	?	?	?	?	?	?
1998 Hansen et al.	?	?	?	?	?	?
1999 Anand et al.	?	?	?	?	?	?
1999 Kuokkanen et al.	?	?	?	?	?	?
2000 Mayr et al.	?	?	?	?	?	?
2001 Adolfsson et al.	?	?	?	?	?	?
2001 Bond et al.	?	?	?	?	?	?
2001 Harding et al.	?	?	?	?	?	?
2001 Saaden et al.	?	?	?	?	?	?
2002 Gaabler et al.	?	?	?	?	?	?
2003 Horton et al.	?	?	?	?	?	?
2003 Statius Muller et al.	?	?	?	?	?	?
2003 Stevenson et al.	?	?	?	?	?	?
2004 Arora et al.	?	?	?	?	?	?
2005 Dias et al.	?	?	?	?	?	?
2006 Bilic et al.	?	?	?	?	?	?
2006 Rafique et al.	?	?	?	?	?	?
2006 Ricardo et al.	?	?	?	?	?	?
2007 Lawton et al.	?	?	?	?	?	?
2007 Winder et al.	?	?	?	?	?	?
2008 Braga-Silva et al.	?	?	?	?	?	?
2008 Dias et al.	?	?	?	?	?	?
2008 Hoffmeister et al.	?	?	?	?	?	?
2008 McQueen et al.	?	?	?	?	?	?
2008 Vinnars et al.	?	?	?	?	?	?
2008 Zhou et al.	?	?	?	?	?	?
2009 Boisjardier et al.	?	?	?	?	?	?
2009 Zyluk et al.	?	?	?	?	?	?
2010 Pike et al.	?	?	?	?	?	?
2010 Ribak et al.	?	?	?	?	?	?
2010 Strub et al.	?	?	?	?	?	?
2011 O'Brien et al.	?	?	?	?	?	?
2011 Raju et al.	?	?	?	?	?	?
2012 Franz et al.	?	?	?	?	?	?
2012 Hannemann et al.	?	?	?	?	?	?
2012 Goyal et al.	?	?	?	?	?	?
2013 Tocco et al.	?	?	?	?	?	?
2014 Buijze et al.	?	?	?	?	?	?
2014 Caporino et al.	?	?	?	?	?	?
2014 Chiang et al.	?	?	?	?	?	?
2014 Drac et al.	?	?	?	?	?	?
2014 Onuber et al.	?	?	?	?	?	?
2014 Hannemann et al.	?	?	?	?	?	?
2014 Moineau et al.	?	?	?	?	?	?
2014 Roschi et al.	?	?	?	?	?	?
2015 Clementson et al. (1)	?	?	?	?	?	?
2015 Clementson et al. (2)	?	?	?	?	?	?
2015 Kim et al.	?	?	?	?	?	?
2015 Stetten et al.	?	?	?	?	?	?
2015 Xia et al.	?	?	?	?	?	?
2016 Abubail et al.	?	?	?	?	?	?
2016 Cegni et al.	?	?	?	?	?	?
2016 Kappos et al.	?	?	?	?	?	?
2016 Miller et al.	?	?	?	?	?	?
2016 Saito et al.	?	?	?	?	?	?
2016 Van Aaken et al.	?	?	?	?	?	?
2017 Batbay et al.	?	?	?	?	?	?
2017 Galal et al.	?	?	?	?	?	?
2017 Gulke et al.	?	?	?	?	?	?
2017 Lyons et al.	?	?	?	?	?	?

Appendix 5: Ethical approvals for cohort/qualitative study



Health Research Authority

West Midlands - Coventry & Warwickshire Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

01 April 2019

Miss Alexia Karantana
Clinical Associate Professor in Hand Surgery, Faculty of Medicine & Health Sciences
University of Nottingham
Academic Orthopaedics, School of Medicine, Faculty of Medicine and Health Sciences
C floor, West Block, Queen's Medical Centre
Nottingham
NG7 2UH

Dear Miss Karantana

Study title:	Cohort Study For Patient Outcomes In The Management Of Finger Fractures and Joint Injuries
REC reference:	19/WM/0087
Protocol number:	19005
IRAS project ID:	254090

Thank you for your letter of 25th March 2019, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will

be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Leaflet OFFJI]	Final V1.0	13 February 2019
Copies of advertisement materials for research participants [Poster OFFJI]	v1.0	21 March 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [To Whom it may concern]	EL PL PI	20 February 2019
Interview schedules or topic guides for participants [Interview guide OFFJI]	v1.0	21 March 2019
Interview schedules or topic guides for participants [FG guide OFFJI]	v1.0	21 March 2019
IRAS Application Form [IRAS_Form_22022019]		22 February 2019
Letter from sponsor [19005 Sponsor Letter]	v3.0	20 February 2019
Letters of invitation to participant [Covering letter Interviews OFFJI]	Final V1.0	13 February 2019
Letters of invitation to participant [Covering letter FG OFFJI]	Final V1.0	13 February 2019
Other [Response to REC committee]	v1.0	21 March 2019
Participant consent form [CONSENT cohort OFFJI]	v1.0	21 March 2019
Participant consent form [CONSENT Interviews OFFJI]	v1.0	21 March 2019
Participant consent form [CONSENT FG OFFJI]	v1.0	21 March 2019
Participant information sheet (PIS) [PIS study OFFJI]	v1.0	21 March 2019
Participant information sheet (PIS) [PIS Interv OFFJI]	v1.0	21 March 2019
Participant information sheet (PIS) [PIS FG OFFJI]	v1.0	21 March 2019
Research protocol or project proposal [PROTOCOL OFFJI Study Final V1.0 130219]	1.0	13 February 2019
Summary CV for Chief Investigator (CI) [Curriculum Vitae Karantana]	Feb 2019 (Summary for Ethics)	20 February 2019
Summary CV for student		
Summary CV for student [CVChristosMousoulis]	022019	25 February 2019
Validated questionnaire [EQ5D5L OFFJI]	Final V1.0	13 February 2019
Validated questionnaire [GROC OFFJI]	Final V1.0	13 February 2019

Validated questionnaire [PEM OFFJI]	Final V1.0	13 February 2019
Validated questionnaire [PROMIS CAT OFFJI]	Final V1.0	13 February 2019

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance>

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:

<https://www.hra.nhs.uk/planning-and-improving-research/learning/>

19/WM/0087	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely



Dr Ronald Jubb

Vice Chair

Email: NRESCommittee.WestMidlands-CoventryandWarwick@nhs.net

Enclosures: *"After ethical review – guidance for researchers"* [\[SL-AR2\]](#)

Copy to: *Ms Angela Shone*

Lead Nation

England: HRA.Approval@nhs.net

Miss Alexia Karantana
Clinical Associate Professor in Hand Surgery, Faculty of
Medicine & Health Sciences
University of Nottingham
Academic Orthopaedics, School of Medicine, Faculty of
Medicine and Health Sciences
C floor, West Block, Queen's Medical Centre
Nottingham
NG7 2UH

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

02 April 2019

Dear Miss Karantana

**HRA and Health and Care
Research Wales (HCRW)
Approval Letter**

Study title:	Cohort Study For Patient Outcomes In The Management Of Finger Fractures and Joint Injuries
IRAS project ID:	254090
Protocol number:	19005
REC reference:	19/WM/0087
Sponsor	University of Nottingham

I am pleased to confirm that [HRA and Health and Care Research Wales \(HCRW\) Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

What are my notification responsibilities during the study?

The document “*After Ethical Review – guidance for sponsors and investigators*”, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The [HRA website](#) also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **254090**. Please quote this on all correspondence.

Yours sincerely,
Catherine Adams

Approvals Manager

Email: hra.approval@nhs.net Research-permissions@wales.nhs.uk

Copy to: Ms Angela Shone

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Leaflet OFFJI]	Final V1.0	13 February 2019
Copies of advertisement materials for research participants [Poster OFFJI]	v1.0	21 March 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [To Whom it may concern]	EL PL PI	20 February 2019
HRA Schedule of Events	1	02 April 2019
HRA Statement of Activities	1	02 April 2019
Interview schedules or topic guides for participants [Interview guide OFFJI]	v1.0	21 March 2019
Interview schedules or topic guides for participants [FG guide OFFJI]	v1.0	21 March 2019
IRAS Application Form [IRAS_Form_22022019]		22 February 2019
Letter from sponsor [19005 Sponsor Letter]	v3.0	20 February 2019
Letters of invitation to participant [Covering letter Interviews OFFJI]	Final V1.0	13 February 2019
Letters of invitation to participant [Covering letter FG OFFJI]	Final V1.0	13 February 2019
Participant consent form [CONSENT cohort OFFJI]	v1.0	21 March 2019
Participant consent form [CONSENT Interviews OFFJI]	v1.0	21 March 2019
Participant consent form [CONSENT FG OFFJI]	v1.0	21 March 2019
Participant information sheet (PIS) [PIS study OFFJI]	v1.0	21 March 2019
Participant information sheet (PIS) [PIS Interv OFFJI]	v1.0	21 March 2019
Participant information sheet (PIS) [PIS FG OFFJI]	v1.0	21 March 2019
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Validated questionnaire [PEM OFFJI]	Final V1.0	13 February 2019
Validated questionnaire [PROMIS CAT OFFJI]	Final V1.0	13 February 2019

IRAS project ID	254090
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Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
All participating organisations will undertake the same activities, as detailed in the protocol and supporting documents	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study	A statement of activities has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used	No funding is being provided to the site by the Sponsor	The Chief Investigator is responsible for research activity at the participating site	Letters of access will be required for those staff undertaking interviews with participants, that are not employed by the host organisation. A standard DBS check with occupational health clearance should be in place.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.

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Appendix 6: Cohort study leaflet



Cohort Study for Patient Outcomes in the Management of Finger Fractures and Joint Injuries (OFFJI study)

You are invited to participate in our study because you have a finger fracture and/or finger joint injury. Please take some time to read this leaflet and consider taking part. Your input will be very much appreciated and will help the management of such injuries in the future.

Hand fractures and joint injuries

Hand fractures (i.e. broken bones) and joint injuries are common. There are 27 bones in the human hand. Any bones or joints in the hand can be fractured/injured (see figure 1). As part of this study we will only look at finger fractures and joint injuries.



Figure 1: The hand bones¹

¹ Anatomy Diagram. Bones in the hands and wrist (2018). URL: <https://anatomyclass01.us/bones-in-the-hands-and-wrist/bones-in-the-hands-and-wrist-wrist-and-hand-joints-basicmedical-key/> [28th August 2018]

Normal treatment of finger fractures and joint injuries

This includes having the hand operated on, or using different methods to promote healing such as a splint or cast. This is decided by the treating surgeon in discussion with the patient. These injuries can be immobilised using various types of splints or casts, and/or can be treated surgically.

This research study

The aim of this study is to improve the evidence base by informing future clinical trials evaluating different treatments for finger fractures. We aim to gather evidence on the likely recovery time after a finger fracture/joint injury, so that we can plan future studies more effectively.

If you agree to take part in this research study, your treatment plan would still be decided by the surgeon based on their expert medical opinion.

What to expect from taking part in this study?

You will be approached by an investigator who will go through the details of the study with you. He/she will ask for your consent to participate. Participation in this study is entirely voluntary and you can withdraw from this study at any point.

You will be asked to complete some questionnaires in clinic and this should not take more than 10 minutes. Taking part in this study will not affect your treatment in any way. You will be sent a similar questionnaire at 6, 12, 24 weeks either to complete by email or by post.

Interviews

Some of you may be invited for an interview. This would last for about 30-60 minutes. It could be done in the hospital (as part of a clinic appointment), at your own home or by telephone. You will be asked about your experience of having a hand fracture/joint injury, the treatment, and the recovery overall. You will be asked to comment on how to improve such studies in the future based on your experience from participating in the study.

Focus groups

At the end of the study, some of you may be invited to one or two focus groups in which we will discuss the research findings and how a future study should be planned. Your contribution to this will be very much appreciated.

A much smaller number of people are needed to take part in the interviews and focus groups, so it is OK to just take part in the questionnaire study if you prefer.

If you would like further information, please contact:

Dr Christos Mousoulis
PhD student in Academic Orthopaedics
Phone: 0115 82 31113
Email: christos.mousoulis@nottingham.ac.uk

If you do not want to be approached by a researcher, please let a receptionist or a member of the team know

Page 2 of 2

Patient outcomes for finger fractures and joint injuries – Leaflet Final Version 1.0 13/02/19

Appendix 7: Cohort study Patient Information Sheet (PIS)



Participant Information Sheet (Final version 1.1: 31/07/20)

IRAS Project ID: 254090

Title of Study: Cohort Study for Patient Outcomes in the Management of Finger Fractures and Joint Injuries (OFFJI)

Name of Chief Investigator: Miss Alexia Karantana

Local Researcher(s): Dr Christos Mousoulis (PhD student), Professor Kim Thomas, Dr Paul Leighton.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

This research is about fractures of the three bones of each of the fingers or the finger joint on either end.

The purpose of the study is to learn more about how patients with finger fractures recover from their injury after receiving different types of treatment. Also, to find out how patients feel about being in a research study, which will help to inform the development of future hand fracture studies.

If you agree to take part in the study, you will be asked to complete questionnaires about your recovery from the injury. If you are willing to talk to us about their injury and about taking part in this research, may invite you for an interview and/or focus group. Only a proportion of participants will be invited for interview and/or focus group. The questionnaires are short and easy to complete and ask about how your hand works and how your health is in general as a result of your injury.

Why have I been invited?

You are being invited to take part because you have a finger fracture. We are inviting participants like you to take part.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form today. However, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

Participating in the study will not affect your medical treatment. Your treatment will be decided by your doctor and you, same as usual. The medical team treating you will not see your answers to the questionnaires, which are confidential.

You will be asked to complete simple questionnaires telling us about your hand in clinic today and online (or post) at 6, 12 and 24 weeks.

Each questionnaire will take about 15 minutes to complete. If willing, at a later date, you may also be offered the opportunity to talk to a researcher about your experience as part of an interview. This will take place either face-to-face at a place convenient to you, or by telephone. The interview will last about 30-60 minutes. There would be questions about your recovery and about taking part in a research study. You will be compensated for any travel expenses, should you wish to travel.

We will also access your medical notes at 6 months after the injury to record any complications.

Towards the end of the questionnaire study we will conduct one or two focus groups. Focus groups involve a small group of patients coming together in a meeting with a researcher to discuss their experience. If you indicate your interest to participate in the interviews/focus groups on the consent form, you will be sent information by email at a later date. Unfortunately, not all who express an interest may be invited to participate as numbers are limited.

Expenses and payments

As a thank you, we will send you a £5 gift voucher every time you send us back a completed set of questionnaires: one at 6 weeks, one at 12 weeks and one at 24 weeks. Participants who complete the 24 week questionnaire will also be entered, in a prize draw of three £50 gift vouchers. Patients who participate in an interview or focus group will be given a £20 gift voucher as a thank you. All travel expenses will be offered for any visits incurred as a result of participation in the research.

Test-retest sub-study

For a small number of participants, we will ask them to complete one of the questionnaires again within a week of the initial meeting in fracture clinic and then again within a week of the 6-week questionnaire. This sub-study will investigate whether the answers to the questionnaires change within a week of recovery. We would be very grateful if you could complete those in a timely fashion please. The participants who do so will be sent two additional £5 thank you Amazon vouchers (one after each questionnaire completion).

What are the possible disadvantages and risks of taking part?

Taking part in the study may require some time from you, especially the interviews and focus groups. The interviews may take place in clinic (tied to a clinic appointment), at your home or over the telephone.

Everything you say will be anonymised and treated with confidentiality.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help patients with such injuries in the future. If we can improve the evidence on how hand fractures are treated, this will help patients and doctors make informed decisions about care. It will also help people to understand the likely timeframe for recovery of their kind of injury.

What happens when the research study stops?

Your treatment after the end of the study will not be affected. We aim to analyse the results of the study and publish them in an academic journal. Participants will receive a summary of the research results and have the option to ask questions. The results will also form part of Dr Christos Mousoulis' PhD thesis. Your contact details will be held in secure University computers for the duration of the study. We would also like to ask for your permission to contact you about your injury in the future please. You can say no to further contact and still be part of the study.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting PALS at QMC hospital (C/O PALS, Freepost, NEA 14614, Nottingham, NG7 1BR, Email: PALS@nuh.nhs.uk, Freephone: 0800 183 0204)

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence during and after the study.

If you join the study, we will use information collected from you and from your medical records during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password-protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally-identifiable information possible. You can find out more about how we use your information and to read our privacy notice at: <https://www.nottingham.ac.uk/utilities/privacy.aspx>.

The data collected for the study will only be looked at by authorised persons from the University of Nottingham who are organising or conducting the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant. Any information about you which leaves the hospital will have your name and address removed and a unique code used, so that you cannot be recognised from it. All research data is kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data. We will retain your contact details for 3 years after the study end, so that we are able to tell you about the findings of the study or possible follow-up studies, unless you advise us that you do not wish to be contacted.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Involvement of the General Practitioner/Family doctor (GP)

We will not notify your GP of the participation in the research study. We are not planning to contact your GP for any other information.

What will happen to the results of the research study?

The results of this study are likely to be published in the medical literature. You will be able to view the published study online after publication. The participants will not be identified in any report/publication. If you agree, we will send you regular newsletters by email about the study (every 3 months) and the final results at the end of the study.

Who is organising and funding the research?

This research is being organised and funded by the University of Nottingham. There is no external funding source for this study.

Who has reviewed the study?

All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by West Midlands - Coventry & Warwickshire Research Ethics Committee.

Further information and contact details

Main contact:	Dr Christos Mousoulis
	PhD student in Academic Orthopaedics
	Phone: 0115 82 31113
	Email: christos.mousoulis@nottingham.ac.uk
Chief investigator:	Miss Alexia Karantana
	Clinical Associate Professor in Hand Surgery
	Faculty of Medicine and Health Sciences
	Phone: 0115 82 31115
	Email: a.karantana@nottingham.ac.uk

Appendix 8: Consent form for the cohort study



University of
Nottingham
UK | CHINA | MALAYSIA

CONSENT FORM (Final version 1.1: date 31/07/20)

Title of Study: Cohort Study for Patient Outcomes in the Management of Finger Fractures and Joint Injuries (OFFJI)

IRAS Project ID: 254090

Name of Chief Investigator: Miss Alexia Karantana, Clinical Associate Professor in Hand Surgery

Please initial box

Name of Participant:

1. I confirm that I have read and understand the information sheet version number 1.1 dated 31/07/20 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand that should I disclose anything which the researchers feel puts me or anyone else at any risk, they may feel it necessary to report this to the appropriate persons. ☐
5. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
6. I agree to take part in the above study. ☐

OPTIONAL SECTION:

7. In addition to the above statements, I agree to be contacted in the future about taking part in optional interviews/focus groups. I understand I will have time to consider this information before taking part. ☐
8. I consent to receiving a summary of the results of the research. ☐
9. I consent to being contacted in the future about other research studies at most within 3 years ☐

TEST-RETEST STUDY:

10. I agree to be sent one of the questionnaires to complete within a week of this meeting and then again a week after the 6 week questionnaire. ☐

_____ Name of Participant	_____ Date	_____ Signature
_____ Name of Person taking consent	_____ Date	_____ Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes ([as appropriate](#))

Appendix 9: Cohort study Data collection forms from REDCap

Version 1.0 - 24 May 2019

OFFJ: Patient Outcomes for Finger Fractures and Joint Injuries
Page 1 of 1

Enrolment

Participant ID _____

Participant number _____

Centre number _____

Participant details

Initials _____
(3 uppercase letters, or 2 separated by a hyphen (-))

Sex ☐ Male
☐ Female

Date of birth _____

Age _____

Injury details

Date of injury _____

Age at time of injury _____

Enrolment details

Date/time of enrolment _____

Baseline

Participant ID	
Does the participant work?	☐ Yes ☐ No
Occupation	☐ Clerical ☐ Light manual ☐ Heavy manual ☐ Fine skill ☐ Other ☐ Not known
Occupation description	
Self employed	☐ Yes ☐ No ☐ Not known
Hand dominance	☐ Right ☐ Left ☐ Both ☐ Not known
Driving	☐ Yes ☐ No ☐ Not known
Does participant have concomitant systemic disease? (diabetes with vascular or neurological complications, advanced cardiac, pulmonary or neurological disease)	☐ Yes ☐ No
Does the patient take any regular GP prescribed medication?	☐ Yes ☐ No
Will the participant be completing follow-up questions online?	☐ Yes ☐ No (If yes, adaptive surveys will be made available for the participant to complete)

Baseline - Injury characteristics

Participant ID	
Side of injury	☐ Right ☐ Left ☐ Bilateral
Open fracture	☐ Yes ☐ No
Nerve injury	☐ Yes ☐ No
Tendon injury (other than mallet)	☐ Yes ☐ No
Requiring local or distal soft tissue flap cover	☐ Yes ☐ No
Mechanism of injury	☐ Simple fall from standing height ☐ High energy fall (e.g. fall from bike, fall from height, fall during sports) ☐ Direct blow from an object (not crush) ☐ RTA ☐ Crush ☐ Punch ☐ Pathological (enchondroma) ☐ Other
Mechanism of injury - please specify	
Injury during sports	☐ Yes ☐ No
Injury sustained at work	☐ Yes ☐ No

Primary injury	☐ Proximal phalanx extra-articular shaft ☐ Proximal phalanx extra-articular base metaphyseal ☐ Proximal phalanx extra-articular neck (sub-condylar) ☐ Proximal phalanx intra-articular base ☐ Proximal phalanx collateral avulsion ☐ Proximal phalanx intra-articular condylar ☐ Middle phalanx extra-articular shaft ☐ Middle phalanx extra-articular base metaphyseal ☐ Middle phalanx extra-articular neck (sub-condylar) ☐ Middle phalanx intra-articular condylar ☐ Middle phalanx intra-articular base - volar plate avulsion, congruent joint ☐ Middle phalanx intra-articular base - subluxated/dislocated joint with intact column ☐ Middle phalanx intra-articular base - pilon # no intact columns ☐ Mallet finger bony ☐ Mallet finger soft tissue
Finger(s) affected	☐ Index ☐ Middle ☐ Ring ☐ Little
Fracture pattern	☐ Undisplaced ☐ Minimally displaced ☐ Displaced
Concurrent same hand/wrist injury	☐ Yes ☐ No
Concurrent same hand/wrist injury details	_____
Concurrent contralateral hand/wrist injury	☐ Yes ☐ No
Concurrent contralateral hand/wrist injury details	_____
Concurrent upper limb injury (same limb)	☐ Yes ☐ No
Concurrent upper limb injury (same limb) details	_____
Concurrent upper limb injury (contralateral limb)	☐ Yes ☐ No
Concurrent upper limb injury (contralateral limb) details	_____
Multiply injured in addition to the above	☐ Yes ☐ No
Multiply injured in addition to the above - details	_____

Baseline - Injury management

Participant ID _____

Surgical management

- ☐ None
☐ K wire fixation
☐ ORIF (screw fixation only)
☐ ORIF (plate and screws)
☐ External fixation
☐ Pre-planned removal of k-wires in theatre
☐ Other

Surgical management (please specify) _____

 Failure of surgical treatment
 Need for further surgery within 6 weeks from surgery

- ☐ Yes
☐ No

 Failure of surgical treatment
 Name procedure

Non-surgical management

- ☐ None
☐ Splint: Bedford gaiter or simple buddy-tapping
☐ Splint: Traction splint (Zimmer or similar)
☐ Splint: Resting splint (holds joint in set position)
☐ Splint: Blocking splint
☐ Splint: Mallet splint
☐ Mobilisation freely (no support at all)
☐ Splint or cast other

Non-surgical management - manipulation

- ☐ Yes
☐ No
☐ Not known

 Failure of non-surgical treatment
 Second manipulation

- ☐ Yes
☐ No

 Failure of non-surgical treatment
 Need for surgery within 6 weeks of injury

- ☐ Yes
☐ No

 Failure of non-surgical treatment
 Name procedure

Complications	☐ None ☐ Non-union ☐ Infection ☐ Nerve injury ☐ Tendon injury ☐ Restricted movement > 6 weeks post injury ☐ Hand weakness > 3 months post injury ☐ Persistent pain > 6 weeks post injury ☐ Malunion requiring further surgery ☐ Malunion accepted, no further surgery performed ☐ Removal of metalwork (other than pre-planned removal of percutaneous or buried k-wires) ☐ Other
Other complications (please specify)	
How were the complications managed?	
Was the participant referred for formal therapy?	☐ Yes ☐ No ☐ Not known
Number of therapy attendances	

Follow-up

Please complete the survey below.

Thank you!

Please ask the participant the following questions:

Global Rating of Change Scale (GROC)

Please rate the overall condition of your injured body part or region FROM THE TIME THAT YOU BEGAN TREATMENT UNTIL NOW

- ☐ A very great deal worse (-7)
- ☐ A great deal worse (-6)
- ☐ Quite a bit worse (-5)
- ☐ Moderately worse (-4)
- ☐ Somewhat worse (-3)
- ☐ A little bit worse (-2)
- ☐ A tiny bit worse (-1)
- ☐ About the same (0)
- ☐ A tiny bit better (1)
- ☐ A little bit better (2)
- ☐ Somewhat better (3)
- ☐ Moderately better (4)
- ☐ Quite a bit better (5)
- ☐ A great deal better (6)
- ☐ A very great deal better (7)

Driving

Do you currently drive?

- ☐ Yes
- ☐ No

When did you resume driving?

(If your injury has not prevented you from driving, please enter the date of injury
([first-event-name][date_of_injury]).)

Working

Are you back at work?

- ☐ Yes
- ☐ No

When did you resume working?

(If your injury has not prevented you from working, please enter the date of injury
([first-event-name][date_of_injury]).)

Recovery

Do you feel that you have fully recovered from your injury?

☐ Yes

☐ No

Comments

Please complete the survey below.

Thank you!

Please ask the participant the following questions:

Are there any other comments you wish to make about taking part in the study? ☐ Yes
☐ No

Please enter any comments you wish to make about taking part in the study:

Is there anything else you would like to tell us? ☐ Yes
☐ No

Please enter anything else you would like to tell us:

Appendix 10: Patient Reported Outcome Measures (PROMs) used in cohort study

10.1. Global Rating of change (GROC)

Please rate the overall condition of your injured body part or region *FROM THE TIME THAT YOU BEGAN TREATMENT UNTIL NOW* (Check only one):

- | | | |
|---|---|---|
| ☐ A very great deal worse (-7) | ☐ About the same (0) | ☐ A very great deal better (7) |
| ☐ A great deal worse (-6) | | ☐ A great deal better (6) |
| ☐ Quite a bit worse (-5) | | ☐ Quite a bit better (5) |
| ☐ Moderately worse (-4) | | ☐ Moderately better (4) |
| ☐ Somewhat worse (-3) | | ☐ Somewhat better (3) |
| ☐ A little bit worse (-2) | | ☐ A little bit better (2) |
| ☐ A tiny bit worse (-1) | | ☐ A tiny bit better (1) |

From: Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. *Control Clin Trials* 1989; 407-15.

10.2. Patient Evaluation Measure (PEM)

PEM questionnaire - These questions are about how your hand is now. There are no right or wrong answers. For each question, give your answer by drawing a circle around the number which shows best how things are for you. Please circle only ONE number for each question.

1. The feeling in my hand is now:

normal	1	2	3	4	5	6	7	absent
--------	---	---	---	---	---	---	---	--------

2. When my hand is cold and/or damp, the pain is now:

non-existent	1	2	3	4	5	6	7	unbearable
--------------	---	---	---	---	---	---	---	------------

3. Most of the time, the pain in my hand is now:

non-existent	1	2	3	4	5	6	7	unbearable
--------------	---	---	---	---	---	---	---	------------

4. The duration my pain is present is:

never	1	2	3	4	5	6	7	all the time
-------	---	---	---	---	---	---	---	--------------

5. When I try to use my hand for fiddly things, it is now:

skilful	1	2	3	4	5	6	7	clumsy
---------	---	---	---	---	---	---	---	--------

6. Generally when I move my hand it is:

flexible	1	2	3	4	5	6	7	stiff
----------	---	---	---	---	---	---	---	-------

7. The grip I my hand is now:

strong	1	2	3	4	5	6	7	weak
--------	---	---	---	---	---	---	---	------

8. For everyday activities my hand is now:

no problem	1	2	3	4	5	6	7	useless
------------	---	---	---	---	---	---	---	---------

9. For my work my hand is now:

no problem	1	2	3	4	5	6	7	useless
------------	---	---	---	---	---	---	---	---------

10. When I look at the appearance of my hand, I feel:

unconcerned	1	2	3	4	5	6	7	embarrassed and selfconscious
-------------	---	---	---	---	---	---	---	-------------------------------

11. Generally when I think about my hand I feel:

unconcerned	1	2	3	4	5	6	7	very upset
-------------	---	---	---	---	---	---	---	------------

10.3. EQ-5D-5L

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

SELF-CARE

- I have no problems washing or dressing myself ☐
- I have slight problems washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities ☐
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

PAIN / DISCOMFORT

- I have no pain or discomfort ☐
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

- I am not anxious or depressed ☐
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am severely anxious or depressed ☐
- I am extremely anxious or depressed ☐

- We would like to know how good or bad your health is TODAY.

The best health
you can imagine

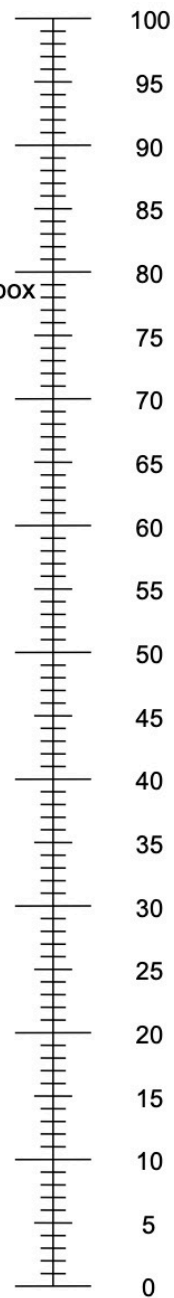
- This scale is numbered from 0 to 100.

- 100 means the best health you can imagine.
0 means the worst health you can imagine.

- Mark an X on the scale to indicate how your health is TODAY.

- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



The worst health
you can imagine

10.4. PROMIS CAT Upper limb

Upper Extremity – Short Form 7a (for patients with no access to internet)

Please respond to each question or statement by marking one box per row.		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA14r 1	Are you able to carry a heavy object (over 10 pounds /5 kg)?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA34	Are you able to wash your back?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA36	Are you able to put on and take off a coat or jacket?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB13	Are you able to carry a shopping bag or briefcase?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB28r 1	Are you able to lift 10 pounds (5 kg) above your shoulder?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB34	Are you able to change a light bulb overhead?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFM16	Are you able to pass a 20-pound (10 kg) turkey or ham to other people at the table?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Upper Extremity – full dataset for computer adaptive testing (from which each patient would only be asked approximately 7 individually selected questions)

Please respond to each question or statement by marking one box per row.		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA14 r1	Are you able to carry a heavy object (over 10 pounds /5 kg)?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA16 r1	Are you able to dress yourself, including tying shoelaces and buttoning your clothes?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA17	Are you able to reach into a high cupboard?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA18	Are you able to use a hammer to pound a nail?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA20	Are you able to cut your food using eating utensils?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA28	Are you able to open a can with a hand can opener?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA29 r1	Are you able to pull heavy objects (10 pounds/ 5 kg) towards yourself?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA34	Are you able to wash your back?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA35	Are you able to open and close a zipper....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA36	Are you able to put on and take off a coat or jacket?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA38	Are you able to dry your back with a towel?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA40	Are you able to turn a key in a lock?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA43 r1	Are you able to write with a pen or pencil?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

PFA44	Are you able to put on a shirt or blouse?...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA48	Are you able to peel fruit?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA50	Are you able to brush your teeth?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA54	Are you able to button your shirt?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB11	Are you able to wash dishes, pots, and utensils by hand while standing at a sink?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB13	Are you able to carry a shopping bag or briefcase?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB15 r1	Are you able to change the bulb in a table lamp?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB16 r1	Are you able to press with your index finger (for example ringing a doorbell)? ...	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB18	Are you able to shave your face or apply makeup?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB19 r1	Are you able to squeeze a new tube of toothpaste?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Are you able to cut a piece of paper with scissors?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB21 r1	Are you able to pick up coins from a table top?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB22	Are you able to hold a plate full of food?..	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB23 r1	Are you able to pour liquid from a bottle into a glass	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB25	Are you able to push open a door after turning the knob?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB26	Are you able to shampoo your hair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB27	Are you able to tie a knot or a bow?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB28 r1	Are you able to lift 10 pounds (5 kg) above your shoulder?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

PFB30	Are you able to open a new milk carton?..	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB31 r1	Are you able to open car doors?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB33	Are you able to remove something from your back pocket?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB34	Are you able to change a light bulb overhead?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB36	Are you able to put on a pullover sweater?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB37 r1	Are you able to turn faucets on and off? ..	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB39 r1	Are you able to reach and get down a 5 pound (2 kg) object from above your head?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB41	Are you able to trim your fingernails?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB56 r1	Are you able to lift one pound (0.5 kg) to shoulder level without bending your elbow?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC43	Are you able to use your hands, such as for turning faucets, using kitchen gadgets, or sewing?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC49	Are you able to water a house plant?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFM2	Are you able to lift a heavy painting or picture to hang on your wall above eye-level?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFM16	Are you able to pass a 20-pound (10 kg) turkey or ham to other people at the table?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFM18	Are you able to continuously swing a baseball bat or tennis racket back and forth for 5 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC8	Does your health now limit you in opening a previously opened jar?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

COHORT STUDY FOR PATIENT OUTCOMES IN THE MANAGEMENT OF FINGER FRACTURES AND JOINT INJURIES (OFFJI)

DATA DESCRIPTION

What data will you create?

- Demographic data for the patients (age, sex, occupation, co-morbidities, driving, details of injury) from the patient in clinic. Some of this is personally sensitive information. However, we do not need to know all the patients' medical history, just if they have a serious medical problem and whether they are taking medication (Yes or No answers). This study is focusing on the finger injuries.
- Responses to Patient Reported Outcome Measure (PROM) questionnaires (GROC, PEM, EQ-5D-5L, PROMIS CAT) (quantitative data), a question about whether they have fully recovered, whether they have returned to work and whether they have resumed driving at baseline, 6, 12 and 24 weeks.
- Data from medical records on any treatment complications
- Interview data (qualitative) which is going to be recorded in a Dictaphone and transcribed by CM.

Data will be captured in REDCap software. This encompasses the whole data collection and processing process. Data will be analysed in STATA.

DATA COLLECTION / GENERATION

What are your methodologies for data collection / generation? How will you ensure data quality? What data standards will you use?

Data will be collected from the patients when they will be recruited in the study in fracture clinic and remotely at 6, 12 and 24 weeks. Patients will sign a consent form for this. Demographic details will be collected in fracture clinic. Patients will complete PROM questionnaires in fracture clinic and remotely at 6, 12, and 24 weeks. They will complete the GROG, PEM, PROMIS CAT and EQ-5D-5L questionnaires. All this data will be collected by REDCap software.

Patients will be interviewed over the phone, at their home, or at QMC hospital in Nottingham. Interviews will be audio recorded and transcribed. Patients will sign a consent form for this. Interview data will be anonymised.

All data will be handled with reference to GDPR and Data Protection Act.

All research staff who recruit and do the interviews have done GCP training.

DATA STORAGE AND SECURITY

Where and how will data will be stored, backed-up, transferred, and secured during the active phase (short to medium term) of research?

Data (demographic details, details of injury, management and answers to PROM questionnaires) is stored in REDCap software. This is specialised software for clinical research that has been approved by UoN.

Paper files (patient details and consent forms) are locked in University of Nottingham cabinets securely.

Interview data from recording device will be transferred as soon as the interview is over to UoN Microsoft Teams. Data will be anonymised.

Electronic files are stored in UoN Microsoft Teams. This is UoN-provided storage. UoN licenses Microsoft Teams, an ISO 27001 information security management compliant service that allows secure and controlled sharing of data amongst the research team. University of Nottingham Teams encrypts data both in transit and at rest and is approved against the University's Handling Restricted Data Policy. The service provides continual failover support. This service provides up to 5TB free-at-point-of-use, and as we do not anticipate generating more than 5TB we will not require any additional costs for use of this service.

DATA MANAGEMENT, DOCUMENTATION, AND CURATION

What are your principles, systems, and major standards for data management and creation? What metadata and documentation will you keep?

Personal data will be collected during this project, and the project has considered ethical and legal implications in its data storage, as well as appropriate security of personal data. All participants will agree to data collection and to long-term retention, archiving, and sharing of their anonymised data. Research will follow standard ethical procedures of the School of Medicine and the University of Nottingham. Specific aspects will be considered by the School ethics committee as appropriate. In particular, the creation of data from interviews will require ethical approval, including consent forms outlining the storage and use for research purposes of data, including access to those data by project researchers and other researchers, both during and after the life of the project. Participants will be informed that they can withdraw their participation at any stage during or after the observations. As we will be working with personal data we will ensure that we comply with the Data Protection Act 2018, including GDPR requirements. This will

include providing research participants with the relevant privacy information and ensuring appropriate safeguards for the storage and handling of data are in place.

On deposit of our data and associated documentation we shall provide catalogue metadata that will facilitate the discovery of our data. This shall conform with the DataCite metadata schema.

The anonymised data (transcripts and questionnaires) will be deposited in the University of Nottingham data archive once all data has been gathered, anonymised, and cleansed. In order to minimise any further risk of disclosure, we shall control access requests to any data containing personal information to ensure the confidentiality of our research participants.

ETHICS & PRIVACY

Are there any ethical or privacy related issues associated with your data?

Data is managed according to the University of Nottingham's Code of Research Conduct and Research Ethics. Paper files (patient details and consent forms) will be stored in locked University cabinets. Interview data will be anonymised. REDCap will be used to store questionnaire data and UoN Microsoft Teams for files.

Patients will sign a consent form before they enrol to the study and before they are interviewed.

The study has been approved by the University of Nottingham (sponsor) and NHS REC Coventry and Warwickshire.

Data will be kept for 7 years after the end of the study according to UoN protocol.

Personal data will be collected during this project, and the project has considered ethical and legal implications in its data storage, as well as appropriate security of personal data. All participants will agree to data collection and to long-term

retention, archiving, and sharing of their anonymised data. Research will follow standard ethical procedures of the School of Medicine and the University of Nottingham. Specific aspects will be considered by the School ethics committee as appropriate. In particular, the creation of data from interviews will require ethical approval, including consent forms outlining the storage and use for research purposes of data, including access to those data by project researchers and other researchers, both during and after the life of the project. will be informed that they can withdraw their participation at any stage during or after the observations. As we will be working with personal data we will ensure that we comply with the Data Protection Act 2018, including GDPR requirements. This will include providing research participants with the relevant privacy information and ensuring appropriate safeguards for the storage and handling of data are in place

DATA PRESERVATION

How will you ensure the long term storage and preservation of data?

All research data created by the project will be deposited in the UoN research data archive, <https://rdmc.nottingham.ac.uk/> The UoN data archive is underpinned by commercial digital storage which is audited on a twice-yearly basis for compliance with the ISO 27001 standard. UoN will retain and preserve research data in line with UoN requirement for a minimum of 7 -years, but data will be retained for longer periods of time where it is of continual value to users. No cost has been charged to this project for data archiving as we anticipate that the amount of data generated for long-term retention will not exceed 50GB (the capacity provided free by the University).

All raw and processed data will be deposited. Anonymised data will be deposited only. Data will be deposited at the end of the project (February 2022).

DATA SHARING AND ACCESS

How will the data generated be shared and published?

Our dataset does not contain any commercially sensitive information and thus will be shared via the University of Nottingham data archive. There will be no need to update the data past the project period.

The anonymised data (transcripts and questionnaires) will be deposited in the University of Nottingham data archive once all data has been gathered, anonymised, and cleansed. In order to minimise any further risk of disclosure, we shall control access requests to any data containing personal information to ensure the confidentiality of our research participants. Access agreements will be written on request in conjunction with the Research Contracts Team.

The existence, range, and nature of the project's original data will be publicised via references in published outputs by including relevant dataset DOIs, as well as via conference presentations and materials produced during the project.

There are no financial requirements for archiving and sharing data in the UoN data archive as the volume of data will not exceed 50GB.

ROLES & RESPONSIBILITIES

Who will be responsible for managing data, data security, data quality, and data security both during the award and post-award?

The research team will be managing data, data security, data quality and data security both during the study and after.

The UoN regulations apply.

The research team will be responsible for study-wide data management, metadata creation, data security and quality assurance of data.

RELEVANT POLICIES

What are the relevant institutional, departmental or study policies on data sharing and data security?

We will ensure that our research aligns with the requirements of the University's Research Data Management Policy, Information Security Policy, Data Protection Policy, Data Transfer Policy, University Retention Schedule, Research Ethics Ethical Framework, and Code of Research Conduct and Research Ethics. As we are working with personal data, we will abide by the Secure Data Handling Policy and Data Protection Policy. All third party commercial data or new data that may be suitable for commercial exploitation will be protected by the University's Intellectual Property policy

IPR

Who will own the copyright and IPR of any data that you will collect or create? Will you create a licence(s) for its use and reuse? If you are planning to use existing data as part of your research, do any copyright or other restrictions determine its use?

The intellectual property of the data generated will remain with the University of Nottingham.

BUDGETING

What are the costs or funding required for capturing, processing, storing, and archiving your data?

There is no cost or funding for capturing, processing, storing and archiving the data for this project.

Appendix 12: PROM results for the individual injuries

Table 50: PEM, PROMIS CAT and EQ-5D-5L results for the individual injuries

		PEM		PROMIS CAT		EQ-5D-5L VAS	
		Mean and SD	Median and IQ range (75-25)	Mean and SD	Median and IQ range (75-25)	Mean and SD	Median and IQ range (75-25)
Proximal phalanx extra-articular fracture	Pre-injury baseline	12.6 (6.1) (n=48)	11 (11- 11) (n=48)	56.4 (8.8) (n=44)	61 (61-54.9) (n=44)	85.7 (12.5) (n=48)	90 (95-80) (n=48)
	Post-injury baseline	48.9 (15.6) (n=18)	50 (61-37) (n=18)	x	x	x	x
	6 weeks	34.1 (19.1) (n=30)	28 (50 -20) (n=30)	44 (11.6) (n=26)	42.4 (54.9-35) (n=26)	78.6 (20.5) (n=30)	85 (90-80) (n=30)
	12 weeks	28.8 (15.9) (n=27)	23 (37-16) (n=27)	48.4 (13.0) (n=25)	54.9 (61-41.4) (n=25)	81.7 (17.1) (n=27)	84 (95-75) (n=27)
	24 weeks	24.9 (15.5) (n=32)	19.5 (34-13) (n=32)	50.6 (11.8) (n=28)	55.4 (61-38.8) (n=28)	82.7 (17.6) (n=31)	86 (94-80) (n=31)
Volar plate injuries	Pre-injury baseline	11.1 (0.5) (n=41)	11 (11-11) (n=41)	58.0 (5.4) (n=37)	61 (61-54.9) (n=37)	83.9 (11.6) (n=41)	90 (90-80) (n=41)
	Post-injury baseline	41.7 (13.2) (n=13)	43 (50-36) (n=13)	x	x	x	x
	6 weeks	31.8 (15.0) (n=30)	27.5 (45-20) (n=30)	45.1 (11.4) (n=25)	42.4 (54.7-34.6) (n=25)	74.9 (20.2) (n=30)	80 (91-65) (n=30)
	12 weeks	28.1 (15.1) (n=27)	22.0 (39-15) (n=27)	50.4 (9.9) (n=23)	52 (61-40.5) (n=23)	82.7 (15.2) (n=27)	85 (93-75) (n=27)
	24 weeks	25.0 (14.0) (n=30)	22.5 (36-14) (=30)	51.2 (12.2) (n=26)	61 (61-39.4) (n=26)	85.6 (14.7) (n=30)	90 (95-80) (n=30)
Mallet finger injuries	Pre-injury baseline	12.3 (6.1) (n=39)	11 (11-11) (n=39)	56.9 (7.4) (n=35)	61 (61-54.5) (n=35)	83.5 (14.6) (n=39)	90 (95-75) (n=39)
	Post-injury baseline	45.4 (15.0) (n=8)	46 (51-32.5) (n=8)	x	x	x	x
	6 weeks	32.2 (14.0) (n=32)	32.5 (39.5-24.5) (n=32)	46.8 (10.7) (n=28)	46.0 (58-38.1) (n=28)	82.8 (15.7) (n=30)	85 (90-80) (n=30)
	12 weeks	29.6 (15.3) (n=28)	27 (40-18) (n=28)	49.4 (11.4) (n=25)	51.2 (61-39) (n=25)	79.9 (17.6) (n=27)	82 (95-74) (n=27)
	24 weeks	22.6 (11.9) (n=28)	18.5 (28.5-14) (n=28)	49.9 (10.7) (n=26)	51.5 (61-40.5) (n=26)	83.3 (11.9) (n=28)	88 (90-77.5) (n=28)

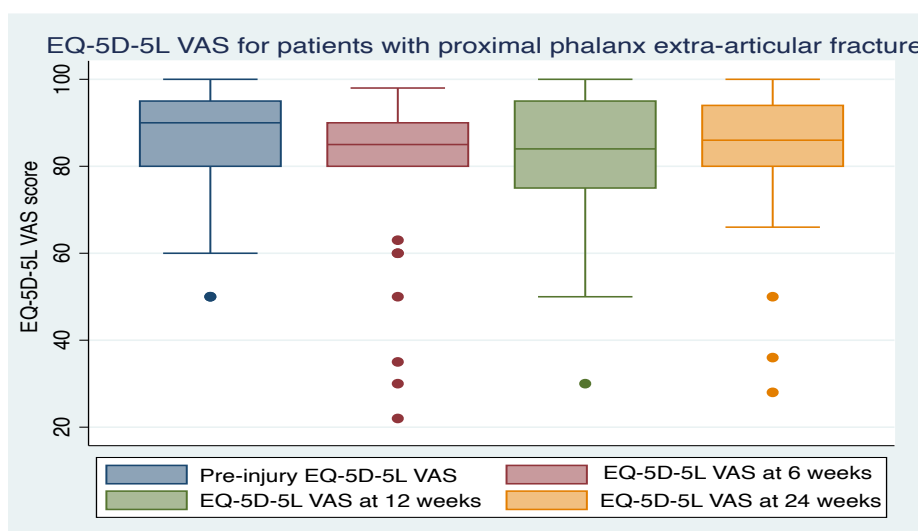
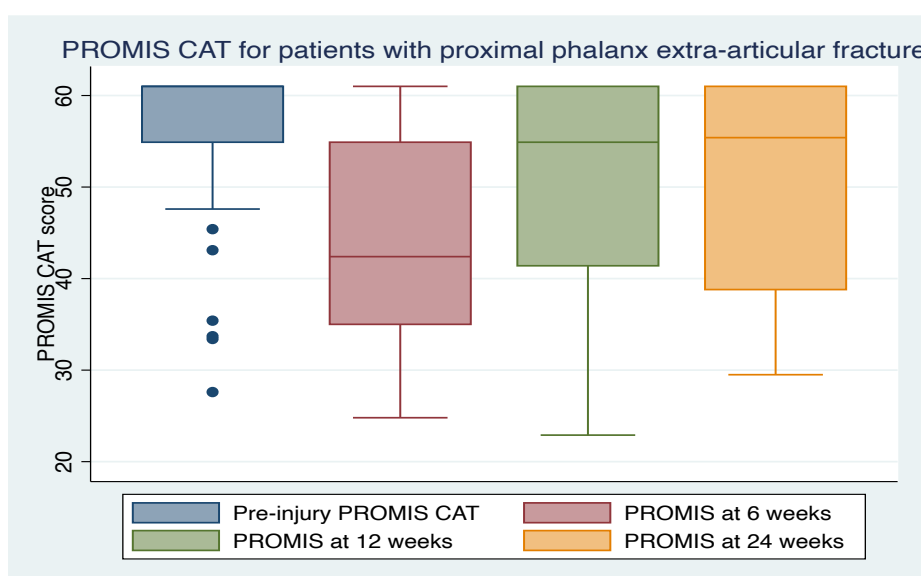
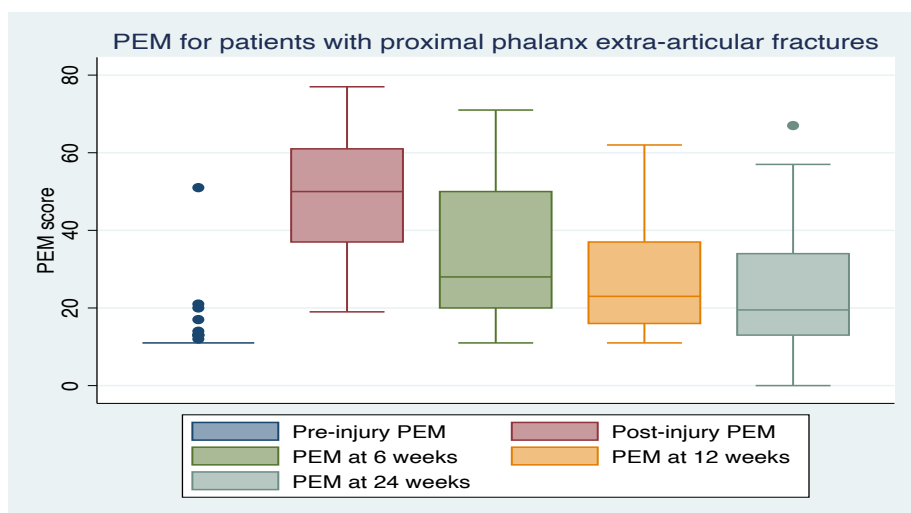


Figure 15: Box and whisker plots for PEM, PROMIS CAT and EQ-5D-5L Visual Analogue Scale (VAS) for participants with proximal phalanx extra-articular fracture. A lower score indicates improvement on the PEM and a higher score indicates improvement on EQ-5D-5L and PROMIS CAT.

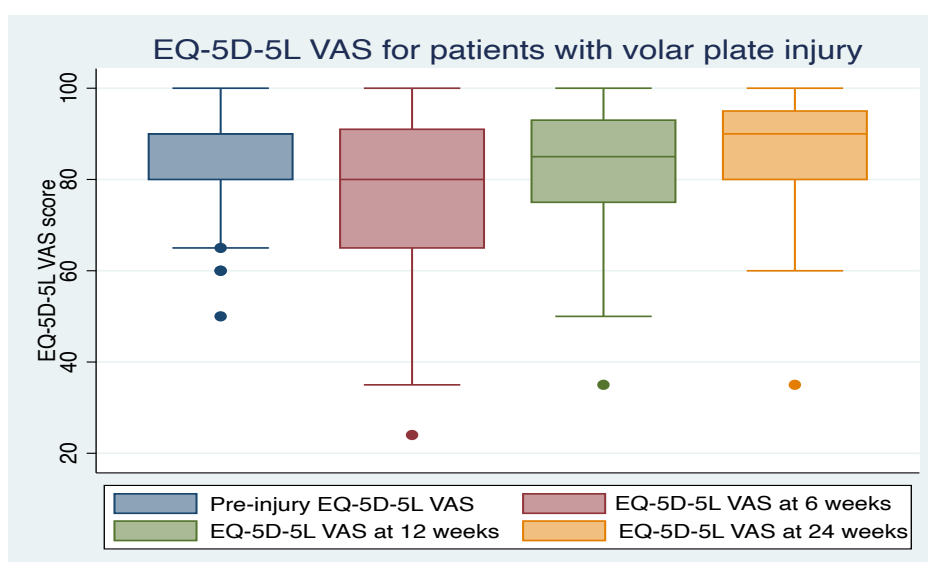
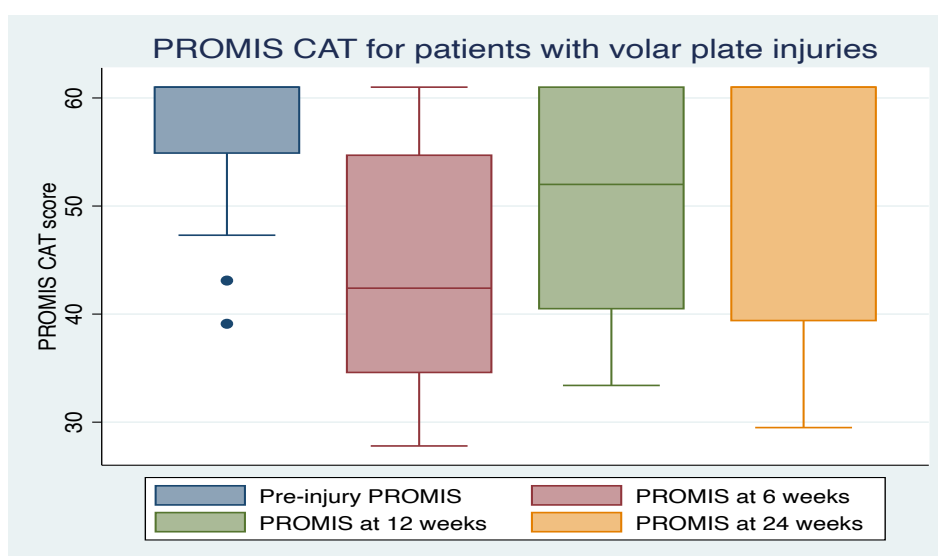
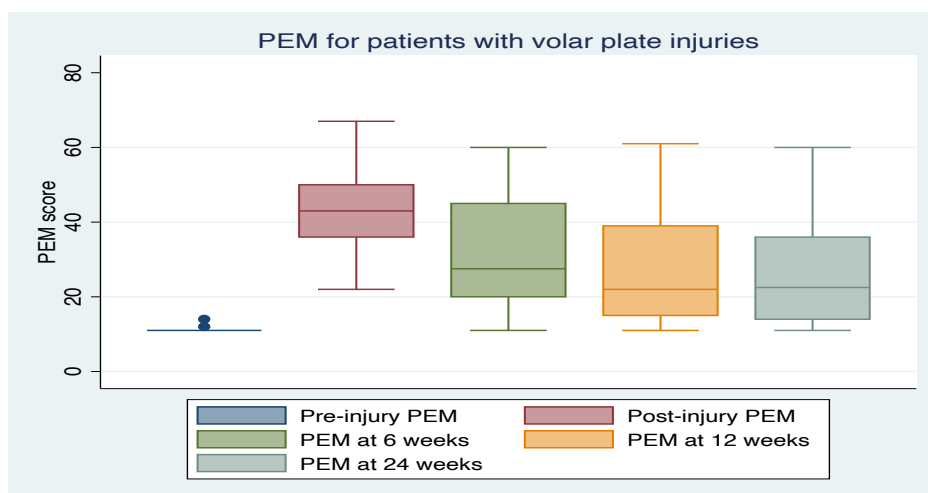


Figure 16: Box and whisker plots for PEM, PROMIS CAT and EQ-5D-5L Visual Analogue Scale (VAS) for participants with volar plate injuries. A lower score indicates improvement on the PEM and a higher score indicates improvement on EQ-5D-5L and PROMIS CAT.

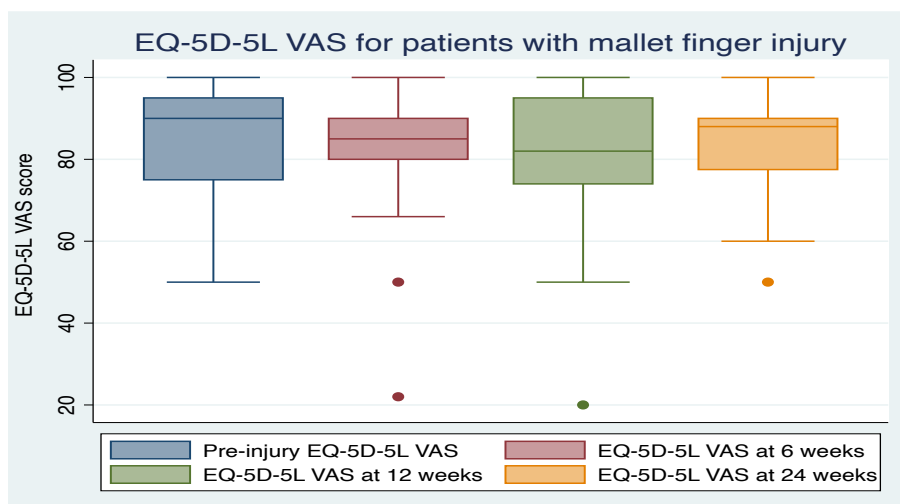
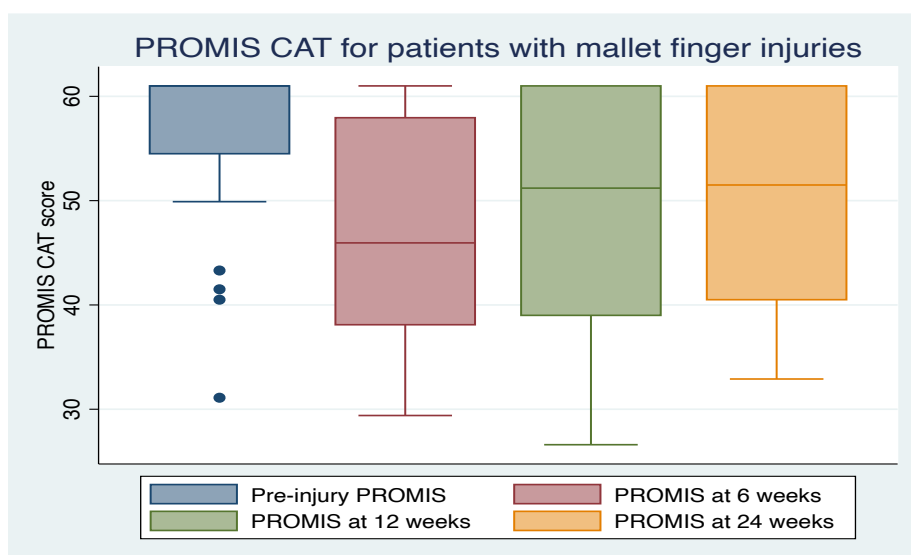
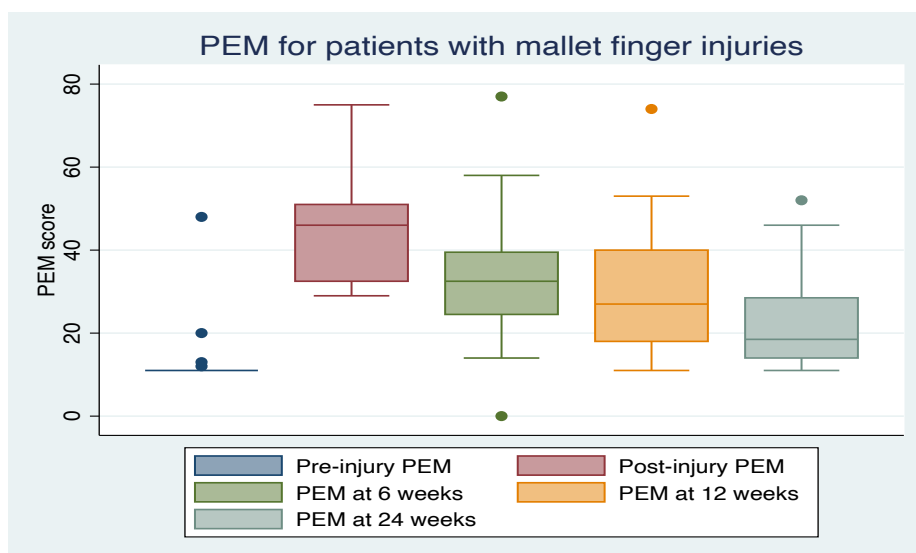


Figure 17: Box and whisker plots for PEM, PROMIS CAT and EQ-5D-5L Visual Analogue Scale (VAS) for participants with mallet finger injury. A lower score indicates improvement on the PEM and a higher score indicates improvement on EQ-5D-5L and PROMIS CAT.

Table 51: EQ-5D-5L results for the individual injuries

EQ-5D-5L								
		Mobility	Self-care	Activity	Pain	Anxiety	Index (UK)	EQ_VAS
Proximal phalanx extra-articular fracture	Pre-injury Baseline (n=48)	1.2	1.2	1.4	1.4	1.3	0.883	85.7
	6 weeks (n=30)	1.3	1.6	2.0	2.2	1.6	0.711	78.6
	12 weeks (n=27)	1.3	1.3	1.6	1.9	1.4	0.781	81.7
	24 weeks (n=31)	1.2	1.2	1.4	1.6	1.4	0.831	82.7
Volar plate injuries	Pre-injury Baseline (n=41)	1.0	1.0	1.0	1.1	1.4	0.943	83.9
	6 weeks (n=30)	1.1	1.4	1.7	2.1	1.5	0.763	74.9
	12 weeks (n=27)	1.1	1.1	1.5	1.9	1.6	0.809	82.7
	24 weeks (n=30)	1.2	1.2	1.5	1.8	1.5	0.821	85.6
Mallet finger injuries	Pre-injury Baseline (n=39)	1.3	1.2	1.1	1.3	1.3	0.904	83.5
	6 weeks (n=31)	1.3	1.4	1.9	1.8	1.4	0.787	82.8
	12 weeks (n=28)	1.4	1.4	1.7	1.9	1.5	0.776	79.9
	24 weeks (n=28)	1.3	1.3	1.4	1.7	1.4	0.822	83.3

Table 52: GROC results for the individual injuries

	Proximal phalanx extra-articular			Volar plate injuries			Mallet finger injuries		
	6 weeks	12 weeks	24 weeks	6 weeks	12 weeks	24 weeks	6 weeks	12 weeks	24 weeks
Total	30	27	32	30	27	30	32	28	28
Worsened (< or = -3)	2/30 (7%)	1/27 (4%)	2/32 (6%)	2/30 (7%)	0/27 (0%)	2/30 (7%)	1/32 (3%)	2/28 (7%)	0/28 (0%)
No change (-2 to 2)	6/30 (20%)	6/27 (22%)	3/32 (9%)	7/30 (23%)	6/27 (22%)	4/30 (13%)	8/32 (25%)	3/28 (11%)	7/28 (25%)
Improved (> or = 3)	22/30 (73%)	20/27 (74%)	27/32 (84%)	21/30 (70%)	21/27 (78%)	24/30 (80%)	23/32 (72%)	23/28 (82%)	21/28 (75%)



Participant Information Sheet for Interviews

(Final version 1.0: 21/03/19)

IRAS Project ID: 254090

Title of Study: Cohort Study for Patient Outcomes in the Management of Finger Fractures and Joint Injuries (OFFJI)

Name of Chief Investigator: Miss Alexia Karantana

Local Researcher(s): Dr Christos Mousoulis (PhD student), Professor Kim Thomas, Dr Paul Leighton.

We would like to invite you to take part in an interview as part of our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

We would like to know more about patients' experiences of having an injured finger and its treatment. We are also interested to know more about your attitudes about being approached to take part in research that is looking at different treatments for your injury. Talking to you and others about your feelings and experiences will give us important insight that will help to guide future practice and develop greater understanding of what it is like for patients who are asked to take part in studies such as this.

Why have I been invited?

You are being invited to take part because you have previously indicated that you are willing to talk to us about your injury and about taking part in this research. We aim to interview 15-20 participants.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will be asked to post the consent form back to us. Your consent will be verbally confirmed before the interview and this will be recorded. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?**Interviews**

If you take part, we will schedule a convenient time to conduct the interview, either over the phone, or at a time and location that is convenient for you. The researcher will talk to you about your personal experience of treatment for your finger fracture and attitudes towards taking part in clinical research.

Interviews will last approximately 30 to 60 minutes, and will be recorded using a digital recorder. Interviews will later be transcribed by a member of the research team with any identifying information removed.

Expenses and payments

A £20 thank you voucher will be given to recognize contribution to study and inconvenience. Travel expenses (bus fare, car parking) and will also be offered for any hospital visits in excess of usual care for interviews.

What are the possible benefits of taking part?

If you do take part, you will be contributing to our knowledge about people's experiences of having an injured finger, which may help future research and patients with such injuries in the future.

What are the possible disadvantages of taking part?

Taking part in this interview study will take up a small amount of your time, but other than this we do not anticipate any disadvantages of taking part.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting PALS at QMC hospital (C/O PALS, Freepost, NEA 14614, Nottingham, NG7 1BR, Email: PALS@nuh.nhs.uk, Freephone: 0800 183 0204)

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence during and after the study.

If you join the study, we will use information collected from you and from your medical records during the course of the research. This information will be kept strictly confidential, stored in a secure and locked office, and on a password-protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally-identifiable information possible. You can find out more about how we use your information and to read our privacy notice at: <https://www.nottingham.ac.uk/utilities/privacy.aspx>.

The data collected for the study will only be looked at by authorised persons from the University of Nottingham who are organising or conducting the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant. Any information about you which leaves the hospital will have your name and address removed and a unique code used, so that you cannot be recognised from it. All research data is kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data. We will retain your contact details for 3 years after the study end, so that we are able to tell you about the findings of the study or possible follow-up studies, unless you advise us that you do not wish to be contacted.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What you say in your interview will be kept strictly confidential, in that the recordings will not be shared with anyone other than the individuals in the research team. With your agreement, we may quote some of the things you have said in writing about the research, but these would be anonymous – your name will not appear in any reports.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?

You will be informed about the results of this study by email at the end of the study. Data will be anonymised and you will not be identified in any report/publication although anonymised quotes might be used. This study will be written up as part of CM's PhD thesis. The results of this study are likely to be published in peer reviewed journals.

Who has reviewed this study?

This research has been checked and approved by the University and the West Midlands - Coventry & Warwickshire National Research Ethics Committee. Service users (people who have had these injuries before) have been involved in designing this study.

Who is organising this research?

This study is being organised the University of Nottingham and the Centre for Evidence Based Hand Surgery in particular.

If you need any further information, please contact us.

Contact details**Chief investigator:**

Miss Alexia Karantana, Clinical Associate Professor in Hand Surgery

Study coordinator:

Dr Christos Mousoulis, PhD student in Academic Orthopaedics

Email: christos.mousoulis@nottingham.ac.uk

Telephone: 0115 82 31113

Address:

Academic Orthopaedics, Trauma and Sports Medicine

School of Medicine

Faculty of Medicine and Health Sciences

C Floor, West Block

Queen's Medical Centre

Nottingham, NG7 2UH

Thank you for reading this information sheet and for considering whether to take part.

Appendix 14: Consent form for Qualitative study



University of
Nottingham
UK | CHINA | MALAYSIA

PARTICIPANT CONSENT FORM FOR INTERVIEWS (Final version 1.0: date 21/03/19)

Title of Study: Cohort Study for Patient Outcomes in the Management of Finger Fractures and Joint Injuries (OFFJI)

IRAS Project ID: 254090

Name of Researcher: Miss Alexia Karantana, Clinical Associate Professor of Hand Surgery

Name of Participant:

Please initial box

1. I confirm that I have read and understand the information sheet version number 1.0 dated 21/03/19 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my data collected in this part of the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand that should I disclose anything which the researchers feel puts me or anyone else at any risk, they may feel it necessary to report this to the appropriate persons ☐
5. I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports. ☐
6. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
7. I agree to take part in the interview. ☐

Name of Participant Date Signature

Name of Person taking consent Date Signature

2 copies: 1 for participant and 1 for the project notes

Patient outcomes for finger fractures and joint injuries – Consent interviews Final Version 1.0 21/03/19

References

- ABUBEIH, H., SALEH, W., THABET, M. & IBRAHIM, A. 2016. Extensor tendon splitting versus extensor tendon sparing approach for miniplate fixation of extraarticular proximal phalangeal fractures. *Current orthopaedic practice*, 27, 623-632.
- ADOLFSSON, L., LINDAU, T. & ARNER, M. 2001. Acutrak screw fixation versus cast immobilisation for undisplaced scaphoid waist fractures. *J Hand Surg Br*, 26, 192-5.
- AGHA, R., COOPER, D. & MUIR, G. 2007. The reporting quality of randomised controlled trials in surgery: a systematic review. *International Journal of Surgery*, 5, 413-22.
- AITKEN, S. & COURT-BROWN, C. 2008. The epidemiology of sports-related fractures of the hand. *Injury, Int J. Care Injured*, 39, 1377-83.
- ALMUGREN, T. S., AL-NAMLAH, A., ALKUBAIDAN, F., ALOTAIBI, H. & ALZIMAMI, I. 2016. Epidemiology and patterns of the hand and distal forearm fractures at King Abdul-Aziz Medical City, Riyadh, KSA. *Journal of Taibah University Medical Sciences*, 11, 86-90.
- ALONSO, J., BARTLETT, S., ROSE, M., AARONSON, N., CHAPLIN, J., EFFICACE, F., LEPLEGE, A., LU, A., TULSKY, D., RAAT, H., RAVENS-SIEBERER, U., REVICKI, D., TERWEE, C., VALDERAS, J., CELLA, D. & FORREST, C. 2013. The case for an international patient-reported outcomes measurement information system (PROMIS®) initiative. *Health and Quality of Life Outcomes*, 11, 210.
- ALTIZER, L. 2003. Hand and wrist fractures. *Orthop Nurs*, 22, 232-9.
- AMMANN, B., SATINK, T. & ANDRESEN, M. 2012. Experiencing occupations with chronic hand disability: narrative of hand-injured adults. *Hand Therapy*, 17, 87-94.
- ANAKWE, R., AITKEN, S., COWIE, J., MIDDLETON, S. & COURT-BROWN, C. 2011. The epidemiology of fractures of the hand and the influence of social deprivation. *The Journal of Hand Surgery (European Volume)*, 36E, 62-5.
- ANAND, N., TANNOURY, T., MEY, S. & WEINSTEIN, R. 1999. Boxer's fracture: a prospective randomized study comparing immediate mobilization to immobilization. *American academy of orthopaedic surgeons annual meeting; 1999 feb 4-8; anaheim (CA)*.
- ARORA, R., LUTZ, M., FRITZ, D., ZIMMERMANN, R., GABL, M. & PECHLANER, S. 2004. Dorsolateral dislocation of the proximal interphalangeal joint: closed reduction and early active motion or static splinting; a retrospective study. *Arch Orthop Trauma Surg*, 124, 486-488.
- AUCHINCLOSS, J. M. 1982. Mallet-finger injuries: a prospective, controlled trial of internal and external splintage. *Hand*, 14, 168-73.
- BAIER, R., JUTKOWITZ, E., MITCHELL, S., MCCREEDY, E. & MOR, V. 2019. Readiness assessment for pragmatic trials (RAPT): a model to assess the readiness of an intervention for testing in a pragmatic trial. *BMC Med Res Methodol*, 19, 156.
- BALASUBRAMANIAN, S., WIENER, M., ALSHAMEERI, Z., TIRUVOIPATI, R., ELBOURNE, D. & REED, M. 2006. Standards of reporting of randomized controlled trials in general surgery. Can we do better? *Ann Surg*, 244, 663-7.
- BALCH, C., NELSON, H. & NIEDERHUBER, J. 2016. Limitations of prospective surgical oncology trials - a US view. *Clinical Oncology*, 13, 6-8.
- BAMFORD, R. & WALKER, D. 2010 A qualitative investigation into the rehabilitation experience of patients following wrist fracture. *Hand Therapy*, 15, 54-61.
- BARKUN, J., ARONSON, J., FELDMAN, L., MADDERN, G. & STRASBERG, S. 2009. Surgical innovation and evaluation. Evaluation and stages of surgical innovations. *Lancet*, 374, 1089-96.
- BARROSO, T., CAVALCANTE, M., DOS SANTOS, J., BELLOTI, J., FALOPPA, F. & DE MORAES, V. 2017. Evidence hierarchies relating to hand surgery: current status and

- improvement. A bibliometric analysis study. *Sao Paulo Medical Journal*, 135, 556-60.
- BATIBAY, S. G., AKGUL, T., BAYRAM, S., AYIK, O. & DURMAZ, H. 2017. Conservative management equally effective to new suture anchor technique for acute mallet finger deformity: A prospective randomized clinical trial. *J Hand Ther*, 31, 429-36.
- BEATON, D. 2003. Simple as possible? Or too simple? Possible limits to the universality of the one half standard deviation. *Medical Care*, 41, 593-596.
- BEATON, D., BOERS, M. & WELLS, G. 2002. Many faces of the minimal clinically important difference (MCID): a literature review and directions for future research. *Curr Opin Rheumatol*, 14, 109-114.
- BECKMANN, J., HUNG, M., VOSS, M., CRUM, A., BOUNSANGA, J. & TYSER, A. 2016. Evaluation of the Patient-Reported Outcomes Measurement Information System Upper Extremity Computer Adaptive Test. *The Journal of hand surgery*, 41, 739-44, e4.
- BERNSTEIN, M. & CHUNG, K. 2006. Hand fractures and their management: an international view. *Injury, Int. J. Care Injured*, 37, 1043-1048.
- BIALOCERKOWSKI, A. 2002. Difficulties associated with wrist disorders - a qualitative study. *Clinical Rehabilitation*, 16, 429-40.
- BILIC, R., SIMIC, P., JELIC, M., STERN-PADOVAN, R., DODIG, D., VAN MEERDERVOORT, H. P., MARTINOVIC, S., IVANKOVIC, D., PECINA, M. & VUKICEVIC, S. 2006. Osteogenic protein-1 (BMP-7) accelerates healing of scaphoid non-union with proximal pole sclerosis. *Int Orthop*, 30, 128-34.
- BOISGONTIER, M., VUILLERME, N., THOMAS, D., PINSAULT, N., EMPRIN, M. & CAILLAT-MIOUSSE, J. L. 2009. Effects of neuromuscular electrical stimulation on the range of motion recovery in hand proximal interphalangeal sprain. *Science and Sports*, 24, 192-195.
- BOND, C. D., SHIN, A. Y., MCBRIDE, M. T. & DAO, K. D. 2001. Percutaneous screw fixation or cast immobilization for nondisplaced scaphoid fractures. *J Bone Joint Surg Am*, 83-a, 483-8.
- BOOKER, C., HARDING, S. & BENZEVAL, M. 2011. A systematic review of the effect of retention methods in population-based cohort studies. *BMC Public Health*, 11, 249.
- BOWER, P., BRUETON, V., GAMBLE, C., TREWEEK, S., SMITH, C. T., YOUNG, B. & WILLIAMSON, P. 2014. Interventions to improve recruitment and retention in clinical trials: a survey and workshop to assess current practice and future priorities. *Trials*, 15, 399.
- BRAAKMAN, M., ODERWALD, E. E. & HAENTJENS, M. H. 1998. Functional taping of fractures of the 5th metacarpal results in a quicker recovery. *Injury*, 29, 5-9.
- BRAGA-SILVA, J., PERUCHI, F. M., MOSCHEN, G. M., GEHLEN, D. & PADOIN, A. V. 2008. A comparison of the use of distal radius vascularised bone graft and non-vascularised iliac crest bone graft in the treatment of non-union of scaphoid fractures. *J Hand Surg Eur Vol*, 33, 636-40.
- BRITTEN, N. 1995. Qualitative research: Qualitative interviews in medical research. *BMJ*, 311, 251.
- BSSH. 2018. *Blue Book on the Management of Distal Radial Fractures* [Online]. Available: https://www.bssh.ac.uk/about/news/122/blue_book_on_the_management_of_distal_radial_fractures [Accessed 19th April 2021].
- BSSH. 2020a. *Finger dislocations*. [Online]. Available: https://www.bssh.ac.uk/patients/conditions/34/finger_dislocations [Accessed 19th April 2021].
- BSSH. 2020b. *Finger sprains* [Online]. Available: https://www.bssh.ac.uk/patients/conditions/33/finger_sprains [Accessed 19th April 2021].

- BSSH. 2020c. *General information on hand fractures* [Online]. Available: https://www.bssh.ac.uk/patients/conditions/31/general_information_on_hand_fractures [Accessed 19th April 2021].
- BSSH. 2020d. *MALIT - Mallet Injuries Trial* [Online]. Available: https://www.bssh.ac.uk/malit-mallet_injuries_trial.aspx [Accessed 19th April 2021].
- BSSH. 2020e. *Mallet finger injury* [Online]. Available: https://www.bssh.ac.uk/patients/conditions/28/mallet_finger_injury [Accessed 19th April 2021].
- BSSH. 2020f. *Skier's thumb* [Online]. Available: https://www.bssh.ac.uk/patients/conditions/32/skiers_thumb [Accessed 19th April 2021].
- BSSH THE BRITISH SOCIETY FOR SURGERY OF THE HAND. 2021. *UK Hand Registry* [Online]. Available: https://www.bssh.ac.uk/professionals/uk_hand_registry.aspx [Accessed 9th April 2021].
- BUIJZE, G. A., GOSLINGS, J. C., RHEMREV, S. J., WEENING, A. A., VAN DIJKMAN, B., DOORNBORG, J. N. & RING, D. 2014. Cast immobilization with and without immobilization of the thumb for nondisplaced and minimally displaced scaphoid waist fractures: a multicenter, randomized, controlled trial. *J Hand Surg Am*, 39, 621-7.
- CALDWELL, P., HAMILTON, S., TAN, A. & CRAIG, J. 2010. Strategies for increasing recruitment to randomised controlled trials: systematic review. *PLoS Med*, 7, e1000368.
- CAPORRINO, F. A., DOS SANTOS, J. B., PENTEADO, F. T., DE MORAES, V. Y., BELLOTI, J. C. & FALOPPA, F. 2014. Dorsal vascularized grafting for scaphoid nonunion: a comparison of two surgical techniques. *J Orthop Trauma*, 28, e44-8.
- CARPENTER, S. & ROHDE, R. 2013. Treatment of phalangeal fractures. *Hand Clin*, 29, 519-534.
- CATTO, J., BLAZEBY, J., HOLMBERG, L., HAMDY, F. & BROWN, J. 2017. In defense of randomized clinical trials in surgery: let us not forget Archie Cochrane's legacy. *European Urology*, 71, 811-9.
- CEPNI, S. K., AYKUT, S., BEKMEZCI, T. & KILIC, A. 2016. A minimally invasive fixation technique for selected patients with fifth metacarpal neck fracture. *Injury*, 47, 1270-5.
- CHAN, J. & SPENCER, J. 2004. Adaptation to hand injury: an evolving experience. *American Journal of Occupational Therapy*, 58, 128-39.
- CHANG, W., WU, J., WANG, H. & JIANG, J. 2014. Therapeutic outcomes of low-level laser therapy for closed bone fracture in the human wrist and hand. *Photomedicine and laser surgery*, 32, 212-218.
- CHUNG, K. C. & SPILSON, S. V. 2001. The frequency and epidemiology of hand and forearm fractures in the United States. *J Hand Surg Am*, 26, 908-15.
- CLAY, N. R., DIAS, J. J., COSTIGAN, P. S., GREGG, P. J. & BARTON, N. J. 1991. Need the thumb be immobilised in scaphoid fractures? A randomised prospective trial. *J Bone Joint Surg Br*, 73, 828-32.
- CLEMENTSON, M., JORGSHOLM, P., BESJAKOV, J., BJORKMAN, A. & THOMSEN, N. 2015a. Union of Scaphoid Waist Fractures Assessed by CT Scan. *J Wrist Surg*, 4, 49-55.
- CLEMENTSON, M., JORGSHOLM, P., BESJAKOV, J., THOMSEN, N. & BJORKMAN, A. 2015b. Conservative Treatment Versus Arthroscopic-Assisted Screw Fixation of Scaphoid Waist Fractures--A Randomized Trial With Minimum 4-Year Follow-Up. *J Hand Surg Am*, 40, 1341-8.

- COCHRANE METHODS. 2018. *RoB2: A revised Cochrane risk-of-bias tool for randomized trials* [Online]. Available: <https://methods.cochrane.org/bias/resources/rob-2-revised-cochrane-risk-bias-tool-randomized-trials> [Accessed 19th April 2021].
- COLQUHOUN, H., LEVAC, D., O'BRIEN, K., STRAUS, S., TRICCO, A., PERRIER, L., KASTNER, M. & MOHER, D. 2014. Scoping reviews: time for clarity in definition methods and reporting. *Journal of Clinical Epidemiology*, 67, 1291-4.
- COMET. 2018. *Core Outcome Set (COS)* [Online]. Available: <https://www.comet-initiative.org> [Accessed 19th April 2021].
- COOK, C. 2008. Clinimetrics corner: the minimal clinically important change score (MCID): a necessary pretense. *The Journal of Manual & Manipulative Therapy*, 16, E82-E83.
- COPAY, A., SUBACH, B., GLASSMAN, S., POLLY, D. & SCHULER, T. 2007. Understanding the minimum clinically important difference: a review of concepts and methods. *The Spine Journal*, 7, 541-546.
- CORTY, E. & CORTY, R. 2011. Setting sample size to ensure narrow confidence intervals for precise estimation of population values. *Nurs Res*, 60, 148-53.
- COUGHLIN, T. 2018. *Physiotherapy interventions & assessment of outcomes in distal radius fractures*. PhD The University of Nottingham.
- CRISTANCHO, S., GOLDSZMIDT, M., LINGARD, L. & WATLING, C. 2018. Qualitative research essentials for medical education. *Singapore Med J*, 59, 622-7.
- CURTIS, E., VAN DER VELDE, R., MOON, R., VAN DEN BERGH, J., GEUSENS, P., DE VRIES, F., VAN STAA, T., COOPER, C. & HARVEY, N. 2016. Epidemiology of fractures in the United Kingdom 1988-2012: variation with age, sex, geography, ethnicity and socioeconomic status. *Bone*, 87, 19-26.
- DACOMBE, P., AMIRFEYZ, R. & DAVIS, T. 2016. Patient-reported outcomes measures for hand and wrist trauma. Is there sufficient evidence of reliability, validity and responsiveness? *Hand (NY)*, 11, 11-21.
- DAL-RE, R., JANIAUD, P. & IOANNIDIS, J. 2018. Real-world evidence: how pragmatic are randomized controlled trials labeled as pragmatic? *BMC Medicine*, 16, 49.
- DAYKIN, A., CLEMENT, C., GAMBLE, C., KEARNEY, A., BLAZEY, J., CLARKE, M., LANE, J. & SHAW, A. 2018. 'Recruitment, recruitment, recruitment'-the need for more focus on retention: a qualitative study of five trials. *Trials*, 19, 76.
- DE ANGELIS, C., DRAZEN, J., FRIZELLE, F., HAUG, C., HOEY, J., HORTON, R., KOTZIN, S., LAINE, C., MARUSIC, A., OVERBEKE, J., SCHROEDER, T. & SOX, H. 2004. Clinical trial registration: a statement from the International Committee of medical journal editors. *N Engl J Med*, 351, 1250-1.
- DE PUTTER, C., SELLES, R., POLINDER, S., PANNEMAN, M., HOVIUS, S. & VAN BEECK, E. 2012. Economic impact of hand and wrist injuries: Health-care costs and productivity costs in a population-based study. *J Bone Jt Surg Am*, 94, e56 (1-7)
- DE VET, H., OSTELO, R., TERWEE, C., VAN DER ROER, N., KNOL, D., BECKERMAN, H., BOERS, M. & BOUTER, L. 2007. Minimally important change determined by a visual method integrating an anchor-based and a distribution-based approach. *Quality of Life Research*, 16, 131-142.
- DE VET, H., TERWEE, C., MOKKINK, L. & KNOL, D. 2011. *Measurement in Medicine: A Practical Guide (Practical Guides to Biostatistics and Epidemiology)*, Cambridge, Cambridge University Press.
- DEMANGE, M. & FREGNI, F. 2011. Limits to clinical trials in surgical areas. *Clinics (Sao Paulo)*, 66, 159-61.
- DESHMUKH, S., MOUSOULIS, C., MARSON, B., GRINDLAY, D. & KARANTANA, A. 2021. Developing a core outcome set for hand fractures and joint injuries in adults: a systematic review. *J Hand Surg Eur Vol*, 46, 488-95.
- DIAS, J., BREALEY, S., CHOUDHARY, S., COOK, L., COSTA, M., FAIRHURST, C., HEWITT, C., HODGSON, S., JEFFERSON, L., JEYAPALAN, K., KEDING, A., LEIGHTON, P., RANGAN,

- A., RICHARDSON, G., ROTHERY, C., TAUB, N., THOMPSON, J. & TORGESON, D. 2016. Scaphoid waist internal fixation for fractures trial (SWIFFT) protocol: a pragmatic multi-centre randomised controlled trial of cast treatment versus surgical fixation for the treatment of bi-cortical, minimally displaced fractures of the scaphoid waist in adults. *BMC Musculoskeletal Disorders*, 17, 248.
- DIAS, J., BREALEY, S., COOK, L., FAIRHURST, C., HINDE, S., LEIGHTON, P., CHOUDHARY, S., COSTA, M., HEWITT, C., HODGSON, S., JEFFERSON, L., JEYAPALAN, K., KEDING, A., NORTHGRAVES, M., PALMER, J., RANGAN, A., RICHARDSON, G., TAUB, N., TEW, G., THOMPSON, J. & TORGESON, D. 2020a. Surgical fixation compared with cast immobilisation for adults with a bicortical fracture of the scaphoid waist: the SWIFFT RCT. *Health Technol Assess*, 24.
- DIAS, J., BREALEY, S., FAIRHURST, C., AMIRFEYZ, R., BHOWAL, B., BLEWITT, N., BREWSTER, M., BROWN, D., CHOUDHARY, S., COAPES, C., COOK, L., COSTA, M., DAVIS, T., DI MASIO, L., GIDDINS, G., HEDLEY, H., HEWITT, C., HINDE, S., HOBBY, J., HODGSON, S., JEFFERSON, L., KANAGARATNAM, K., JOHNSTON, P., JONES, J., KEDING, A., LEIGHTON, P., LOGAN, A., MASON, W., MCANDREW, A., MCNAB, I., MUIR, L., NICHOLL, J., NORTHGRAVES, M., PALMER, J., POULTER, R., RAHIMTOOLA, Z., RANGAN, A., RICHARDS, S., RICHARDSON, G., STUART, P., TAUB, N., TAVAKKOLIZADEH, A., TEW, G., THOMPSON, J., TORGESON, D. & WARWICK, D. 2020b. Surgery versus cast immobilisation for adults with a bicortical fracture of the scaphoid waist (SWIFFT): a pragmatic, multicentre, open-label, randomised superiority trial. *The Lancet*, 396, 390-401.
- DIAS, J. J., DHUKARAM, V., ABHINAV, A., BHOWAL, B. & WILDIN, C. J. 2008a. Clinical and radiological outcome of cast immobilisation versus surgical treatment of acute scaphoid fractures at a mean follow-up of 93 months. *J Bone Joint Surg Br*, 90, 899-905.
- DIAS, J. J., RAJAN, R. A. & THOMPSON, J. R. 2008b. Which questionnaire is best? The reliability, validity and ease of use of the Patient Evaluation Measure, the Disabilities of the Arm, Shoulder and Hand and the Michigan Hand Outcome Measure. *J Hand Surg Eur Vol*, 33, 9-17.
- DIAS, J. J., SAYEED, L. & BHOWAL, B. 2015. MCID for the Patient Evaluation Measure as a Patient Rated Outcome Measure for Dupuytren Contracture. *International Conference on Dupuytren Disease and Related Diseases*. Groningen, NL.
- DIAS, J. J., WILDIN, C. J., BHOWAL, B. & THOMPSON, J. R. 2005. Should acute scaphoid fractures be fixed? A randomized controlled trial. *J Bone Joint Surg Am*, 87, 2160-8.
- DICICCO-BLOOM, B. & CRABTREE, B. 2006. The qualitative research interview. *Medical Education*, 40, 314-21.
- DIXON-WOODS, M. 2011. Using framework-based synthesis for conducting reviews of qualitative studies. *BMC Medicine*, 9, 39.
- DJULBEGOVIC, B. & GUYATT, G. 2017. Progress in evidence-based medicine: a quarter century on. *Lancet*, 390, 415-23.
- DONOVAN, J., ROOSHENAS, L., JEPSON, M., ELLIOT, D., WADE, E., AVERY, K., MILLS, N., WILSON, C., PARAMASIVAN, S. & BLAZEBY, J. 2016. Optimising recruitment and informed consent in randomised controlled trials: the development and implementation of the Quintet Recruitment Intervention (QRI). *Trials*, 17, 283.
- DORING, A., NOTA, S., HAGEMAN, M. & RING, D. 2014. Measurement of upper extremity disability using the Patient-Reported Outcomes Measurement Information System. *J Hand Surg Am*, 39, 1160-5.
- DRAC, P., CIZMAR, I., MANAK, P., HRBEK, J., RESKA, M., FILKUKA, P. & ZAPLETALOVA, J. 2014. Comparison of the results and complications of palmar and dorsal miniinvasive approaches in the surgery of scaphoid fractures. A prospective

- randomized study. *Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub*, 158, 277-81.
- EARP, B. & WATERS, P. 2007. Hand and wrist injuries In: FRONTERA, W. (ed.) *Clinical sports medicine: medical management and rehabilitation*. Philadelphia Saunders Elsevier.
- EDDY, M. 2012. Hands, fingers, thumbs. Assessment and management of common hand injuries in general practice. *Australian Family Physician*, 41, 202-9.
- EQ-5D. 2018. EQ-5D-5L - FAQ [Online]. Available: <https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/faqs/> [Accessed 19th April 2021].
- ERGINA, P., BARKUN, J., MCCULLOCH, P., COOK, J. & ALTMAN, D. 2013. IDEAL framework for surgical innovation 2: observational studies in the exploration and assessment stages. *BMJ*, 346, f3011.
- FITZPATRICK, N. & FINLAY, L. 2008. "Frustrating disability": the lived experience of coping with the rehabilitation phase following finger tendon surgery. *International Journal of Qualitative Studies in Health and Well-being*, 3, 143-54.
- FLETCHER, B., GHEORGHE, A., MOORE, D., WILSON, S. & DAMERY, S. 2012. Improving the recruitment activity of clinicians in randomised controlled trials: a systematic review. *BMJ Open*, e000496.
- FRANCHIGNONI, F., VERCELLI, S., GIORDANO, A., SARTORIO, F., BRAVINI, E. & FERRIERO, G. 2014. Minimal clinically important difference of the disabilities for the arm, shoulder and hand outcome measure (DASH) and its shortened version (QuickDASH). *J Orthop Sports Phys Ther*, 44, 30-9.
- FRANZ, T., VON WARTBURG, U., SCHIBLI-BEER, S., JUNG, F. J., JANDALI, A. R., CALCAGNI, M. & HUG, U. 2012. Extra-articular fractures of the proximal phalanges of the fingers: a comparison of 2 methods of functional, conservative treatment. *J Hand Surg Am*, 37, 889-98.
- FREIBERG, A. 2007. Management of proximal interphalangeal joint injuries. *Can J Plast Surg*, 15, 199-203.
- GABBE, B., WILLIAMSON, O., CAMERON, P. & DOWRICK, A. 2008. Choosing outcome assessment instruments for trauma registries. *American Emergency Medicine*, 12, 751-8.
- GABLER, C., KUKLA, C., BREITENSEHER, M., TRATTNIG, S. & VECSEI, V. 2001. Diagnosis of occult scaphoid fractures and other wrist injuries. Are repeated clinical examinations and plain radiographs still state of the art? *Langenbecks Arch Surg*, 386, 150-4.
- GAEBLER, C., MCQUEEN, M. & VECSEI, V. 2002. Percutaneous screw fixation versus conservative treatment in undisplaced scaphoid fractures. *European journal of trauma*, 28, 98.
- GALAL, S. & SAFWAT, W. 2017. Transverse pinning versus intramedullary pinning in fifth metacarpal's neck fractures: A randomized controlled study with patient-reported outcome. *J Clin Orthop Trauma*, 8, 339-343.
- GALE, N., HEATH, G., CAMERON, E., RASHID, S. & REDWOOD, S. 2013. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*, 13, 117.
- GARRAMONE, J. 1996. A functional analysis of short arm cast vs volar splint immobilization in the treatment of small finger metacarpal neck fractures. *Orthopaedic transactions*, 20, 910.
- GELLMAN, H., CAPUTO, R. J., CARTER, V., ABOULAFIA, A. & MCKAY, M. 1989. Comparison of short and long thumb-spica casts for non-displaced fractures of the carpal scaphoid. *J Bone Joint Surg Am*, 71, 354-7.
- GIDDINS, G. 2015. The non-operative management of hand fractures. *The Journal of Hand Surgery*, 40E, 33-41.

- GOLAN, E., KANG, K., CULBERTSON, M. & CHOUEKA, J. 2016. The epidemiology of finger dislocations presenting for emergency care within the United States. *Hand*, 11, 192-96.
- GOYAL, T., SANKINEANI, S. R. & TRIPATHY, S. K. 2013. Local distal radius bone graft versus iliac crest bone graft for scaphoid nonunion: a comparative study. *Musculoskeletal Surg*, 97, 109-14.
- GRANT, M. & BOOTH, A. 2009. A typology of reviews: an analysis of 14 review types and associated methodologies. *Health Information and Libraries Journal*, 26, 91-108.
- GREENHALGH, T., HOWICK, J. & MASKREY, N. 2014. Evidence based medicine: a movement in crisis? *BMJ*, 348, g3725.
- GRUBER, J. S., BOT, A. G. & RING, D. 2014. A prospective randomized controlled trial comparing night splinting with no splinting after treatment of mallet finger. *Hand (N Y)*, 9, 145-50.
- GULKE, J., LEOPOLD, B., GROZINGER, D., DREWS, B., PASCHKE, S. & WACHTER, N. J. 2017. Postoperative treatment of metacarpal fractures-Classical physical therapy compared with a home exercise program. *J Hand Ther*, 31, 20-28.
- HAM-BALOYI, W. T. & JORDAN, P. 2016. Systematic review as a research method in post-graduate nursing education. *Health SA Gesondheid*, 21, 120-8.
- HAMBIDGE, J., DAVIS, T., SCHRANZ, P., COMPSON, J. & BARTON, N. 1995. Which position for the wrist when immobilising scaphoid fractures. *Journal of bone and joint surgery - british volume*, 77, 12.
- HAMMOUDEH, S., GADELHAQ, W. & JANAHI, I. 2018. Prospective cohort studies in medical research. In: BARRIA, R. (ed.) *Cohort studies in Health Sciences*. London, UK IntechOpen.
- HANDOLL, H. & VAGHELA, M. 2004. Interventions for treating mallet finger injuries. *Cochrane Database Syst Rev*.
- HANNEMANN, P. F., GOTTGENS, K. W., VAN WELY, B. J., KOLKMAN, K. A., WERRE, A. J., POEZE, M. & BRINK, P. R. 2012. The clinical and radiological outcome of pulsed electromagnetic field treatment for acute scaphoid fractures: a randomised double-blind placebo-controlled multicentre trial. *J Bone Joint Surg Br*, 94, 1403-8.
- HANNEMANN, P. F., VAN WEZENBEEK, M. R., KOLKMAN, K. A., TWISS, E. L., BERGHMANS, C. H., DIRVEN, P. A., BRINK, P. R. & POEZE, M. 2014. CT scan-evaluated outcome of pulsed electromagnetic fields in the treatment of acute scaphoid fractures: a randomised, multicentre, double-blind, placebo-controlled trial. *Bone Joint J*, 96-b, 1070-6.
- HANSEN, P. B. & HANSEN, T. B. 1998. The treatment of fractures of the ring and little metacarpal necks. A prospective randomized study of three different types of treatment. *J Hand Surg Br*, 23, 245-7.
- HARDING, I. J., PARRY, D. & BARRINGTON, R. L. 2001. The use of a moulded metacarpal brace versus neighbour strapping for fractures of the little finger metacarpal neck. *J Hand Surg Br*, 26, 261-3.
- HAUGHTON, D., JORDAN, D., MALAHAS, M., HINDOCHA, S. & KHAN, W. 2012. Principles of hand fracture management. *Open Orthop J*, 6, 43-53.
- HEALTH KNOWLEDGE. 2017. *Introduction to study designs - cohort studies* [Online]. Available: <https://www.healthknowledge.org.uk/e-learning/epidemiology/practitioners/introduction-study-design-cs> [Accessed 19th April 2021].
- HEALY, P., GALVIN, S., WILLIAMSON, P. R., TREWEEK, S., WHITING, C., MAESO, B., BRAY, C., BROCKLEHURST, P., MOLONEY, M. C., DOUIRI, A., GAMBLE, C., GARDNER, H. R., MITCHELL, D., STEWART, D., JORDAN, J., O'DONNELL, M., CLARKE, M., PAVITT, S. H., GUEGAN, E. W., BLATCH-JONES, A., SMITH, V., REAY, H. & DEVANE, D. 2018. Identifying trial recruitment uncertainties using a James Lind Alliance Priority

- Setting Partnership – the PRioRiTy (Prioritising Recruitment in Randomised Trials) study. *Trials*, 19, 147.
- HENDERSON, M., WIGHT, D., NIXON, C. & HART, G. 2010. Retaining young people in a longitudinal sexual health survey: a trial of strategies to maintain participation. *BMC Med Res Methodol*, 10, 9.
- HENEGHAN, C., GOLDACRE, B. & MAHTANI, K. R. 2017. Why clinical trial outcomes fail to translate into benefits for patients. *Trials*, 18, 122.
- HENRY, M. 2007. Immediate mobilisation following corrective osteotomy of distal radius malunions with cancellous graft and volar fixed angle plates. *J Hand Surg Eur Vol*, 32, 88-92.
- HENTZ, R., MEALS, R., STERN, P. & MANSKE, R. 2005. Levels of evidence and the Journal of Hand Surgery. *The Journal of Hand Surgery (European Volume)*, 30A, 891-2.
- HERENSTEIN, M., HOLMES, R., MCCULLOUGH, M. & KEITNER, D. 2009. The communication of emotion via touch. *Emotion*, 9, 566-73.
- HIGGINS, J., ALTMAN, D. & STERNE, J. 2017. Chapter 8: Assessing risk of bias in included studies. In: HIGGINS, J., CHURCHILL, R., CHANDLER, J. & CUMPSTON, M. (eds.) *Cochrane Handbook for Systematic Reviews of Interventions version 5.2.0*. Cochrane.
- HOBBY, J., WATTS, C. & ELLIOT, D. 2005. Validity and Responsiveness of the Patient Evaluation Measure as an Outcome Measure for Carpal Tunnel Syndrome. *The Journal of Hand Surgery: British & European Volume*, 30, 350-4.
- HOFMEISTER, E. P., KIM, J. & SHIN, A. Y. 2008. Comparison of 2 methods of immobilization of fifth metacarpal neck fractures: a prospective randomized study. *J Hand Surg Am*, 33, 1362-8.
- HORTON, T. C., HATTON, M. & DAVIS, T. R. 2003. A prospective randomized controlled study of fixation of long oblique and spiral shaft fractures of the proximal phalanx: closed reduction and percutaneous Kirschner wiring versus open reduction and lag screw fixation. *J Hand Surg Br*, 28, 5-9.
- HOWELLS, L., RATIB, S., CHALMERS, J., BRADSHAW, L. & THOMAS, K. 2018. How should minimally important change scores for the Patient-Oriented eczema measure be interpreted? A validation using varied methods. *British Journal of Dermatology*, 178, 1135-1142.
- HUAMANI, C. & GONZALEZ-ALCAIDE, G. 2013. Surgical clinical trials — need for international collaboration. *Lancet*, 382, 1875-6.
- HUETTEMAN, H., SHAUVER, M., NASSER, J. & CHUNG, K. 2018. The desired role of health care providers in guiding older patients with distal radius fractures: a qualitative analysis. *J Hand Surg Am*, 43, 312-20.
- INGRAM, J., GRINDLAY, D. & WILLIAMS, H. 2010. Problems in the reporting of acne clinical trials: a spot check from the 2009 Annual Evidence Update on Acne Vulgaris. *Trials*, 11, 77.
- ISHAQUE, S., JOHNSON, J. & VOHRA, S. 2019. Individualized health-related quality of life instrument Measure Yourself Medical Outcome Profile (MYMOP) and its adaptations: a critical appraisal. *Qual Life Res*, 28, 879-93.
- JAESCHKE, R., SINGER, J. & GUYATT, G. 1989. Measurement of health status. Ascertaining the minimal clinically important difference. *Control Clin Trials*, 407-15.
- JINDAL, R., JINDAL, N. & DASS, A. 2016. Prevalence of hand fractures: a clinical study. *International Journal of Contemporary Medical Research*, 3, 3245-7.
- KAMPER, S., MAHER, C. & MACKAY, G. 2009. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *J Man Manip Ther*, 17, 163-170.
- KAPPOS, E. A., ESENWEIN, P., MEOLI, M., MEIER, R. & GRUNERT, J. 2016. Implantation of a denaturated cellulose adhesion barrier after plate osteosynthesis of finger proximal

- phalangeal fractures: results of a randomized controlled trial. *J Hand Surg Eur Vol*, 41, 413-20.
- KARANICOLAS, P., FARROKHVAR, F. & BHANDARI, M. 2010. Blinding: who, what, when, why, how? *Can J Surg*, 53, 345-348.
- KARANTANA, A., DAVIS, T., KENNEDY, D., LARSON, D., FURNISS, D., GRINDLAY, D., COWAN, K., GIDDINS, G., JAIN, A. & TRICKETT, R. 2021. Common hand and wrist conditions: creation of UK research priorities defined by a Jame Lind Alliance Priority Setting Partnership. *BMJ Open*, 11, e044207.
- KARL, J., OLSON, P. & ROSENWASSER, M. 2015. The epidemiology of upper extremity fractures in the United States, 2009. *J Orthop Trauma* 29, e242-e244.
- KIM, J. K. & KIM, D. J. 2015. Antegrade intramedullary pinning versus retrograde intramedullary pinning for displaced fifth metacarpal neck fractures. *Clin Orthop Relat Res*, 473, 1747-54.
- KINNINMONTH, A. W. & HOLBURN, F. 1986. A comparative controlled trial of a new perforated splint and a traditional splint in the treatment of mallet finger. *J Hand Surg Br*, 11, 261-2.
- KONRADSEN, L., NIELSEN, P. T. & ALBRECHT-BESTE, E. 1990. Functional treatment of metacarpal fractures 100 randomized cases with or without fixation. *Acta Orthop Scand*, 61, 531-4.
- KUOKKANEN, H. O., MULARI-KERANEN, S. K., NISKANEN, R. O., HAAPALA, J. K. & KORKALA, O. L. 1999. Treatment of subcapital fractures of the fifth metacarpal bone: a prospective randomised comparison between functional treatment and reposition and splinting. *Scand J Plast Reconstr Surg Hand Surg*, 33, 315-7.
- LAWTON, J. N., NICHOLLS, M. A. & CHAROGLU, C. P. 2007. Immobilization for scaphoid fracture: forearm rotation in long arm thumb-spica versus Munster thumb-spica casts. *Orthopedics*, 30, 612-4.
- LEE, S., KHAN, T., GRINDLAY, D. & KARANTANA, A. 2018. Registration and Outcome-Reporting Bias in Randomized Controlled Trials of Distal Radial Fracture Treatment. *JB JS Open Access*, 3, e0065.
- LEIGHTON, P., BREALEY, S. & DIAS, J. 2018. Interventions to improve retention in a surgical, clinical trial: a pragmatic, stakeholder-driven approach. *J Evid Based Med*, 11, 12-9.
- LEIGHTON, P., LONSDALE, A., TILDSLEY, J. & KING, A. 2012. The willingness of patients presenting with advanced glaucoma to participate in a trial comparing primary medical vs primary surgical treatment. *Eye*, 26, 300-306.
- LEWIS, S. & WARLOW, C. 2004. How to spot bias and other potential problems in randomised controlled trials. *J Neurol Neurosurg Psychiatry*, 75, 181-7.
- LI, Y., ALOLABI, N., KAUR, M. & THOMAS, A. 2015. A systematic review of utilities in hand surgery literature. *J Hand Surg Am*, 40, 997-1005.
- LONG, C., DESJARDINS-PARK, H., POPAT, R. & FOX, P. 2018. Quality of surgical randomized controlled trials in hand surgery: a systematic review. *Journal of hand surgery - European volume*, 43, 801-7.
- LOSINA, E., WRIGHT, J. & KATZ, J. 2012. Clinical trials in orthopaedics research. Part III. Overcoming operational challenges in the design and conduct of randomized clinical trials in orthopaedic surgery. *J Bone Joint Surg Am*, 94, e35 (1-6)
- LOTGERS, T., LEE, H., GEHRMANN, S., WINDOLF, J. & KAUFMANN, R. 2018. Proximal phalanx fracture management. *Hand (NY)*, 13, 376-83.
- LYONS, R., STANLEY, C. & MCKENNA, P. 2017. Assessment of the use of a synthetic removable polymer splint (fastform polytrexx™) for the treatment of non-displaced scaphoid fractures: prospective randomized trial. *Irish journal of medical science. Conference: 42nd sir peter freyer memorial lecture and surgical symposium. Ireland*, 186, S330.

- MARKIEWITZ, A. 2013. Complications of hand fractures and their prevention. *Hand Clin*, 29, 601-20.
- MASIC, I., MIOKOVIC, M. & MUHAMEDAGIC, B. 2008. Evidence based medicine - new approaches and challenges. *Acta Inform Med*, 16, 219-225.
- MAYR, E., RUDZKI, M. M., RUDZKI, M., BORCHARDT, B., HAUSSE, H. & RUTER, A. 2000. [Does low intensity, pulsed ultrasound speed healing of scaphoid fractures?]. *Handchir Mikrochir Plast Chir*, 32, 115-22.
- MCCREARY, D., SANDBERG, B., BOHN, D., PARIKH, H. & CUNNINGHAM, B. 2018. Interpreting patient-reported outcome results: is one minimum clinically important difference really enough? *Hand (N Y)*, 15, 360-4.
- MCCULLOCH, P., ALTMAN, D., CAMPBELL, W., FLUM, D., GLASZIOU, P., MARSHALL, J. & NICHOLL, J. 2009. Surgical innovation and evaluation 3. No surgical innovation without evaluation: the IDEAL recommendations. *Lancet*, 374, 1105-12.
- MCCULLOCH, P., COOK, J., ALTMAN, D., HENEGHAN, C. & DIENER, M. 2013. IDEAL framework for surgical innovation 1: the idea and development stages. *BMJ*, 346, f3012.
- MCCULLOCH, P., TAYLOR, I., SASAKO, M., LOVETT, B. & GRIFFIN, D. 2002. Randomised trials in surgery: problems and possible solutions. *BMJ*, 324, 1448-51.
- MCMAHON, P. J., WOODS, D. A. & BURGE, P. D. 1994. Initial treatment of closed metacarpal fractures. A controlled comparison of compression glove and splintage. *J Hand Surg Br*, 19, 597-600.
- MCQUEEN, M. M., GELBKE, M. K., WAKEFIELD, A., WILL, E. M. & GAEBLER, C. 2008. Percutaneous screw fixation versus conservative treatment for fractures of the waist of the scaphoid: a prospective randomised study. *J Bone Joint Surg Br*, 90, 66-71.
- MEALS, C. & MEALS, R. 2013. Hand fractures: a review of current treatment strategies. *J Hand Surg Am*, 38, 1021-1031.
- MESHIKHES, A.-W. 2015. Evidence-based surgery: the obstacles and solutions. *International Journal of Surgery*, 18, 159-62.
- MILLER, L., CROSBIE, J., WAJON, A. & ADA, L. 2016. No difference between two types of exercise after proximal phalangeal fracture fixation: a randomised trial. *J Physiother*, 62, 12-9.
- MOHER, D., LIBERATI, A., TETZLAFF, J. & ALTMAN, D. 2009. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *BMJ*, 339, b2535.
- MOINEAU, B. & BOISGONTIER, M. P. 2014. Superimposed electrical stimulation improves mobility of pre-stiff thumbs after ulnar collateral ligament injury of the metacarpophalangeal joint: a randomized study. *Ann Phys Rehabil Med*, 57, 373-80.
- MOMENI, A., LEE, G. & TALLEY, J. 2013. The quality of systematic reviews in hand surgery: an analysis using AMSTAR. *Plast Reconstr Surg*, 131, 831-7.
- MORTON, D. & BICKNELL, C. 2015. Should surgical training include involvement in a clinical trial? *BMJ*, 350, h2045.
- MOSER, A. & KORSTJENS, I. 2018. Series: Practical guidance to qualitative research. Part 3: Sampling, data collection and analysis. *Eur J Gen Pract*, 24, 9-18.
- MOUSOULIS, C., THOMAS, K., LEIGHTON, P., DESHMUKH, S., GRINDLAY, D. & KARANTANA, A. 2019. Treatment interventions for hand fractures and joint injuries: a scoping review of randomized controlled trials. *J Hand Surg Eur Vol*, 45, 111-8.
- NAGENDRAN, M., HARDING, D., TEO, W., CAMM, C., MARUTHAPPU, M., MCCULLOCH, P. & HOPEWELL, S. 2013. Poor adherence of randomised trials in surgery to CONSORT guidelines for non-pharmacological treatments (NPT): a cross-sectional study. *BMJ Open*, 3, e003898.
- NIHR NATIONAL INSTITUTE FOR HEALTH RESEARCH. 2019. *POINT: A multi-centre randomised trial of surgery versus non-surgical splint treatment for proximal*

- phalanx shaft finger fractures in adults* [Online]. Available: <https://fundingawards.nihr.ac.uk/award/NIHR127292> [Accessed 9th April 2021].
- NIHR NATIONAL INSTITUTE FOR HEALTH RESEARCH. 2020. *Hand-2: Needle fasciotomy versus limited fasciectomy for treatment of Dupuytren's contractures of fingers: a randomised non-inferiority trial with an individual participant data network meta-analysis comparison with DISC (ISRCTN18254597) to compare outcomes after collagenase injections* [Online]. Available: <https://fundingawards.nihr.ac.uk/award/NIHR127393> [Accessed 9th April 2021].
- NORMAN, G., SLOAN, J. & WYRWICH, K. 2003. Interpretation of changes in health-related quality of life. The remarkable universality of half a standard deviation. *Medical Care*, 41, 582-592.
- NORREGAARD, O., JAKOBSEN, J. & NIELSEN, K. K. 1987. Hyperextension injuries of the PIP finger joint. Comparison of early motion and immobilization. *Acta Orthop Scand*, 58, 239-40.
- NUFFIELD DEPARTMENT OF ORTHOPAEDICS, R. A. M. D. 2018. *DRAFT 2* [Online]. Available: <https://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/draft-2> [Accessed 19th April 2021].
- O'BRIEN, L. & PRESNELL, S. 2010. Patient experience of distraction splinting for complex finger fracture dislocations. *J Hand Ther*, 23, 249-59.
- O'BRIEN, L. J. & BAILEY, M. J. 2011. Single blind, prospective, randomized controlled trial comparing dorsal aluminum and custom thermoplastic splints to stack splint for acute mallet finger. *Arch Phys Med Rehabil*, 92, 191-8.
- O'CATHAIN, A., GOODE, J., DRABBLE, S., THOMAS, K., RUDOLPH, A. & HEWISON, A. 2014. Getting added value from using qualitative research with randomized controlled trials: a qualitative interview study. *Trials* 15, 215.
- O'CATHAIN, A., THOMAS, K., DRABBLE, S., RUDOLPH, A. & HEWISON, A. 2013. What can qualitative research do for randomized controlled trials? A systematic mapping review. *BMJ Open*, 3, e002889.
- OETGEN, M. & DODDS, S. 2008. Non-operative treatment of common finger injuries. *Curr Rev Musculoskelet Med*, 1, 97-102.
- OLLIVER, B. 2018. Equipoise, ethics, and offering patients participation in studies. *Bone & Joint*, 7.
- OOTES, D., LAMBERS, K. T. & RING, D. C. 2012. The epidemiology of upper extremity injuries presenting to the emergency department in the United States. *Hand (N Y)*, 7, 18-22.
- PATTNI, A., JONES, M. & GUJRAL, S. 2016. Volar plate avulsion injury. *Eplasty*, 16, ic22.
- PEDERSEN, M., THOMSEN, N. & HOVGAARD, C. 1995. Double finger bandage versus Carstam splint for the treatment of volar plate injuries of the proximal interphalangeal joint. *Acta orthopaedica scandinavica*, 66, 72.
- PIKE, J., Mulpuri, K., METZGER, M., NG, G., WELLS, N. & GOETZ, T. 2010. Blinded, prospective, randomized clinical trial comparing volar, dorsal, and custom thermoplastic splinting in treatment of acute mallet finger. *J Hand Surg Am*, 35, 580-8.
- POPE, C., ZIEBLAND, S. & MAYS, N. 2000. Qualitative research in healthcare. Analysing qualitative data. *BMJ*, 320, 114-6.
- POST, S., SELLES, R., MCGROUTHER, D., RITT, M., HOVIUS, S., FRIDEN, J. & WALBEEHM, E. 2013. Levels of evidence and quality of randomized controlled trials in hand and wrist surgery: an analysis of two major hand surgery journals. *J Hand Surg Eur Vol*, 39, 900-2.
- PROBSTFIELD, J. & FRYE, R. 2011. Strategies for recruitment and retention of participants in clinical trials. *JAMA*, 306, 1798-9.

- RAFIQUE, A., GHANI, S., SADIQ, M. & SIDDIQUI, I. A. 2006. Kirschner wire pin tract infection rates between percutaneous and buried wires in treating metacarpal and phalangeal fractures. *J Coll Physicians Surg Pak*, 16, 518-20.
- RAJU, P. K. & KINI, S. G. 2011. Fixation techniques for non-union of the scaphoid. *J Orthop Surg (Hong Kong)*, 19, 80-4.
- RANDALL, T., PORTNEY, L. & HARRIS, B. A. 1992. Effects of joint mobilization on joint stiffness and active motion of the metacarpal-phalangeal joint. *J Orthop Sports Phys Ther*, 16, 30-6.
- REDCAP. 2019. *Software* [Online]. Available: <https://projectredcap.org/software/> [Accessed 19th April 2021].
- REVICKI, D., HAYS, R., CELLA, D. & SLOAN, J. 2008. Recommended methods for determining responsiveness and minimally important differences for patient-reported outcomes. *J Clin Epidemiol*, 61, 102-9.
- RIBAK, S., MEDINA, C. E., MATTAR, R., JR., ULSON, H. J., ULSON, H. J. & ETCHEBEHERE, M. 2010. Treatment of scaphoid nonunion with vascularised and nonvascularised dorsal bone grafting from the distal radius. *Int Orthop*, 34, 683-8.
- RICARDO, M. 2006. The effect of ultrasound on the healing of muscle-pediculated bone graft in scaphoid non-union. *Int Orthop*, 30, 123-7.
- ROBERTSON, G. & WOOD, A. 2015. Fractures in sport: optimising their management and outcome. *World J Orthop*, 6, 850-63.
- ROCCHI, L., MEROLLI, A., MORINI, A., MONTELEONE, G. & FOTI, C. 2014. A modified spica-splint in postoperative early-motion management of skier's thumb lesion: a randomized clinical trial. *Eur J Phys Rehabil Med*, 50, 49-57.
- ROMMENS, P. 1988. [Classification of hand fractures and their treatment]. *Acta Chir Belg*, 88, 55-60.
- ROOSHENAS, L., ELLIOTT, D., WADE, J., JEPSON, M., PARAMASIVAN, S., STRONG, S., WILSON, C., BEARD, D., BLAZEY, J., BIRTLE, A., HALLIDAY, A., ROGERS, C., STEIN, R. & DONOVAN, J. 2016. Conveying equipoise during recruitment for clinical trials: qualitative synthesis of clinicians' practices across six randomised controlled trials. *PLoS Med*, 13, e1002147.
- SAEDEN, B., TORKVIST, H., PONZER, S. & HOGLUND, M. 2001. Fracture of the carpal scaphoid. A prospective, randomised 12-year follow-up comparing operative and conservative treatment. *J Bone Joint Surg Br*, 83, 230-4.
- SAITO, K. & KIHARA, H. 2016. A randomized controlled trial of the effect of 2-step orthosis treatment for a mallet finger of tendinous origin. *J Hand Ther*, 29, 433-439.
- SANDO, I. C., MALAY, S. & CHUNG, K. C. 2013. Analysis of publication bias in the literature for distal radius fracture. *J Hand Surg Am*, 38, 927-934 e5.
- SANDVALL, B., OKOROAFOR, U., GERULL, W., GUATTERY, J. & CALFEE, R. 2019. Minimal clinically important difference for PROMIS physical function in patients with distal radius fractures. *J Hand Surg Am*, 44, 454-459.
- SCHIER, J. & CHAN, J. 2007. Changes in life roles after hand surgery. *Journal of Hand Therapy*, 20, 57-69.
- SINGH, J., JAIN, K., MRUTHYUNJAYA & RAVISHANKAR, R. 2011. Outcome of closed proximal phalangeal fractures of the hand. *Indian J Orthop*, 45, 432-8.
- SINHA, S., SINHA, S., ASHBY, E., JAYARAM, R. & GROCOTT, M. 2009. Quality of reporting in randomized trials published in high-quality surgical journals. *J Am Coll Surg*, 209, 565-71.
- SJOLIN, S. U. & ANDERSEN, J. C. 1988. Clinical fracture of the carpal scaphoid--supportive bandage or plaster cast immobilization? *J Hand Surg Br*, 13, 75-6.
- SLETTEN, I. N., HELLUND, J. C., OLSEN, B., CLEMENTSEN, S., KVERNMO, H. D. & NORDSLETTEN, L. 2015. Conservative treatment has comparable outcome with

- bouquet pinning of little finger metacarpal neck fractures: a multicentre randomized controlled study of 85 patients. *J Hand Surg Eur Vol*, 40, 76-83.
- SLOAN, J. P., DOVE, A. F., MAHESON, M., COPE, A. N. & WELSH, K. R. 1987. Antibiotics in open fractures of the distal phalanx? *J Hand Surg Br*, 12, 123-4.
- SMITH, J. & FIRTH, J. 2011. Qualitative data analysis: application of the framework approach. *Nurse researcher*, 18, 52-62.
- SMITH-FORBES, E., HOWELL, D., WILLOUGHBY, J., PITTS, D. & UHL, T. 2016. Specificity of the minimal clinically important difference of the quick disabilities of the arm shoulder and hand (QDASH) for distal upper extremity conditions. *J Hand Ther*, 29, 81-8.
- SOLLERMAN, C., ABRAHAMSSON, S. O., LUNDBORG, G. & ADALBERT, K. 1991. Functional splinting versus plaster cast for ruptures of the ulnar collateral ligament of the thumb. A prospective randomized study of 63 cases. *Acta Orthop Scand*, 62, 524-6.
- SONG, J. & CHUNG, K. 2010. Observational studies: cohort and case-control studies. *Plast Reconstr Surg*, 126, 2234-2242.
- SORENSEN, J. S., FREUND, K. G. & KEJLA, G. 1993. Functional fracture bracing in metacarpal fractures: the Galveston metacarpal brace versus a plaster-of-Paris bandage in a prospective study. *J Hand Ther*, 6, 263-5.
- SOURMELIS, S., PLATANITIS, G., KORAKIS, T., DARAS, A., SCHINAS, N. & PAPAKOSTAS, C. 1995. Static splinting vs. functional treatment in extra-articular fractures of the proximal phalanges. *Orthopaedic transactions*, 19, 210.
- SRIVASTAVA, A. & THOMSON, S. 2009. Framework Analysis: A Qualitative Methodology for Applied Policy Research. *JOAAG*, 4, 72-9.
- STATIUS MULLER, M. G., POOLMAN, R. W., VAN HOOOSTRATEN, M. J. & STELLER, E. P. 2003. Immediate mobilization gives good results in boxer's fractures with volar angulation up to 70 degrees: a prospective randomized trial comparing immediate mobilization with cast immobilization. *Arch Orthop Trauma Surg*, 123, 534-7.
- STEVENSON, J., MCNAUGHTON, G. & RILEY, J. 2003. The use of prophylactic flucloxacillin in treatment of open fractures of the distal phalanx within an accident and emergency department: a double-blind randomized placebo-controlled trial. *J Hand Surg Br*, 28, 388-94.
- STRUB, B., SCHINDELE, S., SONDEREGGER, J., SPROEDT, J., VON CAMPE, A. & GRUENERT, J. G. 2010. Intramedullary splinting or conservative treatment for displaced fractures of the little finger metacarpal neck? A prospective study. *J Hand Surg Eur Vol*, 35, 725-9.
- SUGRUE, C., JOYCE, C., SUGRUE, R. & CARROLL, S. 2016. Trends in the level of evidence in clinical hand surgery research. *Hand*, 11, 211-215.
- SURESH, K. 2011. An overview of randomization techniques: an unbiased assessment of outcome in clinical research. *J Hum Reprod Sci*, 4, 8-11.
- TAKATA, S., WADE, E. & ROLL, S. 2019. Hand therapy interventions, outcomes, and diagnoses evaluated over the last 10 years: a mapping review linking research to practice. *J Hand Ther*, 32, 1-9.
- TAVAKOL, M. & SANDARS, J. 2014. Quantitative and qualitative methods in medical education research: AMEE Guide No 90: Part I. *Medical Teacher*, 36, 746-56.
- TERLUIN, B., EEKHOUT, I., TERWEE, C. & DE VET, H. 2015. Minimal important change (MIC) based on a predictive modeling approach was more precise than MIC based on ROC analysis. *Journal of Clinical Epidemiology*, 68, 1388-1396.
- TERWEE, C., ROORDA, L., KNOL, D., DE BOER, M. & DE VET, H. 2009. Linking measurement error to minimal important change of patient-reported outcomes. *Journal of Clinical Epidemiology*, 62, 1062-1067.
- THOMSEN, N. O., PETERSEN, M. S. & HOVGGAARD, C. 1995. Treatment of hyperextension injuries to the PIP joint. *J Hand Surg Br*, 20, 383-4.

- TOCCO, S., BOCCOLARI, P., LANDI, A., LEONELLI, C., MERCANTI, C., POGLIACOMI, F., SARTINI, S., ZINGARELLO, L. & NEDELEC, B. 2013. Effectiveness of cast immobilization in comparison to the gold-standard self-removal orthotic intervention for closed mallet fingers: a randomized clinical trial. *J Hand Ther*, 26, 191-200.
- TOKER, S., TURKMEN, F., PEKINCE, O., KORUCU, I. & KARALEZLI, N. 2015. Extension Block Pinning Versus Hook Plate Fixation for Treatment of Mallet Fractures. *J Hand Surg Am*, 40, 1591-6.
- TREWEEK, S., PITKETHLY, M., COOK, J., FRASER, C., MITCHELL, E., SULLIVAN, F., JACKSON, C., TASKILA, T. & GARDNER, H. 2018. Strategies to improve recruitment to randomised trials (Review). *Cochrane Database Syst Rev*.
- TRICCO, A., LILLIE, E., ZARIN, W., O'BRIEN, K., COLQUHOUN, H., LEVAC, D., MOHER, D., PETERS, M., HORSLEY, T., WEEKS, L., HEMPEL, S., AKL, E., CHANG, C., MCGOWAN, J., STEWART, L., HARTLING, L., ALDCROFT, A., WILSON, M., GARRITTY, C., LEWIN, S., GODFREY, C., MACDONALD, M., LANGLOIS, E., SOARES-WEISER, K., MORIARTY, J., CLIFFORD, T., TUNÇALP, Ö. & STRAUS, S. 2018. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med*, 169, 467-73.
- VALDES, K., NAUGHTON, N. & ALGAR, L. 2015. Conservative treatment of mallet finger: a systematic review. *J Hand Ther*, 28, 237-45.
- VALDES, K., NAUGHTON, N. & ALGAR, L. 2016. ICF components of outcome measures for mallet finger: A systematic review. *J Hand Ther*, 29, 388-395.
- VAN AAKEN, J., FUSETTI, C., LUCHINA, S., BRUNETTI, S., BEAULIEU, J. Y., GAYET-AGERON, A., HANNA, K., SHIN, A. Y. & HOFMEISTER, E. 2016. Fifth metacarpal neck fractures treated with soft wrap/buddy taping compared to reduction and casting: results of a prospective, multicenter, randomized trial. *Arch Orthop Trauma Surg*, 136, 135-42.
- VAN ONSELEN, E., KARIM, R., HAGE, J. & RITT, M. 2003. Prevalence and distribution of hand fractures. *Journal of Hand Surgery (British and European Volume)*, 28B, 491-5.
- VERVER, D., TIMMERMANS, L., KLAASSEN, R. A., VAN DER VLIES, C. H., VOS, D. I. & SCHEP, N. W. L. 2017. Treatment of extra-articular proximal and middle phalangeal fractures of the hand: a systematic review. *Strategies Trauma Limb Reconstr*, 12, 63-76.
- VINNARS, B., PIETREANU, M., BODESTEDT, A., EKENSTAM, F. & GERDIN, B. 2008. Nonoperative compared with operative treatment of acute scaphoid fractures. A randomized clinical trial. *J Bone Joint Surg Am*, 90, 1176-85.
- VON KIESERITZKY, J., NORDSTROM, J. & ARNER, M. 2017. Reoperations and postoperative complications after osteosynthesis of phalangeal fractures: a retrospective cohort study. *Journal of Plastic Surgery and Hand Surgery*, 51, 458-62.
- WALENKAMP, M., DE MUINCK KEIZER, R., GOSLINGS, J., VOS, L., ROSENWASSER, M. & SCHEP, N. 2015. The minimum clinically important difference of the patient-rated wrist evaluation score for patients with distal radius fractures. *Clin Orthop Relat Res*, 473, 3235-41.
- WARREN, R. A., NORRIS, S. H. & FERGUSON, D. G. 1988. Mallet finger: a trial of two splints. *J Hand Surg Br*, 13, 151-3.
- WARTOLOWSKA, K., COLLINS, G., HOPEWELL, S., JUDGE, A., DEAN, B., ROMBACH, I., BEARD, D. & CARR, A. 2016. Feasibility of surgical randomised controlled trials with a placebo arm: a systematic review. *BMJ Open*, 6, e010194.
- WARWICK, D., DUNN, R., MELIKYAN, E. & VADHER, J. 2009. *Oxford specialist handbooks in surgery. Hand surgery*, Oxford, Oxford University Press.
- WATSON, N., MARTIN, S. & KEATING, J. 2018. The impact of wrist fracture, surgical repair and immobilization on patients: a qualitative study. *Clinical Rehabilitation*, 32, 841-51.

- WEINSTOCK-ZLOTNICK, G., PAGE, C., GHOMRAWI, H. & WOLFF, A. 2015. Responsiveness of three Patient Report Outcome (PRO) measures in patients with hand fractures: A preliminary cohort study. *Journal of Hand Therapy*, 28, 403-11.
- WELDRING, T. & SMITH, S. 2013. Patient-Reported Outcomes (PROs) and Patient-Reported Outcome Measures (PROMs). *Health Serv Insights*, 6, 61-8.
- WHYBROW, P., PICKARD, R., HRISOS, S. & RAPLEY, T. 2017. Equipose across the patient population: optimising recruitment to a randomised controlled trial. *Trials*, 18, 140.
- WILLIAMS, H., BURDEN-TEH, E. & NUNN, A. 2015. What is a pragmatic clinical trial? *Journal of Investigative Dermatology*, 135, e33.
- WILLIAMSON, P., ALTMAN, D., BLAZEBY, J., CLARKE, M. & GARGON, E. 2012. Driving up the quality and relevance of research through the use of agreed core outcomes. *J Health Serv Res Policy*, 17, 1-2.
- WINTER, M., BALAGUER, T., BESSIERE, C., CARLES, M. & LEBRETON, E. 2007. Surgical treatment of the boxer's fracture: transverse pinning versus intramedullary pinning. *J Hand Surg Eur Vol*, 32, 709-13.
- WORMALD, J., GEOGHEGAN, L., SERAKOWSKI, K., PRINCE, A., PETERS, M., JAIN, A. & RODRIGUES, J. 2019. Site-specific Patient-reported Outcome Measures for hand conditions: systematic review of development and psychometric properties. *Plastic and Reconstructive Surgery - Global Open*, 7, e2256.
- WRIGHT, A., HANNON, J., HEGEDUS, E. & KAVCHAK, A. 2012. Climimetrics corner: a closer look at the minimally clinically important difference (MCID). *Journal of Manual and Manipulative Therapy* 20, 160-166.
- XIA, X. 2015. Kirschner wire and mini-plate fixation in repair of metacarpal and phalangeal fractures: hand function and adverse reactions. *Chinese journal of tissue engineering research* [Online], 19. Available: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/342/CN-01096342/frame.html>.
- ZHOU, F., SHEN, B., WANG, R., FAN, S. & HU, W. 2008. [Clinical contrast of percutaneous pinning with plaster splint and open reduction and pulling out wire in the treatment of mallet fingers]. *Zhongguo Xiu Fu Chong Jian Wai Ke Za Zhi*, 22, 1451-4.
- ZYLUK, A. & BUDZYNSKI, T. 2009. [Conservative vs operative treatment of isolated fractures of phalanges: results of the prospective, randomized study]. *Chir Narzadow Ruchu Ortop Pol*, 74, 74-8.