SURGICAL AND NON-SURGICAL TREATMENT FOR METACARPAL SHAFT FRACTURES IN ADULTS: AN OBSERVATIONAL FEASIBILITY STUDY

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SYNOPSIS

Title	Surgical and non-surgical treatment for metacarpal shaft fractures in adults: an observational feasibility study
Acronym	**FACTS** **F**ractures of **A**dult Meta**C**arpal shaf**TS**
Short title	Metacarpal shaft fractures in adults: an observational feasibility study
Chief Investigator	Alexia Karantana
Objectives	1. Assess feasibility, acceptability and practicality of a RCT of surgical and non-surgical treatment for metacarpal shaft fractures in adults 2. Assess eligibility, recruitment and retention rates and completion of follow-up 3. Identify appropriate outcome measures for use in a future trial 4. Estimate the minimal clinically important difference for the primary outcome measures using quantitative and qualitative assessments 5. Provide complementary, detailed and person-centred insight that will inform RCT design through the identification of barriers to participation amongst patients with MSF
Study Configuration	A dual-centre prospective cohort study.
Setting	Secondary care. Two study centres: 1. Queen's Medical Centre, Nottingham University Hospitals NHS Trust 2. The Pulvertaft Hand Centre, Royal Derby Hospital, University Hospitals of Derby and Burton NHS Foundation Trust
Sample size estimate	As this is a feasibility study, formal sample size calculations for between group comparisons are not appropriate. We aim to recruit 60-84 patients, with comparable numbers in each treatment group.
Number of participants	84 participants
Eligibility criteria	Inclusion criteria • Adults 16 years or older • Radiologically confirmed metacarpal shaft fracture

	• Acute metacarpal shaft fracture affecting the index to little finger(s), presenting within 10 days of injury • Willing and able to give informed consent Exclusion criteria • Fracture(s) of the thumb • Fractures extending into the joint surface • Fracture(s) of the metaphyseal base and/or neck of the metacarpal • Fracture(s) associated with dislocation at the carpometacarpal joint or other adjacent joint dislocation • Open fractures • Undisplaced fractures • Patients who would not be able to adhere to trial procedures or complete the study questionnaires
Description of interventions	This is an observational study. Patients treated in the two participating centres will be recruited to the study. No additional interventions outside of routine care will be undertaken.
Duration of study	Overall duration: 18 months Start date: 01/05/2020 Per participant: 8 months per participant, from time of injury to final planned research follow-up
Outcome measures	Feasibility outcomes relating to participant recruitment; treatment and follow up; clinical and patient reported outcomes; treatment and patient reported costs; and acceptability of treatment/study related procedures.
Statistical methods	All analyses will be carried out using Stata v15.1 or above. Data analyses will primarily be descriptive with 95% confidence intervals to quantify uncertainty in estimates where appropriate. Minimum clinically important effects for each PROM will be estimated using three anchor-based responsiveness statistics; (i) standardised response mean; (ii) effect size; (iii) Guyatt's Responsiveness Index and distribution based methods; using the standard error of measurement, standard deviation and effect size.

ABBREVIATIONS

AE	Adverse Event
AO	Arbeitsgemeinschaft für Osteosynthesefragen
BNF	British National Formulary
BSSH	British Society for Surgery of the Hand
CEBHS	Centre for Evidence Based Hand Surgery
CI	Chief Investigator overall
CRF	Case Report Form
CRPS	Complex Regional Pain Syndrome
DASH	Disabilities of the Arm, Shoulder and Hand Outcome Measure
DELTA	Difference ELicitation in TriAls
DHR	Digital Health Record
DIP	Distal interphalangeal
DMC	Data Monitoring Committee
DNA	Did not attend
EQ-5D-5L	European quality of life questionnaire
GA	General Anaesthetic
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GROC	Global Rating of Change Scale
ICF	Informed Consent Form
ICH	International Council for Harmonisation
IQR	Inter-Quartile Range
IT	Information technology
JAMAR	Jamar Hydraulic Hand Dynamometer
JLA	James Lind Alliance
K-wire	Kirschner wire
MCP	Metacarpophalangeal

MSF	Metacarpal Shaft Fracture(s)
NCTU	Nottingham Clinical Trials Unit
NHS	National Health Service
NIHR	National Institute for Health Research
ORIF	Open reduction internal fixation
OTA	Orthopaedic Trauma Association
PACS	Picture Archiving and Communication System
PEM	Patient Evaluation Measure
PI	Principal Investigator at a local centre
PIP	Proximal interphalangeal
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PROM	Patient Reported Outcome Measure
PROMIS-UE	Patient Reported Outcome Measurement Information System Upper Extremity
PSP	Priority Setting Partnership
PSSRU	Personal Social Services Research Unit
QALY	Quality Adjusted Life Years
*Quick*DASH	Shortened Disabilities of the Arm, Shoulder and Hand Outcome Measure
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
R&D	Research and Development department
ROC	Receiver Operating Characteristic
ROM	Range of Motion
SAE	Serious Adverse Event
SD	Standard Deviation
SEM	Standard Error of Measurement
SMS	Short Message Service
TAM	Total Active Motion

UoN	University of Nottingham
UK	United Kingdom
VAS	Visual Analogue Scale

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STUDY BACKGROUND INFORMATION AND RATIONALE

Metacarpal shaft fractures (MSF) are common traumatic hand injuries, reported to represent18-31% of hand fractures (1-4). They usually affect young adult males, often in the third decade of life (1, 5), with the fourth and fifth metacarpal most commonly injured (1, 2, 5, 6).

The metacarpal was the most commonly injured bone in the hand, accounting for 47% (302/637) of injuries presenting to a tertiary hand centre (3). This was also supported by findings of a study from Birmingham, UK, in which metacarpal fractures made up 56% of hand fractures (5). The majority of which are fractures of the fifth metacarpal, which is the most frequently injured metacarpal in all age groups (3, 5). Metacarpal fractures may be divided into fractures of the neck, shaft, base or a combination of the above, as per the AO/OTA Fracture and Dislocation Classification Compendium (7). Most are fractures of the metacarpal neck, however an ongoing review of all hand fractures treated at Queen's Medical Centre, Nottingham, in a 12 month period, revealed that shaft fractures make up 25% of all metacarpal fractures.

In 2016, there were 23.5 million Accident and Emergency (A&E) department attendances with fractures being the second most common reason for presentation (8). As hand fractures make up 25% of all A&E attendances (9) and MSF comprise 18-31% of hand fractures(1-4, 6), MSF therefore place a significant burden on healthcare resources. Furthermore, a House of Commons briefing paper on Accident and Emergency department statistics reported a 6% yearly increase in the number of fractures and injuries overall (8).

MSF occur due to direct or indirect trauma and are often simple closed injuries following axial loading, a direct blow or torsional loading of the digit (10). Treatments used in routine clinical care for these injuries usually give good results in the majority of cases, however, MSF can be associated with soft tissue injury, including tendon laceration, and compartment syndrome of the hand in the context of severe hand trauma (11). Neurovascular injuries are rare following simple closed fractures, but more common with severe open injuries, particularly in the case of injuries as a result of sharp objects (12).

MSF predominantly affect those of working age (2-4, 13, 14) and are thus associated with significant cumulative morbidity (15). Missed time off work significantly increases the economic burden of MSF (15). However, there is no UK specific data on the healthcare associated costs, socioeconomic or societal costs of these injuries.

Although the outcome after MSF treatment is usually good, MSF can limit hand range of motion (ROM) and grip strength, lead to an extensor lag of the injured finger from shortening and may rarely cause rotational deformity of the finger (16, 17). This may rarely cause significant disability and lead to long-term negative functional sequelae, such as loss of the ability to work and live at the preinjury level. For the majority, optimising treatment of these injuries may have significant short-term benefits in both quality of life and return to work for these patients.

As with any hand fracture, the primary goal of treatment is to restore optimal hand function while providing value for money for the NHS. Treatment aims to control pain and restore and/or maintain satisfactory alignment. MSF can be managed non-surgically with appropriate reduction and immobilisation (18). Techniques include closed reduction, casting, splinting or simple mobilisation. However, MSF may also be treated with a variety of surgical techniques, including Kirschner-wires (K-wires), intra-osseous wires, interfragmentary compression screws, plates or external fixators (17).

Surgical treatment has the potential benefits of faster recovery of hand function and improved fracture position. However, it is more invasive and carries the risk of complications including tendon adhesions, neurovascular injury and infection (19). Non-surgical treatment may involve the use of a cast or splint which is inconvenient to the patient, and may result in an imperfect fracture position. However, it avoids a scar and surgical complications.

There is wide variability in the management of MSF. There is persistent controversy regarding acceptable parameters of deformity. The reported acceptable limits of fracture angulation and shortening vary widely. Some authors opine that the index and long fingers can tolerate up to 20˚ of angulation, whereas others state that only up to 5˚ are acceptable (18, 20). Similar differences are reported for the ring and little fingers. For shortening, most agree that more than 5mm is unacceptable, but some authors are more restrictive, accepting only up to 2mm of shortening before proceeding to surgical intervention (18, 20).

Rationale for current study

Despite the prevalence of MSF, the evidence guiding their treatment is limited and there is no consensus on the best practice management approach. Though there are a small number of single-centre, retrospective and prospective studies (21-27), there are no randomised controlled trials (RCT) investigating treatment modalities for MSF. As a result, current management remains guided by surgeon preference and local practice. Retrouvey et al (2018) demonstrated significant inconsistencies in the management of single metacarpal fractures (28). The study highlighted the lack of clear guidelines dictating treatment, possibly leading to these inconsistencies (28).

A systematic review undertaken in 2019 of surgical versus non-surgical treatment for MSF identified 699 records. There were no RCTs. The only retrospective cohort study had several key limitations including small patient numbers, low follow-up rate (17%) and lack of use of a patient-reported outcome measure validated in MSF (27). A search of the WHO ISCTRP portal also revealed no ongoing or registered trials worldwide.

Though the use of patient reported outcome measures (PROM) for assessing outcomes in both the clinical and research setting has increased in recent years, there is limited evidence of reliability, validity, and responsiveness in a hand and wrist trauma population. There is no information on the use of PROMs to assess the outcome of MSF. A systematic review by Dacombe et al (2016) concluded that whilst the DASH and PRWE have some evidence of reliability, validity, and responsiveness in a hand and wrist trauma population, other PROMs do not (29).

There is a lack of good quality, large comparative trials to guide the treatment of MSF. There are no published or ongoing RCTs or cohort studies comparing surgical versus non-surgical treatment for metacarpal shaft fractures.

There are several gaps in the literature:

1. No consensus on acceptable parameters of deformity or displacement, leading to widespread variation in treatment
2. No core outcome sets for hand trauma, so we do not know which outcome measure is best suited for the study of MSF
3. No qualitative data exploring patient experience of MSF and their treatment
4. No evaluation of the cost-effectiveness of treatment modalities for MSF
5. No high-quality published evidence comparing treatment modalities for MSF

The lack of existing evidence supports the need for a well-designed, pragmatic, multi-centre RCT to identify the most beneficial and cost-efficient treatment for MSF in adults. This study aims to assess the feasibility, acceptability and practicality of such a trial by providing information about; study design, numbers of eligible patients, recruitment, completion of follow-up, selection of appropriate outcome measures, assessment of minimal clinically important difference for selected outcome measures, costs of treatment, sample size calculation and measures to optimise participant recruitment, engagement and retention in a future trial.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

1. To investigate the feasibility and acceptability of conducting a pragmatic multi-centre RCT to assess the clinical and cost-effectiveness of surgical versus non-surgical treatment for MSF in adults.
2. To provide complementary, detailed and person-centred insight that will inform RCT design through the identification of barriers to participation amongst patients with MSF, and to develop novel solutions to engage these cohorts in research.

OBJECTIVES

The following objectives were developed in collaboration with RCT methodologists and informed by discussions between patients, clinicians and therapists at the MSF Consensus Workshop, held by the Centre for Evidence Based Hand Surgery in Nottingham, November 2018.

How objective will inform the definitive trial	**Objective**
Recruitment for a future trial	1. Define eligibility criteria for the future trial, which correctly identify appropriate patients for whom a treatment decision is suitable 2. Estimate the proportion of referred NHS patients who meet these eligibility criteria 3. Assess recruitment and retention rates
Outcomes for use in a future trial	4. Evaluate outcomes for use as primary and secondary outcomes 5. Calculate minimal clinically important difference (MCID) for the proposed primary outcome measure 6. Investigate feasibility of collecting outcome data frequently, in order to capture subtle improvements in patient or clinician assessed outcomes

Follow-up	7. Estimate follow up and outcome completion rates for both clinic and remotely assessed outcomes 8. Explore optimum time-points for follow-up
Sample size calculation	9. Estimate the sample size required for a definitive study
Use of remote assessments in a future trial	10. Evaluate the utility and acceptability of remote completion of health resource use questionnaires to assess the impact of care on health service use and productivity 11. Evaluate the utility and acceptability of remote, electronically administered patient assessments
Economic assessment	12. Inform the design of a future cost-effectiveness analysis by exploring the costs of treatment modalities through capture of NHS resource use and representative micro-costing.
Patient-centred insight into research design, conduct and delivery	13. To explore participant experience of MSF, treatment and recovery 14. To explore participant experience of research processes and study burden associated with outcome measures 15. To gain recommendations on future study design and mechanisms to facilitate study delivery
Facilitate engagement and retention amongst patients with MSF in a future trial	16. To explore the use of health technology applications and social media in optimising participation and engagement in research

STUDY DESIGN

STUDY CONFIGURATION

A dual-centre prospective cohort study to assess the feasibility of a RCT comparing surgical and non-surgical treatment for MSF in adults. This is a feasibility study and therefore between-group comparisons of surgical and non-surgical treatments are not planned. The outcomes of interest include feasibility outcomes relating to; assessment of eligibility, recruitment and retention rates; completion of follow-up; evaluation of outcome measures and calculation of the MCID for the primary outcome measures using quantitative and qualitative assessments and establishing the feasibility of data collection methods and appropriate time-points for use in a future trial.

A nested qualitative study consisting of two elements, patient interviews and focus groups, will be conducted to provide patient-centered insight into study procedures and explore the individual impact of the injury. Patients will be selected from the prospective cohort study and further written informed consent separately sought.

An economic evaluation to estimate costs of treatments for metacarpal shaft fractures through representative micro-costing will be undertaken. Resource use directly linked to the MSF and its sequela and/or complications over the 6 months of follow-up will be recorded for each participant. Unit cost data will be obtained from national databases such as NHS Reference costs, the British National Formulary (BNF) and Personal Social Services Research Unit (PSSRU) Costs of Health and Social Care (30).

Patients will be recruited from hand fracture clinics at two secondary care centres, Queen's Medical Centre, Nottingham (where the majority of MSF are treated non-surgically) and the Pulvertaft Hand Centre, Royal Derby Hospital, Derby (where some are treated surgically). Written informed consent will be attained from all participants. Patients will receive care as per the treating clinician. There will be no randomisation, allocation of treatment or blinding/concealment of allocation.

A two by two by two factorial design randomised sub-study will be nested within the main cohort study. Once participants have consented to the cohort study or qualitative study, they will be randomised to a sub-study that will evaluate the use of text messages to maximise data collection and participant retention in the study. The interventions will be:

- Frequency of SMS messages – participants will receive either fortnightly or monthly messages
- Two-way communication - text message requiring a response from the participant versus a notification message only
- Personalisation - personalised text message versus a standard automated message

Outcomes

Feasibility outcomes are:

1. Number and proportion of patients assessed for eligibility
2. Size of the eligible patient pool available for recruitment
3. Identification of primary outcome measures for use in a future RCT
4. Estimation of the MCID for selected outcome measures
5. Completion of follow-up assessments
6. Evaluation of the use of text messages in optimising data collection and retention

Follow up

Patients will be reviewed in a face-to-face clinic visit at 6 weeks and thereafter remotely at 3 and 6 months from recruitment.

Stopping rules and discontinuation

Study participants may voluntarily withdraw from part of, or the whole study at any time. There are no planned interim data analyses and no stopping rules for this observational study.

STUDY MANAGEMENT

The study is funded by a National Institute for Health Research Doctoral Fellowship awarded to Miss Rowa Taha (NIHR300197). It is sponsored by the University of Nottingham and will be managed and co-ordinated from the Centre for Evidence Based Hand Surgery, University of Nottingham.

The Chief Investigator has overall responsibility for the study and shall oversee study management.

Miss Rowa Taha, Clinical Research Fellow in Hand Surgery (RT), will be responsible for recruitment and consent of eligible study participants at Queen's Medical Centre. Eligible participants at the Pulvertaft Hand Centre will be consented by a research associate.

RT will be responsible for collection of clinical, resource and patient reported outcome data, data storage, management and analysis at both Nottingham and Derby Hospitals. She will be responsible for the day-to-day management of the study and will liaise closely with the CI throughout the duration of the study.

RT will maintain a close working relationship with the Pulvertaft Hand Centre and will make regular visits to the centre, to assess recruitment, study procedures and address any issues that may arise.

The data custodian will be the Chief Investigator.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: The recruitment period for the study is anticipated to be 6-9 months. Participant follow-up will continue for a maximum of 8 months following the end of recruitment.

Participant Involvement Duration: 8 months from recruitment to final follow-up.

End of the Study

The end of the study will be the completion of the study report. This will allow sufficient time for the completion of protocol procedures, data collection and analysis. The end of the study will be reported to the Sponsor and REC within 90 days.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

Participants will be recruited from hand fracture clinics at two sites, Queen's Medical Centre, Nottingham University Hospitals NHS Trust, and the Pulvertaft Hand Unit at the Royal Derby Hospital, University Hospitals of Derby and Burton NHS Foundation Trust. The initial approach will be from a member of the patient's usual care team (which may include the

local investigator in each site) and information about the study will be on display in the relevant clinical areas.

Eligible patients will be identified by a member of their usual care team, which may be a specialist registrar, fellow or consultant, during their clinic consultation. If the patient is willing to consider participation, they will be given the participant information leaflet and offered the opportunity to discuss the study with a research associate during the same visit. The investigator or research associate will inform the participant of all aspects pertaining to participation in the study and provide participant information sheets.

Posters about the study and Participant Information Sheets (PIS) will be readily available in clinical waiting areas and examination rooms. Posters will also be on display advising all patients attending the hand fracture clinic that they may be approached by a member of the research team and to inform clinical staff if they would prefer not to be approached. All patients who notify clerical or clinical staff of their intent for exclusion will not be approached regarding the study.

The Participant Information Sheets, consent forms and all other study documentation will only be available in English as the selected patient reported outcome measures are not validated in other languages. Therefore, all participants must understand the English language to participate in the study.

The patient will be given sufficient time to consider the information provided. If the patient wishes to participate in the study, they will be asked to provide full written informed consent. Once the patient has given full written informed consent, they will be invited to complete the baseline questionnaires.

It will be explained to the potential participant that entry into the study is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and may be used in the final analyses where appropriate.

Upon completion of all study visits and questionnaires, participants who have consented to this, will receive an end-of-study letter accompanied by the initial Participant Information Sheet thanking them for their participation and informing them that their involvement in the study is complete.

Remote recruitment of participants

Virtual fracture clinic
Where patients are reviewed in a virtual fracture clinic, a member of their usual care team, which may be a therapist, specialist registrar, fellow or consultant will identify potentially eligible patients.

A copy of the PIS will be posted to potentially eligible participants along with the clinical letter. Contact details of the research team will be included and if the patient is willing to consider participation, they may contact the research team directly to discuss the study in detail.

Emergency Department Minors (EDM) or equivalent pathway
Potentially eligible participants may be identified in the EDM (or equivalent local pathway for hand fracture patients) by a member of their usual care team, which may include an

Emergency Nurse Practitioner (ENP), clinician or therapist. They will offer the patient a copy of the PIS and ask them if they are willing to be contacted to learn more about the study.

If so, a research associate will contact the patient, after 24-48 hours, via their preferred method of communication to explain the study in detail, informing them of all aspects pertaining to participation in the study and to answer any questions they may have regarding study participation. Full PIS and consent form documents will be provided either electronically or by post.

If they are willing to take part in the study, they will be invited to complete the informed consent form, providing verbal confirmation of their intent for study participation. Participants who agree to take part in the study will be sent a copy of the informed consent form to sign and return electronically or by post, along with a prepaid envelope for return of the signed written consent form.

If participants do not have the facilities to sign and return the form, the research associate will complete the informed consent form during the remote consultation, marking the participant's initials on the consent form as appropriate. A copy of this completed consent form will be sent electronically to the participant and they will be asked to confirm receipt of the form by way of a return email. A reply from the participant's personal email address confirming the details of the consent form and their willingness to participate in the study will be taken as confirmation of written informed consent.

If necessary, a hard copy of the consent form will be posted to participants, along with a prepaid envelope for return of the signed written consent form.

Once consent is obtained, the participant will complete baseline patient-facing assessments (i.e. patient questionnaires) remotely. Other baseline information will be collected via telephone interview.

Eligibility criteria

Inclusion criteria

- Adults 16 years or older
- Radiologically confirmed metacarpal shaft fracture
- Acute metacarpal shaft fracture affecting the index to little finger(s), presenting within 10 days of injury
- Willing and able to give informed consent
- Ability to understand English

The shaft/diaphysis is defined as per the AO/OTA Fracture and Dislocation Classification Compendium, 2018, "as that part of the bone between the two end segments". The proximal and distal end segments of the long bones are defined by a square whose sides are the same length as the widest part of the epiphysis/metaphysis in question (Heim's system of squares)(7). The shaft/diaphysis may be divided into three equal parts defining the location of the diaphyseal fracture as follows:

a. Proximal 1/3rd
b. Middle 1/3rd
c. Distal 1/3rd

Exclusion criteria

- Fracture(s) of the thumb
- Fractures extending into the joint surface
- Fracture(s) of the metaphyseal base and/or neck of the metacarpal
- Fracture(s) associated with dislocation at the carpometacarpal joint or other adjacent joint dislocation
- Open fractures
- Undisplaced fractures, defined as those with a visible fracture line on radiographs but anatomical alignment, i.e. the bone fragments remain aligned with no evidence of movement of the fracture fragments on anteroposterior, lateral or oblique radiographs
- Patients who would not be able to adhere to study procedures or complete the study questionnaires

Expected duration of participant participation

8 months
Participants will be expected to attend a research clinic at 6 weeks for assessment of clinical measures and completion of PROMs. Further assessments will be undertaken remotely at 3 and 6 months, via email or post (depending on participant preference). Those who consent to the qualitative study will be invited for interview at 6 weeks and at 3-6 months. They will be invited to attend three focus groups as follows: at 6-8 weeks, 10-12 weeks and 4-6 months following their injury. 8 months reflects the longest time that a participant will be involved, allowing sufficient time to conduct focus groups with participants who consent to this part of the study. For the majority of participants, the total duration of participant participation will be 6 months.

Removal of participants from therapy or assessments/Participant Withdrawal

Participants may be withdrawn from the study at their own request. The participants will be made aware that this will not affect their future care. Participants will be made aware (via the information sheet and consent form) that should they withdraw, the data collected to date may still be used in the final analysis.

Informed consent

Participant Information Sheets (PIS) will be provided to patients and they will have the opportunity to discuss the study before agreeing to take part. Written informed consent will be sought before enrolment into the study. The Informed Consent Form will be signed and dated by the participant before they enter the study. The Investigator will explain the details of the study and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation. Informed consent for participation in the qualitative element of the study will be separately sought following explanation of the two patient interviews required and the number and purpose of the focus groups.

One copy of the written informed consent will be kept by the participant, one will be kept by the Investigator, and a third will be retained in the patient's hospital records.

Should there be any subsequent amendments to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended consent form which will be signed by the participant.

STUDY TREATMENT AND REGIMEN

A participant pathway flowchart is illustrated in Figure 1 and the schedule of research assessments in Table 1. The timing of the study treatment interventions and clinical follow-up will be as per current care and will be recorded.

FLOW DIAGRAM OF STUDY

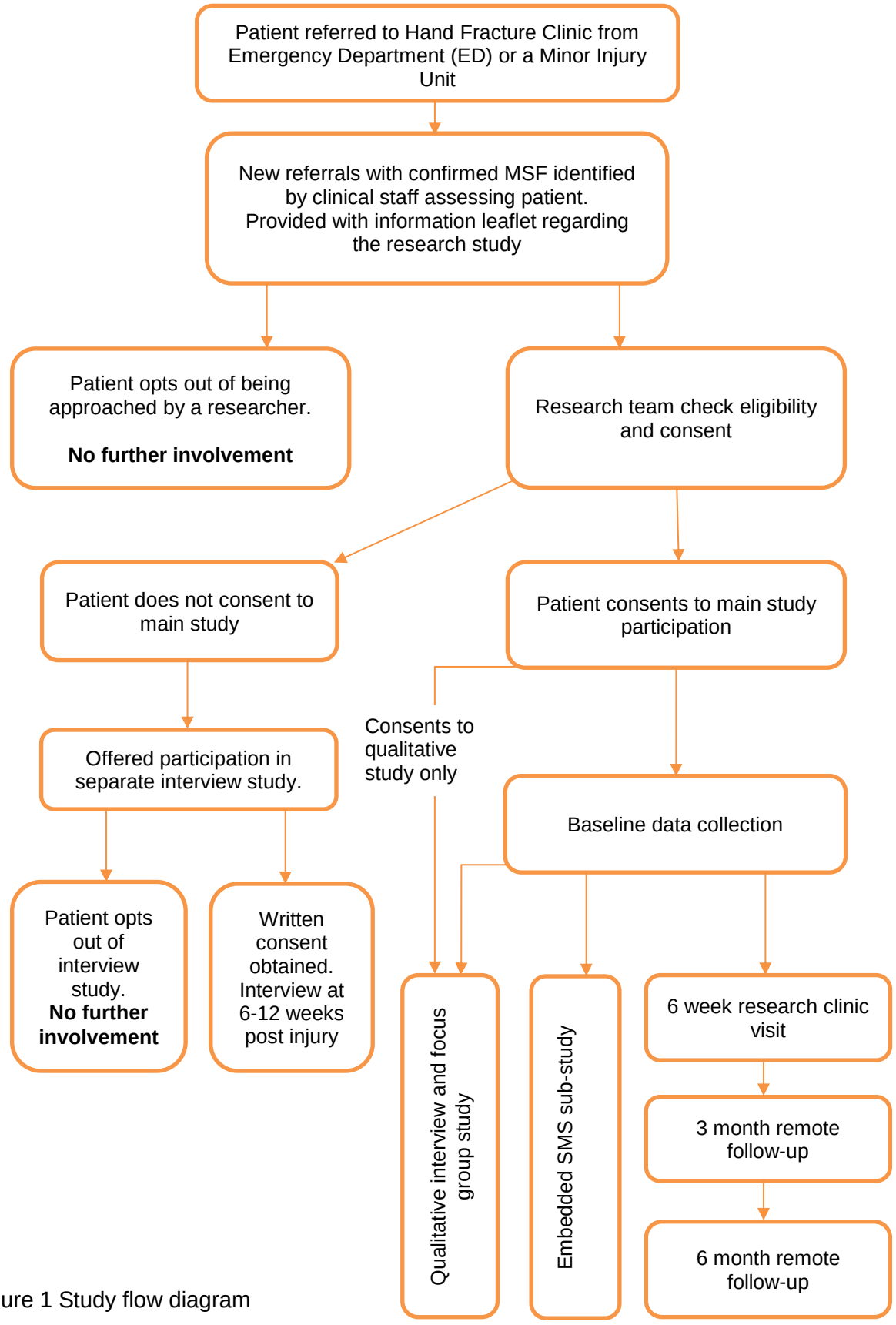

Figure 1 Study flow diagram

FLOW DIAGRAM OF STUDY: REMOTE RECRUITMENT

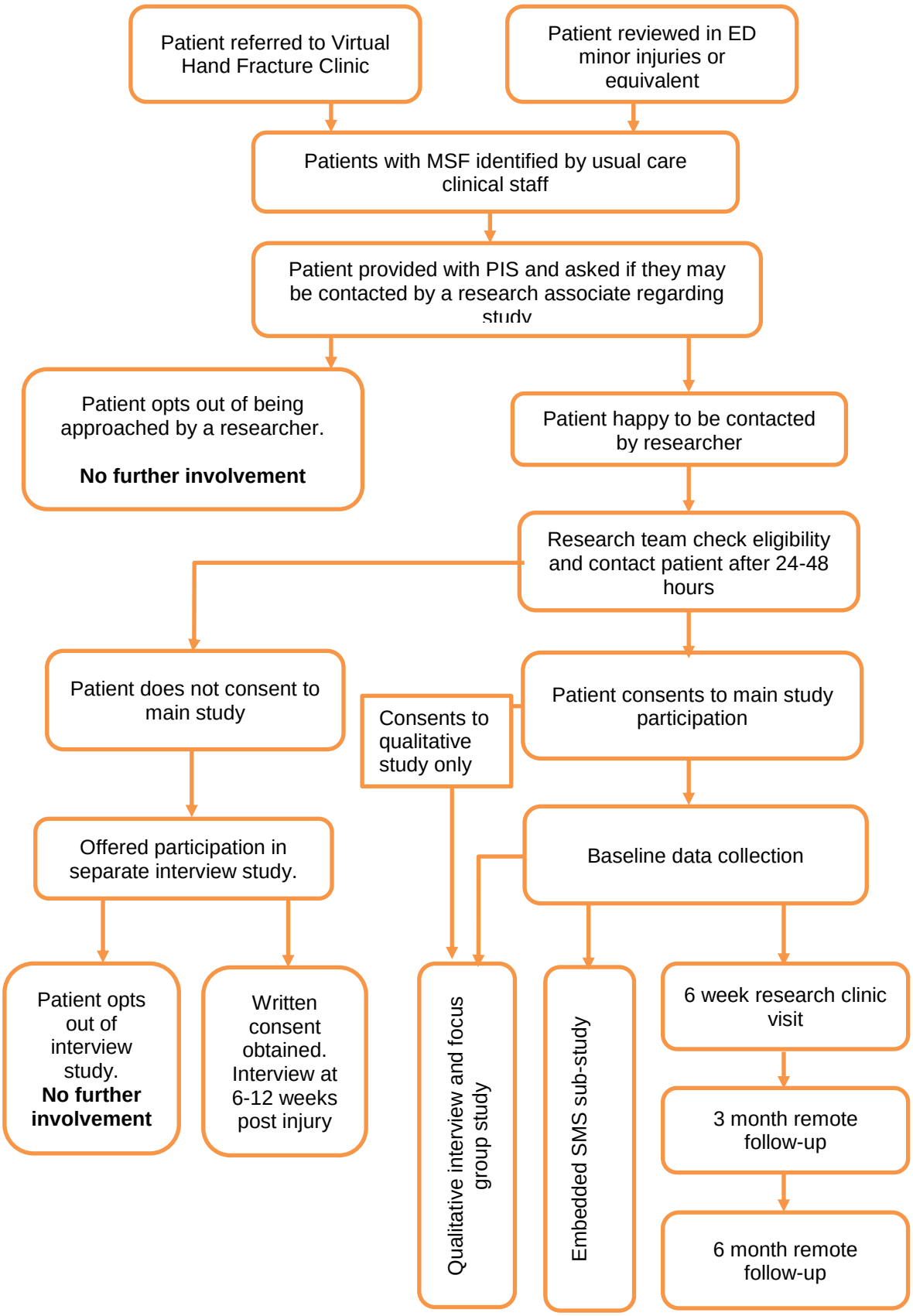

Figure 2 Study flow diagram: remote recruitment

STUDY PROCEDURES AND ASSESSMENTS

Table 1 Study procedures and assessments

	Screening and enrollment	6 week research clinic visit	3 month remote follow-up	6 month remote follow-up
Screen for eligibility	X			
Consent	X			
Baseline characteristics and patient demographics	X			
Record details of treatment	X	X	X	X
Hand Health Profile of the Patient Evaluation Measure (PEM)	Preinjury and baseline	X	X	X
Patient Reported Outcome Measurement Information System Upper Extremity (PROMIS-UE)	Baseline	X	X	X
Shortened Disabilities of the Arm, Shoulder and Hand Questionnaire (*Quick*DASH)	Preinjury and baseline	X	X	X
European quality of life questionnaire (EQ-5D-5L)	Preinjury and baseline	X	X	X
Global rating of change (GROC) scale	Baseline	X	X	X
ROM		X		
Grip strength		X		
Rotation		X		
Extensor lag		X		
Radiographic evaluation of routine care and post treatment imaging		X		
Complications		X	X	X
Interviews with consented individuals for nested qualitative study		X	X	
Focus groups with consented individuals for nested qualitative study		X	X	X
Participant self-reported return to work		X	X	X
NHS hospital resource use data		X		

Treatments

Both proposed surgical and non-surgical treatments represent current practice and are provided as usual care by hand specialists in the NHS. This observational study will not interfere with current care for the treatment modalities under comparison.

There will be no randomisation, allocation of treatment or blinding/concealment of allocation. Patients will undergo standard care as per their treating clinician. Patients will enter a group according to their primary mode of treatment on enrolment into the study. This will be decided by the patient's clinical care team and will not be affected by their involvement in the study.

Surgery: Any surgical treatment, defined as insertion of metal via an open or percutaneous approach in an operating theatre, such as open reduction internal fixation (ORIF), closed reduction internal fixation, intramedullary or extramedullary wiring and external fixation.

Non-surgical treatment: Any "non-surgical" treatment, defined as regimens with or without reduction (partial or complete) of the fracture, any type of splinting or cast, and/or immediate or delayed mobilisation delivered in a clinic or therapy room environment.

Rehabilitation: All patients will receive physiotherapy/hand therapy as per their treating physician and local policy. There will be no restriction on additional therapies as per the concomitant treatments section.

The mode of treatment and type, including length of immobilisation (if any) and any change in treatment will be recorded.

Follow-up

Follow-up will be as follows (see Table 2):

- Research clinic visit at 6 weeks
- Remote follow-up at 3 and 6 months
- Text messages as per embedded SMS sub-study

Participants who do not have access to a computer or email can opt for postal versions of questionnaires.

At any time during follow-up, study participants will be able to contact the study team for assistance with the questionnaires (technical support or clarification). The study team will send reminders (via telephone, text message, letter or email) to participants that questionnaires are ready for completion and will follow-up (via telephone, text message, letter or email) outstanding questionnaires to achieve maximum completion.

Details of the data collection at each time point are summarised in Table 2.

Table 2 Data collection time points

Time point	Data collection
Baseline	Demographic data, injury details, PEM, Quick DASH, EQ-5D-5L, GROC
6 weeks	ROM, grip strength, extensor lag, PEM, PROMIS-UE, Quick DASH, EQ-5D-5L, GROC, complications, resource use
3 months	PEM, PROMIS-UE, Quick DASH, EQ-5D-5L, GROC, complications, resource use

6 months	PEM, PROMIS-UE, Quick DASH, EQ-5D-5L, GROC, complications, resource use

Assessments

Patient Reported Outcome Measures (PROM)
Discussions between clinicians, patients, therapists and researchers at the MSF consensus workshop supported the use of a PROM as the primary outcome measure in a future RCT. As there are no core outcome sets for hand trauma, I will assess which of the following PROM are best suited for studying MSF. The following were prioritised due to their ease of use and validity. They will be collected at baseline, 6 weeks, 3 months and 6 months.

Patient Evaluation Measure (PEM)
The PEM consists of 11 items relating to hand function and appearance, each scored from one to seven from best/normal to worst. It was described in 1995 by Macey and Burke following an international multidisciplinary meeting in the UK (31). It is reliable, valid and responsive for assessing hand disorders (32, 33) and is the PROM of choice in the British Society for Surgery of the Hand (BSSH) National UK Hand Registry (www.ukhr.net).

Patient-Reported Outcomes Measurement Information System Upper Extremity (PROMIS-UE)
The PROMIS UE (PROMIS® UE Item Bank v2.0) is a computerised adaptive test, developed by the United States National Institute of Health using item response theory. It has been validated in upper limb fracture and is designed to minimise patient burden and theorised to measure latent traits more precisely than existing PROMs (34). For participants who do not engage with electronic means, a paper-based short form alternative version is available.

Shortened Disabilities of the Arm, Shoulder and Hand Outcome Measure (*Quick*DASH)
The Disabilities of the Arm, Shoulder and Hand Score (DASH) is the most commonly used PROM in hand and wrist trauma, and has consistently demonstrated good reliability, validity and responsiveness in several psychometric studies (35). It consists of 11 items, developed from the original 30-item DASH to improve practicality and eliminate item redundancy (36).

European quality of life questionnaire (EQ-5D-5L)
The EQ-5D-5L is a validated, generalised and standardised instrument comprising a Visual Analogue Scale (VAS) measuring self-rated health and a health status instrument, consisting of a five-level response for five domains related to daily activities (37). This standardised measure of health status provides a simple, generic measure of health for clinical and economic appraisal (38).

Global Rating of Change (GROC)
The GROC scale is commonly used as an anchor when calculating MCID. It is designed to quantify a patient's improvement or deterioration over time, thus providing a means of measuring self-perceived change in health status (39). A 7 point scale ranging from -3 (very much worse) to +3 (very much better), with 0 indicating "unchanged", will be used.

At baseline, participants will be invited to complete the above questionnaires electronically on an iPad, which will be specifically provided for the sole use of the study. Each participating centre will be provided with an iPad to aid collection of the data. iPads will be used due to their ease of use for study participants and portability, allowing research consultations to be held in rooms without IT equipment.

All participants will also complete the above questionnaires during their 6 week research visit, either using an iPad or desktop computer/laptop depending on the IT facilities available in the consultation room.

Thereafter, PROMs will be collected remotely at 3 and 6 months. Participants who do not have access to a computer or e-mail can opt for postal versions of questionnaires. A pre-paid envelope will be provided for return of postal questionnaires.

Clinical Outcomes

The following clinical outcomes will be collected at the 6 week research clinic visit;

1. Active Range of motion of the affected digit
2. Grip strength of the affected hand
3. Rotation
4. Extensor lag of the affected digit

Range of Motion (ROM)

Active range of movement of affected digit(s) will be assessed with a finger goniometer using a standardised protocol. A single Total Active Motion (TAM) score will be derived by adding metacarpophalangeal (MCP) flexion, proximal interphalangeal (PIP) flexion and distal interphalangeal (DIP) flexion and subtracting any MCP, PIP or DIP extension deficit. Hyperextension of joints will be recorded as zero. TAM of the affected digit will be divided by the TAM of the contralateral unaffected digit to derive a % TAM for analysis. Where the contralateral unaffected digit is unavailable, this will be replaced by the mean TAM of the unaffected same digits available in the sample.

Grip Strength

Palmar grip will be assessed using a hydraulic dynamometer (Jamar) following a standardized protocol for administration (40). The best of three trials will be recorded for the affected side and unaffected hands. For analysis, percentage grip strength will be derived by dividing measurements in the affected hand by the unaffected hand. Where a contralateral unaffected hand is not available, this will be replaced by the mean grip strength of the unaffected hands available in the sample.

Rotation

Rotation of the affected digit will be checked by assessing nail plate alignment with the fingers flexed at the MCP joint, partially flexed at the PIP joint and extended at the DIP joint (as per figure 3 below). The angle of the nail should correspond to the plane of the palm. Some rotation may be normal for the patient, therefore comparison to the contralateral side is imperative.

If the participant is unable to flex the joints as described above, rotation will be assessed by assessing nail plate alignment, in comparison to the contralateral hand, by looking at the fingers end-on with the fingers held as flexed as pain allows.

The presence of finger crossover of the affected digit, in comparison to the contralateral side, will be assessed by asking the participant to make a fist. Pseudorotation of the metacarpal may be seen as a rotational deformity of the digit on initial assessment which is no longer apparent on subsequent examinations. There is a high incidence of pseudorotation of the metacarpal due to soft tissue swelling (41).

Rotation will be assessed at baseline and 6 weeks.

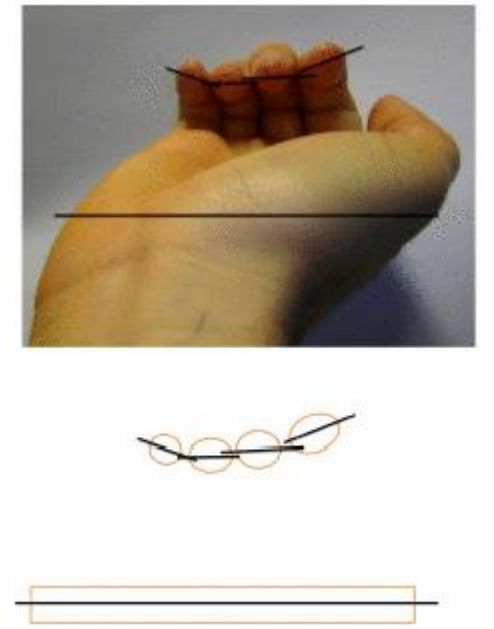

Figure 3 Examination of rotation of the fractured digit. Reproduced from Principles of Hand Fracture Management by D. N Haugton et al, 2012, The Open Orthopaedics Journal 6(Suppl 1:M5) 43-53

Extensor lag
The presence of an extensor lag will be assessed by asking the participant to extent the fingers at the MCP, PIP and DIP joints. Any residual lag in extension of the injured digit at the MCP joint with the PIP and DIP joints held in extension in comparison to its neighbouring digits, will be measured using a finger goniometer. Extensor lag at the MCP joint of the injured digit will be assessed at 6 weeks.

Radiographic evaluation
No additional radiographs, other than those taken as part of routine care will be undertaken. However, it is anticipated that participants will receive radiographs as part of the initial assessment of their injury. The following parameters will be assessed on initial radiographs, taken at the time of presentation to a healthcare facility:

- Laterality
- Fracture location
- Fracture morphology
- Shortening
- Angulation
- Step-off deformity

Location
The location of the fracture will be determined, by finding its centre on the anteroposterior radiograph, as described in the AO/OTA Fracture and Dislocation Classification Compendium. The distance from the centre of the fracture to the base of the metacarpal (length a) will be calculated, and recorded as a proportion of the total length of the metacarpal, (from the base to the tip of the distal segment, length b), as per Figure 3.

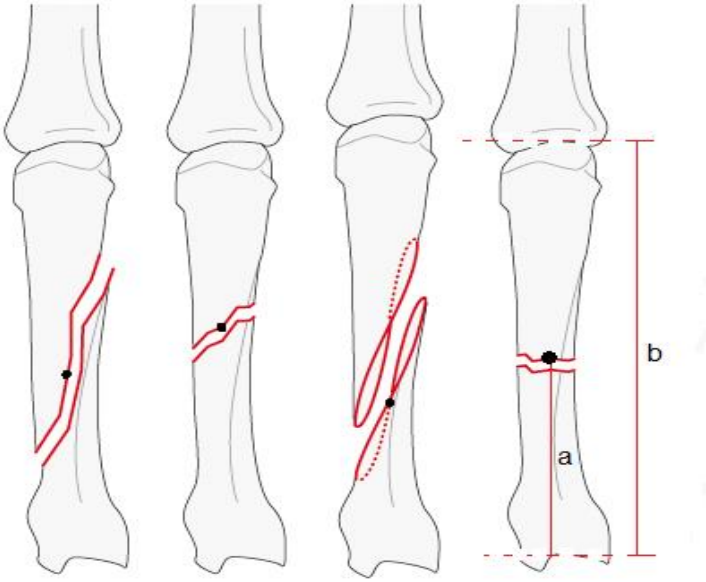

Figure 4 Calculating location of metacarpal shaft fracture on anteroposterior radiographs, a(mm)/b (mm)

The centre is defined as follows (see Figure 4):

- In a simple fracture, the centre of the fracture is obvious.
- In a wedge fracture, the centre is at the level of the broadest part of the wedge.
- In a fragmentary wedge and a multi-fragmentary fracture, the centre can be determined only after reduction.

Fracture morphology

Fracture pattern will be described as per the AO/OTA fracture classifications (7). Spiral, transverse and oblique fractures have a single circumferential disruption of the diaphysis. An oblique fracture forms an angle ≥30° to a line perpendicular to the long axis of the bone (see Figure 4).

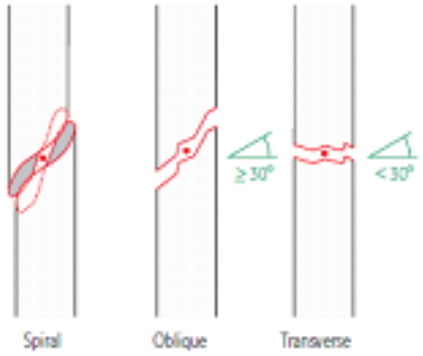

Figure 5 Calculating the centre of the fracture on anteroposterior radiogarphs. Reproduced from Meinberg EG, Agel J, Roberts CS, Karam MD, Kellam JF. Fracture and Dislocation Classification Compendium-2018. J Orthop Trauma. 2018;32 Suppl 1:S1–S170

Oblique fractures can be subcategorized as “long oblique” (fracture line is between 30° and 60° relative to the long axis of the bone) and “short oblique” fractures (approximately 30° relative to the long axis of the bone). A transverse fracture forms an angle ≤ 30˚ to a line perpendicular to

the long axis of the bone. A multi-fragmentary fractures consist of more than two fracture fragments (7).

Shortening
Shortening, in mm, will be assessed using standard Picture Archiving and Communication System (PACS) measurement tools. There are challenges in accurately measuring shortening in MSF, as it may be due to overlap or angulation. Westbrook & Davis 2007 described a method for evaluating metacarpal fractures of the little finger, utilising radiographs of the injured and contralateral hand for comparison (42). However, additional radiographs of the contralateral uninjured hand will not be taken as part of this observational feasibility study. Accurate estimates of shortening of the injured metacarpal in comparison to the contralateral uninjured hand are therefore unattainable. As such, shortening in transverse and short oblique fractures may be assessed by measuring overlap of fracture fragments. Assessing anchor points in long oblique or angulated fractures is difficult and therefore accurate estimates of shortening in such cases may not be possible.

Angulation
Mid-medullary canal measurement on the lateral view will be used to calculate angulation. The distal line is drawn from the mid-medullary point in the centre of the fracture, to the most distal point of the metacarpal head, and the proximal line centrally through the medullary canal of the shaft (Figure 6). The angle between these two lines will be measured using standard PACS software. This method has demonstrated good inter and intra-observer reliability and validity in studies of metacarpal neck fractures (43, 44).

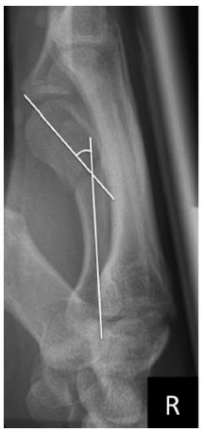

Figure 6 Method of mid-medullary canal measurement on the lateral view. Reproduced from Sletten, I. N., Nordsletten, L., Hjorthaug, G. A., Hellund, J. C., Holme, I., & Kvernmo, H. D. (2013). Assessment of volar angulation and shortening in 5th metacarpal neck fractures: an inter- and intra-observer validity and reliability study. Journal of Hand Surgery (European Volume), 38(6), 658–666.

Step-off deformity
The presence of a step-off deformity, such that the fracture line at one cortex (i.e. dorsal) of one fracture fragment overlaps the fracture line at the opposite cortex (i.e. palmar) of the adjacent fragment, as viewed on lateral, anteroposterior or oblique radiographs, will be recorded.

Return to work and recreational activities
Return to work and recreational activities will be self-reported by participants. The number of days off work, ability to perform usual activities whilst at work and ability to participate in their usual recreational activities will be recorded at the 6 week research clinic visit. This will also be

assessed in the work and sports/performing arts modules of the QuickDASH, collected at 6 weeks, 3 months and 6 months.

Resource use
A purposely designed proforma will be used to collect patient NHS resource level information and return to work. Use of primary, secondary and community health-care, use of splints/casts and medications, as well as Personal Social Service costs, out-of-pocket expenses and lost productivity information will be collected at the 6 week research clinic. Patient recollection of resource use has been shown to be accurate in terms of the intensity of use of different services (45).

Number of therapy and outpatient appointments will be sought from the clinical records. Unit cost data will be obtained from national databases such as NHS reference costs, the BNF and PSSRU Costs of Health and Social Care (30). Where these are not available, the unit cost will be estimated in consultation with the finance officer at each participating centre.

Complications
Complications will be identified by review of the patients' healthcare records at 6 weeks, 3 months and 6 months. Cosmesis will be assessed from question 10 of the PEM, at 6 weeks, 3 months and 6 months. Other participant reported complications will be recorded at the 6 week research clinic visit.

Criteria for terminating study

As this is an observational feasibility study, there are no anticipated safety or efficacy concerns. As such, there are no criteria for terminating the study. If, in the highly unlikely event the study is discontinued prematurely, all data collected up until that point will be archived according to the archiving section below.

STATISTICAL CONSIDERATIONS

Sample size and justification

As this is a feasibility study, formal sample size calculations for between group comparisons are not appropriate. However, we will seek to include as many as 84 participants in the study, aiming for comparable numbers in each treatment group. This will be achieved through our target recruitment rate of two-three patients/week over a 6 month period, totalling between 56-84 patients.

This sample size will enable estimation of recruitment fraction with margin of error (half width of 95% confidence interval) of <9 percentage points, and of proportions estimated from the recruited sample, such as completeness of follow up, to within 13 percentage points.

Analysis of outcomes

To address the feasibility aims, data analyses will primarily be descriptive with 95% confidence intervals to quantify uncertainty in estimates where appropriate. As estimation of between-treatment differences in patient-reported or clinical outcomes is not a study objective, methods are not described here.

A flow diagram showing progress through all stages of the study will be produced. Number of eligible participants approached, recruited, enrolled and completeness of data analyses and follow-up will be recorded. Recruitment rates to both the main cohort and qualitative elements of

the study will be noted and compared. Number of eligible patients approached and not enrolled will also be recorded.

Numbers and characteristics of participants will be summarised using appropriate descriptive statistics. Descriptive summaries of outcome data at each time point will be presented. Completeness of data collection will be compared between the two groups.

Stata statistical software (StataCorp LLC, Texas USA) v15.1 or above will be used to analyse the data. Details regarding planned analyses for the SMS sub-study will be documented in a Statistical Analysis Plan.

Minimal Clinical Important Difference (MCID)

Minimum clinically important differences for each patient reported outcome measure (PROM) at 3 months will be estimated using three anchor-based responsiveness statistics: (i) standardised response mean; (ii) effect size and (iii) Guyatt's Responsiveness Index. This analysis, along with participant ranking of different PROMs, will guide the choice of PROM for the definitive trial.

An estimation of the MCID will also be calculated by distribution based methods, using the standard error of measurement, standard deviation and effect size. Estimating the MCID using both anchor and distribution based methods allows for triangulation of results and assessment of any variation in estimates. The minimal detectable change will also be calculated to ensure the MCID is greater than the measurement error of the PROM.

The sensitivity and specificity of the PROM will be assessed in conjunction with the MCID, as calculated above.

Any subsequent amendments to this initial statistical analysis plan will be clearly stated and justified.

ECONOMIC EVALUATION

Direct observation of procedures will be used to produce a 'micro-cost' estimate for surgical and non-surgical treatments by combining resource use with unit costs provided by hospital finance departments. Duration of each procedure, theatre staffing, consumables, imaging, supplementary devices, post-operative recovery time and rehabilitation inputs will be recorded from primary sources, such as theatre log systems and patients' electronic and paper clinical records.

Standard unit costs will be used to estimate NHS costs of care in the 6 months post-treatment. Unit cost data will be obtained from national databases such as the BNF and PSSRU Costs of Health and Social Care 2017 (30).

Health related quality of life will be estimated using the EuroQol (EQ-5D-5L) (38). The EuroQol (EQ-5D-5L) will be collected at baseline, 6 weeks, 3 months and 6 months.

Participant self-reported return to work data will be collected. The 6 week research clinic visit will also be used to record indirect costs borne by participants and carers as a result of attending hospital visits, as well as direct non-medical costs (including travel expenses) attributable to their injury.

Procedures for missing, unused and spurious data

As this is a feasibility study, establishing the amount of missing data is a feasibility objective and therefore methods to address such data are not applicable.

Definition of populations analysed

This section is not applicable to this study as there will be no allocation of treatment and therefore no non-compliance issues.

NESTED QUALITATIVE STUDY

Qualitative study background and rationale

A qualitative study, consisting of patient interviews and focus groups, will be integrated into the study to provide detailed patient-centred insight into acceptability and research conduct. All patients who agree to participate in the cohort study and those who do not will be offered the opportunity to take part in the qualitative study. Written informed consent will be separately attained for this element of the study.

Recent research has supported the integration of qualitative research within randomised controlled trials and feasibility studies (46-49). This body of work highlights the role of qualitative research in generating personalised and complementary insight to support the design and delivery of trials, as well as informing the interpretation and implementation of findings (46-49). The literature also suggests that there is greater potential to improve trial/study delivery where qualitative elements are fully embedded within the main trial/study (47). Moreover, the integration of qualitative methodology within trials/studies has also been explicitly advocated by Medical Research Council (MRC) Guidelines for the Development and Evaluation of Complex Interventions (50, 51).

Issues often addressed using qualitative methodology include; the lived experience of the condition of interest and how it is perceived; the acceptability and feasibility of interventions or outcome measures collected; the design and conduct of the research; and the impact of the research on the individual. These are all pertinent topics in the assessment of MSF.

Little is published on patient experience following MSF. Exploring issues such as perception of the injury, its impact on work and personal life, as well as the socioeconomic impact, are integral to understanding the overall experience of MSF. Exploring participants' perceptions around study procedures and collection of study data will provide valuable information to inform the design of the future trial. This, alongside the fact that MSF affect a young and often transient population, with low recruitment and retention rates experienced in similar patient groups in previous studies (27, 52), supports the integration of this qualitative study within the prospective cohort study (53).

Aim

To provide complementary, detailed and person-centred insight that will inform RCT design through the identification of barriers to participation amongst patients with MSF, and to develop novel solutions to engage these cohorts in research.

Objectives

1. To explore participant experience of MSF, treatment and recovery
2. To explore participant experience of research processes and study burden associated with outcome measures

3. To gain recommendations on future study design and mechanisms to facilitate study delivery
4. To explore the use of health technology applications and social media in optimising participation and engagement in research

Qualitative study regimen

Participant selection and sampling

A purposive sample of 12-16 participants, who indicate a willingness to be interviewed and/or attend focus groups, will be recruited to the qualitative study. Participants who decline to participate in the main cohort study will also be invited for interview. We will aim for a minimum of 12 participants from the main cohort study, with equal numbers from both treatment groups, and four outside the study. This will ensure a broad dataset.

A pre-defined sampling frame will be constructed to guide participant selection and to ensure the interview and focus group sample broadly reflects general patterns in the incidence of MSF, prioritising young people (under 40 years) (See Table 3). There will be some natural variation within such a group, allowing us to make some exploratory comments about occupation, etc. alongside stronger conclusions about the experience/opinion of younger men.

Table 3 Sampling frame

	Age		**Participants who do not consent to cohort study**
	Under 40 years	**Over 40 years**	
Surgical treatment	4	2	2
Non-surgical treatment	4	2	2
Total	**8**	**4**	**4**

Patient Interviews

Individual patient interviews will be used to generate detailed, personalised and contextualised accounts of the injury, its treatment and their experience (or opinion about) involvement in research. An interview guide will be used to ensure broadly similar topics are covered in both interviews and across participants. However, interviews will be semi-structured to allow in depth exploration of individual expressions.

Aligned to the cohort study, we would like to interview 12-16 participants from both treatment arms as well as those who decline to take part in the main cohort study. We will aim for 12 participants from the main cohort study, with equal numbers from both treatment groups, and four outside the main cohort.

Participants will be interviewed once at 6 - 8 weeks, with a preference for face-to-face interviews, to provide insight regarding medium-term trajectory, research processes and the injury and its treatment. There will be an option for patients to choose to have a telephone/teleconference interview if necessary, instead of a face-to-face interview. Participants' thoughts on research payments and payment schedules is also of interest to the clinical research population and will be explored in individual interviews. Interviews are expected to last 45 - 60 minutes.

At 3 - 6 months, following clinical and patient-reported data collection (i.e. at the study primary follow-up point), participants (previously interviewed at 6 – 8 weeks) will be offered a telephone consultation (or fact-to-face interview if preferred), to reflect on their overall recovery. Second interviews are expected to be of a shorter duration in comparison to the initial interview, lasting approximately 20 - 30 minutes (see Table 4).

Those who decline to take part in the study will be invited to interview to discuss research processes. Interviewing those who do not consent to both the main cohort and qualitative study will provide invaluable information regarding study processes and ensure a round dataset. The same interview schedule will be used for participants who decline to participate in the main cohort study, with some slight adjustments in the prompts used and phrasing of questions.

Table 4 Timing of interviews

Interview	Mode	Timing
First interview	Face – to - face	6 - 8 weeks
Second interview	Telephone or face – to - face	3 - 6 months

All interviews will be conducted by RT at locations and times of convenience for participants, which may be Queen's Medical Centre, Nottingham, the Pulvertaft Hand Centre, Derby, the individual's own home or by telephone (as per participant preference). Interviews will be audio-recorded and fully transcribed by RT.

Researchers will be subject to the University of Nottingham's fieldwork and lone working policies when conducting interviews at the participant's homes or outside of University premises. This requires a risk assessment to be completed and authorised by the school safety officer prior to any fieldwork being initiated.

All reasonable expenses will be reimbursed and appropriate payment in line with "INVOLVE" recommendations offered to participants. A nominal payment of £15 per interview will be offered to all participants by means of a gift voucher.

Focus groups

Focus groups will aim to cover a range of outcome topics, research processes and to investigate the use of technology and social media in healthcare research. Focus groups encourage interaction between individuals and group discussions, allowing consensus agreement to be reached where possible.

Three focus groups will be held as outlined in table 5 below. These will all be held at Queen's Medical Centre, Nottingham and will be facilitated by RT. There will be an option for a teleconference or video conference focus group session if necessary, instead of a face-to-face focus group. The timing of focus groups will depend on the availability of participants to ensure accessibility and inclusivity to all participants. Focus groups typically work well with approximately eight individuals. Therefore, we will aim for eight participants per focus-group. All focus groups will be audio-recorded and fully transcribed by RT.

Timing of focus groups

- Focus group one 6 - 8 weeks
- Focus group two 3 – 4 months
- Focus group three 5 - 6 months

All reasonable expenses will be reimbursed and appropriate payment in line with “INVOLVE” recommendations offered to participants. A nominal payment of £25 per focus group attendance will be offered to all participants by means of a gift voucher.

Table 5 Outline of focus groups

Group	Focus	Timing
Focus group one	Suitability of outcome measures and clinical assessments	6 – 8 weeks following injury
Focus group two	Research process and challenges to participant involvement	3 - 4 months following injury
Focus group three	Use of digital applications and social media in clinical research	5 – 6 months following injury

Qualitative data management

Interviews and focus groups will be audio-recorded and fully transcribed by RT, using recording software held by the Centre for Evidence Based Hand Surgery, University of Nottingham.

All data recordings and transcripts are classed as source data and will be retained in the study archives. Personal identifiers will be removed to maintain confidentiality. They will be stored securely as described in detail in the data protection section.

Qualitative study analysis

NVivo 12 or above Pro software (QSR International Pty Ltd, Victoria, Australia) will be used to organise and analyse qualitative data.

A thematic, inductive approach as described by Braun and Clarke (54), will be used to analyse interview and focus group data. We will adopt a six-phase systematic approach consisting of; (1) data familiarisation - reading and re-reading the data; (2) generation of initial codes - generating succinct labels (codes) that identify important features of the data that might be relevant to answering the research question; (3) identification of themes through merging and grouping of codes - to identify significant broader patterns of meaning (potential themes) and collating data relevant to each theme; (4) review of generated themes – checking themes against the dataset and refining them where necessary; (5) defining and naming themes – developing a detailed analysis of each and deciding the informative name for each theme; and (6) finalisation of themes and generation of a final report – weaving together the analytic narrative and data extracts, and contextualising the analysis in relation to existing literature.

ADVERSE EVENTS

The occurrence of an adverse event as a result of participation in this observational study is not expected.

Complications of MSF and current treatments

The treatments patients receive are widely available within the NHS. Adverse events that could be due to these treatments are therefore outcomes for this study (complications) and will be collected as such, rather than reported as an adverse event. Reporting of complications associated with

treatment delivery will be recorded in study CRFs in a structured format and do not need to be reported to the REC. Complications specific to this study are listed below.

- Stiffness of the affected finger at 6 weeks defined as persistent restriction in range of motion compared with the contralateral uninjured digit.

- Infection, as defined by the National Institute for Health and Care Excellence (NICE) guideline, Surgical site infections: prevention and treatment [NG125] (55).
    - Requiring oral antibiotics only
    - Requiring IV antibiotics
    - Requiring surgical washout/debridement
    - Requiring surgical washout, debridement and removal of metalwork

- Delayed wound healing, defined as any wound that has not healed by 2 weeks, in line with the definition used in the Scaphoid Waist Internal Fixation for Fractures Trial (SWIFFT), due to comparability of the patient cohort (young, adult males) (52, 56).

- A diagnosis of CRPS as documented in the healthcare records.

- Tendon complications
    - Tendon irritation; characterised by pain, swelling and functional impairment of the affected tendon.
    - Tendon laceration or rupture; defined as partial or complete disruption of the tendon identified on clinical examination or direct inspection (in theatre).

- Nerve complication (hypoesthesia or numbness in the territory of a nerve).

- Malunion, defined as healing of the fracture in a non-anatomical position that leads to functional impact or impaired use of the hand, which is not acceptable to the participant.
    - Leading to surgical intervention (corrective osteotomy) by 6 months

- Non-union, defined as symptomatic persistent visible fracture line characterised by absence of full bridging trabeculae on radiographs at >3 months post injury, as diagnosed by the treating team.
    - Leading to surgical intervention (non-union surgery) by 6 months

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, informed consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) Research & Development (R&D) departments, and the Health Research Authority (HRA), if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval/favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Department of Health Policy Framework for Health and Social Care, 2017.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant or other legally authorised representative shall both sign and date the Informed Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Study Master File. A second copy will be filed in the participant's medical notes and a signed and dated note made in the notes that informed consent was obtained for the study.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

RECORDS

Case Report Forms

Each participant will be assigned a study identity code number, allocated at enrolment, for use on CRFs, other study documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd/mm/yy).

CRFs will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, date of birth, local hospital number or NHS number, and Participant Study Number (the Study Recruitment Log), to permit identification of all participants enrolled in the study, in accordance with regulatory requirements and for follow-up as required.

CRFs shall be restricted to those personnel approved by the Chief or local Principal Investigator and recorded on the 'Study Delegation Log.'

CRFs are an integral part of the study and subsequent reports. The CRFs, therefore, must be legible and complete.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, current medical records, laboratory results and records. A CRF may also completely serve as its own source data. Only study staff as listed on the Delegation Log shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The CRF and all source documents, including progress notes and copies of laboratory and medical test results shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The CRF will only collect the minimum required information for the purposes of the study. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method). Information about the study in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information. The data will not be used outside the University premises.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for study participants and staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

STUDY CONDUCT AND DATA

Study conduct and data may be subject to systems audit of the Study Master File for inclusion of essential documents; permissions to conduct the study; Study Delegation Log; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, timeliness of visits); adverse event recording and reporting; accountability of study materials and equipment calibration logs. Entries on CRFs may be verified by inspection of a sample of CRFs against the source data for verification of entries made. In addition, the subsequent capture of the data on the study database will be checked.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The Study Master File and study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons.

STATEMENT OF CONFIDENTIALITY

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above. Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

Results of this study will be reported fully and made publicly available when the research has been completed. The outcomes of the study will be prepared as a research paper for publication in suitable peer-reviewed journals. Reporting will be in compliance with Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (57). In order to fulfil reporting guidelines, a copy of the research paper will also be sent to the National Institute for Health Research (NIHR) programme issuing the funding contract.

The findings will be presented at national and international meetings of relevant scientific societies, such as the British Society for Surgery of the Hand Scientific Meeting, Federation of European Societies for Surgery of the Hand Meeting and the International Federation of Societies for Surgery of the Hand Meeting. We will also publish key findings on the Centre for Evidence Based Hand Surgery (CEBHS) website, and via the "Hand Evidence Updates", distributed by the CEBHS to over 800 national and international members.

Feedback from the Metacarpal Shaft Fracture Patient Advisory Group will guide distribution of findings to the public. This will include but not be limited to; newsletters, local media outlets, events and plain English summaries of all published journal articles. Social media platforms will also be used to maximise dissemination of key findings as supported by evidence from the Nottingham Clinical Trials Unit (58, 59).

The study forms part of Miss Rowa Taha's doctoral project and will also be included in her final thesis.

USER AND PUBLIC INVOLVEMENT

Patients and the public have played a central role in selecting the management of MSF as a key research priority and developing the proposed project. The Hand Surgery Research Prioritisation workshop, attended by clinicians, therapists and patients, recommended the management of MSF as a key research priority (60). This was ratified by the James Lind Alliance Priority Setting Partnership on Common Conditions Affecting the Hand and Wrist (61). This joint collaboration with the BSSH involved 261 individuals, of which 41% were patients/carers and 59% were clinicians (61).

Furthermore, a MSF Consensus Workshop was held in Nottingham in 2018, bringing together patients with MSF, clinicians, therapists and researchers to share their experiences and develop the PICO framework for a future multi-centre trial. Group discussions informed the eligibility criteria and identified areas of focus for the feasibility work. Selection of patient-centred outcome measures, timing of assessments and follow-up for the proposed study were discussed. A variety of outcome measures were reviewed and the QuickDASH and PROMIS-Upper Extremity were subsequently added. One clinic visit in addition to virtual follow-up was included and follow-up was adjusted to 3 and 6 months following patient discussions. Feedback from patients who attended the workshop has informed all aspects of the research including research design, choice of outcome measures and length and location of follow-up.

This study protocol, participant information sheets and relevant consent forms have been reviewed by PPI members, with feedback provided to optimise their utility. We will set up a MSF Patient Advisory Group to inform the design, delivery and output of the research. The group will meet quarterly to discuss progress and address any issues that arise. An electronic PPI platform will also be created on the CEBHS website, to encourage regular input from patients/public.

Members of the MSF Patient Advisory Group have helped to design the interview guide for the qualitative study. Feedback from the interviews and focus-groups will also help to inform study processes throughout the study, with amendments made depending on the feedback of the advisory group.

Incorporating patient and public involvement in all aspects of the research pathway, from research design to co-development and review of all study documents, supports our commitment to ensuring sustained and meaningful PPI throughout the study.

STUDY FINANCES

Funding source

This study is funded by the National Institute for Health Research via an NIHR Doctoral Fellowship awarded to Miss Rowa Taha. This protocol is independent research supported by the National Institute for Health Research (NIHR Doctoral Fellowship - Stage 2, Miss Rowa Taha,

NIHR300197). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care."

Participant stipends and payments

Participants will not be paid to participate in the study. A nominal payment for participation in the qualitative part of the study will be offered to participants who undertake interviews and/or focus-groups. A nominal payment of £15 per interview and £25 per focus group attendance, in line with Nottingham University Hospitals NHS trust policy and "INVOLVE" recommendations, will be offered to participants by means of a gift voucher.

Travel expenses will be offered for any hospital visits in excess of usual care.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)____Alexia Karantana_____

Signature:____

Date: __14.04.2020

Deputy chief- investigator: (name) ___ROWA TAHA_____

Signature:____  _____

Date: _07.04.2020_____

Co- investigator: (name) ___Tim Davis_____

Signature: 

Date: 09.04.20

Supervising statistician: (name) Alan Montgomery

Signature: 

Date: 9 April 2020

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