Standardised Outcomes for Hand fractures and joint Injuries in adults (SO-HANDI study): Delphi Study

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Short title: SO-HANDI study – Delphi Study

Acronym: SO-HANDI

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SYNOPSIS

Title	Standardised Outcomes for Hand fractures and joint Injuries in adults (SO-HANDI study): Delphi
Acronym	SO-HANDI
Short title	SO-HANDI study - Delphi
Chief Investigator	Dr Alexia Karantana
Objectives	To identify the most important outcome domains that should be measured/assessed in clinical research relating to adult patients with hand fractures or joint injuries, with a consensus towards development of core outcome set
Study Configuration	Delphi study
Setting	Secondary care
Sample size estimate	There is no formal technique for calculating sample size for Delphi studies. There are three key stakeholder groups (hand surgeons, hand therapists, patients) and the aim is to recruit at least 30 people in each group to the study
Number of participants	Minimum 90
Eligibility criteria	Able to understand written/typed English; AND Membership of key stakeholder group: • Hand surgeon (independent practitioner level such as Consultant or equivalent) – this could include plastic surgeons or orthopaedic surgeons if a majority of their workload involves hand surgery • Hand therapist – once qualified, working independently (i.e. beyond training years) and subspecialised in hand therapy • Adult patient (≥18 ; no max limit) with either current or past diagnosis of a 'hand fracture or joint injury' as per following inclusion/exclusion criteria: ➢ Inclusion criteria: ▪ Injury including: – Phalangeal fractures – Metacarpal fractures – Carpal fractures – Distal radius fractures – Avulsion fractures

	– Primary ligamentous injury – Primary tendinous injury (closed and in proximity to a joint) – Dislocation – Subluxation ➢ Exclusion criteria: ▪ Injury including: – Primary nerve injuries of the hand – Complex hand injuries involving traumatic amputation/nerve injuries/'mangled hand' – Open primary tendinous injuries
Description of interventions	Online questionnaire (with option for postal format if required)
Duration of study	Recruitment prior to first round of questionnaire for 6-8 weeks. Overall duration of ~4 months for questionnaires to be completed. ~8 months including above and analysis. Questionnaire will consist of three rounds with analysis and restructuring of the questionnaire between each round. 15-20 minutes to complete each round
Methods of analysis	Results from each round will be analysed using pre-set consensus thresholds as elaborated further in protocol

ABBREVIATIONS

CEBHS	Centre for Evidence Based Hand Surgery
CI	Chief Investigator overall
COMET	Core Outcome Measures in Effectiveness Trials
COS	Core outcome set
COS-STAD	Core Outcome Set Standards for Development
GCP	Good Clinical Practice
HF & JI	Hand fractures and joint injuries
NHS	National Health Service
OMERACT	Outcome Measures in Rheumatology
PI	Principal Investigator at a local centre
PIS	Participant Information Sheet
PPI	Patient and public involvement
REC	Research Ethics Committee
R&D	Research and Development department
UK	United Kingdom
UoN	University of Nottingham
US	United States of America

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STUDY BACKGROUND INFORMATION AND RATIONALE

Description of the condition

Humans use their hands for a variety of actions in work, recreation and even defence (including bracing during a fall) or violence. This explains to a large extent why hands are frequently injured.

Hand fractures and joint injuries (HF & JI) are common, with a Netherlands-based study finding that 19% of all fractures diagnosed at a University hospital Emergency Department were hand fractures (phalanx, metacarpal or carpal). Approximately 76% of these were in patients aged 20 years or older [1]. The study did not determine an incidence based on the population served by the Emergency Department. A more recent and larger-scale study based in the United States of America (US) analysed data from 8 states and reported that the commonest upper limb fracture in the 18- to 34-year age group were metacarpal and phalangeal fractures (16.1 and 12.5 per 10,000 person-years, respectively) [2]. The same study also reported that in the 35- to 49-year age group, phalangeal fractures were the commonest upper extremity fracture (11.5 per 10,000 person-years). The results of this study fit with the findings of a previous United Kingdom (UK)-based study which estimated the overall incidence of hand fractures (phalangeal, metacarpal and carpal) in adults aged 20 years or more as being 18.0 per 10,000 person-years [3].

In terms of wrist fracture, a multi-centre UK-based study on patients aged 35 years or above with a distal radius (with or without distal ulna) fracture estimated an age-adjusted incidence of these injuries to be 36.8 per 10,000 person-years in women, and 9.0 per 10,000 person-years in men [4]. At the time of the study (2001), this would have extrapolated to an annual incidence of approximately 58,000 distal radius fractures in women and 13,000 in men.
The numbers stated above are likely an underestimation, as they do not account for people who do not seek medical attention for their injury or, typically in these studies, patients who may have had community/primary care management of their injury.

'Joint injuries' is an umbrella term for a number of pathologies including dislocations and subluxations (with either soft tissue injury or associated fractures), avulsion fractures and intra-articular fractures [5]. However, it can also include purely tendinous (e.g. mallet finger, acute Boutonniere's) and ligamentous (e.g. collateral ligament rupture) injuries. Due to the range of potential injuries within this term, and paucity of incidence data it is difficult to quantify the epidemiological state of 'joint injuries' – sufficed to say, it adds to the 'disease burden' as outlined above.

Why it is important to do this study

HF & JI can have significant impact on patients and healthcare resources due to restrictions on use of the hand for activities of daily living, work and leisure. O'Neill et al found that approximately 1 in 5 of their study population (with distal radius fractures) required admission to hospital, indicating the potential burden of such injuries on specialist resources [4]. A Dutch-based study analysed their national Injury Surveillance System and estimated that hand (metacarpal and phalangeal) fractures accounted for approximately 6.3% of total costs of injuries presenting to Emergency Departments in the Netherlands. This equated to

US$278 million in 2007, and considered a combination of healthcare and productivity cost [6]. HF & JI are therefore common injuries with importance both to patients and healthcare providers, and a significant economic impact to society.

The recent James Lind Alliance Priority Setting Partnership (PSP) on common conditions affecting the wrist and hand highlighted the importance of outcome selection in clinical research to patients, carers and clinicians – all five of the 'Top 10 Uncertainties' relating to hand fractures or joint injuries had an element of 'outcome' or 'result' as part of the unresolved question [7]. In recent years it has become increasingly accepted that this element should incorporate a patient perspective [8].

Despite the clear significance of such injuries at both a personal and a macroeconomic level, there is typically not a consensus on optimal treatment. There are a variety of treatment modalities and this, alongside a lack of consistency in outcome reporting and research methodology standards, makes it challenging to interpret the available evidence. Several reviews of the management of HF & JI highlight “inadequate outcome assessment” and “large variation in reported outcomes” [9–11]. Use of multiple, non-comparable outcomes across what might otherwise, on an individual basis, be considered ‘good quality trials’ hinders meta-analysis and impairs an evidence-based approach to healthcare.

One solution to this problem is a core outcome set (COS). A COS aims to define a minimum set of outcomes that should be assessed in any trial which should then improve consistency and comparability between trials [12]. In this way, more trials would likely be suitable for meta-analysis. There is also the theoretical benefit of reducing reporting bias if there is a COS for the condition under study, as there would be an expectation that all outcomes from a COS should be reported on and any omission would be quite glaring.

Work has been to done to establish standards by which COSs should be developed, and this has highlighted the importance of involving key stakeholders, including patients (or their representatives) as well as clinicians [13].

This study is a vital step in COS development, to determine the consensus of opinion on the importance of outcome domains to key stakeholder groups including patients with lived experience of hand fractures and joint injuries, hand surgeons and hand therapists.

<u>Scope</u>

Defining the scope of a core outcome set is an initial and important step in the process of COS development as highlighted in the Core Outcome Set Standard for Development (COS-STAD) recommendations [13]. Within the domain of ‘scope’ the authors of COS-STAD state the following should be clarified:

1. Research or practice setting(s) in which the COS is to be applied
2. Health condition(s) covered by the COS
3. Population(s) covered by the COS
4. Intervention(s) covered by the COS [13p4].

We have set out to develop the scope of the COS in-line with these recommendations, and the same scope will apply to this study. For the purposes of this COS, 'hand fractures and joint injuries' will include any and all of the following:

- Phalangeal fracture
- Metacarpal fracture
- Carpal fracture (scaphoid, lunate, triquetral, pisiform, trapezium, trapezoid, capitate, hamate)
- Distal radius fracture (with or without distal ulna fracture)
- Any injury with physical damage localised to a joint between the bones listed above, including dislocation, subluxation, volar plate injury, avulsion injury, ligamentous tears/sprains/ruptures, closed tendon ruptures/tears)

The COS scope will include the treatment of acute injuries as well as chronic problems such as mal- or non-union.

Complex hand injuries (e.g. 'mangled hand' and amputations requiring replantation) are outside the scope of this COS. However, a COS developed from this work might form part of the range of outcomes selected for a trial on these types of complex hand injuries.

STUDY OBJECTIVES AND PURPOSE

PURPOSE

The purpose of this study is to support COS development by identifying consensus of opinion from key stakeholder groups about pertinent outcomes of HF & JI treatment. Data gathering will be accomplished through online questionnaire over multiple rounds.

PRIMARY OBJECTIVE

To refine a comprehensive list of outcomes domains relevant to the treatment of HF & JI to a shorter list by considering the key stakeholder views and determining consensus through anonymised feedback across multiple rounds.

SECONDARY OBJECTIVE

To explore whether an alternative Delphi methodology, with items that meet the threshold for 'consensus in' or 'consensus out' being removed from subsequent rounds, would have impacted on the results obtained. This can be done with retrospective analysis by identifying which outcome domains, if any, meet an endpoint earlier than the final (third) round and what their status was (i.e. consensus in or out).

STUDY DESIGN

STUDY CONFIGURATION

Consensus development study using Delphi methods

STUDY MANAGEMENT

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

The data custodian will be the Chief Investigator.

The PhD student will lead in the study design and management, participant recruitment, questionnaire design, data analysis and write-up, supported by the academic supervisors.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration:
Enrolment will begin following ethics approval, and will run for approximately 2 months. Then the overall multi-round survey process and analysis can take place and is expected to take approximately 6 months.

Participant Duration:
The Delphi study will be three rounds running over the course of approximately 6 months. There will be a period of 6-8 weeks prior to the start of the 1st questionnaire round during which recruitment will take place. Each round will take 10-20 minutes for participants to complete.

End of the Study

The end of the study will be after analysis of the questionnaire data is complete and a report produced.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

Recruitment

A range of stakeholders will need to be recruited as Delphi panellists for the online questionnaire. Invitations will be circulated to patients through leaflets and posters in the Queen's Medical Centre adult fracture clinics and online via the Centre for Evidence Based Hand Surgery website as well as social media.
Clinicians (hand surgeons and hand therapists) will be recruited from a number of sources:

- Via contacting national and international orthopaedic, hand therapist and hand surgery societies to ask for representative members (as per eligibility criteria) who would be willing to commit to the multiple rounds of questionnaires. International Federation of Societies for Surgery of the Hand/Hand Therapists
- The Centre for Evidence Based Hand Surgery (CEBHS) Hands Surgery Evidence Updates mailing list – this is freely accessible and run by the CEBHS information specialist and subscribers to the list include mostly clinical practitioners with an interest in clinical research updates relevant to hand surgery.

Invitations will also be sent to research groups with recent publications in the field of hand fractures and joint injuries. This will be achieved by email to corresponding authors of papers covered in our systematic review.

The recruitment methods for healthcare professionals described above will potentially improve the internationality of the Delphi panellist pool as well as including the clinician researcher perspective.
Patient participants (those with relevant current or past diagnosis) will be recruited from a range of pathways, including social media call to recruitment, posters displayed in fracture clinics at Queen's Medical Centre, relevant patient advisory groups (such as that of the Centre for Evidence Based Hand Surgery, University of Nottingham), patients who have participated in the SO-HANDI interviews and focus groups and given consent to be contacted about further research, and potentially from the fracture clinic at Queen's Medical Centre itself (initial approach will be from a member of the patient's usual care team of fracture clinic doctors, nurses or therapist).

The survey will have detailed information pertaining to taking part in the study on the first screen/front page. For pragmatic reasons, only participants who are able to understand written/typed English will be eligible. Potential participants will be required to contact a researcher via email or telephone to express interest in entering the study.
It will be explained to the potential participant that entry into the study is entirely voluntary. It will also be explained that they can withdraw at any time but if this is due to an issue which we can remedy (without compromising the scientific integrity of the study) and the participant would otherwise wish to continue to take part, then we will try to resolve the issue. In the event of their withdrawal it will be explained that we will keep information about them that we already have in order for the research to be reliable.

Eligibility criteria

Inclusion criteria

Able to understand written/typed English; AND
Membership of key stakeholder group:

- Hand surgeon (independent practitioner level such as Consultant or equivalent) – this could include plastic surgeons or orthopaedic surgeons if a majority of their workload involves hand and wrist surgery
- Hand therapist – once qualified, working independently (i.e. beyond training years) and subspecialised in hand therapy
- Adult patient (≥18 ; no max limit) with either current or past diagnosis of a 'hand fracture or joint injury' as per previous study inclusion/exclusion criteria:
  - Inclusion criteria:
    - Injury including:
      - Phalangeal fractures
      - Metacarpal fractures
      - Carpal fractures
      - Distal radius fractures
      - Avulsion fractures
      - Primary ligamentous injury
      - Primary tendinous injury (closed and in proximity to a joint)
      - Dislocation

        - Subluxation
    - Exclusion criteria:
        - Injury including:
            - Primary nerve injuries of the hand
            - Complex hand injuries involving traumatic amputation/nerve injuries/'mangled hand'
            - Open primary tendinous injuries

Exclusion criteria

For patient stakeholder group participants, injury including:

- Primary nerve injuries of the hand
- Complex hand injuries involving traumatic amputation/nerve injuries/'mangled hand'
- Open primary tendinous injuries

Inability to give informed consent

Expected duration of participant participation

Recruitment will occur over an initial 6-8 weeks period. Study participants will then be participating in the study for 3 rounds of questionnaire over the course of approximately 6 months. Each round will take 10-20 minutes to complete.

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. 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 then we will keep any information about them that we already have. This data may still be used in the final analysis.

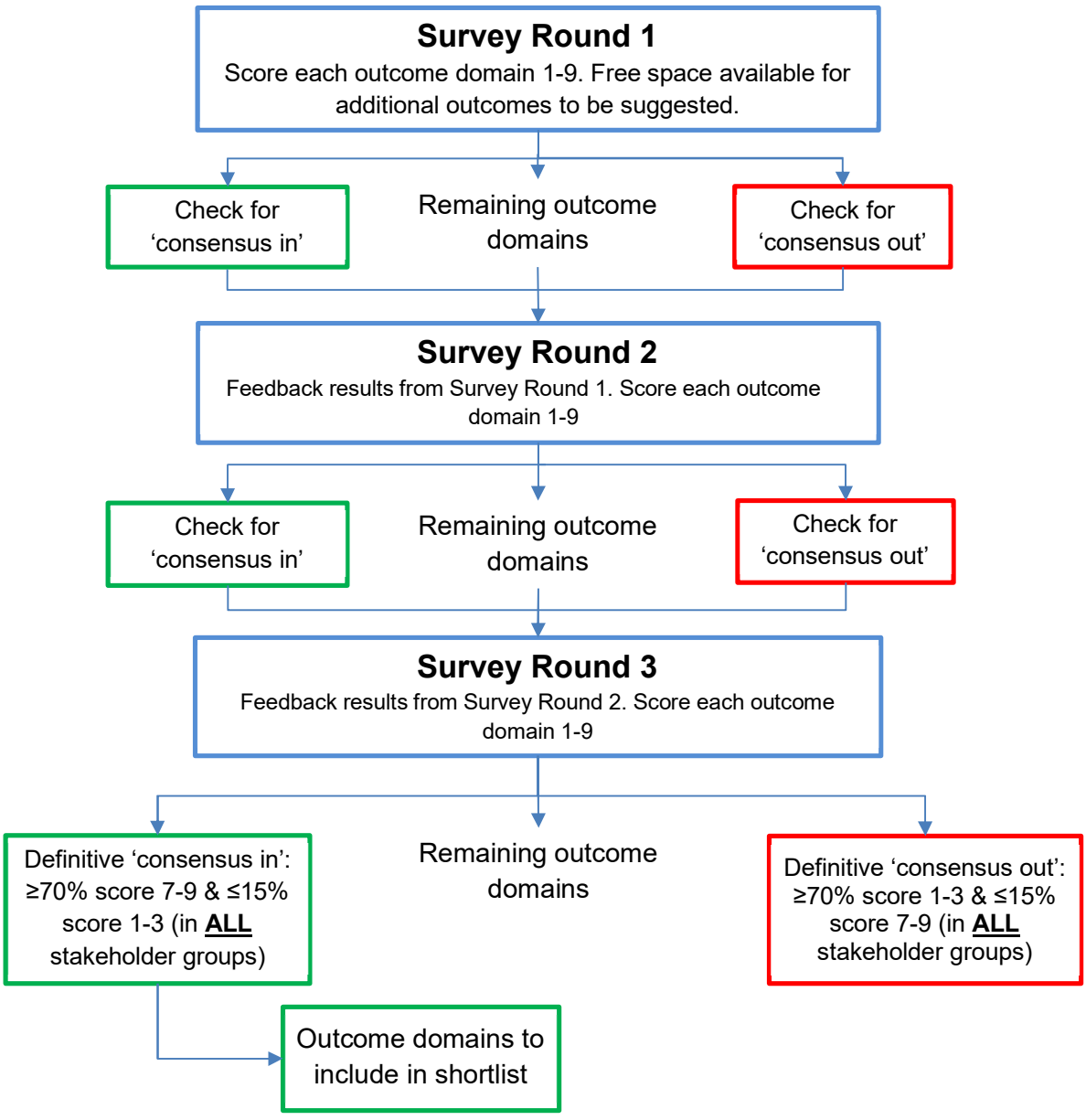
Informed consent

Invitations sent out as summarised earlier will provide contact details to allow potential participants to contact the researchers. The researchers will then provide an appropriate link to the online survey to participants. An initial registration page will include ticking boxes to confirm consent. Therefore completion and submission of this will be taken as informed consent, and no separate written informed consent will be sought. Text that will be used to form this consent statement on the eventual registration page is included in a separate document which covers the planned text for the registration page.

If for some reason a participant is unable to complete an online registration form or questionnaire, we may nevertheless be able to register on their behalf if they instead complete a paper copy. In this case a completed copy returned to us will be taken as informed consent.

STUDY REGIMEN

Invitations will be made to potential participants as described earlier. Initial contact will explain the study and why we have selected these particular potential participants. For those interested in learning more, a participant information sheet will be provided. All participants who decide to take part will be sent a link to the online questionnaire (or paper copy equivalent if necessary, with their answers then uploaded by us to the online system). Completion of each round of questionnaire will be taken as consent for ongoing participation in the study.



The survey itself will be hosted remotely via the DelphiManager software on University of Liverpool systems. This has been produced by the Core Outcome Measures in Effectiveness Trials (COMET) Initiative team specifically to assist with running of Delphi surveys pertaining to development of core outcome sets. Participants will be asked to rate

candidate outcome domains on a 1-9 Likert scale of 'importance'. There will be an option for participants to select 'unable to score'. Email, telephone and/or SMS reminders will be utilised to update participants on the upcoming start date for questionnaire completion and closure in each round as well as to send reminders to non-responders in order to minimise attrition across the Delphi .

The checks for 'consensus in' and 'consensus' out after Rounds 1 and 2 will use the same consensus thresholds as the definitive consensus check at the end of Round 3, i.e. 'consensus in' requires ≥70% score 7-9 & ≤15% score 1-3 in all stakeholder groups, while 'consensus out' requires ≥70% score 1-3 & ≤15% score 7-9 in all stakeholder groups. However, the checks at the end of the earlier rounds are for information purposes only and will not be used to reduce the number of items entering the next round.

Once recruitment is complete, the link to Survey Round 1 will be sent to all participants. This will allow synchronisation of the ensuing stages across all participants. If for some reason recruited participants decide that they no longer wish to take part and do not complete the questionnaire, then further participants may be recruited in their place as long as the questionnaire for Survey Round 1 has not yet closed. Further recruitment in this manner will only be done if necessary, and only in Survey Round 1.

On completion of Survey Round 1 all results will be collated and analysed. Any outcome domains which have met the consensus 'in' or 'out' threshold will be noted, but all items will enter Round 2. In addition, suggestions from participants for additional outcomes will be considered and may also be added to Round 2.

In Survey Round 2, the results from Survey Round 1 will be fed back to participants so that they are aware of the overall scoring by each stakeholder group for all outcome domains. They will then be asked to provide their rating for the outcome domain again, with the freedom to keep their score the same as in Survey Round 1 or alter it as they wish. Participants will also be provided a reminder of how they had scored the item in the previous round.

On completion of Survey Round 2 the results will be analysed according to the consensus criteria outlined earlier. Any outcome domains which have met the consensus 'in' or 'out' threshold will be noted, but all items will enter Round 3.

In Survey Round 3, the results from Survey Round 2 will be fed back to participants in a similar process to the previous round. They will therefore see anonymised scoring feedback from the three stakeholder groups, as well as their own specific score for each item in the previous round. There will then be a final rating required for each outcome domain.

The results from Survey Round 3 will be analysed according to the consensus criteria outlined earlier. There will also be an opportunity here to compare the final results with that of a theoretical alternative Delphi method which would have removed 'consensus in' or 'consensus out' results after each round.

Compliance

Compliance with completion of the questionnaire rounds will be monitored. Email, telephone and/or SMS reminders will be utilised to update participants on the upcoming start date for questionnaire completion and closure in each round as well as to send reminders to non-responders in order to minimise attrition across the Delphi.

Criteria for terminating the study

There is no expectation that the study would need to be terminated earlier than planned.

ANALYSES

Methods

The DelphiManager software used to run the questionnaire and collect data is based in the UK on the University of Liverpool system. The results will then be accessed and analysed on UoN computers, and backed up to the UoN servers. It is expected that analysis of the data will involve Microsoft Excel.

Primary analysis of data will use the consensus thresholds described earlier after each round. This will involve the ratings of all participants who provide a score from 1-9 – any who instead indicate that they are 'unable to score' a particular item will not be included in the determination of consensus for that item.

There may be differential attrition across the stakeholder groups, but using the consensus thresholds outlined (based on percentages per stakeholder group rather than the overall Delphi cohort) means that each stakeholder group will continue to have an equal weighting throughout the study.

Sample size and justification

An approximate minimum target of 30 participants per stakeholder group (three stakeholder groups – patients, hand surgeons, hand therapists). However, there will be no upper limit set for total number of participants.

ADVERSE EVENTS

The occurrence of an adverse event as a result of participation within this study is not expected and no adverse event data will be collected.

ETHICAL AND REGULATORY ASPECTS

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee

(REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, 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 participant information sheets 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 or assent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. In the case of this questionnaire-based study, as part of registering for the questionnaire there will be tickbox statements that participants will be asked to agree to in order to confirm that they wish to participate. For subsequent steps in the study, completion and submission of a questionnaire will be taken as informed consent and separate written informed consent will not be sought.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasise 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. However, any research data already collected through submission of questionnaires will be kept and will still be used for analysis purposes.

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 for some reason the Consent Process needs to be amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Consent Process by the REC and use of the amended process (including for ongoing participants).

RECORDS

Study Forms

Each participant will be assigned a study identity code number, for use on study forms, 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), month and year of birth (mm/yy) and gender.

Further data to be collected will include:

- Country of residence – as the questionnaire will be online and international participation is desired alongside national participation
- Years of experience working as an independent (Consultant level or equivalent) hand surgeon or hand therapist for the clinician stakeholder groups
- For the patient stakeholder group – specific injury of which they have lived experience and approximate time since sustaining this injury

These data will help to inform the study analysis in terms of demographic characteristics of the participant cohort.

Study forms 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, month and year of birth, and Participant Study Number, to permit identification of all participants enrolled in the study, in case additional follow-up is required. Study forms shall be restricted to those personnel approved by the Chief Investigator and recorded as such in the study records.

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.

The Chief or local Investigator shall sign a declaration ensuring accuracy of data recorded in the study form.

Source documents

Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, study records, completed questionnaires and email correspondence. A study form may also completely serve as its own source data. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

The study form and all source documents 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 study form will only collect the minimum required information for the purposes of the study. Study forms 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 any 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.

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 clinical study participants and study 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

Study conduct may be subject to systems audit for inclusion of essential documents; permissions to conduct the study; 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); accountability of study materials and equipment calibration logs.

STUDY DATA

Monitoring of study data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. Monitoring and audit of the conduct of the research will be as per the research sponsor's (University of Nottingham) standard operating procedure. Due to the nature of the study and no anticipated impact on medical care for patients, external monitoring would only be performed at the Sponsor's request.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research 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 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 anonymised audio recordings, 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. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal 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

The results of this study will be submitted for publication in a peer-reviewed journal as standalone work and will also be written up as part of the PhD student's thesis. If any quotes are used, these will be anonymised to prevent identification of participants.

USER AND PUBLIC INVOLVEMENT

Patient and public involvement (PPI) has been undertaken to refine the methodology of the Delphi study and review of patient-facing documents. The Delphi items have been discussed and optimised with hand and wrist fracture patients, derived from outcome domains identified via a completed systematic review of treatment outcomes and through interviews/focus groups with patients. Further ongoing PPI work is planned to ensure that the items are clearly understandable and accessible to all stakeholders. Further text to help define the outcome domain label and provide examples where necessary will also be examined through PPI work.

STUDY FINANCES

Funding source

This study is funded by the AOUK&I through a Research Grant Award, and the British Society for Surgery of the Hand and the Centre for Evidence Based Hand Surgery.

Participant stipends and payments

On submission of the final round of completed questionnaires, patient participants will be given a £30 gift voucher in appreciation of their contribution and for any inconvenience caused. These will be for those patient participants who have remained engaged with the entire study (i.e. completed all three questionnaire rounds).
All participants who complete all three questionnaire rounds will be recognised as a SO-HANDI Delphi panellist in the study report and any associated publication (providing appropriate consent has been given).

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)__Alexia Karantana_____

Signature: 

Date: __15/10/2020__

PhD Student: (name)___Sandeep Deshmukh_____

Signature: 

Date: __15/10/2020__

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