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RESEARCH ARTICLE

Optimising management of complex regional pain syndrome to improve clinical outcomes throughout the therapy care pathway in England: Protocol for a qualitative interview and observational study with patients and clinicians

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Abstract

Introduction: Complex Regional Pain Syndrome (CRPS) is a disabling and distressing chronic pain condition characterised by a range of sensory, motor, autonomic and trophic symptoms. Guidelines recommend early referral for therapies that promote movement of the painful limb. However, evidence suggests a lack of defined therapy pathways for CRPS.

Aims: The current study aims to explore CRPS therapy management in centres of excellence in England, and outside of these settings, to understand what facilitates and hinders best practice. The overall aim is to develop a draft stratified package of care to expedite patient access to optimal CRPS therapy across the management pathway.

Methods and Analysis: Semi-structured interviews will be conducted with therapists working in CRPS centres of excellence and with therapists in other settings. Observations of therapy interventions in CRPS centres of excellence and interviews with patients who have received this care, will also help to identify potential key care package components. Interview data will be analysed using thematic analysis, mapped to the Theoretical Domains Framework (TDF), and Intervention Mapping Adapt (IMA) framework. Observations will be described and documented using the TDF headings.

Conclusion: A triangulation protocol for qualitative health research will be used to integrate all data. Online stakeholder events will be held using consensus methods to agree a draft package of care for future implementation following further refinement, testing and evaluation.

Clinical Trial Registration: The trial was registered with ISRCTN registry on 24 February 2022 (ISRCTN16917807).

KEYWORDS
care package, complex regional pain syndrome, therapy

1 | INTRODUCTION

Complex Regional Pain Syndrome (CRPS) is a highly distressing and severely disabling chronic pain condition, most commonly arising following injury or surgery to a limb. As well as severe, persistent pain, CRPS is associated with other changes in the limb including swelling, changes in hair and nail growth, skin temperature and skin colour (Harden et al., 2010). European population studies of CRPS equate to approximately 40,000 people living with CRPS in the UK (de Mos et al., 2007). Although this is a relatively small number of people, CRPS causes significant burden to individuals and the National Health Service (NHS). People with CRPS often request amputation of their limb due to pain severity, dislike of the limb and loss of function. Amputation is not recommended by best practice guidelines and may lead to increased personal and societal burden (Goebel et al., 2018).

There is no cure for chronic CRPS and, whilst the majority of CRPS cases resolve spontaneously in the first few months, retrospective studies report symptoms persist for between 22% and 64% of patients ≥3 years after diagnosis (Bean et al., 2014; Zyluk, 1998). UK guidelines recommend prompt diagnosis and early referral for therapies that encourage movement and use of the limb from the outset (Goebel et al., 2018). Expert clinical opinion states this approach gives patients the best chance of a good health outcome, and there is some evidence to support this (Gillespie et al., 2016; Goebel et al., 2018). However, anecdotal evidence suggests that due to the relative rarity of CRPS, therapists outside of CRPS centres of excellence can lack confidence and competence in diagnosing and treating CRPS.

A 2017 Freedom of Information request revealed no care pathway or agreed initial management exists for CRPS in 82% of English NHS Trusts with CRPS-relevant services (Gillespie et al., 2018). A recent survey of clinicians working in the field of CRPS, further identified that over half of UK respondents reported difficulty in recognising the signs and symptoms of CRPS, highlighting a lack of awareness of the condition by healthcare professionals (Grieve et al., 2019).

NHS centres of excellence for CRPS do exist in England, and there are also a number of clinicians with expertise in CRPS in England who provide specialist CRPS practice within fracture and pain services in secondary care. However, it would be impractical and inappropriate for all individuals with CRPS to be referred to these services at the point of diagnosis as many cases resolve spontaneously within the first few months and those experiencing mild CRPS symptoms may not require a multi-professional team (Goebel et al., 2018 ; Zyluk, 1998). Guidance recommends referring patients if they present with moderate or severe symptoms and no positive treatment response is visible between 4 weeks and 2 months (Goebel et al., 2018 ; Goebel et al., 2019). Therapists therefore do require the ability to recognise when symptoms are not responding or progressing, and this can be challenging in practice because the low incidence of CRPS can mean that a therapist may only see a handful of cases per year. Accordingly, there is often considerable delay from symptom onset to referral to a CRPS centre of excellence, meaning that only a very limited number of people with severe CRPS can benefit from this specialist care. The current pathway of care therefore can lead to delayed access to optimal management.

For the purposes of this research, CRPS centres of excellence have been defined as those represented within the CRPS UK Clinical & Research Network, established in 2006 as a collaboration between those UK NHS trusts and academic institutions with a particular interest in CRPS.

Notwithstanding the depth of experience of therapists in CRPS centres of excellence, there has to date been little opportunity to describe the full range of therapies that they deliver, or to explore which of these could be applied earlier in the pathway. To address this knowledge gap, this study aims to: (1) better understand the needs and concerns of therapy practitioners across the care pathway in England, including those therapists working outside of CRPS centres of excellence; (2) more clearly understand the specialist therapy interventions within CRPS centres of excellence; and (3) explore the nature of the patient and clinician experiences in those centres.

The overarching aim of the research is to develop a draft therapy care package that will provide a stratified approach to rehabilitation based on the level of severity/complexity of the presenting patient, and the skills and resources available to the treating therapist. It is anticipated that this will expedite access to therapies for CRPS across the care pathway.

The research questions are.

1. What are the needs of physiotherapists, occupational therapists and hand therapists in England in relation to a CRPS care package for use outside CRPS centres of excellence?
2. What therapies are offered in CRPS centres of excellence and how are these delivered?
3. What could be the components of a care package for the management of CRPS by therapists outside of CRPS centres of excellence?

The research questions will be addressed through three work packages.

1. Qualitative interviews with (a) people with CRPS, (b) physiotherapists, occupational therapists and hand therapists working in CRPS centres of excellence, and (c) physiotherapists, occupational therapists and hand therapists working in England with people with CRPS in settings outside of CRPS centres of excellence.
2. Observations of routine clinical consultations containing interventions/interactions with patients and delivered by therapists working in CRPS centres of excellence.
3. An iterative series of online stakeholder events to consider the information generated from the interviews and observations and use consensus methods to agree a draft package of therapy care.

2 | METHODS AND ANALYSIS

This protocol is version 5.0 dated 12 December 2022.

2.1 | Study design

This study compromises qualitative and co-design methods. The qualitative research is underpinned by a Qualitative Description Approach which allows the voices of those delivering and receiving therapies for CRPS to be elicited (Bradshaw et al., 2017).

2.2 | Study setting

In response to the Covid-19 pandemic and service pressures within the NHS, as many study elements as possible have been purposefully designed to be conducted remotely, including all qualitative interviews and the stakeholder events. Observations of therapy delivery are anticipated to be in person or online subject to which method of service delivery is usual practice at included study sites.

This study will be hosted at the Royal United Hospitals Bath NHS Foundation Trust (RUH), and the University of the West of England (UWE). Additional study sites, who will facilitate patient recruitment for interviews and the observation of therapy sessions, will be identified during the course of the research.

2.3 | Participants and sample size

The sample selection and recruitment strategy differ depending on the work package. The inclusion and exclusion criteria are stated in Table 1 and the sample sizes can be found in Table 2.

2.3.1 | Sample selection and recruitment for qualitative interviews

Interview set A: Patient participants will be approached via service leads and/or therapists working within CRPS centres of excellence in England within their normal clinical activity. The study team will have previously engaged with these service leads and/or therapists either via their Research and Development departments or by virtue of them having consented to contact during their participation in interview set B (see below). Patients may also be approached via the CRPS UK Registry (https://www.crpsnetworkuk.org/). Purposeful

TABLE 1 Inclusion and exclusion criteria.

	Participant eligibility	
	Inclusion	**Exclusion**
Interview set A:	Patients diagnosed with CRPS according to the Budapest diagnostic criteria (Harden et al., 2010) and who are engaging with, or have engaged with CRPS care in a therapy service in England.	Patients where receipt of therapy for CRPS is/was not in England. Potential participants without access to either a PC, tablet, mobile device, or telephone.
Interview set B:	Physiotherapists, occupational therapists and hand therapists working in England in CRPS centres of excellence.	Therapists and other health care professionals not working in England.
Interview set C:	Physiotherapists, occupational therapists and hand therapists working in England outside of CRPS centres of excellence.	Therapists and other health care professionals not connected with delivery of care for people with CRPS. Potential participants without access to either a PC, tablet, mobile device, or telephone.
Clinical observations:	Patients and therapists during a routine clinic consultation delivered by physiotherapists, occupational therapists and hand therapists working in England CRPS centres of excellence. Patients diagnosed with CRPS according to the Budapest diagnostic criteria (Harden et al., 2010) and who are engaging with CRPS care in a therapy service in England.	Therapists and other health care professionals not working in England. Therapists and other health care professionals not connected with delivery of care for people with CRPS. Consultations not conducted in England.
Stakeholder meetings	Physiotherapists, occupational therapists and hand therapists working in England with people with CRPS. Patients diagnosed with CRPS according to the Budapest diagnostic criteria (Harden et al., 2010) and who are engaging with, or have engaged with CRPS care in a therapy service in England. Representatives from integrated care systems with responsibility for the planning and provision of musculoskeletal (MSK) and pain services in England.	Therapists, commissioners, and other health care professionals not working in England, or connected with delivery of care for people with CRPS. Patients where receipt of therapy for CRPS is/was not in England. Potential participants without access to either a PC, tablet, mobile device, or telephone.

TABLE 2 Sample size estimates based on expert opinion of numbers required for indicative findings.

Interview set A	Approximately $n = 20$ patients
Interview set B	$N = 8–12$ physiotherapists/occupational therapists/hand therapists
Interview set C	$N = 12–16$ physiotherapists/occupational therapists/hand therapists
Clinical observations	$N = 6–12$ consultation sessions
Stakeholder meetings	N = approximately 20 attendees

recruitment will seek to ensure views are elicited from a heterogeneous sample of patients in terms of type of specialist CRPS practice service attended, age, gender, ethnicity and duration of CRPS. A subsample of patients from other settings outside of CRPS centres of excellence may be recruited via therapists engaging in interview set C (see below). This decision will be informed by the findings from interview set C.

Interview set B: Therapists from CRPS centres of excellence will be invited to participate via members of the CRPS UK Registry or by approach from their Research and Development departments. The appropriate organisations have already been identified via a prior information gathering exercise. Participant selection will be purposeful to ensure representation from physiotherapy, occupational therapy and hand therapy.

Interview set C: Therapists working outside of CRPS centres of excellence will be identified from an opt-in question in a prior electronic survey. Purposeful sampling will be applied to elicit views from a heterogeneous cohort of therapists (physiotherapists/occupational therapists/hand therapists), and from as wide a range of secondary care settings as possible for example, major acute hospitals, district general hospitals, community hospitals, community outpatient units. Potential participants will be approached via email addresses already provided to the study team for this purpose.

2.3.2 | Sample selection and recruitment for clinical observations

Physiotherapists, occupational therapists and hand therapists working in CRPS centres of excellence, and who participated in interview set B, will be invited to take part in clinical observations. Additional recruitment, if required, will be facilitated via the specialist CRPS service leads in England as identified by the CRPS UK Registry or via individual Research and Development departments, as identified in the prior information gathering exercise. The study team will contact the Research and Development departments of all participating organisations to ensure they are set up appropriately as Research Sites. Therapists who consent to participate, or a member of their clinical team, will then approach eligible potential patient participants during normal clinical activities, provide a participant information leaflet (PIL) and seek permission to pass their contact details back to the study team.

2.3.3 | Sample selection and recruitment for stakeholder meetings

Patient representatives, therapists from CRPS centres of excellence, therapists working in settings outside of CRPS centres of excellence and Musculoskeletal (MSK) systems leaders with responsibility for planning and providing MSK and pain services within local Integrated Care Systems will be invited to stakeholder events. Recruitment of patients and healthcare professionals will be via the earlier work packages subject to their prior agreement to be contacted for this purpose. Direct approaches will be made to relevant commissioners, identified through our existing networks. In addition to invitations to patients who have participated in prior work packages, patient representatives from CRPS patient charities will be invited to review the draft therapy care package and to provide feedback. Feedback will also be sought from the members of a therapists' online consultation forum, hosted on the study's dedicated website.

2.3.4 | Sample recruitment – all work packages

All potential participants will be provided, in advance, with an appropriate PIL, consent form (electronic or on paper) and contact details of the study team. Eligibility will be confirmed by a member of the study team and there will be opportunity to ask questions before consent is received. In the case of interviews and the stakeholder meetings, consent will be received verbally by a study team member. Written consent from patients participating in the clinical observations will be received at the time of the clinic appointment, with consent from therapists provided electronically beforehand. No data will be collected without receipt of full informed consent.

2.4 | Data collection

1. Qualitative interviews

Topic guides will be compiled by members of the research team, including a Patient and Public Involvement (PPI) contributor. The topic guides will be piloted with a PPI contributor and with relevant therapists prior to data collection.

Interview set A: Online or telephone semi-structured interviews, of up to 45 min, will explore: patients' experience of therapy prior to, and during, their engagement with therapies at centres of excellence for CRPS; aspects of therapy interventions they liked or disliked; reflections on changes in behaviour they have made or been encouraged to make; their perception of the acceptability and feasibility of self-management strategies; their perception of the need for specific therapy interventions and self-management strategies to be available in other settings outside of CRPS centres of excellence.

Interview set B: Online or telephone semi-structured interviews of up to 60 min will be conducted with therapists from CRPS centres of excellence. Data will be elicited to understand participants'

reflections on therapy delivery in specialist services: what works well and less well, the aims and goals of services, programme outcomes, and their perceptions of the need for therapy-led CRPS interventions across the care pathway.

Interview set C: Online or telephone semi-structured interviews of up to 45 min with therapists working with people with CRPS in settings outside of CRPS centres of excellence in England will seek to understand more about what works well, and less well for CRPS management currently in their contexts; what therapies are needed locally; and which interventions would be considered practical to provide earlier in the care-pathway.

Each interview, including the giving of consent, will be digitally audio-recorded (with video off if Microsoft Teams is used), anonymised, transcribed verbatim, and uploaded to QSR NVivo 1.6.2 software.

2. Observations of routine clinical consultations

Consultations led by therapists in centres of excellence for CRPS will be video recorded to capture and describe the structure and delivery of therapies by physiotherapists, occupational therapists, and hand therapists. Topic areas are anticipated to include education, active range of movement exercises, passive range of movement exercises, strength training, desensitisation programmes/sensory re-education programmes, pacing advice and graded motor imagery. Ideally, the observations will also capture therapy delivery to people with CRPS at a range of condition duration and at different categories of consultation (e.g. initial consultation/assessment or follow up treatment). It is anticipated that therapy consultations will be predominantly with individual patients, however, group therapy sessions may be included (with consent from all parties) if deemed appropriate by the delivering therapist in consultation with the study team.

A member of the study team will attend each specialist CRPS practice service to observe and record consultations.

3. Online stakeholder events

Prior to the online stakeholder event, a six-step triangulation protocol for qualitative health research will be applied to the data already collected and analysed in the prior work (Farmer et al., 2006). This protocol will identify the completeness, convergence, complementarity, and dissonance of key themes across the datasets.

The outcomes of the analysis from the work packages described above, and any reflections from the triangulation exercise, will be discussed during an iterative series of online stakeholder events. Two or three events are anticipated, each lasting approximately 2 hours in which patient representatives; therapists from specialist services; therapists working in local integrated care systems, and commissioners will be involved.

The risk of adverse events during data collection are considered minimal and are not anticipated. Full risk assessments have been completed for each work package. All participants will be provided with the contact details of the study team and will be encouraged to make contact if they feel stressed because of participation. The study team have prepared a document which contains appropriate signposting to organisations who can provide support. If an adverse event does occur, the Chief Investigator will ensure that these are recorded and reported appropriately.

1. **Data Analysis:** Qualitative interviews

Data from interview sets A and B will be analysed using thematic analysis (Braun & Clarke, 2006) and with reference to the Theoretical Domains Framework (TDF) (Cane et al., 2012). Combining these data will facilitate the understanding of experiences however an indicator of the data source (patient or therapist working in specialist CRPS practice centres) will be retained within the analysis, in order to ensure the distinct perspectives of each cohort can be identified.

The interviews with therapists working in settings outside of CRPS centres of excellence in interview set C will be more exploratory in nature and will be analysed using Braun and Clarke's (2006) method, guided by the principles of step one of the Intervention Mapping Adapt (IMA) approach: needs assessment and assessment of organisational capacity (Bartholomew Eldredge et al., 2016).

2. Observations of routine clinical consultations

Informed by the IMA approach (Bartholomew Eldredge et al., 2016) video recordings of the observed clinical consultation will be reviewed in order to manually complete an electronic record of the structure and delivery of any therapy interventions delivered. These will be described and documented in tabular format using the headings from the TDF (Cane et al., 2012). The software package QSR NVivo 1.6.1 will be used to support the analysis process.

3. Online stakeholder events

Nominal Group Techniques (McMillan et al., 2016) will be used to capture opinion from all group members. By this method, consensus will be achieved on which intervention components could be included within the draft therapy care package. Consideration will be given to the feasibility of delivery in settings outside of CRPS centres of excellence. Discussions will also inform the preliminary development of additional educational materials to support recommendations generated.

2.5 | Data management

All personal data will be collected, managed, and used in accordance with the General Data Protection Regulation (GDPR) (EU) 2016/679, the Data Protection Act 2018 (or any successor legislation) and any other legislation directly relating to privacy laws that apply. All participants will be provided with a PIL which will include a privacy notice explaining how their data will be managed before, during and after their participation in the study. A data management plan will be created to ensure that the data collected is managed appropriately.

The data collected will only be used for the purposes of the research study.

All electronic files will be securely stored on restricted university servers. Research data will be pseudonymised at the point of data collection. All interviews will be recorded using the embedded recording function on Skype for Business or Microsoft Teams. Audio files will be transferred into the restricted university servers at the researcher's earliest convenience. Recordings will be transcribed verbatim and anonymised by the study team or a UWE approved transcription service. Once transcribed, audio recordings will be deleted.

Observations will be captured using a university owned video camera. Video recordings will be transferred into the restricted university server as soon as possible. Once these have been described and documented, the recordings will be deleted.

Recordings of the stakeholder workshops will be recorded using the embedded recording function within Microsoft Teams, transferred into the restricted university server at the researcher's earliest convenience and password protected. These will be used to compile notes of the discussion which will be stored in the same way. Once the notes have been compiled, all recordings will be deleted.

Personal and sensitive research data will be deleted once the study has been analysed and written for publication. At the end of the study, anonymised data will be archived in a university research data archive facility and kept for 10 years and then destroyed.

2.6 | Study monitoring

To ensure the study is being conducted appropriately, a study steering committee (SSC) will convene every three to 4 months. The SSC will provide expert advice and overall supervision for the project and will comprise three independent members and three members of the study team. A separate project management group (PMG) will also be established and will consist of all co-applicants and the research associate. The group will meet formally every three to 4 months, interspersed with informal meetings when required. All members will be expected to contribute to the successful delivery of the study using their individual expertise.

2.7 | Patient and Public Involvement

Patient and public involvement has been integral to the development of this study. A PPI focus group was held at the outset with five people with CRPS. They unanimously endorsed the importance of research on the topic of CRPS therapies, highlighting the considerable impact that therapies have on their functioning and the need to improve the provision of therapies throughout the CRPS care pathway. The need for therapists to have sufficient education to effectively deliver appropriate therapy interventions was also identified. Feedback from the focus group was integral to defining the scope of the proposed work and two PPI research partners provided input to the funding application, with one taking a co-applicant role.

Our two patient research partners will continue to provide input and oversight. The PPI co-applicant will be a member of the PMG; the other will sit on the SSC. Both PPI research partners will be involved in managing the research, will advise on the analysis of results, and will support the dissemination of the research findings. They will also be invited to provide input to relevant future funding applications.

2.8 | Ethics and dissemination

This study has been reviewed and given a favourable ethical opinion by London-Brent Research Ethics Committee, UK (reference 21/PR/1763) on 14 January 2022 and approved by the NHS Health Research Authority (REC), UK on 24 February 2022. Favourable ethical opinion was also received from the Faculty Research Ethics Committee of the University of the West of England on 23 February 2022 (ref: HAS.22.02.074). If amendments are required, these will be submitted at the earliest opportunity and then communicated to the study team, R&D departments of those NHS Trusts involved, the ISRCTN registry and participants if appropriate. Substantial amendments will not be implemented until a review has been conducted and approval has been received from the NHS REC.

The datasets generated during and/or analysed during the current study are not expected to be made available due to the qualitative nature of the study and the capacity of the study team to ensure the complete dataset is fully anonymised prior to sharing. Additionally, the study team do not have ethical approval or participant consent to share the dataset, only for extracted data to be anonymised and published. However, the research team will ensure effective knowledge mobilisation strategies from the outset of the research. Only the study team members will have access to the final datasets. The corresponding author can be contacted for access to the full protocol.

On completion of the study, summary reports will be prepared and circulated to the research participants, patient-specific charities, and advocate organisations. Summaries will also be shared via social media and the project website. The first iteration of an intervention briefing document will be tailored for, and distributed to, different professional groups including the British Association of Hand Therapists, the Chartered Society of Physiotherapy, the Royal College of Occupational Therapists, the Royal College of General Practitioners and the British Orthopaedic Association. It is anticipated that endorsement by these bodies will encourage uptake of these practice recommendations throughout the health and care system. Presentations will be made to clinician, academic, and commissioner groups where appropriate. A final research report will be collated for the funder, the NIHR. Publications will be submitted to peer-reviewed journals and conference presentations will be prepared and submitted for the purpose of informing scholarly audiences.

AUTHOR CONTRIBUTIONS

All authors qualify for authorship in accordance with the definition provided by the International Committee of Medical Journal Editors (ICMJE). Alison Llewellyn, Candida McCabe, Nicola Walsh, Jennifer Pearson and Catherine Rolls conceptualised and designed the study

and were involved with funding acquisition, making substantial contributions. All authors were involved with drafting and revising the study protocol. Jessica Coggins and Alison Llewellyn wrote the first draft of the manuscript based on the study protocol. All authors contributed and approved the final version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

ETHICS STATEMENT

Favourable opinion was received from London-Brent Research Ethics Committee, UK (ref 21/PR/1763), 14 January 2022.

TRIAL SPONSOR

The trial sponsor is the University of the West of England, Bristol UK.

STUDY STATUS

The study commenced in May 2021. Data collection is currently underway and due to be completed in June 2023. The study is scheduled to end in July 2023.

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REFERENCES

Bartholomew Eldredge, L. K., Markham, C. M., Ruiter, R. A., Kok, G., Fernandez, M. E., & Parcel, G. S. (2016). *Planning health promotion programs: An intervention mapping approach* (4th ed.). John Wiley & Sons.

Bean, D. J., Johnson, M. H., & Kydd, R. R. (2014). The outcome of complex regional pain syndrome type 1: A systematic review. *The Journal of Pain*, *15*, 677–690. https://doi.org/10.1016/j.jpain.2014.01.500

Bradshaw, C., Atkinson, S., & Doody, O. (2017). Employing a qualitative description approach in health care research. *Global Qualitative Nursing Research*, *4*, 2333393617742282. https://doi.org/10.1177/2333393617742282

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*, 77–101. https://doi.org/10.1191/1478088706qp063oa

Cane, J., O'Connor, D., & Michie, S. (2012). Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science*, *7*, 37. https://doi.org/10.1186/1748-5908-7-37

Data Protection Act. 2018. *Data Protection Act 2018* [online]. GOV.UK. Retrieved January 26, 2023, from https://www.gov.uk/government/collections/data-protection-act-2018

de Mos, M., De Bruijn, A. G. J., Huygen, F. J. P. M., Dieleman, J. P., Stricker, B. C., & Sturkenboom, M. C. J. M. (2007). The incidence of complex regional pain syndrome: A population-based study. *Pain*, *129*, 12–20. https://doi.org/10.1016/j.pain.2006.09.008

Farmer, T., Robinson, K., Elliott, S. J., & Eyles, J. (2006). Developing and implementing a triangulation protocol for qualitative health research. *Qualitative Health Research*, *16*, 377–394. https://doi.org/10.1177/1049732305285708

Gillespie, S., Cowell, F., Cheung, G., & Brown, D. (2016). Can we reduce the incidence of complex regional pain syndrome type I in distal radius fractures? The Liverpool experience. *Hand Therapy*, *21*, 123–130. https://doi.org/10.1177/1758998316659676

Gillespie, S., Cowell, F., McCabe, C., & Goebel, A. (2018). Complex regional pain syndrome acute care pathways in England: Do they exist and what do they look like? *Hand Therapy*, *23*, 95–99. https://doi.org/10.1177/1758998318764182

Goebel, A., Barker, C., Birklein, F., Brunner, F., Casale, R., Eccleston, C., Eisenberg, E., McCabe, C. S., Moseley, G. L., Perez, R., & Perrot, S. (2019). Standards for the diagnosis and management of complex regional pain syndrome: Results of a European Pain Federation task force. *European Journal of Pain*, *23*, 641–651. https://doi.org/10.1002/ejp.1362

Goebel, A., Barker, C. H., Turner-Stokes, L., Atkins, R. M., Cameron, H., Cohen, H., Cowell, F., Eldridge, P., Fullilove, S., Gillespie, S., Guly, H., Henderson, J., Ikkos, G., Jepson, F., Johnson, M., Lane, N., Lewis, J., Lewis, S., Mani-Babu, S., … Yates, B. (2018). *Complex regional pain syndrome in adults: UK guidelines for diagnosis, referral and management in primary and secondary care*. Royal College of Physicians. https://www.rcplondon.ac.uk/guidelines-policy/complex-regional-pain-syndrome-adults

Grieve, S., Llewellyn, A., Jones, L., Manns, S., Glanville, V., & McCabe, C. S. (2019). Complex regional pain syndrome: An international survey of clinical practice. *European Journal of Pain*, *23*, 1890–1903. https://doi.org/10.1002/ejp.1463

Harden, R. N., Bruehl, S., Perez, R. S., Birklein, F., Marinus, J., Maihofner, C., Lubenow, T., Buvanendran, A., Mackey, S., Graciosa, J., & Mogilevski, M. (2010). Validation of proposed diagnostic criteria (the "Budapest Criteria") for complex regional pain syndrome. *Pain*, *150*, 268–274. https://doi.org/10.1016/j.pain.2010.04.030

McMillan, S. S., King, N., & Tully, M. P. (2016). How to use the nominal group and Delphi techniques. *International Journal of Clinical Pharmacology*, *38*, 655–662. https://doi.org/10.1007/s11096-016-0257-x

Zyluk, A. (1998). The natural history of post-traumatic reflex sympathetic dystrophy. *Journal of Hand Surgery*, *23*, 20–23. https://doi.org/10.1016/s0266-7681(98)80211-8

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