

BMJ Open Protocol for a scoping review of interventional trials in complex regional pain syndrome: evaluation of adherence to the core outcome set, SPIRIT-PRO and CONSORT-PRO guidelines

Hannah Cork ¹, Alex Deutsch,² Rachel Kyte,³ Dale Turner ³, Derek Kyte ³

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¹Herefordshire and Worcestershire Health and Care NHS Trust, Worcester, UK
²The Dudley Group NHS Foundation Trust, Dudley, UK
³School of Health and Wellbeing, Department of Allied Health, University of Worcester, Worcester, UK

Correspondence to

Hannah Cork;
hannah.cork5@nhs.net

ABSTRACT

Introduction Complex regional pain syndrome (CRPS) is a debilitating chronic pain condition that severely reduces quality of life. Physiotherapy is a key component of management; however, high-quality evidence to inform optimal practice is limited. Variability in outcome measurement and poor reporting quality may hinder the ability to synthesise findings and inform best practice. Although international guidelines for reporting patient-reported outcomes (PROs) have been developed to address these issues and a CRPS Core Outcome Set (COS) has been published, the extent to which they have been adopted in CRPS research remains unclear. This protocol describes a scoping review, which aims to explore whether randomised controlled trials evaluating physiotherapy interventions for adults with CRPS adhere to COS recommendations and comply with PRO reporting guidelines.

Methods and analysis The design of the scoping review will align with the Joanna Briggs Institute methodology. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews will be used to guide reporting. Electronic databases including MEDLINE, CINAHL, Embase, CENTRAL and PsycINFO will be searched in addition to the WHO International Clinical Trials Registry Platform (WHO-ICTRP). Titles, abstracts and full texts will be screened by two independent reviewers. Data extraction and synthesis will follow, with discrepancies resolved through discussion with a third reviewer. Adherence to the CRPS COS will be assessed by mapping trial outcomes to COS domains, and compliance with Standard Protocol Items Recommendations for Interventional Trials: Patient-Reported Outcome Extension (SPIRIT-PRO) and Consolidated Standards of Reporting Trials: PRO Extension (CONSORT-PRO) guidelines will be evaluated against checklist items. Data will be summarised descriptively, with subgroup analysis comparing trials initiated before and after COS publication.

Ethics and dissemination Ethical approval is not required as the study involves no collection of primary data. Findings will be disseminated via peer-reviewed journals, conference presentations and concise reports prepared for key stakeholders.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The protocol is informed by the Joanna Briggs Institute guidance for scoping reviews and reporting is guided by the Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols.
- ⇒ A structured search strategy developed in partnership with a library specialist will be used across multiple databases and trial registries to capture relevant material.
- ⇒ Two reviewers will independently screen, extract and map data with a third reviewer resolving disagreements to minimise bias.
- ⇒ The team includes experienced researchers, academics and clinicians, which strengthens methodological rigour and clinical relevance.
- ⇒ The eligibility criteria will be limited to trials published in English language, which may exclude some otherwise relevant material.

Registration This protocol is registered on Open Science Framework and is available at <https://doi.org/10.17605/OSF.IO/BFH82>.

INTRODUCTION

Complex regional pain syndrome (CRPS), a type of chronic primary pain,^{1 2} is disproportionately severe and persists longer than the usual course of the inciting event.³ Although the underlying cause remains uncertain, the condition is typically characterised by altered nociceptive processing, without evidence of actual or potential tissue damage that would activate peripheral nociceptors, or any identifiable pathology to explain the pain.^{4 5} The incidence of CRPS is between 5 and 26 per 100 000 person years,^{6 7} and healthcare costs are 20% higher for those affected.⁸ Symptoms are severely debilitating and significantly reduce quality of life.^{9 10}

To manage CRPS effectively, a comprehensive approach is required with physiotherapy a key component.³ However, there is currently a lack of high-quality evidence and consensus regarding the optimal physiotherapy management of CRPS.¹¹ A key reason for this may be lack of consistency in the outcome measures used across clinical trials, coupled with poor-quality reporting.¹¹

Inconsistency in randomised controlled trial (RCT) outcomes is recognised as a major limitation in health research.¹² This is because it makes it difficult to compare and synthesise findings across studies and draw broader conclusions.¹³ The lack of standardised outcomes can lead to inconsistent evidence regarding the effectiveness of health interventions, making it challenging to determine best practice.¹³ In response, core outcome sets (COS) have been developed.¹⁴ A COS represents an evidence-based stakeholder consensus on the minimum outcome domains that should be measured and reported in all clinical trials for a specific health condition or intervention.¹⁵

A COS for CRPS was published in 2017, with recommended domains including pain, disease severity, participation/physical function, emotional/psychological function, self-efficacy, catastrophising and patients' global impression of change.¹⁶ These domains would be primarily measured using patient-reported outcome measures (PROMs), which are used in RCTs to collect information directly from patients about their health condition and its impact on their daily life.¹⁷ The use of PROMs in clinical trials is informed by two key international guidance documents: SPIRIT-PRO (Standard Protocol Items Recommendations for Interventional Trials: Patient-Reported Outcome Extension)¹⁸; and CONSORT-PRO (Consolidated Standards of Reporting Trials: PRO Extension).¹⁹

However, it remains unclear if clinical trials are currently: (1) adhering to the CRPS COS¹⁶ and consistently measuring recommended PROs; and/or (2) adequately complying with SPIRIT-PRO¹⁸ and CONSORT-PRO¹⁹ guidelines.

The aim of this study is to conduct a scoping review of RCTs evaluating physiotherapy interventions for adults with CRPS to determine whether:

1. The measurement domains and PROMs used align with CRPS COS¹⁶ recommendations.
2. Trials comply with SPIRIT-PRO¹⁸ and CONSORT-PRO¹⁹ guidelines.

METHODS AND ANALYSIS

The proposed scoping review will be informed by the Joanna Briggs Institute (JBI) methodology for scoping reviews.^{20 21} For reporting, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) will be used.²² The review protocol is registered on Open Science Framework and is available at <https://doi.org/10.17605/OSF.IO/BFH82>. The scoping review commenced

in September 2025, with completion planned for December 2026.

Eligibility criteria

A pragmatic approach was adopted to establish a comprehensive and applicable inclusion and exclusion criteria. This included considering elements from both the Population, Intervention, Comparators, Outcomes (PICO) and Population, Concept, Context (PCC) frameworks.^{23 24} Reports will, therefore, be selected according to the criteria outlined below:

Inclusion criteria

- ▶ RCTs of any design (eg, parallel, crossover or cluster).
- ▶ Trials of adults, aged 18 years or older, diagnosed with CRPS-1 or CRPS-2 or an alternative associated diagnostic label such as post-traumatic algodystrophy; post-traumatic dystrophy; post-traumatic neurodystrophy; post-traumatic osteoporosis; post-traumatic pain syndrome; causalgia; Sudeck's atrophy; Sudeck's osteodystrophy; sympathalgia; reflex sympathetic dystrophy or traumatic arthritis. Both contemporary and older terms associated with CRPS will be incorporated to maximise coverage and minimise the risk of missing potentially relevant trials during the searching and screening phase.
- ▶ Trials that evaluate any physiotherapy intervention. In alignment with a 2022 CRPS Cochrane review,¹¹ physiotherapy interventions will be defined as: 'manual therapy (eg, mobilisation, manipulation, massage, desensitisation); therapeutic exercise and progressive loading regimens (including hydrotherapy); electrotherapy (eg, transcutaneous electrical nerve stimulation, therapeutic ultrasound, interferential, shortwave diathermy, laser); physiotherapist-administered education (eg, pain neuroscience education) as well as cortically directed sensory-motor rehabilitation strategies (eg, graded motor imagery, mirror therapy, sensory motor retuning, tactile discrimination training)'.¹¹
- ▶ Trials from inception to present-day published in English.

Exclusion criteria

- ▶ Reports that are not RCTs (eg, observational studies, case series or case reports).
- ▶ Trials with participants younger than 18 years of age, and adults not diagnosed with CRPS-1 or CRPS-2 or without an alternative associated diagnostic label as listed above.
- ▶ Trials that do not evaluate a physiotherapy intervention as listed above.
- ▶ Trials not published in English.

Information sources

MEDLINE (EBSCOhost interface), CINAHL (EBSCOhost interface), Embase (OVID interface), CENTRAL (via Cochrane Library) and PsycINFO (OVID interface) databases will be searched electronically. To supplement

this, the WHO International Clinical Trials Registry Platform (WHO-ICTRP) search portal will be used to identify further eligible trials that may not have been captured through database searching.

To ensure literature saturation, a hand search of reference lists of included trials will be conducted and Web of Science will be used to conduct citation searching.

Protocols of the RCTs eligible to be included in the review will be sourced by either: (1) identifying the trial registration number and searching the appropriate trial registry; (2) reviewing the supplementary material of the RCT publication to identify if the protocol has been published; or (3) an email request sent to the named corresponding author of the published RCT report.

Search strategy

A structured search validation procedure will be employed to ensure the comprehensiveness and reliability of the search strategy. This process will begin with the identification of a set of key sources that are expected to be retrieved if the search strategy is effective. These sources will serve as benchmarks against which the initial search results will be evaluated.

In partnership with a library specialist, the search strategy will be tested using a series of pilot queries designed to reflect the scope and key concepts of the research topic. The results will be assessed for relevance, coverage and alignment with the research objectives. Where necessary, the strategy will be refined iteratively by adjusting search terms, Boolean operators, filters and database selections.

To further enhance the robustness of the validation process, the search strategy will be reviewed by a subject matter expert or academic peer. This review will help identify any potential gaps or biases in the search approach. Additionally, where applicable, controlled vocabulary (eg, Medical Subject Headings) will be incorporated to improve precision and consistency across databases.

See online supplemental material 1 for the search strategy adapted for each database.

Screening

All reports generated from the literature search will be imported into systematic review indexing software (Rayyan).²⁵ Duplicates will be removed prior to screening. Screening will consist of two stages. During the first stage, review authors (HC, AD and DT) will independently screen titles/abstracts of all reports generated from the search against the inclusion/exclusion criteria. Full text will be obtained for reports that appear to meet the inclusion criteria or where there is any uncertainty. Corresponding authors will be contacted via email if full texts are unavailable. For the second stage, review authors (HC, AD and DT) will independently review full texts and decide whether the inclusion criteria are met. An adapted PRISMA V.2020 Flow Diagram²⁶ will be used to present the selection process from identification through to inclusion.

At both title/abstract and full-text stages, discrepancies will be discussed until a consensus is reached and advice will be sought from the guarantor of the review, DK, to resolve any disagreements regarding eligibility if necessary.

Reviewers will pilot the screening process using the first 10% of hits generated from the search strategy to ensure consistent application of the inclusion/exclusion criteria.

Data extraction

For each trial included in the review, data will be extracted to a prespecified data extraction tool in Microsoft Excel. Key trial characteristics will be captured, including citation, aims, design, participants, intervention details, comparison and timeframes for follow-up.

In order to assess adherence to the CRPS COS¹⁶ and compliance with SPIRIT-PRO¹⁸ and CONSORT-PRO¹⁹ guidelines, a twofold approach will be adopted.

To assess adherence to the CRPS COS,¹⁶ two review authors (HC and RK) will independently extract data from each trial, including measurement domains and PROMs used. Discrepancies will be discussed until a consensus is reached and advice will be sought from the guarantor of the review, DK, to resolve any disagreements if necessary.

To assess compliance with SPIRIT-PRO¹⁸ and CONSORT-PRO¹⁹ guidelines, two review authors (HC and DK) will independently extract data from each trial, including a text excerpt and page number evidencing achievement of the SPIRIT-PRO¹⁸ and CONSORT-PRO¹⁹ checklist items. Discrepancies will be discussed until a consensus is reached and advice will be sought from RK to resolve any disagreements if necessary.

Corresponding authors will be contacted via email in case of missing data.

Reviewers will pilot the extraction process with three trials and refine the draft data extraction tool, see online supplemental material 2, as required to ensure all relevant data are captured and a consistent approach is adopted.

Quality appraisal

The quality of included trials in the review will be evaluated using the risk-of-bias tool (RoB 2).²⁷ Review authors (HC and DK) will independently extract data to determine risk-of-bias judgements in accordance with the RoB 2 guidance.²⁸ Judgements will be documented in a prespecified table in Microsoft Excel. Discrepancies in judgements will be discussed until a consensus is reached and advice will be sought from a third review author to resolve any disagreements if necessary.

Data analysis

Mapping data will be presented through tables, diagrams and figures and analysed descriptively. A prespecified subgroup analysis will be completed to determine if there is a difference in adherence to the CRPS COS¹⁶ between CRPS RCTs that were designed before (from inception) and after the publication of the COS (to present-day).



In order to assess adherence to the CRPS COS¹⁶ and compliance with SPIRIT-PRO¹⁸ and CONSORT-PRO¹⁹ guidelines, a twofold approach will be adopted.

To assess adherence to the CRPS COS,¹⁶ two review authors (HC and RK) will independently map data to the COS using prespecified mapping rules described below. Discrepancies in decisions will be discussed until a consensus is reached and advice will be sought from the guarantor of the review, DK, to resolve any disagreements if necessary.

CRPS COS domain adherence

This will involve assessing whether each CRPS COS¹⁶ domain has been measured in a given RCT. This will be recorded as a binary outcome for each domain:

1. 'Yes' if the domain is measured.
2. 'No' if the domain is not measured.

PROM usage mapping

This will involve mapping all PROMs used across included trials. For each domain, the specific PROM(s) used will be recorded. This will allow for:

1. A descriptive overview of PROM usage patterns across trials.
2. A post-hoc commentary on the extent to which these PROMs align with the COS recommendations.

This approach acknowledges that some recommended PROMs (eg, PROMIS) may not be widely used or available in all regions and allows for a more nuanced understanding of current practice.

To assess compliance with SPIRIT-PRO¹⁸ and CONSORT-PRO¹⁹ guidelines, two review authors (HC and DK) will independently map data to the SPIRIT-PRO¹⁸ and CONSORT-PRO¹⁹ checklists as described below. Discrepancies in decisions will be discussed until a consensus is reached and advice will be sought from RK to resolve any disagreements if necessary.

SPIRIT-PRO adherence

This will involve assessing whether each SPIRIT-PRO checklist¹⁸ item has been documented in a given RCT. This will be recorded as a binary outcome for each item:

1. 'Present' if the checklist item is documented.
2. 'Absent' if the checklist item is not documented.

CONSORT-PRO adherence

This will involve assessing whether each CONSORT-PRO checklist¹⁹ item has been documented in a given RCT. This will be recorded as a binary outcome for each item:

1. 'Present' if the checklist item is documented.
2. 'Absent' if the checklist item is not documented.

One point will be assigned for each item 'present'.

Reviewers will pilot the mapping process with three trials to refine the process and adjust decision rules as required and ensure a consistent approach is adopted.

Patient and public involvement

Two individuals with lived experience of CRPS and chronic pain met with the lead researcher to discuss the

aims and proposed plans for the review. The insights and perspectives shared by these individuals were used to inform protocol development.

DISCUSSION

A key contribution of this proposed scoping review will be its potential to support researchers improve the design, conduct and reporting quality of CRPS trials measuring PROs. By systematically mapping the measurement domains and PROMs used, alongside PRO reporting practices, methodological gaps can be identified. Improved adherence to the CRPS COS¹⁶ and PRO reporting guidelines^{18 19} would likely improve the consistency and transparency of CRPS trial findings. This would help reduce existing barriers to meta-analysis, including heterogeneity in PROs, lack of standardisation in PRO data reporting and selective PRO reporting.^{29 30} Overall, this would likely improve the accessibility and comparability of research findings for the benefit of patients and clinicians. This would be particularly valuable for improving patient care by helping to inform best practice.

This proposed scoping review has several strengths. First, the protocol was developed using the JBI best practice guidance for scoping review protocols³¹ and based on adapted items of the Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols (PRISMA-P)^{32 33} ensuring rigorous methodology from the outset. A comprehensive and reliable search strategy established by undertaking a structured validation procedure will be employed across multiple databases and trial registries to ensure coverage of relevant material. Title, abstract and full-text screening as well as data extraction and mapping will be completed by two independent reviewers with a third reviewer resolving disagreements if necessary, reducing risk of bias and improving accuracy. In addition, a series of pilots will be carried out to iteratively refine the search strategy, screening, data extraction and mapping processes as necessary to enhance the quality of the review.

However, it should be acknowledged, the eligibility criteria will be limited to trials published in English language, which may result in the exclusion of trials that could have been included in the review.

Ethics and dissemination

This study is a scoping review of existing literature and does not involve primary data collection; therefore, ethical approval is not required. Findings will be disseminated through publication in a suitable peer-reviewed journal, a scientific conference as appropriate and other routes as applicable, for example, charities/organisations engaged with CRPS research.

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Contributors HC and DK conceived the study and developed the protocol with advice and input from all authors. HC and AD engaged with patient and public involvement and engagement activities. HC prepared the first draft of the

manuscript. All authors revised the manuscript. DK acted as guarantor for the project.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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ORCID iDs

Hannah Cork <https://orcid.org/0009-0001-4211-1791>

Dale Turner <https://orcid.org/0009-0009-7717-2330>

Derek Kyte <https://orcid.org/0000-0002-7679-6741>

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