

# An investigation of current practice to inform a draft therapy care package for people with Complex Regional Pain Syndrome, for use by therapists in community settings

<b>Submission date</b> 18/02/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/02/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/04/2024	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Complex Regional Pain Syndrome (CRPS) is a severe pain condition which affects a limb, usually following injury or surgery. Symptoms include extreme sensitivity, swelling, altered limb temperature and colour, sweating, and changes in hair and nail growth. CRPS is rare, poorly understood and incurable.

To improve limb movement, people are referred to local therapy services. Early treatment is key to good outcomes but the rarity of CRPS means therapists often know little about CRPS and how best to manage it. A limited number of NHS CRPS specialist centres exist in England, but patients can only access these specialist services if local services have “failed” to improve their symptoms.

We will develop a package of therapies for CRPS that can be offered by therapists in local non-specialist clinics. Providing the right therapies early on will improve care for the majority, and enable those with more complex needs quicker access to specialist centres.

### Who can participate?

Patients diagnosed with CRPS and physiotherapists, occupational therapists and hand therapists working in England in non-specialist and specialist CRPS practice

### What does the study involve?

In our study we will:

- Interview specialist CRPS therapists, patients who have attended specialist CRPS clinics, and therapists from non-specialist settings treating CRPS, to learn what works well, and less well and what therapies are needed locally, and are practical to provide, earlier in the care-pathway.
- Observe therapies as they happen during in specialist centres so we can describe these in

detail.

c) Use this information to compile a package of therapies that can be tailored for treating people with CRPS in non-specialist settings, including an educational materials for therapists.

We will work with patients, therapists, health service commissioners, and experts, to refine this proposed package for future testing.

We have involved patients in all stages of our research and will continue to do so. We will share findings through conferences, patient and public engagement channels, and academic publications.

What are the possible benefits and risks of participating?

Participating in this study will help us to gain a better understanding of the current provision of CRPS treatments and will contribute to the development of a future stratified care package of therapies for use in non-specialist settings. We do not foresee any risks to participants arising from taking part in this study

Where is the study run from?

University of the West of England (UK)

When is the study starting and how long is it expected to run for?

May 2021 to April 2023

Who is funding the study?

National Institute for Health Research (NIHR) (UK).

Who is the main contact?

Dr Alison Llewellyn, [alison.llewellyn@uwe.ac.uk](mailto:alison.llewellyn@uwe.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Alison Llewellyn

### Contact details

Centre for Health and Clinical Research

School of Health and Social Wellbeing

Glenside Campus

University of the West of England

Bristol

United Kingdom

BS16 1DD

+44 1173287495

[alison.llewellyn@uwe.ac.uk](mailto:alison.llewellyn@uwe.ac.uk)

## Additional identifiers

Integrated Research Application System (IRAS)

304399

**Central Portfolio Management System (CPMS)**

51670

**National Institute for Health and Care Research (NIHR)**

200753

## **Study information**

### **Scientific Title**

Establishing evidence-based management of Complex Regional Pain Syndrome to improve clinical outcomes throughout the care pathway (ENACT-CRPS)

### **Acronym**

ENACT-CRPS

### **Study objectives**

An investigation of current practice to inform a draft therapy care package for people with Complex Regional Pain Syndrome, for use by therapists in community settings

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 14/01/2022, London – Brent Research Ethics Committee (80 London Road, Skipton House, London, SE1 6LH, UK; +44 2071048128; brent.rec@hra.nhs.uk), ref: 304399

### **Study design**

Observational qualitative

### **Primary study design**

Observational

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Complex Regional Pain Syndrome

### **Interventions**

Please note Work Package 1 (survey of current CRPS therapy practice) has been completed. This was prior work that did not require HRA or NHS Research Ethics approvals. The current application relates to Work Packages 2-4. The research team includes a PPI member who has reviewed and approved the protocol and other study documents. This is registered at ISRCTN: <https://www.isrctn.com/ISRCTN11618379>

### **Interview Study - Work Package 2:**

Work package 2 aims to assess the nature of the need for a CRPS care package in non-specialist settings and to describe and document the therapies offered in specialist CRPS practice centres.

Qualitative interviews were considered the most appropriate method to do this as they provide access to the individual experiences and opinion of a potentially heterogeneous subject group. This work package comprises three sets of individual semi-structured interviews: a) with CRPS patients (n=~20), b) with CRPS therapists working in specialist CRPS practice centres (n=8-12) (including physiotherapists, occupational therapists and hand therapists), and c) with physiotherapist, occupational therapists and hand therapists working in England with people with CRPS in non-specialist settings (n=12-16).

Therapists working in specialist CRPS practice centres will be identified via clinicians who have contributed to previous development work for this study and who were contacted through their links with the CRPS UK Network (a collective of academics and clinicians working in the field of CRPS, and which also hosts a CRPS patient registry). Patients will be recruited via service leads and/or therapists working within specialist CRPS practice services in England. Recruitment of therapists working in England with people with CRPS in non-specialist settings will be from respondents to a prior survey (Work Package 1, already completed) and who have given consent to be contacted in relation to the interview study.

The research team will receive consent from all participants prior to data collection commencing. All interviews will be conducted by telephone or online and will be structured according to a sample-specific topic guide developed by the research team. These will be piloted with a Patient and Public Involvement (PPI) representative, and with relevant therapists, prior to data collection.

The duration of interviews with CRPS therapists working in specialist CRPS practice centres will be up to 60 minutes, all other interviews are anticipated to be up to 45 minutes. Data will be analysed to identify themes.

#### Observational Study - Work Package 3:

The aim of work package 3 is to identify potential key care package components by observing interventions/interactions between Complex Regional Pain Syndrome (CRPS) patients and specialist therapists. Observations were deemed the most appropriate method to fully understand the structure and delivery of therapies, particularly where multiple interventions may occur concurrently within a therapy session.

Specialist therapists (physiotherapists, occupational therapists and hand therapists) who participate in work package 2 will be invited to take part in work package 3. Additional recruitment, if required, will be facilitated via the specialist CRPS service leads in England as identified by the CRPS UK Registry.

Consent will be received from specialist therapists participating in Work Package 3 prior to the identification of patient participants. The consented therapist or a member of their clinical team will then identify eligible patients and approach them to seek permission to pass their contact details back to the study team. A member of the study team will receive consent and will then liaise with the therapist and agree the date and time for the observation to be conducted.

The delivery of therapy sessions in a number of specialist CRPS practice centres will be observed and video-recorded by a member of the research team who will be present, but unobtrusive in the room. It is anticipated that between 6 and 12 individual therapy sessions will be captured. Data will be analysed by reviewing each video and recording, in a tabular format, each intervention component observed.

#### Stakeholder Workshops - Work Package 4

An iterative series of online stakeholder events (2-3 events) will be held to reach consensus on a draft package of care. Using this approach will enable the research team to facilitate a structured interaction which captures individual opinion from all attendees.

Patient representatives, therapists from specialist services, therapists working in non-specialist settings, and musculoskeletal (MSK) systems leaders with responsibility for planning and providing MSK and pain services within local integrated care systems will be invited to attend

(n=~20). 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 and patient representatives from two national CRPS patient charities: CRPS UK and Burning Nights, will also be invited. During the stakeholder events the outcomes of the analysis from work packages 2 and 3 will be discussed and consensus methods used to agree the content of the proposed draft therapy care package. Discussions will also inform the preliminary development of educational materials to accompany the care package. The online workshops will be audio-recorded in order that comprehensive notes can be compiled to capture the discussion.

Dissemination activities will include: summary reports for research participants, patient-specific charities and advocate organisations, clinicians and commissioners; use of social media and the study website (with links to relevant reports as appropriate); first iteration of an intervention briefing document: "A Guide to Delivering Therapy-Led Interventions for CRPS in Non-Specialist Settings" tailored for, and distributed to, different professional groups e.g. 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. Interim and final research reports will be provided to the funder (NIHR) and findings will also be disseminated via peer-reviewed journal publications, conference presentations intended for scholarly audiences, and via the professional networks of the research team.

### **Intervention Type**

Other

### **Primary outcome(s)**

The perceptions and practices of therapists who manage people with Complex Regional Pain Syndrome will be collected via semi-structured interviews and clinical observations.

### **Key secondary outcome(s)**

1. The perceptions of patients with Complex Regional Pain Syndrome regarding their experiences of therapy will be collected via semi-structured interviews.
2. The components of a draft therapy care package for use by the therapists in the community will be achieved via consensus methods using nominal group techniques in an iterative series of stakeholder events

### **Completion date**

30/07/2023

## **Eligibility**

### **Key inclusion criteria**

Work Package 2:

1. Patient Interviews: 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
2. Therapist Interviews: Physiotherapists, occupational therapists and hand therapists working in England in non-specialist and specialist CRPS practice settings

Work Package 3:

3. Physiotherapists / occupational therapists / hand therapists working in England with people with CRPS in specialist CRPS practice settings.

4. 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.

Work Package 4:

5. Physiotherapists, occupational therapists and hand therapists working in England with people with CRPS in specialist and non-specialist settings.

6. Patients diagnosed with CRPS according to the Budapest diagnostic criteria and who are engaging or have engaged with CRPS care in a therapy service in England.

7. Representatives from Integrated Care Systems with responsibility for the planning and provision of musculoskeletal and pain services in England.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

Work Package 2:

1. Therapists and other health care professionals not working in England.

2. Therapist and other health care professionals not connected with delivery of care for people with CRPS.

3. Patients where receipt of therapy for CRPS is/was not in England.

4. Participants without access to either a PC/tablet/mobile device/telephone.

Work Package 3:

5. Therapists and other health care professionals not working in England.

6. Therapists and other health care professionals not connected with delivery of care for people with CRPS.

7. Patients where receipt of therapy is not in England.

Work Package 4:

8. Therapists, commissioners, and other health care professionals not working in England, or connected with delivery of care for people with CRPS.

9. Patients where receipt of therapy for CRPS is/was not in England

10. Potential participants without access to either a PC/tablet/mobile device/telephone.

### **Date of first enrolment**

22/01/2022

### **Date of final enrolment**

30/06/2023

## **Locations**

## **Countries of recruitment**

United Kingdom

England

## **Study participating centre**

**Centre for Health and Clinical Research**

School of Health and Social Wellbeing

Glenside Campus

University of the West of England

Bristol

United Kingdom

BS16 1DD

## **Study participating centre**

**Royal United Hospital**

Combe Park

Bath

United Kingdom

BA1 3NG

## **Sponsor information**

### **Organisation**

University of the West of England

### **ROR**

<https://ror.org/02nwg5t34>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

NIHR Central Commissioning Facility (CCF)

### **Funder Name**

National Institute for Health Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

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.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		28/03/2023	30/03/2023	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes