ISRCTN16917807 https://doi.org/10.1186/ISRCTN16917807

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

Submission date
18/02/2022

Recruitment status
No longer recruiting

Registration date
24/02/2022

Overall study status
Completed

Last Edited
17/04/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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:
a) 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.
b) 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

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)
304399

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 51670, NIHR200753, IRAS 304399

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
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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?
Protocol article		28/03/2023	30/03/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes