ISRCTN56474274 https://doi.org/10.1186/ISRCTN56474274

Identifying the core clinical outcomes for measurement in future complex regional pain syndrome (CRPS) clinical studies

Submission date
03/04/2019

Recruitment status
No longer recruiting

Registration date
01/05/2019

Overall study status
Completed

Last Edited
10/10/2022

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Complex Regional Pain Syndrome (CRPS) is a chronic pain condition that has severe negative impacts on patients' quality of life. It is difficult to treat and is not well understood. Whilst there has been success in standardising diagnosis of the condition, it has been difficult to bring together findings from research studies, as researchers and clinicians may not always measure the same features. This means that it has not been possible to combine data from different studies and therefore evidence about the condition is often limited to findings from studies with small numbers of patients. We now need to create a recommended set of those features that all CRPS research studies should measure in the future. This will enable us to pool findings from different studies and, from this wider evidence, understand more about the causes, course and best treatment approaches for CRPS. An international group of patients, clinicians, researchers and industry representatives has already agreed a minimum set (COMPACT-Q) of questionnaires that patients complete to tell researchers about their CRPS. This is currently being tested for use in future CRPS clinical studies in adults. The aim of this study is to define a minimum set of the features that clinicians (e.g. doctors, physiotherapists, occupational therapists) measure or assess in CRPS research studies. Once this core "clinical" set has been defined, the existing systems for collecting and storing this information will be modified, and researchers around the globe will be encouraged to use the new minimum clinical outcome set.

Who can participate?
Clinician, academic, industry representative or patient representative with expertise/experience in Complex Regional Pain Syndrome, members of the International Association for the Study of Pain Special Interest Group for Complex Regional Pain Syndrome, members of the Complex Regional Pain Syndrome International Research Consortium, or members of the COMPACT consortium.

What does the study involve?
The participants review a list of outcomes currently used in CRPS research studies, and rate these for relevance for researchers who want to answer the question "What is the clinical presentation and course of CRPS, and what factors influence it?". The findings are analysed and

those outcomes with the highest ratings are considered at a workshop of experts for inclusion in a core outcome set to be recommended for use in all future CRPS research studies.

What are the possible benefits and risks of participating?
This study will not benefit participants directly. However, the results will help develop a standard core set of clinical outcomes for use in future CRPS research studies. In the long term this will help researchers answer some of the important questions about CRPS. There are no risks in taking part in the study.

Where is the study run from?
Royal United Hospitals Bath NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2018 to April 2020

Who is funding the study?
Reflex Sympathetic Dystrophy Syndrome Association (USA)

Who is the main contact?
Dr Alison Llewellyn
Alison.Llewellyn@uwe.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Alison Llewellyn

ORCID ID
https://orcid.org/0000-0002-8769-832X

Contact details
University of the West of England
Glenside Campus
Blackberry Hill
Bristol
United Kingdom
BS16 1DD
+44 (0)117 3287495
Alison.Llewellyn@uwe.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Protocol v1 25.2.19

Study information

Scientific Title
COMPACT-C: An e-Delphi study to define internationally agreed core clinical outcome measures for Complex Regional Pain Syndrome clinical studies

Acronym
COMPACT-C

Study objectives
This study is a consensus approach to defining a minimum core set of clinical outcome measures (COMPACT-C) that will complement the current COMPACT patient-reported outcome measurement set. Collecting international data using these core measurement sets will enable researchers to answer the research question: What is the clinical presentation and course of CRPS, and what factors influence it?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/03/2019, Faculty of Health and Applied Sciences Research Ethics Committee at the University of the West of England (Dr Julie Woodley, Chair of Faculty of Health and Applied Sciences Research Ethics Committee, Glenside Campus, Blackberry Hill, Bristol, UK BS16 1DD; Tel: +44 (0)117 32 81170; Email: researchethics@uwe.ac.uk), ref: HAS.19.02.142

Study design
International e-Delphi survey and consensus workshop

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Complex regional pain syndrome

Interventions
The study methodology is an electronic-Delphi study, supported by face-to-face workshops. The stages are as follows:
1. Workshop 1: to consider expert opinion and the results of a systematic literature review in order to identify a full list of clinical outcome measures used in complex regional pain syndrome clinical studies.
2. Electronic Delphi Round 1: to survey clinicians, academics and others working in the field of CRPS. Respondents will be asked to review the list of clinical outcomes arising from Workshop 1 and to rate the scientific relevance of each outcome on a 9-point Likert scale, in relation to the question "What is the clinical presentation and course of CRPS, and what factors influence it?".

Responses will be collated to create Round 2.
3. Electronic Delphi Round 2: Respondents who completed Round 1 will be presented with a personalised survey comprising the individual ratings they provided in Round 1 and the group median rating for each outcome. Any free text comments provided in Round 1 will also be displayed in an anonymised manner. Participants will be asked to re-rate each outcome in light of this information.
4. Workshop 2; to consider those outcomes rated consistently most highly in the electronic Delphi Round 2 and to agree the draft ‘core clinical outcome measurement set’.
5. Experts in the field of CRPS will consider any practical limitations to the final selected outcomes (financial, equipment or time restrictions) and agree the final 'core clinical outcome measurement set'. They will also ensure this can be appropriately presented and supported on the COMPACT data management system.

Intervention Type
Other

Primary outcome(s)
Identification of a core clinical outcome measurement set, agreed via collecting ratings of the relevance of clinical outcomes to the question "What is the clinical presentation and course of CRPS, and what factors influence it?". This method uses a Likert 1-9 rating scale at two timepoints: baseline and following feedback of baseline median group ratings

Key secondary outcome(s))
Modification of the existing COMPACT data management system is agreed by expert opinion, so that it can collect and store core outcome data from future clinical studies

Completion date
30/04/2020

Eligibility

Key inclusion criteria
1. Participants must be a clinician, academic, industry representative or patient representative with expertise/experience in Complex Regional Pain Syndrome
2. Participants may be members of the International Association for the Study of Pain Special Interest Group for Complex Regional Pain Syndrome, members of the Complex Regional Pain Syndrome International Research Consortium, or members of the COMPACT consortium.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
74

Key exclusion criteria
Not a clinician/academic/researcher working in the field of Complex Regional Pain Syndrome

Date of first enrolment
11/04/2019

Date of final enrolment
22/05/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Coombe Park
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
Royal United Hospitals Bath NHS Foundation Trust

ROR
https://ror.org/058x7dy48

Funder(s)

Funder type
Other

Funder Name
Reflex Sympathetic Dystrophy Syndrome Association

Alternative Name(s)
RSDSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. The repository is within the secure electronic environment of the University of the West of England and/or on secure servers at the Royal United Hospitals Bath NHS Foundation Trust. Authorised members of the UK study team will have access to the data. Anonymised data will be made available to wider (non-UK) team members at the discretion and invitation of the study CI, or their appointed representative, and under the terms of a collaborative agreement. Data may also be looked at by representatives of regulatory authorities solely for the purpose of checking that the study is being carried out correctly. Study data will be held for a minimum of five years and may be re-used for sub-group analyses by the study team within this period. Personal data will be held for two years after the study is finished in order to address any queries that might arise during the dissemination of the work, but will not be shared outside the UK study research team. Informed consent will be obtained from all electronic Delphi participants prior to data collection. All data will be held according to Good Clinical Practice and data protection requirements including the General Data Protection Regulation (GDPR), and the Data Protection Act (2018) in the UK.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/07/2022	01/08/2022	Yes	No
Participant information sheet	Participant information sheet version 1	11/11/2025	11/11/2025	No	Yes
Protocol file		25/02/2019	10/10/2022	No	No