

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/05/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2022	Condition category Signs and Symptoms	<input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Expert/stakeholder opinion to define core outcome measures

Study setting(s)

Internet/virtual

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2018

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

Age group

Adult

Sex

Both

Target number of participants

Min 50, max 300

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**

England

United Kingdom

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

Sponsor details

Coombe Park
Bath
England
United Kingdom
BA1 3NG
+44 (0)1225 465479
Jane.carter14@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.ruh.nhs.uk>

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

Publication and dissemination plan

The researchers plan to publish findings and recommendations in a peer-reviewed scientific journal with an intent to publish date of around one year after the overall study end date. They

will submit one or more abstracts for poster presentation at a scientific conference. They will publish the results on relevant websites and include a lay summary where applicable.

Intention to publish date

30/11/2021

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	version 1	04/07/2022	01/08/2022	Yes	No
Protocol file		25/02/2019	10/10/2022	No	No