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Collecting COMPACT data for CRPS clinical studies 1.0

Submission date
30/07/2018

Registration date
26/09/2018

Last Edited
25/07/2023

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

☒ Prospectively registered
☒ Protocol
☐ Statistical analysis plan
☒ Results
☐ Individual participant data

Plain English summary of protocol

Background and study aims

Complex Regional Pain Syndrome (CRPS)is a persistent pain condition that remains incompletely understood and challenging to treat. Currently, it is difficult to bring research findings from many different studies together because researchers may not always use the same questionnaires. There is therefore limited evidence on the causes, course and best management of CRPS. An international group of patients, clinicians, researchers and industry representatives has agreed a minimum set of questionnaires (COMPACT) for use in future CRPS clinical studies in adults. The aim of this study is to test how practical it is to collect research data from patients with CRPS using a core set of questionnaires (COMPACT©). COMPACT is the acronym for Core Outcome Measurement set for complex regional PAin syndrome Clinical sTudies. The study also tests an electronic data capture system (ALEA) which will be used to collect and manage the COMPACT data.

Who can participate?

Patients aged 18 and over with CRPS who are being seen for a face to face clinical visit

What does the study involve?

Patients are asked to complete the set of COMPACT questionnaires on two occasions: on paper at the start of the study and on paper or using an online version at 6 months. Patients are invited to give feedback on their experience of completing COMPACT. Clinicians use an electronic questionnaire to feedback their experience of data collection.

What are the possible benefits and risks of participating?

This study will not benefit patients directly. However, the results will help to develop a standard questionnaire set for CRPS research studies. In the long term this may help researchers answer some of the big questions about CRPS. There is no particular risk in taking part in the study. Responses to the patient-completed questionnaires will not be seen by a health professional and so, if any of the questions raise issues or concerns, the participant is advised to speak to their family doctor or a member of the research team. The only disadvantage in taking part is the time it takes to complete the questionnaire set each time.

Where is the study run from?
1. Royal United Hospitals Bath NHS Foundation Trust (UK) (lead site)
2. Balgrist University Hospital (Switzerland)
3. CSSS Pierre Boucher (Canada)
4. Reuth Rehabilitation Hospital (Israel)
5. Nagoya University (Japan)
6. Hospital São Camilo (Brazil)
7. University of South Australia (Australia)
8. Cleveland Clinic (USA)

When is the study starting and how long is it expected to run for?
June 2018 to June 2021

Who is funding the study?
1. Royal United Hospital Charitable Fund (UK)
2. Swiss Accident Insurance Fund (Switzerland)

Who is the main contact?
Mrs Sharon Grieve
sharon.grieve1@nhs.net

Contact information

Type(s)
Scientific

Contact name
Mrs Sharon Grieve

ORCID ID
https://orcid.org/0000-0002-3509-3468

Contact details
Royal National Hospital for Rheumatic Diseases
Upper Borough Walls
Bath
United Kingdom
BA1 1RL
+44 (0)1225 465941
sharon.grieve1@nhs.net

Additional identifiers

Protocol serial number
38787

Study information

Scientific Title

A multi-centre study to explore the feasibility and acceptability of collecting data for Complex Regional Pain Syndrome clinical studies using a core measurement set

Study objectives

This is a multi-centre international study to test how practical it is to collect research data from patients with Complex Regional Pain Syndrome (CRPS), using a core set of questionnaires (COMPACT©). COMPACT is the acronym for Core Outcome Measurement set for complex regional PAin syndrome Clinical sTudies. The trialists also wish to test an electronic data capture system (ALEA) which will be used to collect and manage the COMPACT data.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/08/2018, South Central-Hampshire A Research Ethics Committee (Level 3, Block B, Whitefriars, Bristol BS1 2NT, UK; Tel: +44 (0)207 1048241; Email nrescommittee.southcentral-hampshirea@nhs.net), REC ref: 18/SC/0322

Study design

Observational; Design type: Validation of outcome measures

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Complex regional pain syndrome

Interventions

Interventions as of 11/12/2018:
This is a multi-centre study in the UK and international CRPS populations, to test the feasibility and acceptability of collecting outcome measurement data using a paper and electronic version of the core measurement set.

Eight countries will participate in this study recruiting their own cohort of patients and obtaining their own ethical and institutional approvals. Centres with the necessary resources to collect and manage COMPACT data have been recruited, but the centres vary in terms of culture, language and healthcare organisational structures so as to offer insight into the challenges we are most likely to encounter in a future multi-national study. This approach ensures a wide range of ethical and governance requirements are also reflected.

The study is not aiming to obtain statistically significant data but to ascertain the practicalities and acceptability of collecting data using COMPACT across a range of different cultures and populations.

Recruitment
The study will recruit adults (≥ 18 years) with CRPS I or II, meeting the Budapest diagnostic clinical criteria, and who are being seen for a face to face clinical visit. This inclusion criteria

ensures a wide range of patients will be recruited to represent different ages, CRPS disease durations, gender, ethnicity and COMPACT access requirements. Patients will be excluded if they are unable to understand the written word or unable to write, and/or unable to give informed consent.

The trialists will ask each centre to collect ≥ 10 (maximum 30) complete Baseline (Time 1) and Follow Up (Time 2) questionnaires which it is anticipated to take between 12 and 15 months.

Patients attending the participating study centres will be identified by the local multi-disciplinary team as potential recruits to this study. This can be at any point in their treatment pathway. A member of the multidisciplinary team undertaking the routine clinical visit will provide potential research patients with a recruitment pack which will include:
1. An invitation letter
2. A participant information sheet
3. Consent form (two copies, as one is for the patient's own records)
4. The baseline COMPACT questionnaire set
5. Contact details form
6. A pre-paid envelope as required by each country

At this point an opportunity for questions or discussion will be available with a member of the research team; face to face or via an identified telephone or email contact.

Each centre will be asked to record the number of recruitment packs distributed. This will be compared with the actual number of patients recruited to provide information regarding recruitment methods and rates.

Informed consent

Informed consent will be obtained by the return of a signed and dated consent form to the local team. This will include consent to provide their contact details (address and/or email) to enable them to be contacted regarding data collection at Time 2 (T2). Two consent forms will be provided in the recruitment pack so that the patient can keep one copy for their own records.

Data collection

COMPACT comprises of (1) a patient completed document and (2) a clinician completed document;

1. The patient completed document is collected at Baseline (Time 1) and at 6 month Follow Up (Time 2).
This includes standardised patient reported questionnaire outcome measures as listed below:
1.1. Date of birth, gender, CRPS affected limb, limb dominance prior to CRPS, CRPS duration, participation in employment/education/voluntary work
1.2. Pain intensity Numeric Rating Scale
1.3. Short-form McGill Pain Questionnaire(SF-MPQ-2)-the six neuropathic pain items (Dworkin et al 2009)
1.4. PROMIS 29 Profile (version 2) (Cella et al 2007)
1.5. PROMIS suicide ideation question (Pilkonis et al 2011)
1.6. Pain Catastrophizing Scale (Sullivan et al 1995)
1.7. EQ-5D-5L (Herdman et al 2011)
1.8. Pain Self-efficacy Questionnaire (Nicholas 2007)
1.9. CRPS symptom questions
1.10. Patient Global Impression of Change (completed at Follow Up only)

For the international centres, these questionnaires will be available in country specific translations where necessary.

Many of these questionnaires are already available in the languages used by the participating centres. Where documents require translation these will be undertaken by the research partners in each country under strict adherence to the 'best practice' translation standards (Brunner et al 2010). This uses a forwards and backwards translation approach to ensure the meaning of text is the same across each of the countries. The research team have proven expertise and track record of undertaking these translation procedures. PROMIS has a specific translation methodology which needs to be followed. Translations are already available in some of the required feasibility study languages. The remaining translations are currently underway by groups outside COMPACT and we anticipate that they will be available in Spring 2018.

2. The clinician completed document.
This comprises the CRPS Severity Score (Harden et al 2010) which is completed by the clinician. The CSS will be collected as routine practice and the data only included in the study if the patient completes the COMPACT documentation and gives informed consent.

In order to participate in this study, recruitment centres are required to complete the CRPS Severity Score (CSS) as part of routine clinical care. The CSS is directly derived from the Budapest CRPS diagnostic criteria (Harden et al 2010). This is a routine data collection tool that is used by a clinically qualified healthcare professional to confirm the diagnosis of CRPS. The CSS data are required to be collected at baseline, and can additionally be collected six months later at Time 2 if a study patient attends a clinical appointment at this time.

Data will be collected at two time points.
Time 1 - Baseline
This will comprise the baseline patient reported COMPACT questionnaire set, and the CSS which is completed by the clinician.

Time 2 - Follow up at six months after Time 1 (+/- 2 weeks)
This will comprise the follow up patient reported COMPACT questionnaire set and, if the participant has a clinical review scheduled at this time, the CSS. The questionnaire set at Time 2 differs only by collecting less demographic data and includes a patient global impression of change. The CSS is not a compulsory part of Time 2 data collection.

Data collection process at Time 1
If an individual chooses to participate, then they will return the signed and dated consent form, contact details form and the COMPACT questionnaire set to the local study centre. The contact details form will ask patients to select one of the two options of data collection at Time 2;
1. Paper
2. Electronic - using a unique log-in to access ALEA

The instructions in the Patient Information Sheet will ask potential participants to complete the questionnaire on a single day, if possible, so that the information is representative of their health at a specific time point. The date of questionnaire completion is recorded by the patient on the COMPACT document. Patients will be accepted on to the study whenever the COMPACT documents are returned. Contact details for all patients will be recorded by the study coordinator at each site.

Those who choose not to participate, and are willing to give a reason, will be directed to complete Section B of the contact details form. This can be returned in the pre-paid envelope. This information will inform a future protocol.

Data collection process at Time 2
Patients will receive the 6 month follow up COMPACT questionnaire set via their preferred method of data collection which was selected at Time 1.

Data collection at Time 2 using a paper version.
For those selecting receipt of a paper version, the COMPACT questionnaire set and an accompanying letter will be sent to patients by post shortly before the 6 month time point. A pre-paid envelope will be supplied, for return to the local study team.

Alternatively, if the patient has a clinical visit scheduled at the 6 month time point, the above documents may be given to the them at this visit. The clinician should also complete the CSS.

Data collection at Time 2 using electronic data collection, via ALEA
Approximately two weeks before the 6 month time point, the patient will receive an email containing a unique Pin number which will allow access to ALEAs electronic Patient Reported Outcome (e-PRO) environment (https://prod.tenalea.net/ciru/ePRO/). Instructions will be supplied for the patient on how to change the pin number to a unique password and how to complete the COMPACT questionnaire via a computer, tablet or smartphone. Text preceding the questionnaire will re-familiarise the patient with the study.

At Time 2, if COMPACT is not completed online or returned by post within 14 days, one reminder letter will be sent by post or email.

CSS at Time 2
The CSS will be accepted at Time 2 if it is completed +/- 2 weeks of the patient COMPACT document T2 completion date. If the CSS is not completed at Time 2, the researcher will record the reason (for example, no clinical visit scheduled; outside +/- 2 week window)

Feedback on data collection experience by clinicians
A short questionnaire will be sent by email from the lead centre (Bath, UK) to the principal investigator at each centre asking clinicians about their experience of data collection. The questions asked will be informed by matters that have arisen in the Project Management group's regular meetings. It will invite feedback regarding the time required by the clinician for data collection at each Time point, the ease of the process etc.

Workshop
A single workshop will be convened which ideally will run alongside an international meeting. This COMPACT workshop will review findings of the feasibility study. The attendees (approximately 15-20) will comprise COMPACT group members; patients, clinicians, researchers and representatives from industry. The final documents will be agreed through consensus. The process for registering with COMPACT, seeking ethical approvals, translation processes, data collection and data management will be finalised. Any other pertinent issues identified from the findings will also be agreed.

The following criterion will need to be met before COMPACT can be disseminated to a wider population;

It is demonstrated that it is feasible and acceptable to collect and securely store outcome measurement data using a paper and electronic version of the core measurement set, in the CRPS population both in the UK and overseas.

Regular reports will be submitted to our funders throughout the study period. Study updates and study results will be available on the websites of the CRPSUK Network, CRPS International Research Consortium and the IASP Special Interest Group or on request.

A broad time table of the study is outlined below:
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9- 25 months Recruitment and data collection, Time 1 and 2
22-30 months Analysis of study data
24-28 months Clinician feedback
30-31 months Final COMPACT and data collection processes to be agreed and begin preparation of publication

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At Time 2, if COMPACT is not completed online or returned by post within 14 days, one reminder letter will be sent by post or email.

CSS at Time 2

The CSS will be accepted at Time 2 if it is completed +/- 2 weeks of the patient COMPACT document T2 completion date. If the CSS is not completed at Time 2, the researcher will record the reason (for example, no clinical visit scheduled; outside +/- 2 week window)

Feedback on data collection experience by research patients

One focus group will take place at each participating centre on one occasion after Time 2.
An invitation within the Time 2 study information will give patients the opportunity to contact their local recruitment centre if they are interested in participating in this group. It is anticipated 6-8 patients per centre (no less than 4) will participate. They will be asked to share their experience of completing COMPACT; paper and electronic where applicable. This will be facilitated by a local researcher appointed by the country specific study centre and conducted in the country specific language. Focus groups will be recorded and field notes taken. The field notes will be translated into English for analysis. For centres with < 4 people willing to attend a focus group, patients will be offered a phone conversation with a researcher, to share their experience of completing COMPACT. This will be informed by the focus group topic guide, and field notes taken and translated as above.

Feedback on data collection experience by clinicians

A short questionnaire will be sent by email from the lead centre (Bath, UK) to the principal investigator at each centre asking clinicians about their experience of data collection. The questions asked will be informed by matters that have arisen in the Project Management group's regular meetings. It will invite feedback regarding the time required by the clinician for data collection at each Time point, the ease of the process etc.

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9- 25 months Recruitment and data collection, Time 1 and 2
22-30 months Analysis of study data
24-28 months Focus group and clinician feedback
30-31 months Final COMPACT and data collection processes to be agreed and begin preparation of publication

Intervention Type
Other

Primary outcome(s)
The proportion of participants having a fully completed COMPACT questionnaire at Time 1 (baseline) and Time 2

Key secondary outcome(s))
Secondary outcome measures as of 12/12/2018:
1. Feedback on data collection experience by research participants
2. Feedback from the clinicians about their experience of data collection
3. Comparison of the paper version and e-version of the COMPACT questionnaire, to establish any variants in quality across different media

Previous secondary outcome measures:
1. Feedback on data collection experience by research participants at the focus group
2. Feedback from the clinicians about their experience of data collection
3. Comparison of the paper version and e-version of the COMPACT questionnaire, to establish any variants in quality across different media

Completion date
01/06/2021

Eligibility

Key inclusion criteria
Adults (≥ 18 years) with CRPS I or II meeting the Budapest diagnostic clinical criteria who are being seen for a face to face clinical visit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
98

Key exclusion criteria
Unable to understand the written word or unable to write, and/or unable to give informed consent

Date of first enrolment
01/10/2018

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
United Kingdom

England

Australia

Brazil

Canada

Israel

Japan

Switzerland

United States of America

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust (lead site)
Bath
United Kingdom
BA1 3NG

Study participating centre
Balgrist University Hospital
Zurich
Switzerland
-

Study participating centre
CSSS Pierre Boucher
Longueuil
Canada
-

Study participating centre
Reuth Rehabilitation Hospital
Tel Aviv
Israel
-

Study participating centre
Nagoya University
Nagoya
Japan
-

Study participating centre
Hospital São Camilo
San Paolo
Brazil
-

Study participating centre
University of South Australia
Adelaide
Australia
-

Study participating centre

Cleveland Clinic
Cleveland
United States of America
-

Sponsor information

Organisation
Royal United Hospitals Bath NHS Foundation Trust

ROR
https://ror.org/058x7dy48

Funder(s)

Funder type
Charity

Funder Name
Royal United Hospital Charitable Fund

Funder Name
SUVA

Alternative Name(s)
Swiss Accident Insurance Fund, Schweizerischen Unfallversicherungsanstalt

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/07/2023	25/07/2023	Yes	No
Protocol article		11/07/2019	30/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes