



Royal United Hospitals Bath **NHS**
NHS Foundation Trust



ISSUE 03:

December 2018

Core Outcome Measurement set for complex regional PAin syndrome Clinical sTudies



COMPACT membership

The COMPACT consortium is comprised of patients, clinicians, researchers and industry representatives from fifteen countries across the globe. We currently have over 65 members.

COMPACT is supported by the CRPS International Research Consortium (IRC) - www.crp Consortium.org

The IRC aims to promote research related to improving the future for people living with CRPS. If you would like to find out more about their work or to register your interest in becoming a member, please contact Debra Nelson-Hogan:

dhogan@crpsconsortium.org



International Research Consortium
for Complex Regional Pain Syndrome

Welcome to the third COMPACT Newsletter

A tremendous amount of work has been achieved since the COMPACT international consortium was established in 2013. We are most grateful to the IASP CRPS Special Interest Group and the International Research Consortium for CRPS, for their continued support. This newsletter will provide an overview of progress since our second issue. Once again, we would like to thank all the consortium members for their continued support, hard work, enthusiasm and commitment. We would also like to take the opportunity to introduce Lisa Buckle, our new COMPACT administrator, and Dr Alison Llewellyn, who is leading the COMPACT –C study (see page 3).

With best wishes from

Candy, Sharon, Ali and Lisa

In this issue:

Building an international registry	2
COMPACT-Q update	3
COMPACT-C update	4
COMPACT publications	5

Building an international clinical research registry for CRPS

The COMPACT consortium was established to agree a minimum core set of standardised patient-reported questionnaire, and this work is now completed and published:

Grieve S, Perez RSGM, Birklein F, Brunner F, Bruehl S, Harden RN, Packham T, Gobeil F, Haigh R, Holly J, Terkelsen A, Davies L, Lewis J, Thomassen I, Connett R, Worth T, Vatine J-J, McCabe C (2017) Recommendations for a first Core Outcome Measurement set for complex regional PAin syndrome Clinical sTudies (COMPACT). Pain 158(6): 1083-1090

COMPACT is now divided into two further studies:

- ⇒ **COMPACT-Q (Questionnaire)** - a feasibility study to test the practicalities of collecting **patient-reported** data from an international population, using the core measurement set
- ⇒ **COMPACT-C (Clinical)** - a Delphi study to define the core **clinical** outcome measures

Together, these data will answer the question “**What is the clinical presentation and course of CRPS, and what factors influence it?**”

Introducing ALEA

We are establishing a registry to provide researchers with access to a large and consistent international data set. This will include demographic data, the published patient-reported outcome measures and the core clinical outcomes (once defined). These data will be collected and managed using an electronic data management system.

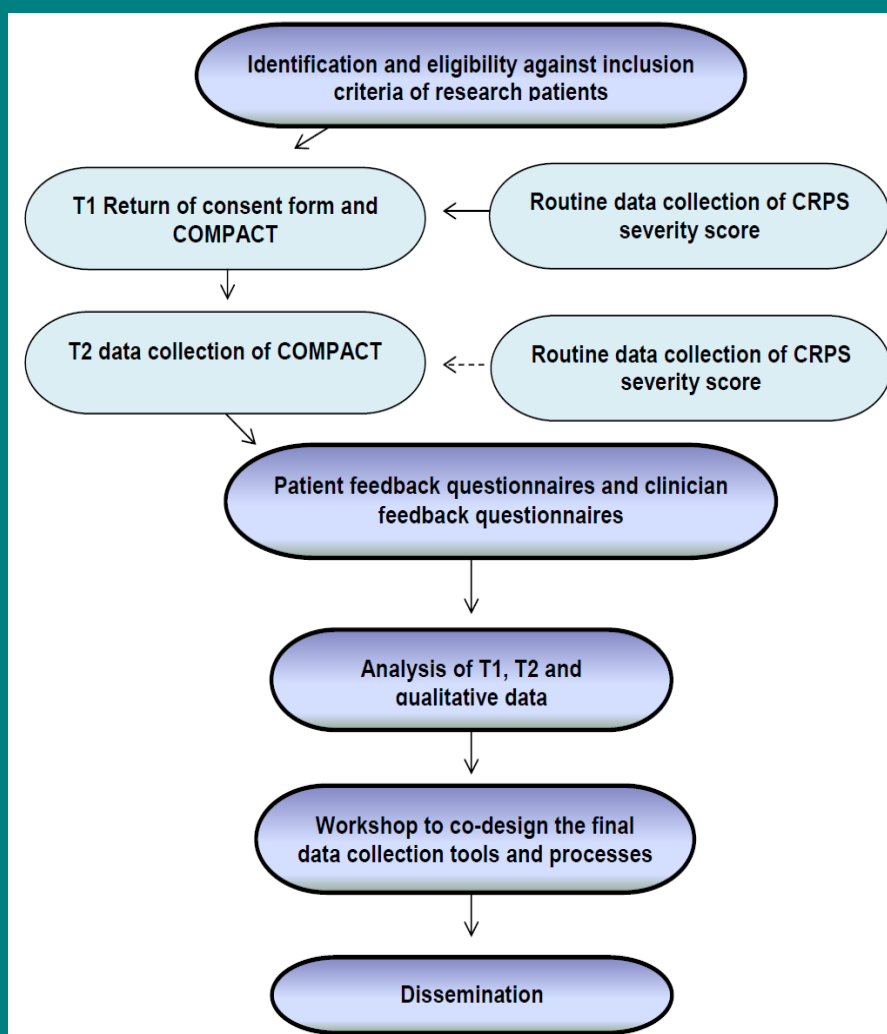
After careful consideration of different systems, we agreed that ALEA would work best for us. Managed and developed by the University of Southampton (UK) in collaboration with FormsVision BV, ALEA is easy to use. Clinical data can be captured and securely stored. Features such as automated scoring, follow-up alerts and translations are ideal for the COMPACT registry. Patients can input data directly using the ALEA ePRO platform. The system also has an extensive reporting facility for analysing data.

COMPACT – Q*

* **Q = questionnaire.** The study involves capturing patient-reported data via questionnaires at baseline (T1) and six-month follow-up (T2)

This is a multi-centre study to explore the feasibility and acceptability of collecting data for Complex Regional Pain Syndrome clinical studies using our agreed patient self-reported questionnaire core measurement set.

We currently have seven international recruiting centres: UK, Switzerland, Canada, Japan, USA, Israel and Australia. Each centre will recruit ≥ 10 (maximum 30) adults with CRPS I or II who meet the Budapest diagnostic criteria and are being seen for a face to face clinical visit.



UK ethical approval was obtained in August 2018 and a feasibility study meeting was held in Boston, USA in September. Following feedback from the Principal Investigators at that meeting, an amendment has been approved to change the way we collect feedback from patients regarding their experience of completing COMPACT.

UK recruitment opened in December 2018. We hugely appreciate the enthusiasm and commitment from the teams at our international research centres. Where applicable, they have been busy translating the study documents and, once completed, will be seeking local ethical approval before also opening recruitment.

We wish to thank our funders for this study: the Swiss National Accident Insurance Fund (SUVA) and Charitable Funds at the Royal National Hospital for Rheumatic Diseases, Bath, UK

suva

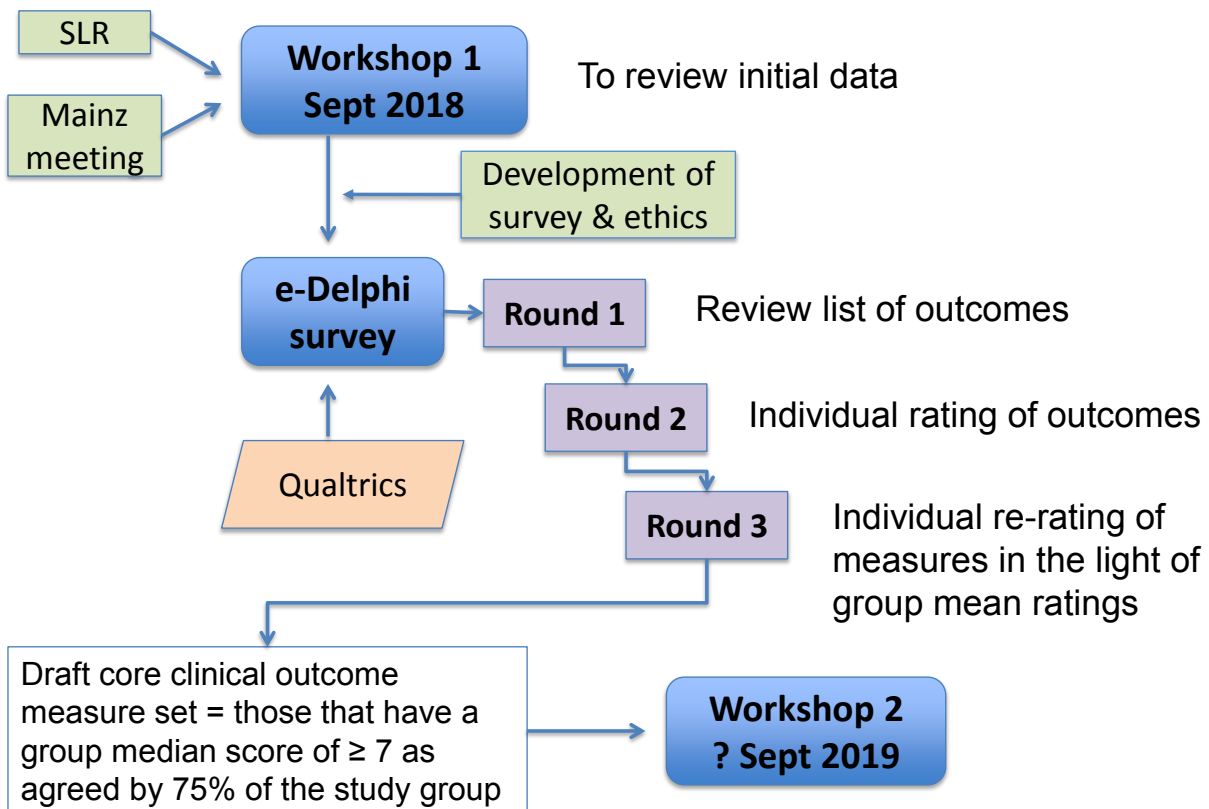
NHS
Royal United Hospitals Bath
NHS Foundation Trust

COMPACT-C**

* **C = clinical.** The study is focused on the outcomes directly measured by clinicians or researchers, not the things patients tell us

This study aims to define the core clinical outcome measures for use in CRPS clinical research via a 3-round e-Delphi survey. Clinicians and researchers will be recruited via the IASP CRPS SIG and the IRC. Consented participants will review a list of possible clinical outcomes, then rate each in order of priority to be included in the final core set. Preparation of project documents, including an application to UK ethics, and familiarisation of the survey platform Qualtrics is currently in progress.

COMPACT-C - Plan of investigation



We are most grateful to the Reflex Sympathetic Dystrophy Syndrome Association (RSDSA) for funding this work.



COMPACT publications since Issue 2

Packham T, Bean D, Johnson M, MacDermid J, Grieve S, McCabe C, Harden RN (2018) Measurement properties of the SF-MPQ-2 Neuropathic Qualities subscale in persons with CRPS: validity, responsiveness and Rasch analysis. Pain Medicine ISSN 1526-4637

Oral Presentations

Grieve, S. Building an international research registry for CRPS. IASP SIG business meeting at the 17th World Congress on Pain, Boston USA. September 2018

THANK YOU

A huge thank you to Lindsay Davies for all of her work as COMPACT administrator. She continues to be a key member of the Bath team, but is now working on other projects.

Also, thank you to all consortium members who are spreading news of COMPACT by incorporating mentions into their presentations.

Using COMPACT-Q: the legal stuff!

While we are setting up COMPACT, it is important that researchers seek permission to use some of the patient-reported questionnaire outcome measures within the core measurement set (COMPACT-Q). In addition, specific standard permissions and procedures may be required when wishing to translate the questionnaire outcome measures. It is the researcher's responsibility to ensure that all the necessary permissions are in place. We will let you know when you can access COMPACT from us directly.

Thank you

We wish to maintain a register of all researchers using COMPACT. Please email us with:

- ⇒ Title of Study
- ⇒ Chief Investigator
- ⇒ Lead Site
- ⇒ Are you using the COMPACT patient-reported questionnaire set alone, or with the clinician reported CRPS Severity Score (CSS)?

For further information regarding any aspect of COMPACT, please contact:

Lisa Buckle, COMPACT Administrator
Royal National Hospital for Rheumatic Diseases
Upper Borough Walls
Bath, UK BA1 1RL

Email: ruh-tr.compact@nhs.net