

COMPACT

Core Outcome Measurement set for complex regional
Pain syndrome Clinical studies

ISSUE 02 – May 2017



COMPACT members at Workshop 3: Bath 2015

COMPACT membership

The COMPACT consortium is comprised of patients, clinicians, researchers and industry representatives from fifteen countries across the globe. We currently have 60 members, many of whom have contributed to the four workshops held since November 2013.

Welcome to the Second COMPACT Newsletter

The COMPACT international consortium was established in 2013, under the auspices of the IASP CRPS Special Interest Group, to agree upon a minimum core set of outcome measures recommended for use in CRPS clinical trials. A tremendous amount of work has been achieved and we are pleased to have recently published the recommendations for the core measurement set. This newsletter will provide an overview of progress since the first newsletter nearly a year ago. Once again, we would like to thank all the consortium members for their continued support, hard work, enthusiasm and commitment. With best wishes from

Candy, Sharon and Lindsay

Change to the COMPACT acronym

The eagle-eyed amongst you may have noticed the subtle change to the meaning of the acronym COMPACT. We have changed the 'T' from Trials to studies as we wish to recommend the core measurement set for all clinical research studies, not exclusively for trials. We are grateful to the manuscript review team at PAIN for prompting us to clarify this.



International Research Consortium
 for Complex Regional Pain Syndrome

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 International Research Consortium
 (IRC)

www.crpconsortium.org

In this issue:

Funding success	2
Recommendations for COMPACT	2
COMPACT feasibility study	3
Reporting the COMPACT survey	3
COMPACT publications	4

Recommendations for a first Core Outcome Measurement set for complex regional PAin syndrome Clinical sTudies (COMPACT)

Following extensive work, detailed in issue 1 of the newsletter, the recommendations for COMPACT are presented in Table 1. We would like to refer you to the paper recently published in PAIN which describes the development process in detail and provides further information ‘Recommendations for a first Core Outcome Measurement set for complex regional PAIn syndrome Clinical sTudies (COMPACT)’. The full reference can be found on page 4 of this newsletter. It is recommended that COMPACT be completed by all patients at two time points, baseline and 6 months, with additional assessment at 3 and/or 12 months, if possible. It is recommended the CRPS Severity Score (Harden et al, 2010) be completed at baseline as a minimum (Fig. 1). We ask that anyone wishing to use COMPACT, notify the administrative team in Bath (contact details on page 4).

Domain	Outcome Measure
Participant characteristics	Demographic data
Pain	Numeric Rating Scale
	PROMIS 29 Profile (version 2) (Cella et al 2007)
	Short-form McGill Pain Questionnaire SF-MPQ-2, six neuropathic pain items (Dworkin et al 2009)
	PROMIS 29 Profile (version 2)
	EQ-5D-5l (Herdman et al 2011)
Disease severity	CRPS Severity Score (Harden et al. 2010)
	CRPS symptom questions
Participation and physical function.	PROMIS 29 Profile (version 2)
	EQ-5D- 5L
Emotional and psychological function	PROMIS 29 Profile (version 2)
	PROMIS suicidal ideation question (Pilkonis et al 2011)
	EQ-5D- 5L
Catastrophizing	Pain Catastrophizing Scale (Sullivan et al 1995)
Self efficacy	Pain Self-efficacy Questionnaire (Nicholas 2007)
Patient's global impression of change	Patient Global Impression of Change [#]

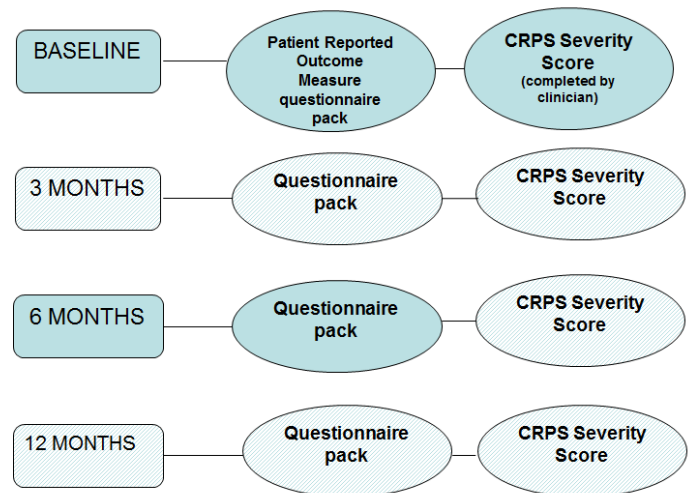


Fig 1. Using COMPACT

Funding success

The COMPACT consortium has recently been awarded funding from SUVA, a Swiss insurance company, to conduct the feasibility study (page 3). We are grateful to SUVA for their support and to our COMPACT member, Dr Florian Brunner, for leading this application. Funding has also been received from Charitable Funds at the Royal National Hospital for Rheumatic Diseases, Bath, UK to explore the potential of using an electronic data management system to collect and manage the COMPACT data.



Table 1. Outcome measures included in COMPACT

[#] not at baseline

COMPACT survey findings

You may be one of the many health professionals who completed an international online survey in Summer 2016. This survey had two aims:

- to learn about existing care delivered to patients with CRPS
- to establish which questionnaire outcome measures are being commonly used by the international CRPS research community in clinical trials for CRPS

The latter is relevant to the COMPACT study and the findings were reported as a poster presentation at the British Pain Society annual scientific meeting in Birmingham, UK in May 2017. We discovered that of the 271 respondents in 35 countries, 19% (n=52) reported they, or their organisation, recommended the use of questionnaire outcome measures for CRPS clinical trials. The questionnaires most frequently used are listed in Table 2.

The survey will act as a baseline for us to measure the impact of COMPACT at a later date.

We intend for the survey to be repeated in 2019.

Domain	Questionnaire Outcome Measure most frequently used
Pain	Visual Analogue Scale (n=13)
Physical Function	Disabilities of the Arm, Shoulder and Hand (DASH) (n= 16)
Emotional and psychological function	Pain Catastrophising Scale (n=9)
Quality of life	36-Item Short Form Health Survey (SF-36) (n=8).

Table 2. Most frequently used outcome measures

The Next Step..

The COMPACT feasibility study

This will likely commence in Autumn 2017 and will test the feasibility and acceptability of collecting outcome measure data using COMPACT in the CRPS population, at selected sites internationally. This is essential prior to widespread adoption by the CRPS research community as a whole.

In addition, we intend to test the feasibility of using an existing data management system to collect and manage the COMPACT data. The resultant database has the potential to be the largest database of CRPS outcome measures and demographic data. This will enable researchers to access a consistent, international dataset, which can be used to gain a better understanding of CRPS, identify precipitating factors and target therapeutic approaches. We are currently in discussion with the CRPS International Research Consortium and COMPACT members to decide which is the best data management system to meet our needs.

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

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COMPACT publications since Issue 1

Packham T, Cappelleri J, Sadosky A, MacDermid J, Brunner F. **Measurement properties of painDETECT: Rasch analysis of responses from community-dwelling adults with neuropathic pain.** BMC Neurology [serial online]. March 4, 2017;17:1-9.

Grieve, S, Perez, R, Birklein, F, Brunner, F, Bruehl, S, Harden, R, Packham, T, Gobeil, F, Haigh, R, Holly, J, Terkelsen, A, Davies, L, Lewis, J, Thomassen, I, Connett, R, Worth, T, Vatine, J, & McCabe, C (2017). **Recommendations for a first Core Outcome Measurement set for complex regional Pain syndrome Clinical sTudies (COMPACT).** Pain. Feb 4. doi: 10.1097/j.pain.0000000000000866. [Epub ahead of print]

Packham T, Bean D, Johnson MH, MacDermid JC, Grieve S, McCabe C, Harden RN. **Measurement properties of the SF-MPQ-2 Neuropathic subscale in persons with CRPS: validity, responsiveness and Rasch analysis.** Paper in preparation

We wish to maintain a register of all researchers using COMPACT. If you are using COMPACT, please email:

ruh-tr.compact@nhs.net

and include the:

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

This registry will contribute to an internal dataset, which will allow the comparison of data and facilitate recruitment to collaborative studies.

THANK YOU

A huge thank you to all consortium members who are spreading news of COMPACT by incorporating mention of COMPACT into their presentations.

Oral Presentations

Grieve S, COMPACT overview and update. IASP SIG Business Meeting at the 16th World Congress on Pain, Japan, Sept 2016.

Poster Presentations

Grieve S, Manns S, Glanville V, Llewellyn A, McCabe C. **A survey of questionnaire outcome measures currently used in Complex Regional Pain Syndrome clinical trials.** Poster presentation. British Pain Society Annual Scientific Meeting, Birmingham UK, May 2017

While we are setting up COMPACT, it is important that researchers seek permission to use some of the questionnaire outcome measures within the core measurement set (COMPACT). 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

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