

COMPACT

**Core Outcome Measures for complex regional
 Pain syndrome Clinical Trials**

ISSUE 01 – July 2016



COMPACT members at Workshop 1:
 November 2013

COMPACT Membership

The COMPACT consortium is comprised of patients, clinicians, researchers and industry representatives from fifteen countries; Switzerland, Germany, Netherlands, Canada, United States, Denmark, Norway, Israel, Australia, New Zealand, South Africa, Japan, Argentina, Brazil and United Kingdom. We currently have 55 members, many of whom have contributed to the four workshops held since November 2013.

Welcome to the First 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. Nearly three years have flown by and a huge amount has been achieved. This newsletter provides an overview of the progress which has been made since our first meeting in Bath, UK, in November 2013. We are very grateful to all the consortium members for their continued support, hard work, enthusiasm and commitment. With best wishes from

Candy, Sharon and Lindsay

The COMPACT Workshops

Workshop 1: November 2013, Bath, UK (n= 27)

Workshop 2: May 2014, Chicago, USA (n= 15)

Workshop 3: January 2015, Bath, UK (n= 20)

Workshop 4: August 2015, Zurich, Switzerland (n= 18)

(n= attendees)



COMPACT members at Workshop 3:
 January 2015

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The COMPACT Development Process

The development of COMPACT was informed through workshops and supplementary work, using an iterative consensus process. The most pertinent research question was agreed as :

‘What is the clinical presentation and course of CRPS and what factors influence it?’

This question was considered by the consortium to be

- the most important topic for enquiry and
- to address a question which required international collaboration and pooling of data, and
- unable to be investigated without a consistent data set

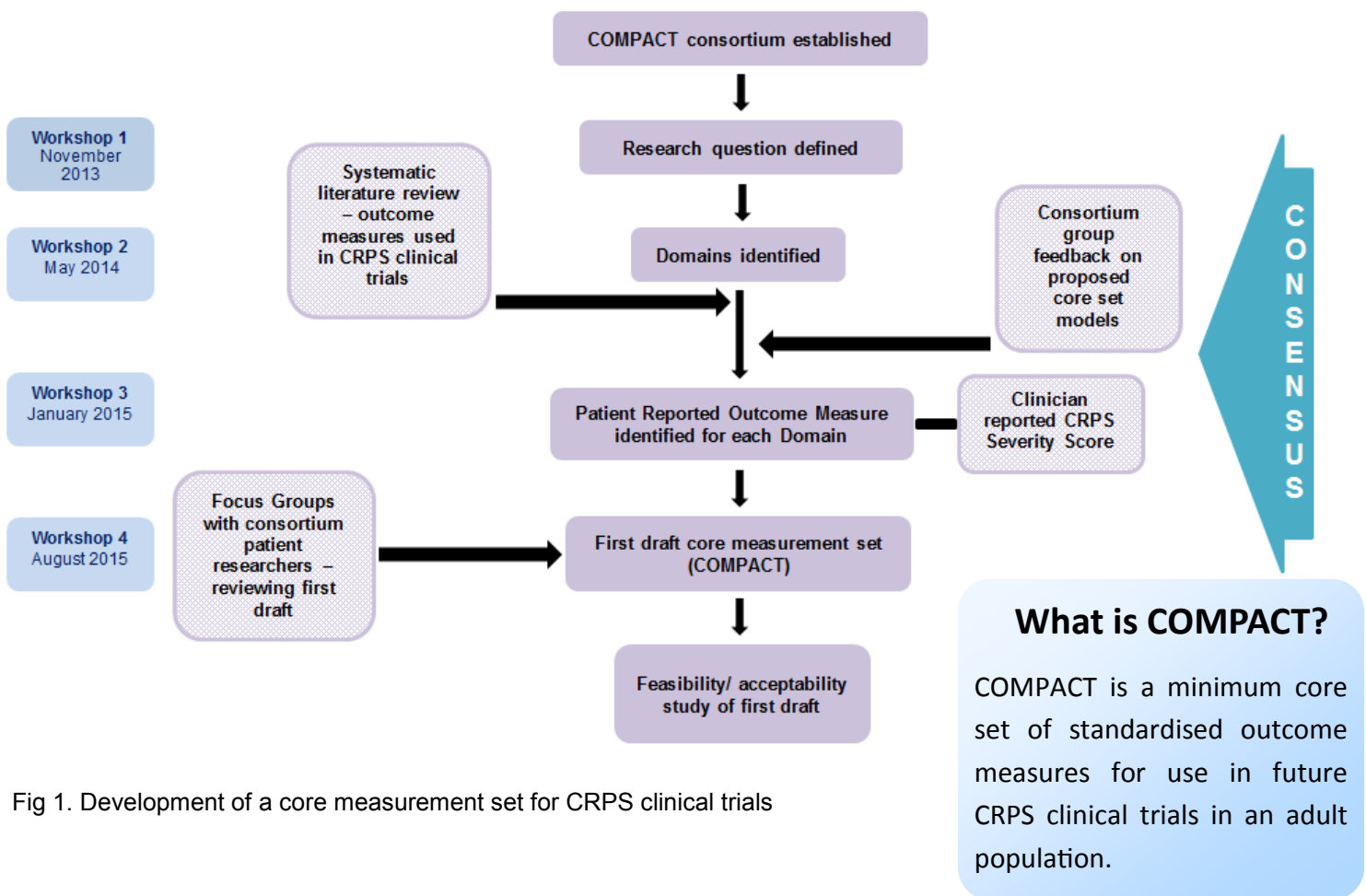


Fig 1. Development of a core measurement set for CRPS clinical trials

The domains encompassing the key concepts necessary to answer the research question were agreed upon as: pain, disease severity, participation and function, emotional and psychological function, self efficacy, catastrophizing and patient's global impression of change. The first draft core measurement set included the optimum generic or condition-specific patient reported questionnaire outcome measures, which captured the essence of each domain (see Table 1, p3).

Using COMPACT

The current draft version of COMPACT is presented in Table 1. The final version of COMPACT will be available for use by researchers worldwide, following completion of a feasibility study (see The Next Step, bottom right). 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. The minimum recommendation of two time points will capture any variation of CRPS since onset. It is recommended the CRPS Severity Score (Harden et al, 2010) be completed at baseline as a minimum (Fig. 2).

DOMAIN	PROPOSED OUTCOME MEASURE*
Participant characteristics	Demographic data
Pain	Pain intensity
	Short-form McGill Pain Questionnaire SF-MPQ-2 (Dworkin et al 2009)
	PROMIS 29 Profile (version 2) (Cella et al 2007)
	EQ-5D- 5L (Herdman et al 2011)
Disease severity	CRPS Severity Score (Harden et al. 2010)
	CRPS symptom questions
Participation and 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 [#]

Table 1. Patient reported outcome measures included in COMPACT (Draft version)

* Proposed outcome measures prior to feasibility study

[#] Will be completed at time point 2 only

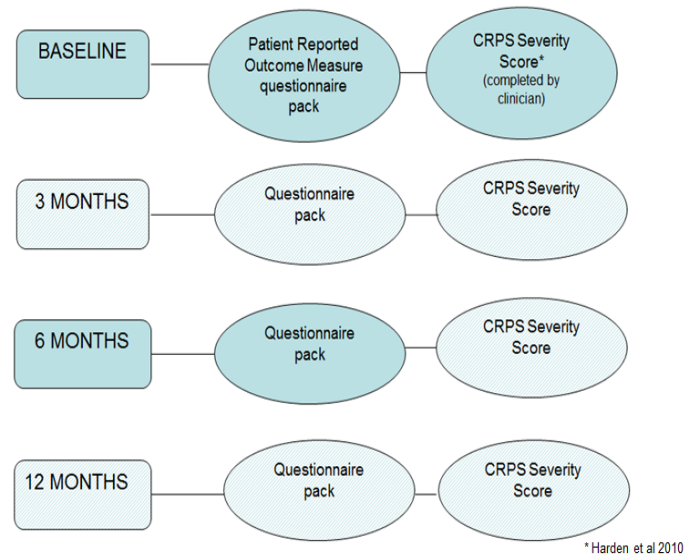


Fig 2. Using COMPACT

The Next Step...

... is to 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 as a data collection tool. We anticipate the feasibility study will commence in Autumn 2016.

With grateful thanks to our funders:



- The Balgrist Foundation, Balgrist University Hospital, Zurich, Switzerland.
- Dutch National CRPS Patient Organization, Netherlands

COMPACT Publications

Grieve, S, Jones, L, Walsh, N, & McCabe, C 2015, 'What outcome measures are commonly used for Complex Regional Pain Syndrome clinical trials? A systematic review of the literature'. *European Journal Of Pain*. 20(3), 331-340.

Packham T, Cappelleri JC, Sadosky A, MacDermid JC, Brunner F. **Measurement properties of painDETECT: Rasch analysis of responses from persons with neuropathic pain**. BMC Neurology: submitted Dec. 2015; revised version resubmitted May 2016.

Grieve S & McCabe C, Perez RSGM, Birklein F, Brunner F, Bruehl S, Harden N, Packham T, Gobeil F, Haigh R, Holly J, Terkelsen, A, Davies L, Lewis J, Thomassen I, Connett R, Worth T, Vatine, JJ. **Core Outcome Measures for complex regional PAin syndrome Clinical Trials (COMPACT): Development of a core measurement set** (paper in preparation).

Oral Presentations

Grieve S, Perez RSGM, Birklein F, Brunner F, Bruehl S, Harden N, Moskovitz P, Packham T, Gobeil F, Haigh R, Holly J, Knudsen LF, Schlereth T, Davies L, Lewis J, Worth T, Vatine, JJ, Thomassen I, Terkelsen A, Sontheim C, Connett R, McCabe CS. **Core Outcome Measures for complex regional PAin syndrome Clinical Trials (COMPACT): a first draft core measurement set**. British Journal of Pain. vol. 10, 2 suppl: pp. 5-91. British Pain Society Annual Scientific Meeting. May 2016. Harrogate, UK.

Packham T, Cappelleri JC, Sadosky A, MacDermid JC, Brunner F. Poster presentation. Canadian Pain Society. **Measurement properties of painDETECT: a Rasch analysis**. May 2016: Vancouver, Canada.

Oral Presentations (continued)

Grieve S, Perez RSGM, Birklein F, Brunner F, Bruehl S, Harden N, Moskovitz P, Packham T, Gobeil F, Haigh R, Holly J, Knudsen LF, Schlereth T, Davies L, Lewis J, Worth T, Vatine, JJ, Thomassen I, Terkelsen A, Sontheim C, Connett R, McCabe CS. **Development of a core measurement set in CRPS**. CRPS IASP SIG conference. Zurich, Switzerland. August 2015.

Poster Presentations

Holly J, Grieve S, Perez RSGM, Birklein F, Brunner F, Bruehl S, Harden N, Packham T, Gobeil F, McCabe C, Moskovitz P, Haigh R. **Outcome Measure for complex regional PAin syndrome Clinical Trials**. Canadian Physiotherapy Association Congress. May 2016.

Grieve S, Perez RSGM, Birklein F, Brunner F, Bruehl S, Harden N, Moskovitz P, Packham T, Gobeil F, Haigh R, Holly J, Knudsen LF, Davies L, Lewis J, Worth T, Thomassen I, McCabe CS. **Core Outcome Measures for complex regional PAin syndrome Clinical Trials (COMPACT): Development of a core measurement set**. 9th congress of the European Pain Federation. EFIC. September 2015.

Grieve S, Jones L, Walsh N, McCabe C. **What outcome measures are being used in Complex Regional Pain Syndrome clinical trials? A systematic literature review**. Poster presentation at British Pain Society Annual Scientific Meeting (ASM). April 2015.

If there are budding designers amongst you, we would love ideas for a COMPACT logo.

Contributions to the next issue of the COMPACT newsletter are welcomed. Please contact: Lindsay Davies.

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