

# Protocol: An e-Delphi study to define internationally agreed core clinical outcome measures for Complex Regional Pain Syndrome clinical research studies

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## Background & objectives

- Complex Regional Pain Syndrome (CRPS) is a disabling chronic pain condition, characterised by sensory, motor and autonomic abnormalities, usually in a single limb.
- CRPS clinical studies have tried to capture the multi-dimensional nature of the condition. However, the range of outcome measures used has hindered the meaningful comparison and pooling of data<sup>1</sup>.
- To date, the COMPACT consortium has:
  - published recommendations for a minimum core set of patient-reported outcome measures<sup>2</sup>
  - established an international registry to collect and manage these data.
- The current study aims to use an electronic Delphi process to develop a complementary set of clinical outcome measures.

## Method

- We have already conducted a systematic literature review, and held workshop with clinicians and academics.
- From these, a list of clinical outcomes has been developed for potential inclusion in a core clinical outcome set.
- We are currently preparing to conduct an international 2-round e-Delphi study.
- The e-survey will be sent to members of the International Association for the Study of Pain Special Interest Group for CRPS, and members of the International Research Consortium for Complex Regional Pain Syndrome.



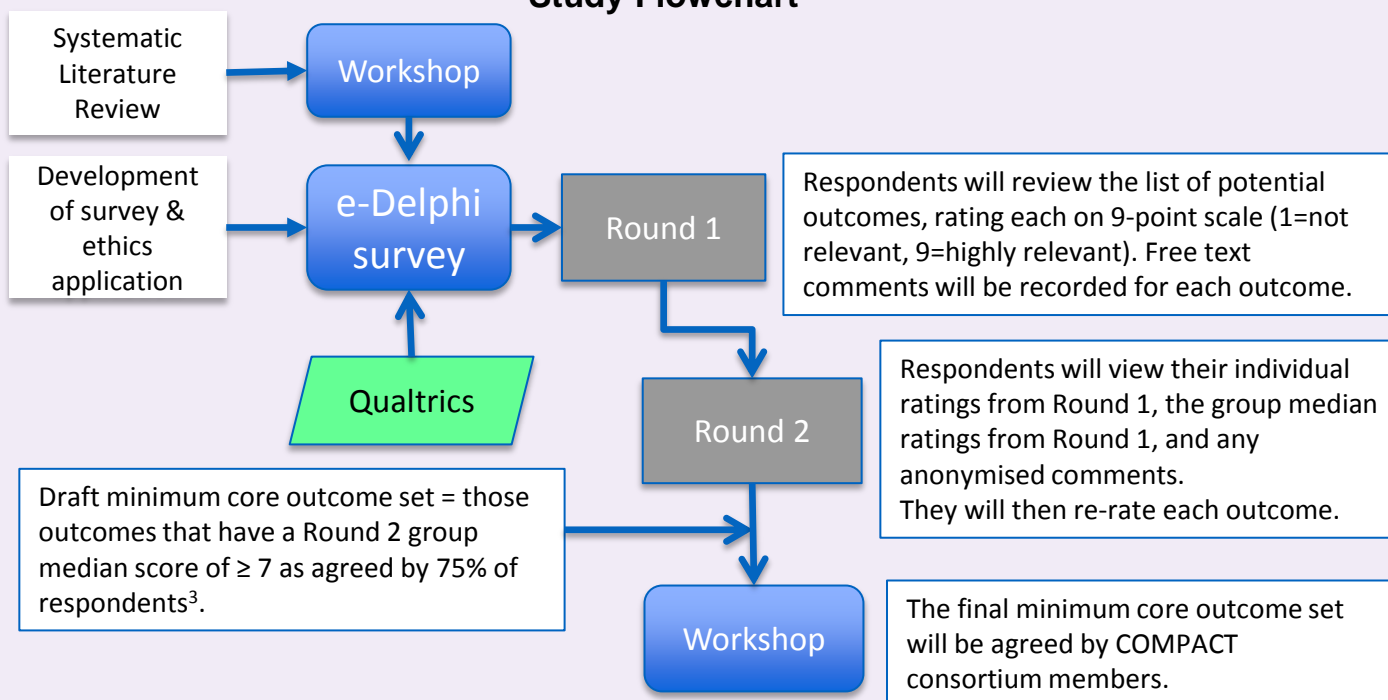
Core Outcome Measurement set for complex regional PAin syndrome Clinical sTudies.

## Study outline

E-survey respondents (clinicians and researchers) will be asked to consider each potential outcome for its relevance to the question:

**“What is the clinical presentation and course of CRPS, and what factors influence it?”**

### Study Flowchart



**8. PSYCHOLOGICAL**  
Please rate the scientific relevance of each outcome in relation to the question “What is the clinical presentation and course of Complex Regional Pain Syndrome, and what factors influence it.” You can use the space underneath each outcome to add an optional comment if you wish.

	1	2	3	4	5	6	7	8	9
Ba. Clinical assessment of anxiety	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bb. Clinical assessment of depression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

**6. PHYSIOLOGICAL**  
Please rate the scientific relevance of each outcome in relation to the question “What is the clinical presentation and course of Complex Regional Pain Syndrome, and what factors influence it.” You can use the space underneath each outcome to add an optional comment if you wish.

	1	2	3	4	5	6	7	8	9
9a. Nature and extent of hair changes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9b. Nature and extent of nail changes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
9c. Nature and extent of skin changes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
9d. Assessment of bone density	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Conclusions

Findings from the study will inform the final combined set of patient-reported and clinical outcome measures which will be advocated for use in all CRPS clinical studies.

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### References

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