Pilot International Registry for Complex Regional Pain Syndrome

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Background

- Complex Regional Pain Syndrome (CRPS) is a persistent pain condition mainly affecting a single limb[1].
- Due to its low incidence multi-centre collaborative research is needed to achieve sufficient sample sizes for meaningful studies.
- Currently a wide range of outcome measures are used to capture the heterogeneous nature of the condition[2].
- Previous research agreed and recommended a questionnaire core outcome measurement set for use in CRPS clinical studies[3] – 'Core Outcome Measurement set for complex regional PAin syndrome Clinical sTudies' (COMPACT).
- The study aims are in Table 1. We did not aim to derive statistically significant data.

Aims of study	
1	To test the feasibility and acceptability of collecting outcome data using this core measurement set in an international population
2	To test and refined an electronic data management system to collect and manage the data **(https://www.aleaclinical.eu).**
3	To ascertain the practicalities of collecting outcome data across a range of different populations and cultures.

Table 1: Aims of study

- The findings will inform the final data collection tools and processes which will comprise the first international, clinical research registry for CRPS.


COMPACT
COMPLEX REGIONAL PAIN SYNDROME
Core Outcome Measurement set for complex regional Pain syndrome Clinical sTudies (COMPACT)
6 MONTH FOLLOW UP QUESTIONNAIRE
Thank you for taking the time to complete this questionnaire.
We would like to ask you about your experience of living with Complex Regional Pain Syndrome. The following questions will ask you about various aspects of your experience. There are six sections.
Please could we ask you not to take too long considering your answers, but complete each question based on your first thoughts.
Date questionnaire completed:
Day ... Month ... Year ....

The study received UK ethical approval from South Central-Hampshire A Research Ethics Committee: Reference number 18/SC0322. In addition, local ethical approval was obtained by the research team at each international research centre.

Methods

- Adults (≥ 18 years) with CRPS, meeting the Budapest diagnostic clinical criteria, were recruited to the study from seven international research centres (figure 1)

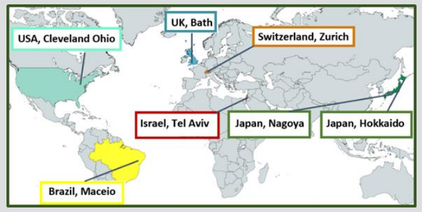

Figure 1: Research centres

- Where applicable, study documents were translated into local languages following a best practice protocol.
- After informed consent, a questionnaire comprising the core set outcome measures was completed on two occasions; on paper at baseline (T1) and at 6 months (T2) at all sites with the exception of Brazil, who undertook T2 at three months. T2 data were collected at 3 months in Brazil to compare whether a shorter timeframe improved the response rate.
- At T2 participants chose to complete COMPACT using a paper or electronic version. Participants were asked to provide written feedback on their experience of completing the questionnaires.
- During a face to face clinical assessment, clinicians completed the CRPS severity score (CSS)[4] at T1 and optionally, at T2. At each research centre, clinicians delivering the study provided feedback on their experience of data collection. Ethical approval was obtained at each international centre by the relevant research team.

Results

- Study recruitment was completed in September 2020. Preliminary findings are reported here.
- 98 adults were recruited (female n=66; mean age 46.6 years, range 19-89), of whom 31 chose to receive the T2 questionnaire in an electronic format.
- Preliminary findings suggest a lower completion rate for those responding to the electronic questionnaire at T2.
- Fifty five participants completed both T1 and T2.
- The CSS was completed in English by clinicians at all sites with the exception of Brazil where it was completed in the local language.
- Participants could choose to provide feedback on their experience of completing questionnaires. n=18 provided feedback on paper version and n=4 on the electronic version of the questionnaire (figure 2)

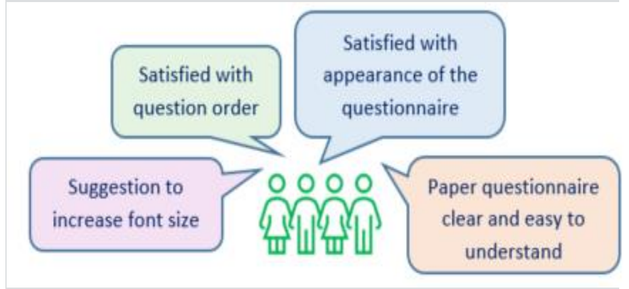

Figure 2: Participant feedback

- Analysis of clinician feedback is incomplete and will be reported later.

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Conclusions

- This study confirmed the questionnaire core outcome data is feasible and acceptable to collect, according to a set protocol, in clinical practice.
- Future work will explore participant retention strategies which can be incorporated into the final registry protocol.
- The ALEA electronic data management system provided a robust means of collecting and managing the data efficiently and accessibly across an international population.
- Future analysis will include investigation of missing data, establish optimal data collection points and will inform the ethical, institutional and governance processes for the future registry.

Relevance to Patient Care This study will inform the design and delivery of the first international clinical research registry for CRPS. The registry will enable researchers to access a consistent, international dataset which will be used to gain a better understanding of the potential phenotypes of CRPS, risk factors and targeted treatment approaches.

References: [1]Harden et al (2010) Validation of proposed diagnostic criteria (the "Budapest Criteria") for Complex Regional Pain Syndrome. Pain.150(2):268-274; [2]Grieve et al (2016), What outcome measures are commonly used for Complex Regional Pain Syndrome clinical trials? A systematic review of the literature. Eur J Pain. 20:331–340; [3]Grieve et al (2017) Recommendations for a first Core Outcome Measurement set for Complex Regional Pain Syndrome Clinical sTudies (COMPACT). Pain. 158(6):1083-1090. [4]Harden et al (2017) A prospective, multisite, international validation of the Complex Regional Pain Syndrome Severity Score. Pain. (158)8, pp.1430–1436.