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Development of the Coeliac Disease Assessment Questionnaire (CDAQ)

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Introduction

Evaluating health-related quality of life (HRQOL) in people with coeliac disease can provide a greater understanding of the condition than can be achieved by assessing clinical factors alone. HRQOL is assessed using patient reported outcome (PRO) measures, short questionnaires that measure health from the patient's perspective. There are two existing disease-specific PROs that measure HRQOL in adults with coeliac disease, the Coeliac Disease Questionnaire (CDQ) (Häuser et al., 2007) and the Coeliac Disease Quality of Life Survey (CD-QOL) (Dorn et al., 2010). However, there are limitations with both measures, in particular, with regards to the derivation and subsequent reduction of items.

The aim of this study was to develop a new PRO measure to assess HRQOL in adults with coeliac disease that meets current development guidelines, for example, those provided by the U.S. Food and Drug Administration (US FDA, 2009).

Methods

Items for the new measure, the Coeliac Disease Assessment Questionnaire (CDAQ), were developed following qualitative interviews with adults with coeliac disease, and refined through expert panels, cognitive interviews, and a translatability assessment. A draft version of the CDAQ was completed by 412 people with coeliac disease. Analysis of this data enabled the number of items to be reduced and dimensions to be generated. The key steps involved in the development of the CDAQ are shown in Figure 1 below.

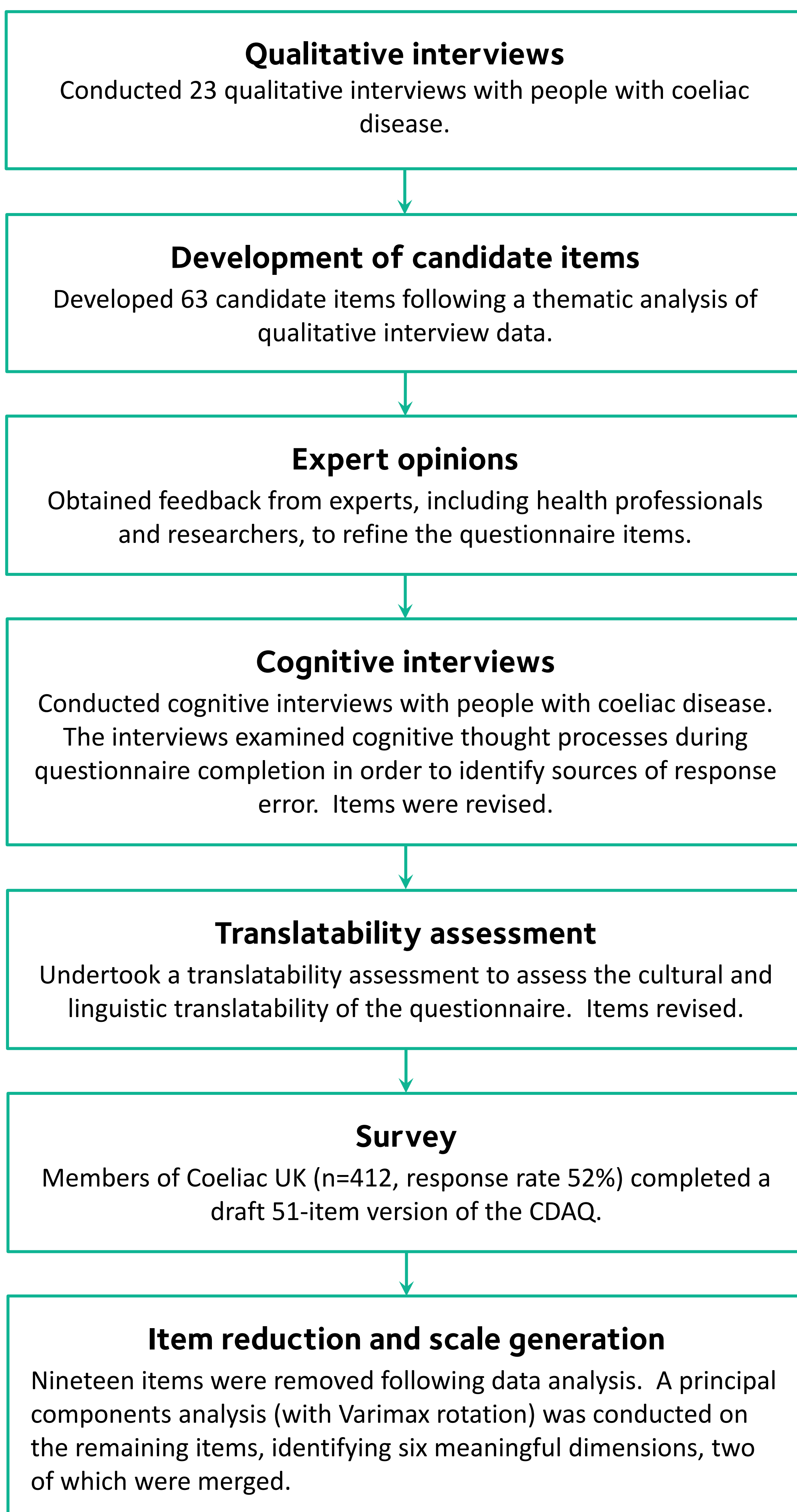


Figure 1. Methodology for the development of the Coeliac Disease Assessment Questionnaire

Results

The final version of the CDAQ contains 32 items addressing five dimensions: stigma (8 items); dietary burden (8 items); symptoms (5 items); social isolation (5 items); and worries and concerns (6 items). The questionnaire measures HRQOL over the past four weeks. Cronbach's alpha values ranged between 0.82 and 0.88 for all dimensions, indicating good internal consistency.

The dimensions, Cronbach's alpha values and example items are shown in Figure 2.



The CDAQ

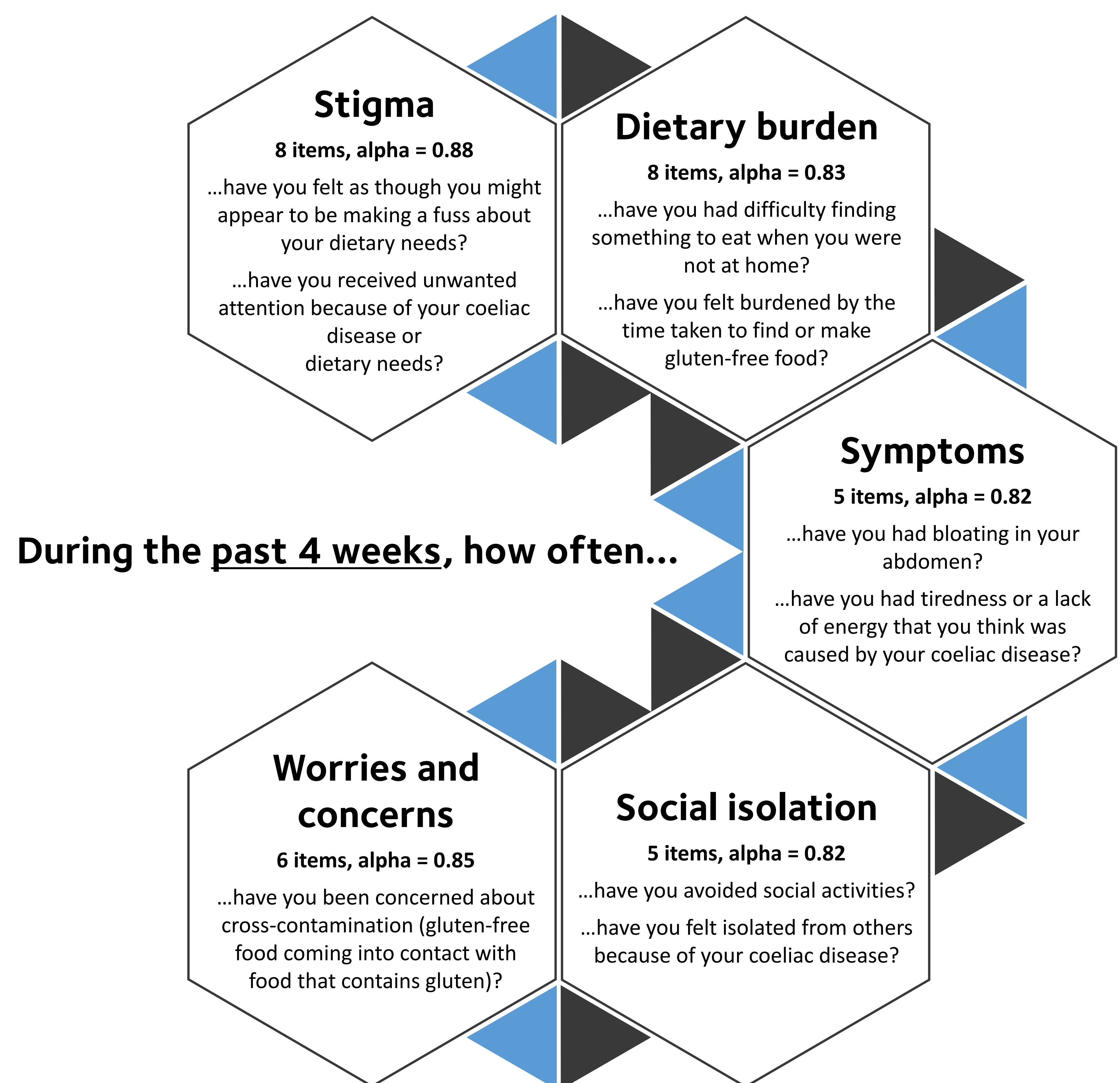


Figure 2. Coeliac Disease Assessment Questionnaire dimensions and example items

Conclusions

A new patient-reported outcome measure, the Coeliac Disease Assessment Questionnaire (CDAQ), has been developed according to current guidelines. The measure can be used in a range of settings, including clinical trials and clinical practice. For example, the questionnaire can be used in clinical trials to evaluate the effect of treatments on health-related quality of life. This will provide a broader understanding of the treatment than can be achieved by assessing clinical impact alone. Further assessment of the CDAQ's reliability and validity is currently underway.

Acknowledgements

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References

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