Development of the Coeliac Disease Assessment Questionnaire (CDAQ)

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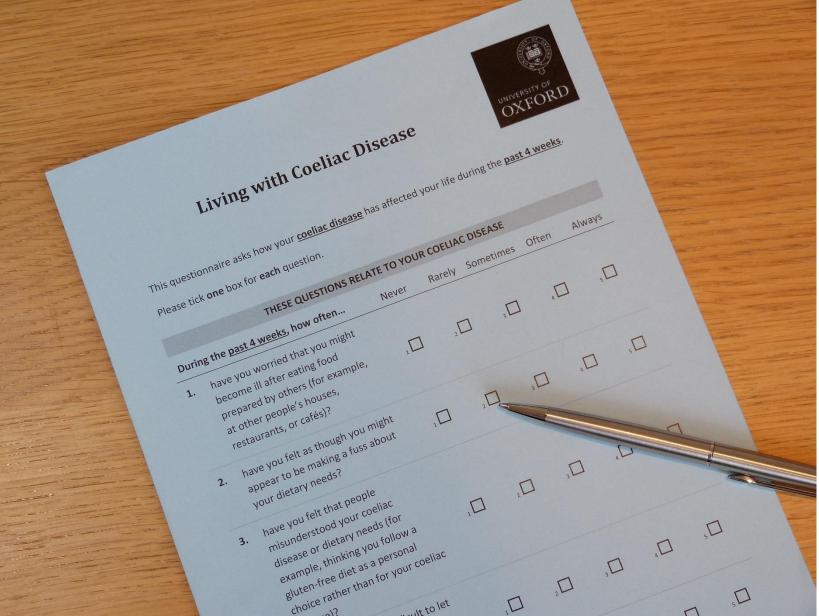
Introduction

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 Celiac 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.

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.





...have you had bloating in your

abdomen?

...have you had tiredness or a lack

of energy that you think was

caused by your coeliac disease?

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.

Qualitative interviews Conducted 23 qualitative interviews with people with coeliac disease.

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



Stigma Dietary burden 8 items, alpha = 0.88 8 items, alpha = 0.83 ...have you felt as though you might ...have you had difficulty finding appear to be making a fuss about something to eat when you were your dietary needs? not at home? ...have you received unwanted ...have you felt burdened by the attention because of your coeliac time taken to find or make disease or gluten-free food? dietary needs? Symptoms 5 items, alpha = 0.82

During the past 4 weeks, how often...

Development of candidate items

Developed 63 candidate items following a thematic analysis of qualitative interview data.

Expert opinions

Obtained feedback from experts, including health professionals and researchers, to refine the questionnaire items.

Cognitive interviews

Conducted cognitive interviews with people with coeliac disease. The interviews examined cognitive thought processes during questionnaire completion in order to identify sources of response error. Items were revised.

Translatability assessment

Undertook a translatability assessment to assess the cultural and linguistic translatability of the questionnaire. Items revised.

Worries and concerns

6 items, alpha = 0.85

...have you been concerned about cross-contamination (gluten-free food coming into contact with food that contains gluten)?

Social isolation

5 items, alpha = 0.82

...have you avoided social activities? ...have you felt isolated from others because of your coeliac disease?

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.

Survey

Members of Coeliac UK (n=412, response rate 52%) completed a draft 51-item version of the CDAQ.

Item reduction and scale generation

Nineteen items were removed following data analysis. A principal components analysis (with Varimax rotation) was conducted on the remaining items, identifying six meaningful dimensions, two of which were merged.

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

Acknowledgements

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References

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