

THE COELIAC DISEASE ASSESSMENT QUESTIONNAIRE (CDAQ): DEVELOPMENT OF A PATIENT-REPORTED OUTCOME MEASURE

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OBJECTIVES

Coeliac disease is an autoimmune condition affecting approximately 1% of the population. The only treatment is a gluten-free diet, although research is underway to develop other treatments. Quality of life has predominantly been assessed using generic patient-reported outcome (PRO) measures. There are two existing disease-specific PROs that assess quality of life in adults with coeliac disease, the Celiac Disease Questionnaire (CDQ)¹ and the Coeliac Disease Quality of Life Survey (CD-QOL)². However, there are limitations in the development of both measures, including the derivation of items. For example, the CD-QOL has no symptom items, and the CDQ did not conduct interviews or focus groups as part of its development. Consequently, the content validity of these measures may be limited. The purpose of the current study was to develop a new PRO, based on qualitative interview data, investigating the health-related quality of life of adults living with coeliac disease.

Coeliac Disease

- Coeliac disease is a chronic autoimmune disease in which an immune response is triggered by the consumption of gluten (a protein contained in wheat, barley, rye) resulting in intestinal damage.
- Classic symptoms experienced prior to diagnosis include diarrhoea, abdominal discomfort, fatigue and weight loss.
- Treatment is a life-long gluten-free diet.
- The condition is typically diagnosed by serological testing followed by duodenal biopsy.

METHODS

Candidate items for the Coeliac Disease Assessment Questionnaire (CDAQ) were developed through qualitative interviews with adults with coeliac disease (n=23), and refined using input from experts (n=12) and cognitive interviews (n=10). This was followed by an exploratory factor analysis to investigate the factor structure of the CDAQ, and quantitative analysis of the validity and reliability of the finalised CDAQ.

Recruitment, data collection and analysis:

- Interview participants were recruited through Coeliac UK, a charity for people living with coeliac disease, and snowball sampling. Variation was sought across demographic and disease characteristics, including gender, age, and duration since diagnosis. Interviews explored the impact of coeliac disease on the participants' quality of life and were analysed thematically.

- Experts, including clinicians, researchers, and Coeliac UK employees, were recruited through an Internet search and snowball sampling. Nine experts participated in a meeting and three experts took part in in-depth interviews. Experts commented on candidate CDAQ items and its comprehensiveness.

- Cognitive interview participants were recruited through online social networking groups and a database of people previously expressing an interest in our research. Interviews lasted approximately one hour and were conducted in two rounds. During the interviews, participants completed the CDAQ and the interviewer explored the participants' cognitive processes using a 'verbal probing' technique.

Revisions were made to the candidate items following each of these stages.

Finally, a translatability assessment was conducted. This was followed by two surveys:

- **Survey 1** determined the final items and structure of the CDAQ using principal components analysis (PCA) and assessed internal consistency.
- **Survey 2** evaluated test-retest reliability and construct validity. In survey 2, participants also completed the SF-36v2, and the CDAQ a second time after two weeks.

RESULTS

Sixty-three candidate items were developed through analysis of the interviews, and refined to give 51 candidate items to include in survey 1 (response rate: n= 412, 52.0%). The final CDAQ contains 32 items in five domains which were guided by PCA: stigma (8 items); dietary burden (8 items); symptoms (5 items); social isolation (5 items); and worries and concerns (6 items). Domain scores and an overall index score can be calculated. Cronbach's alpha values (internal consistency) ranged between 0.82 and 0.88 for all domains. Survey 2 (response rate: n=276, 34.5%) showed that CDAQ scores were more strongly correlated with the SF-36v2 mental health dimensions as had been expected. Of the 167 participants returning the follow-up CDAQ, 145 rated the impact of coeliac disease 'about the same' and were included in the test-retest analysis. Intraclass correlation coefficients ranged from 0.79-0.89.

CONCLUSIONS

This research has identified the wide variety of ways in which coeliac disease impacts on the quality of life of people living with the condition. A new disease-specific PRO measure has been developed to assess these limitations. Further research will look into the responsiveness of the CDAQ using larger sample sizes, and over a longer period of time.

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