The Coeliac Disease Assessment Questionnaire (CDAQ): responsiveness to change

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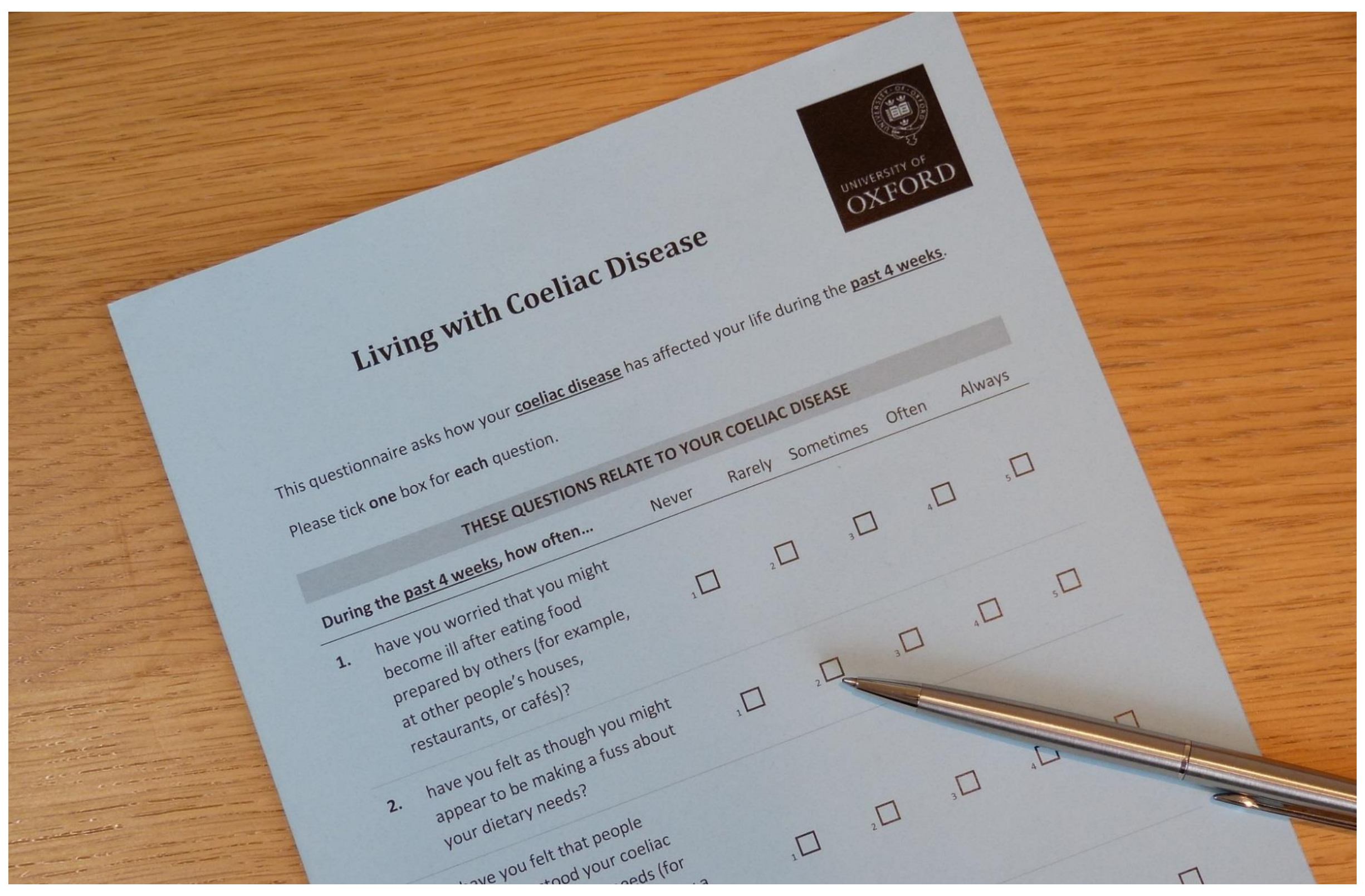
Introduction

The Coeliac Disease Assessment Questionnaire (CDAQ) is a 32-item patient-reported outcome measure (PROM) developed to assess quality of life in adults with coeliac disease. It is suitable for use in research, including clinical trials, and clinical practice. The CDAQ is a reliable and valid measure, but its ability to detect change over time is yet to be assessed. Therefore, the aim of this study was to assess the CDAQ's responsiveness to change.

The CDAQ

- 32-item questionnaire addressing 5 dimensions:
  - Stigma
  - Dietary burden
  - Symptoms
  - Social isolation
  - Worries and concerns
- Dimension scores and an overall summary score can be calculated.
- Scores range from 0 to 100, with a higher score indicating a better quality of life.



Living with Coeliac Disease

This questionnaire asks how your coeliac disease has affected your life during the past 4 weeks.

Please tick one box for each question.

THESE QUESTIONS RELATE TO YOUR COELIAC DISEASE

During the past 4 weeks, how often...	Never	Rarely	Sometimes	Often	Always
1. have you worried that you might become ill after eating food prepared by others (for example, at other people's houses, restaurants, or cafés)?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
2. have you felt as though you might appear to be making a fuss about your dietary needs?	1 ☐	2 ☐	3 ☐	4 ☐	

Methods

Responsiveness to change was assessed by conducting a survey of Coeliac UK members (n=1443). As the impact of coeliac disease most predictably changes following diagnosis (and the introduction of a gluten-free diet), only recently-diagnosed members were invited to participate. Members were asked to complete a postal (n=500) or online (n=943) survey, answering the CDAQ at two points in time, four months apart. A four month time period between completions was considered appropriate to allow changes in health, particularly symptoms, to occur.

Baseline, follow-up, and change scores for each of the CDAQ's five dimensions, and Overall index score were calculated. The following distribution-based indicators of responsiveness to change were calculated: effect size (ES), standardized response mean (SRM), and minimal detectable change (MDC).

Paired t-tests were used to assess the change between baseline and follow-up scores. Statistical significance was set at p<0.05 with a 95% confidence interval.

Ethics approval was granted by the University of Oxford's Central University Research Ethics Committee (Reference no: MS-IDREC-C1-2015-177).

Results

In total, 277 respondents completed both questionnaires and were included in the analysis. The mean interval between completing the first and second questionnaires was 130 days ± 11.47 days (range: 68-205). The mean time since diagnosis at baseline was 5.21 months (SD 2.99). The majority of respondents were female (59.2%, n=164), married or in a civil partnership (63.3%, n=171), White British (92.1%, n=255), working (including full-time, part-time and self-employed work) (62.9%, n=166), and had never consumed gluten since their diagnosis (71.6%, n=207).

The results of the distribution-based analysis are shown in Table 1. Small to moderate effect sizes (ES) for the CDAQ Overall index score (0.19), Symptoms (0.27), and Worries and concerns (0.19) domains were found. Small to moderate standardized response means (SRM) for the Overall index score (0.37) and dimension scores (0.22-0.39), except Stigma (0.03), were found. The minimal detectable change (MDC) is estimated as 2.06 for the overall index score, and between 14.08 and 18.99 for the dimension scores.

Table 1. Baseline, follow-up and change scores (mean and standard deviation) for the CDAQ Overall index score and dimension scores, and distribution-based analyses (ES, SRM, SEM and MDC)

CDAQ dimension	n	Baseline m (SD)	Follow-up m (SD)	Change m (SD)	95% CI	p	ES	SRM	ICC	SEM_{ICC}	MDC_{ICC} 90%
Overall index score	252	51.77 (18.20)	55.15 (17.39)	3.37 (9.12)	2.24 – 4.50	<0.001	0.19	0.37	0.89	1.10	2.06
Stigma	273	52.78 (22.63)	53.13 (21.34)	0.34 (13.29)	-1.24 – 1.93	0.67	0.02	0.03	0.85	7.64	14.26
Dietary burden	268	37.50 (17.79)	40.04 (17.68)	2.54 (10.86)	1.24 – 3.85	<0.001	0.14	0.23	0.82	7.54	14.08
Symptoms	272	58.89 (22.73)	65.04 (20.62)	6.14 (15.77)	4.25 – 8.02	<0.001	0.27	0.39	0.8	10.17	18.99
Social isolation	269	64.09 (24.64)	67.51 (22.73)	3.42 (15.46)	1.56 – 5.27	<0.001	0.14	0.22	0.86	9.22	17.22
Worries and concerns	269	46.75 (21.53)	50.82 (22.40)	4.07 (13.22)	2.49 – 5.66	<0.001	0.19	0.31	0.78	8.08	18.86

Typical effect size (ES) values: 0.2 (small), 0.5 (medium), and 0.8 (large)

Discussion

In a sample of people with recently-diagnosed coeliac disease, the Overall index, Symptoms, and Worries and concerns scores have been found to be responsive to change. The remaining dimensions (Stigma, Dietary burden, and Social isolation) were less responsive. This study highlights the challenges faced assessing responsiveness in coeliac disease, where much of the impact on quality of life is as a result of following a gluten-free diet. Although the study aimed to include people with newly-diagnosed coeliac disease, the mean time since diagnosis at the time of the baseline survey was approximately 5 months. Therefore, in this sample, some changes (e.g. improvement in symptoms) would have occurred prior to the respondent's enrolment in the study, whereas other changes (e.g. reduced stigma or dietary burden) may take longer to occur or may not occur in a sample that continues to follow a gluten-free diet. The study also lacked a specific intervention. To overcome this, the CDAQ's responsiveness should be assessed in clinical trials of therapeutic treatments which aim to supplement or replace the gluten-free diet. An analysis using anchor-based indicators of responsiveness is underway.

Acknowledgements and funding

We would like to thank Coeliac UK for their recruitment support and the respondents for taking part in the study. The study was funded by Coeliac UK. Michele Peters is a senior researcher of the Department of Health funded Policy Research Unit on Quality and Outcomes of Person-centred care (QORU), a collaboration between the London School of Economics and Political Science (LSE) and the Universities of Kent and Oxford.

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