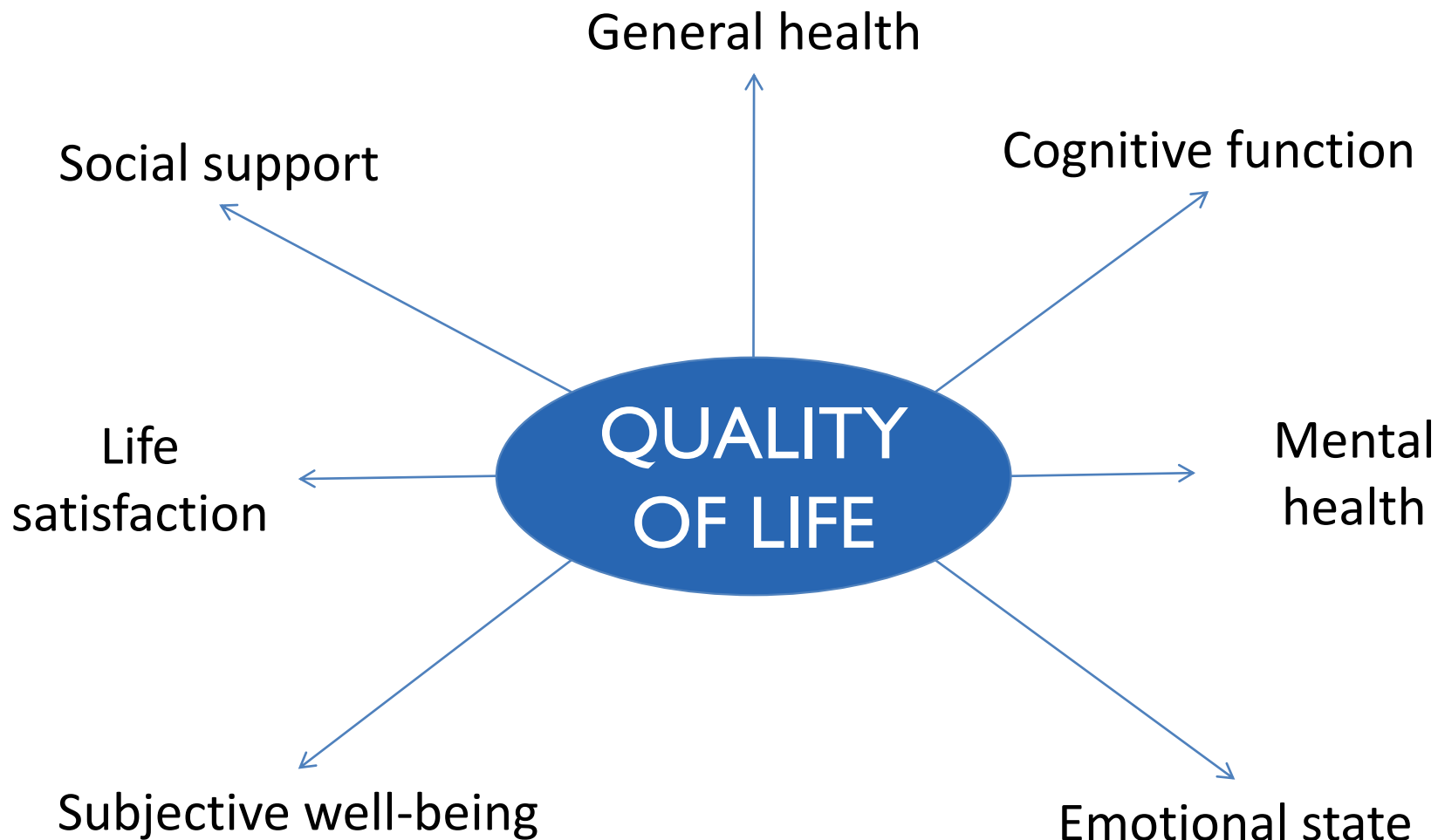


# Measuring quality of life in coeliac disease: the development of the Coeliac Disease Assessment Questionnaire (CDAQ)

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(Jenkinson and McGee, 1998)

# Patient-reported outcome measures

## Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Compared to one year ago, how would you rate your health in general now?

Much better now	Somewhat better	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Generic, e.g. SF-36

## MINI ASTHMA QUALITY OF LIFE QUESTIONNAIRE (MiniAQLQ)<sup>®</sup>

SELF-ADMINISTERED UNITED KINGDOM VERSION

Please complete all questions by circling the number that best describes how you have been during the last 2 weeks as a result of your asthma.

IN GENERAL, HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS DID YOU:

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	Hardly Any of the Time	None of the Time
1. Feel SHORT OF BREATH as a result of your asthma?	1	2	3	4	5	6	7
2. Feel bothered by or have to avoid DUST in the environment?	1	2	3	4	5	6	7
3. Feel FRUSTRATED as a result of your asthma?	1	2	3	4	5	6	7
4. Feel bothered by COUGHING?	1	2	3	4	5	6	7
5. Feel AFRAID OF NOT HAVING YOUR ASTHMA MEDICATION AVAILABLE?	1	2	3	4	5	6	7
6. Experience a feeling of ST TIGHTNESS or T HEAVINESS?	1	2	3	4	5	6	7
7. Feel bothered by or have to stop CIGARETTES in the environment?	1	2	3	4	5	6	7
8. Experience DIFFICULTY DOING A GOOD DEEP BREATH as a result of your asthma?	1	2	3	4	5	6	7
9. Experience UNEXPECTED WHEEZING?	1	2	3	4	5	6	7
10. Experience EXCESSIVE PHLEGGY?	1	2	3	4	5	6	7

Disease-specific,  
e.g. MiniAQLQ

# Healthcare policy

- NHS Outcomes Framework 2015/16
  - Domain 2 (of 5): ‘Enhancing quality of life for people with long-term conditions’
- Since 2009, the English NHS has routinely collected PROMs data for:
  - Hip replacements
  - Knee replacements
  - Groin hernia
  - Varicose veins
- US Food and Drug Administration (FDA) recommends PROMs are used in clinical trials.

# Coeliac disease PROMs

- The SF-36 is the most commonly used measure to assess quality of life in CD
- Two published disease-specific measures:

## The Celiac Disease Questionnaire (CDQ) (Hauser et al., 2007)

- Patient interviews not conducted as part of its development
- Poor test-retest reliability

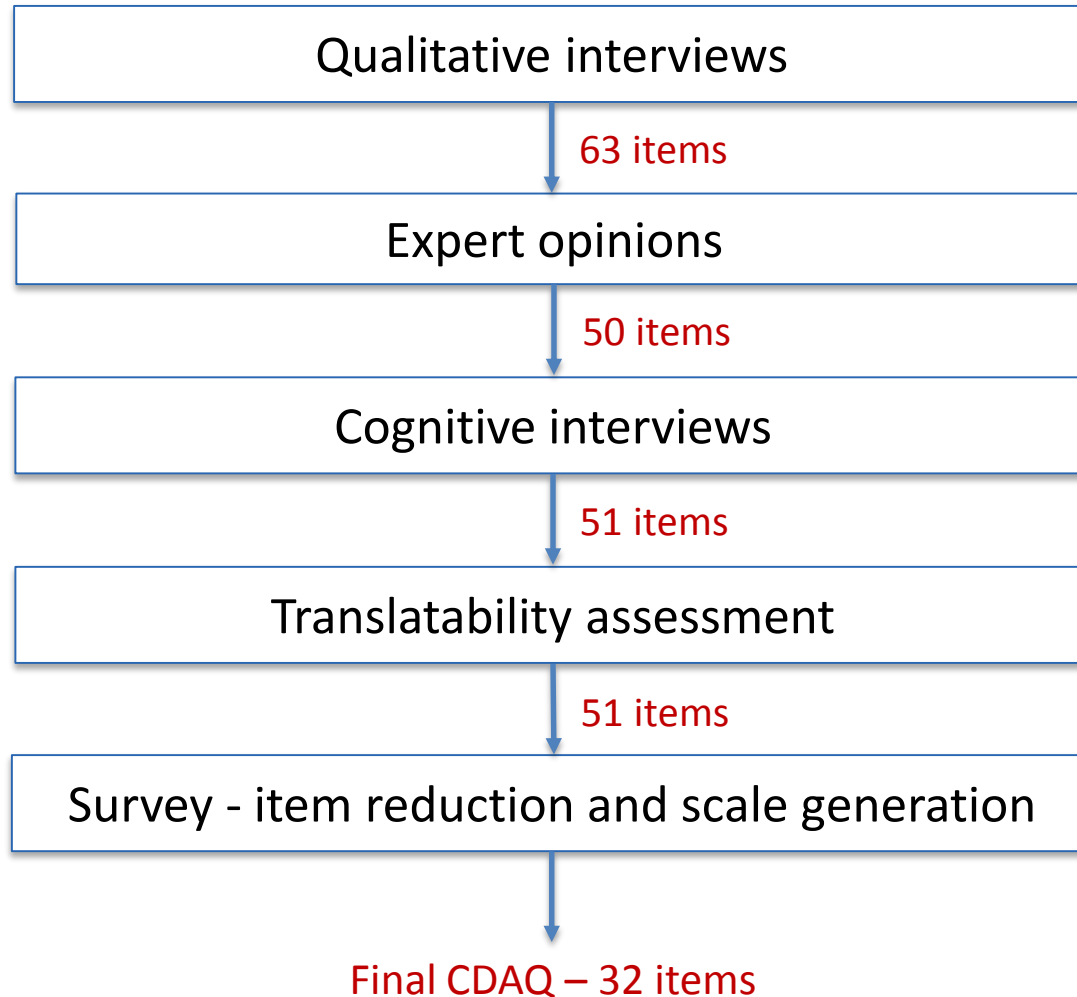
## Coeliac Disease Quality of Life Survey (CD-QOL) (Dorn et al., 2009)

- No questions about symptoms
- Standard measurement properties not assessed or not reported adequately.

# Overview

- Development of the Coeliac Disease Assessment Questionnaire (CDAQ)
- Scoring the CDAQ
- Quality of the questionnaire (measurement properties)
- How the CDAQ can be used

# Development of the CDAQ



# Qualitative interviews

- **Purpose: to explore how quality of life is affected by CD**
- Recruitment
  - Coeliac UK and snowball sample
- Purposive sampling strategy
  - Gender, age, ethnicity, duration of diagnosis, clinical presentation
- The interviews (n=23)
  - 50 minutes – 2 hours
- Thematic analysis





# Quality of life themes

## Gluten-free diet

- Acceptability of gluten-free food
- Cross-contamination
- Eating outside of the home
- Food choice
- Food shopping
- Risk

## Symptoms

"I'm a bit scared about travelling, not

"You kind of wish that if you ate it [gluten] you'd collapse down on the floor clasp[ing] at your stomach and get whisked off to hospital because then people would see a reaction (F, 59yrs old).

(F, 32yrs old)

weight

## Impact on activities

- Avoiding social activities
- Holidays
- Other social activities
- Planning ahead
- Time
- Travelling
- Work

## Relationships

- Lack of understanding
- Support
- Trust

## Financial issues

Feelings of isolation were described as feeling 'alone', 'out there in the wilderness', 'an outsider', and 'at sea'.

# The development of candidate items

The following questions ask about how much your coeliac disease or gluten-free diet has affected you during the past 4 weeks.

Please tick one box for each question and answer all questions.

During the <u>past 4 weeks</u> , how often...	N/A	Never	Rarely	Sometimes	Often	Always
1. did you worry that you might be unwell after eating out (for example, at a friend's house, restaurant, or café)?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. did you feel embarrassed or uncomfortable discussing your condition or dietary needs?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. did you feel as though you might appear to be making a fuss about your dietary needs?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. have you felt that people misunderstood your condition or dietary needs (for example, referring to your condition as a lifestyle choice)?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. did you find it difficult to let people know they have misunderstood your condition or dietary needs?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. did you receive unwanted attention because of your condition or dietary needs?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Draft questionnaire  
- 63 items

# Expert opinions

Dietitians

GPs

Coeliac UK



Academic  
researchers

Consultant  
Gastroenterologist

# Cognitive interviews

- **Purpose: to identify sources of response error by examining respondents' thought processes occurring during questionnaire completion.**
- Interviews conducted over the phone (n=20) and face-to-face (n=2)
- Interview duration: one hour
- Generic questions, e.g. 'Did you have any problems understanding or answering any of those questions?'
- Item-specific questions, e.g. 'What does the term 'cross-contamination' mean to you?'
- Two rounds

# Cognitive interviews

**Original item:** ...did you worry that you would be unwell  
while away from your home?

**Source of response error:** participants' interpreted “away from your home” as holidaying or being away for the weekend, rather than any instance of being away from their home as intended.

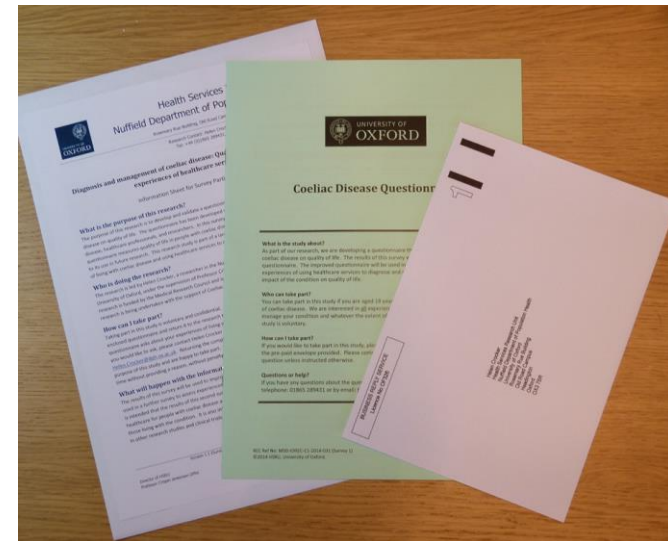
**Amended item:** ...did you worry that you would be unwell  
when out of the house?

# Translatability assessment

- **Purpose: to identify and resolve linguistic and cultural translatability issues, thus minimising problems arising in future translations.**
- PROMs often translated for international use
- Language-country combinations selected:
  - Arabic (Egypt)
  - German (Germany)
  - Finnish (Finland)
  - Simplified Chinese (China)
  - French (France)
  - Spanish (Argentina)
- In-country translators

# Survey

- **Purpose: to reduce the number of items in the questionnaire and generate scales**
- Cross-sectional survey of 800 members of Coeliac UK
  - aged 18 years or older,
  - reported a medical diagnosis of coeliac disease,
  - had not opted-out of being contacted for research purposes,
  - and lived in the UK.
- Response rate: 52% (n=412)



# Survey data – item reduction

- Reviewed distribution of responses for each item
- Items deleted if:
  - Floor effect > 50% (i.e. 50% selecting ‘never’)
  - Missing data > 5%
  - High inter-item correlation > 0.8

Item No	Item (abbreviated)	Missing data		Distribution of responses, n=411				
		No response n (%)	N/A n (%)	Never n (%)	Rarely n (%)	Sometimes n (%)	Often n (%)	Always n (%)
1	Worried become ill	0	-	39 (9.5)	62 (15.1)	131 (31.9)	105 (25.5)	74 (18.0)
10	Concern about results of tests	3 (0.7)	29 (7.1)	101 (24.6)	96 (23.4)	106 (25.8)	48 (11.7)	28 (6.8)
14	Had pain	1 (0.2)	-	144 (35.0)	90 (21.9)	110 (26.8)	51 (12.4)	15 (3.6)
16	Daily activities limited	3 (0.7)	-	160 (38.9)	126 (30.7)	78 (19.0)	33 (8.0)	11 (2.7)
17	Difficulties work-related activities	1 (0.2)	43 (10.5)	216 (52.6)	85 (20.7)	45 (10.9)	16 (3.9)	5 (1.2)
24	Felt depressed	2 (0.5)	-	162 (39.4)	80 (19.5)	100 (24.3)	56 (13.6)	11 (2.7)

- 11 items deleted



# Survey data – scale generation

Principal Components Analysis (PCA) with Varimax rotation (40 items)



8 items deleted

(high inter-item correlations; weak factor loadings ( $<0.5$ ))



PCA with Varimax rotation (32 items)



Six meaningful factors; two factors merged

# The CDAQ

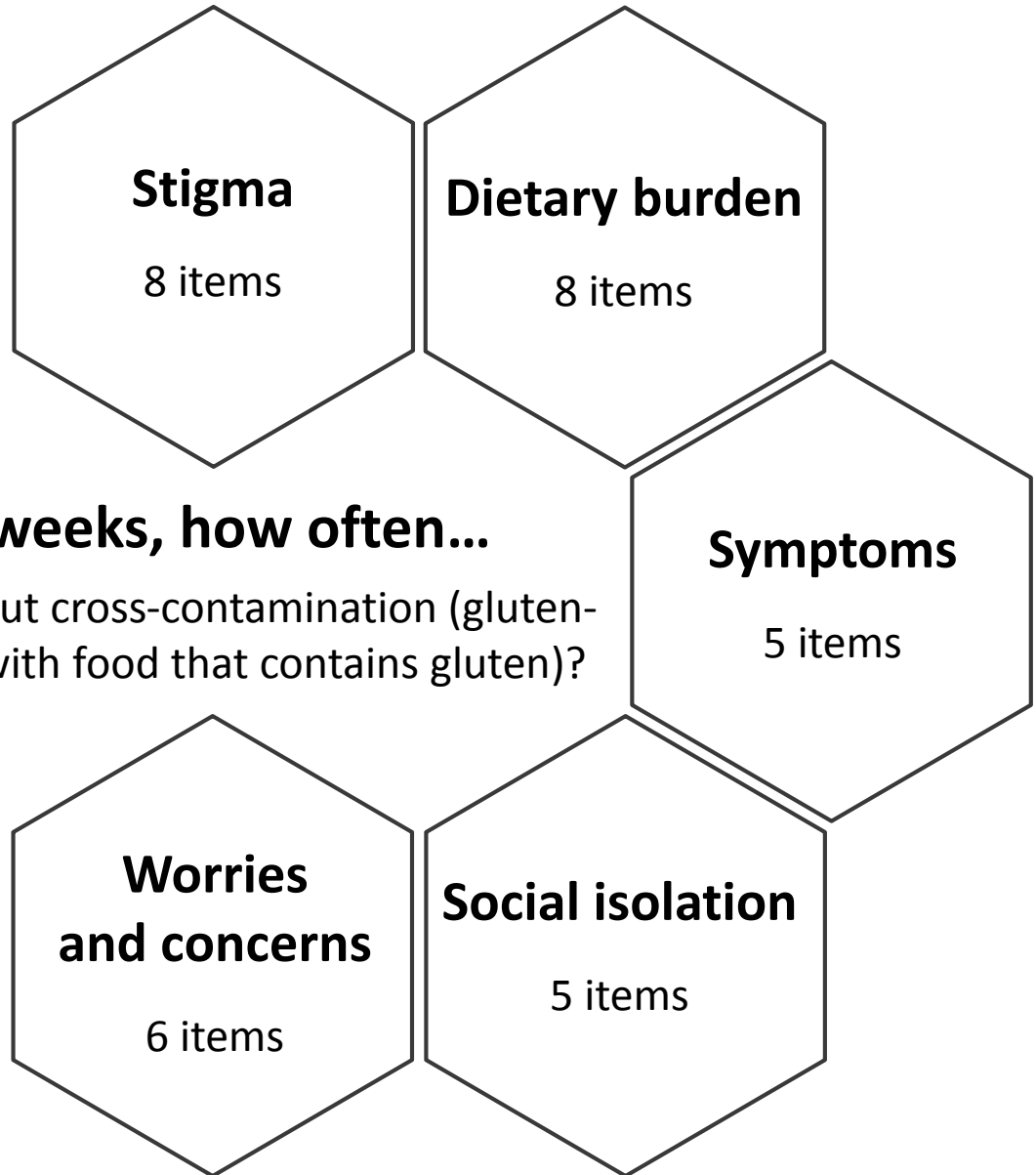
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## Living with Coeliac Disease

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 <u>past 4 weeks</u> , 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)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. have you felt as though you might appear to be making a fuss about your dietary needs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. have you felt that people avoid your coeliac needs (for	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

# The CDAQ



**During the past 4 weeks, how often...**

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

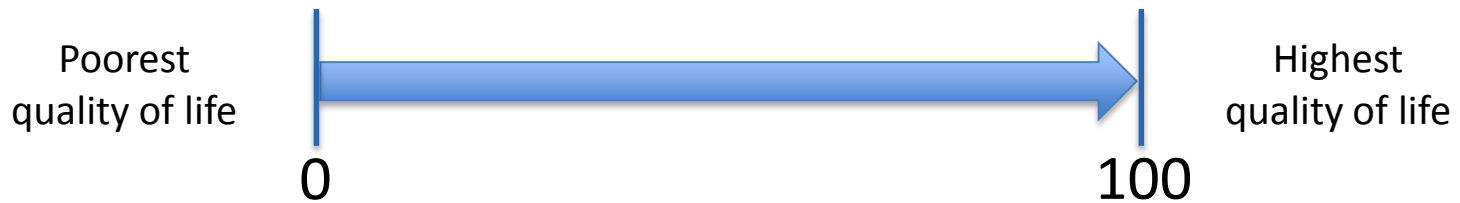
- Never
- Rarely
- Sometimes
- Often
- Always

# Scoring the CDAQ

- Each item is scored from 1 - 5

Never	Rarely	Sometimes	Often	Always
1	2	3	4	5

- Items within each dimension are summed to create five dimension scores



- An overall index score can be calculated as follows:

$$\text{OVERALL INDEX SCORE} = (\text{STIGMA SCORE} + \text{DIETARY BURDEN SCORE} + \text{SYMPTOMS SCORE} + \text{SOCIAL ISOLATION SCORE} + \text{WORRIES AND CONCERNS SCORE}) / 5$$

# Reliability of the CDAQ

- Internal consistency reliability
  - *Assesses whether items within each dimension are measuring the same underlying construct.*
  - Cronbach's alpha ranges from 0.82-0.88 (ideal range: 0.7-0.9)
- Test-retest reliability
  - *Assesses the stability of test scores over time.*
  - People completed the CDAQ twice, two weeks apart (n=145)
  - Intraclass correlation coefficient (ICC) ranges from 0.79-0.89 (ideally > 0.7)

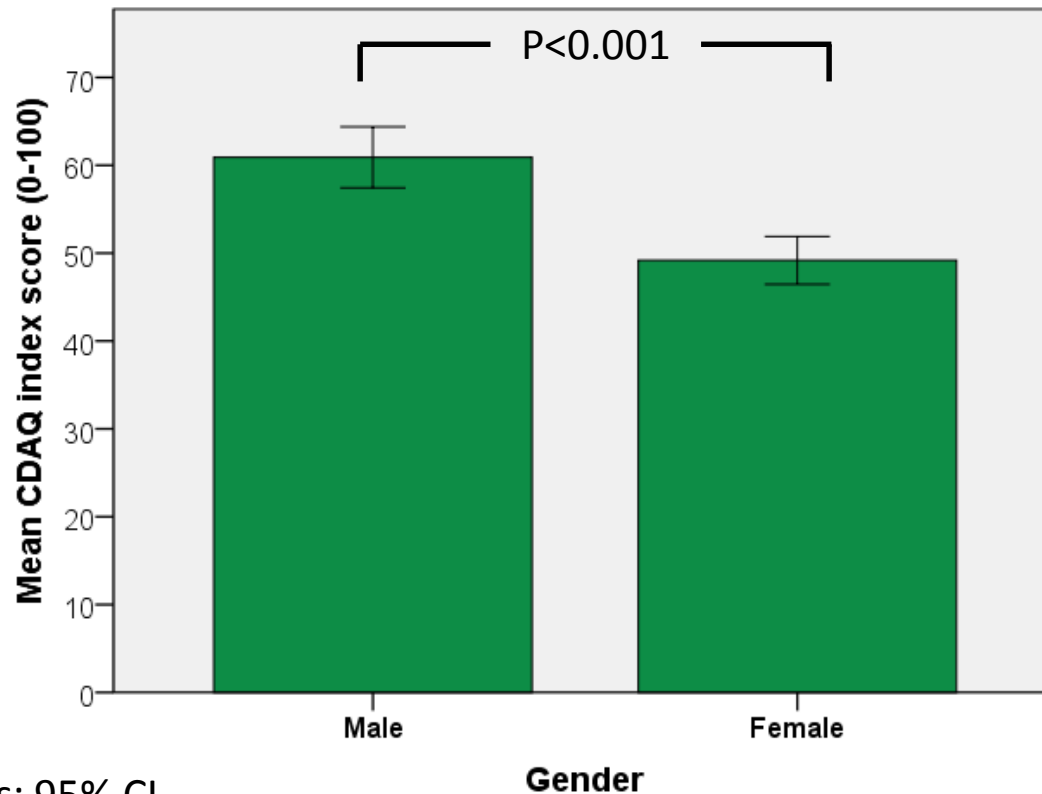
# Validity of the CDAQ

*An instrument is valid if it measures what it purports to measure.*

- Content validity
  - *Whether the instrument covers all aspects of the construct being measured.*
  - Achieved through the involvement of people with CD and experts.
- Construct validity
  - CDAQ and SF-36 administered together
  - CDAQ correlated more strongly with emotional domains

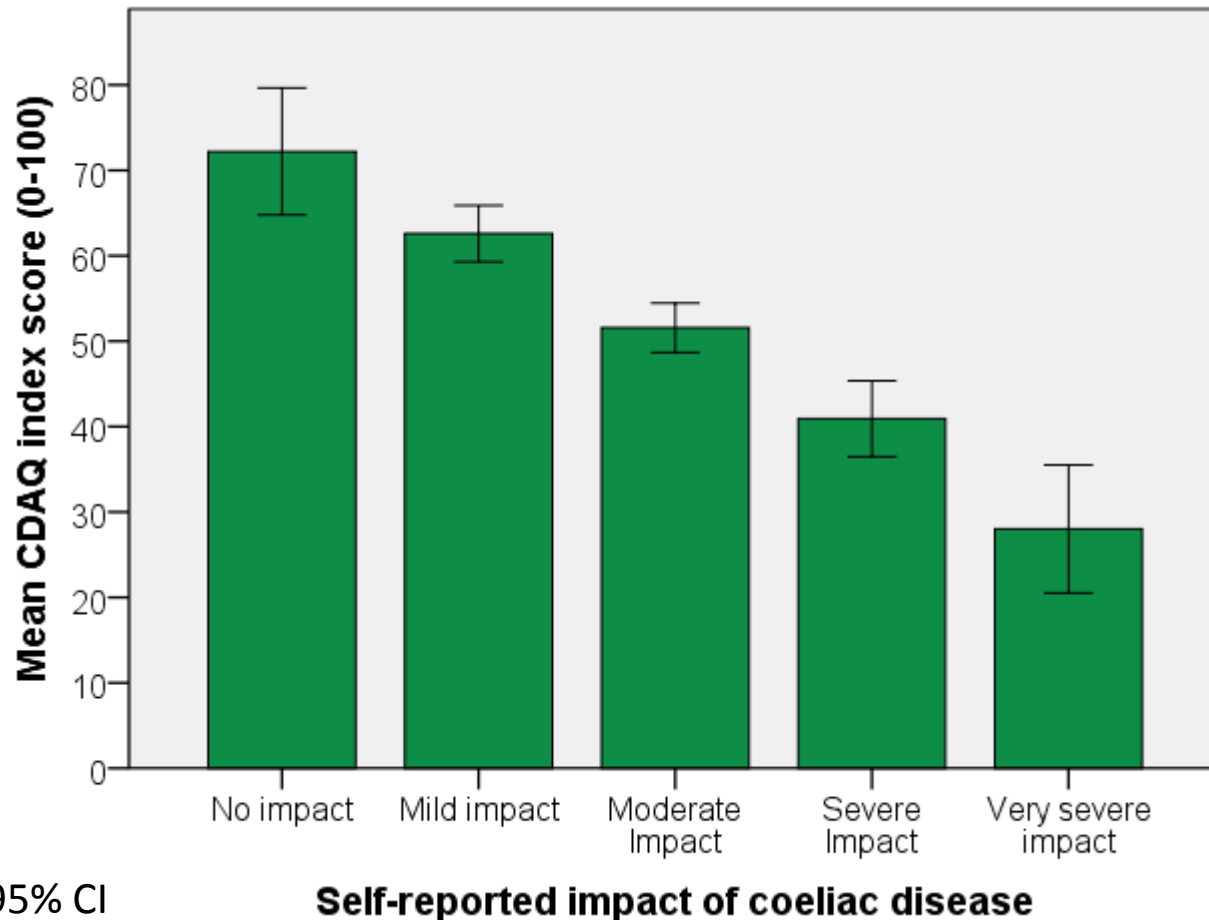
# Validity of the CDAQ

- Known groups validity
  - Gender,  $H_0$ : Females report lower QOL than males



# Validity of the CDAQ

“Thinking about your coeliac disease, how much does it impact on you and your health?”





# Responsiveness to change

- *The ability of a measure to detect change over time*
  - One year study, part-funded by Coeliac UK
  - Recruited Coeliac UK members diagnosed within the last year
  - Cohort asked to complete CDAQ twice, four months apart.
  - Example transition question: *'Compared with the last time you completed this questionnaire four months ago, how would you rate the impact of your coeliac disease on you and your health now?'*
  - Minimal Important Difference (MID) will be calculated - the minimal amount of change that is important to the patient.
  - No. of people who have completed first questionnaire: 360

# Uses of the CDAQ

- Clinical trials
  - Endpoint to assess the effectiveness of treatments
  - Administer CDAQ before and after treatment to assess impact on QOL
- Ongoing management of patients
  - Patients could complete the CDAQ annually
  - Those reporting poor quality of life could be identified and offered additional support.

# Conclusion

- Identified existing measures of quality of life in CD and discussed their limitations;
- Described the process of developing the CDAQ;
- Shown that the CDAQ is a reliable and valid measurement instrument;
- Discussed potential uses of the CDAQ.

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- Dr Michele Peters



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