

PSYCHOMETRIC VALIDATION OF THE CELIAC DISEASE SYMPTOM DIARY V2.1 USING DATA FROM A PHASE 2 STUDY IN PATIENTS WITH MODERATE TO SEVERE CELIAC DISEASE

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Poster

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Psychometric validation of the Celiac Disease Symptom Diary version 2.1 confirms it is a reliable, valid, and responsive patient-reported outcome measure for assessing gastrointestinal symptom severity in moderate to severe celiac disease.

KEY POINTS

- The CDSD v2.1 is a daily electronic diary assessing five celiac disease symptoms (diarrhea, abdominal pain, bloating, nausea, tiredness) on a 5-point scale with 24-hour recall, developed to address an unmet need for symptom assessment in celiac disease clinical trials.
- Data from a phase 2 randomized, placebo-controlled trial (NCT5353985) of zamaglutinase in 153 patients with moderate to severe celiac disease were used for validation, with patients exposed to low levels of gluten to simulate inadvertent exposure while maintaining a gluten-free diet.
- Test-retest reliability was adequate with ICC values of 0.66 to 0.72 for average GI symptom severity scores and 0.49 to 0.52 for percentage of symptom-free days; convergent validity showed moderate-to-strong correlations (0.51–0.75) with the Gastrointestinal Symptom Rating Scale.
- The measure demonstrated responsiveness with correlations above 0.37 with the Patient Global Impression of Severity and 0.32–0.37 with the Patient Global Impression of Change, and meaningful within-patient change thresholds were 0.42 for average GI severity and 1 to 2 symptom-free days per week.

- The findings support constructing clinical study endpoints based on change in average GI symptom severity or percentage of symptom-free days in patients with moderate to severe celiac disease.

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