

Patient-Reported IBS-C Symptom Severity Correlates Positively With Financial Burden: IBS In America 2024 Real-World Survey

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Background

- Irritable bowel syndrome with constipation (IBS-C) is known to impose a significant financial burden on patients in terms of direct and indirect healthcare costs.^{1,2}
- The IBS In America 2024 online survey was designed to gain insight into the experiences of individuals with IBS nationwide, including health status, quality of life, and symptom burden.^{3,4}
- This study was carried out using real-world data from the IBS In America 2024 survey to characterize the relationship between participant-reported IBS-C symptom severity and financial toxicity.

Methods

Study Design

- Ardelyx supported the IBS In America 2024 survey extension study in partnership with Health Union from January 15 to April 14, 2024.
- Participants were United States (US) residents aged ≥18 years who met these self-reported criteria: had been diagnosed with IBS-C, were currently seeing a health care provider to treat IBS-C, and had used over-the-counter or prescription treatment for IBS-C.
- Financial toxicity was assessed using select items from the Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity (FACT-COST®) scale, Version 2.⁵
 - The full scale includes 12 statements with responses ranging from "Not at all" to "Very much," as applicable within the past 7 days.
- In this analysis, an overall FACIT-COST score was not calculated because the full FACIT-COST assessment was not used, and the outcomes were not interpreted in the context of other research using the FACIT-COST assessment.
- Symptoms of IBS-C were assessed using 2 Patient-Reported Outcomes Measurement Information System® (PROMIS®) gastrointestinal (GI) symptom scales.^{6,7}
 - The PROMIS Scale v1.0 -- Gastrointestinal Belly Pain 5a (PROMIS GI Belly Pain) scale includes 5 items that assess abdominal pain frequency, intensity, and quality over the past 7 days, as well as bothersomeness and interference with daily activities.
 - The PROMIS Scale v1.0 -- Gastrointestinal Constipation 9a (PROMIS GI Constipation) scale includes 9 items that assess constipation-related symptoms and the bothersomeness of these symptoms over the past 7 days.
- Both PROMIS GI measures use T-scores. A higher T-score represents more of the concept being measured.⁸
 - A score of 50 represents the average of the US general population, while T-scores of 60 and 40 are 1 standard deviation worse and better than average, respectively.

Statistical Methods

- Financial burden was rated as a function of the following:
 - PROMIS GI Scale scores (T-score <60 vs ≥60).
 - Well controlled on current IBS treatment plan (not vs somewhat vs very well controlled).
 - Frequency of IBS-C episodes (daily vs weekly or less often).
- Pearson correlations were used to assess covariation between financial toxicity and symptom severity items.
- One-way analysis of variance (ANOVA) and multivariate analysis of variance (MANOVA) analyses were used to assess differences in financial toxicity between levels of symptom severity.

Results

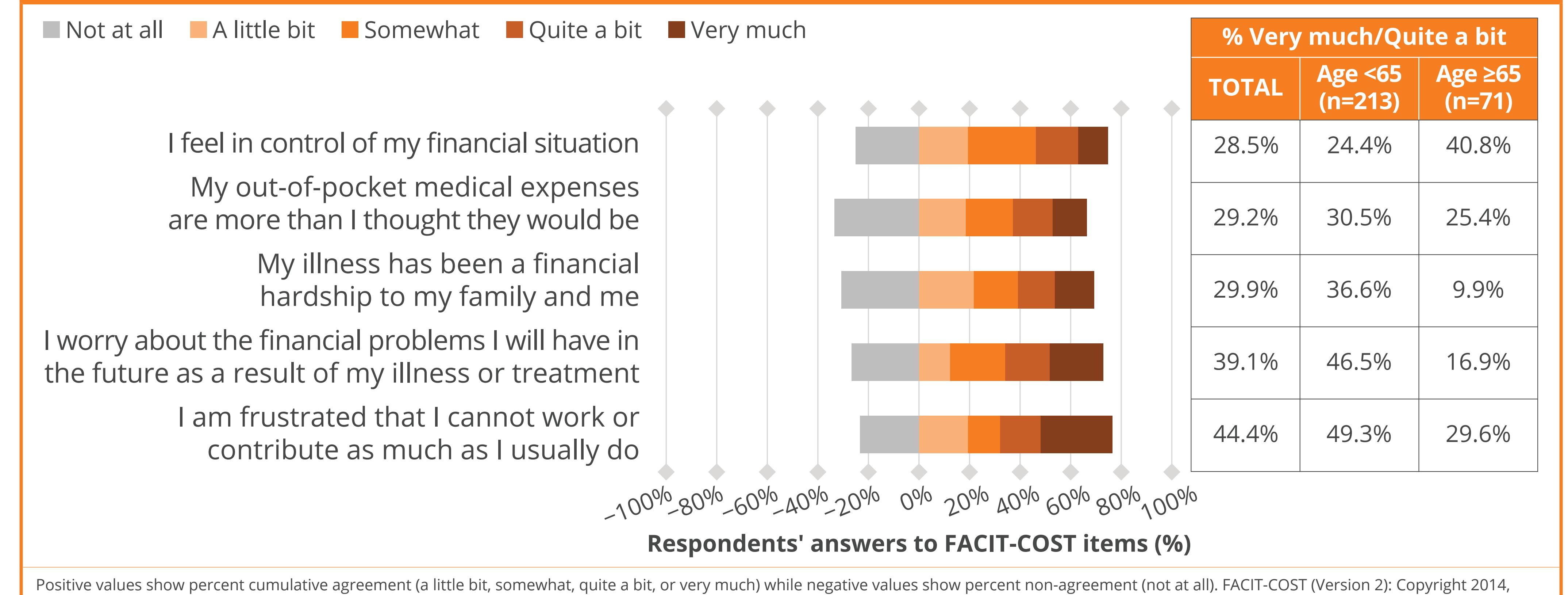
Respondents (Table 1)

- Respondents were predominantly female (92%) and White (87%).

Health-Related Economic Burden (Figure 1)

- Agreement with financial toxicity items differed significantly by age:
 - Significantly fewer respondents aged <65 years felt in control of their financial situation compared with those aged ≥65 years ($F(1,282)=7.181$; $P<0.01$).
 - Significantly more respondents aged <65 years reported greater financial hardship ($F(1,282)=19.290$; $P<0.001$), concerns about their financial future ($F(1,282)=20.886$; $P<0.001$), and frustrations about work or contributions ($F(1,282)=8.583$; $P<0.005$) versus those aged ≥65 years.

Figure 1: FACIT-COST: Health-Related Economic Burden



Positive values show percent cumulative agreement (a little bit, somewhat, quite a bit, or very much) while negative values show percent non-agreement (not at all). FACIT-COST (Version 2): Copyright 2014, FACIT-The University of Chicago, Used with permission. FACIT-COST, Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity.

Symptom Severity

- The mean T-scores were 60.8 and 62.3 for the PROMIS GI Constipation Scale and PROMIS GI Belly Pain Scale, respectively.

Relationships Between Financial Toxicity and Symptom Severity/Control

- Responses on the FACIT measures of financial toxicity correlated positively with the severity of constipation, abdominal pain, and IBS episode frequency, and correlated negatively with reported control of IBS on the current treatment plan (Table 2).
- Overall financial toxicity was significantly related to constipation severity, abdominal pain severity, the level of IBS control on the current treatment plan, and IBS episode frequency (Table 3).
- Participants with higher PROMIS Scale T-scores for constipation (Figure 2A) and abdominal pain (Figure 2B) reported greater financial burden across all financial toxicity items versus participants with lower T-scores.
- Poor IBS symptom control and higher frequency of IBS episodes had a significant negative impact on participants' financial situation (Figure 3A and 3B).

Table 2: Relationships Between Financial Toxicity Items and Symptom Severity: Results From Pearson Correlations

FACIT-COST item	PROMIS GI Constipation Scale T-score	PROMIS GI Belly Pain T-score	My IBS is well controlled with my current treatment plan ^a	Frequency of IBS-C episodes ^b
I am frustrated that I cannot work or contribute as much as I usually do	0.282 ^c	0.442 ^c	-0.330 ^d	0.171 ^c
I worry about the financial problems I will have in the future as a result of my illness or treatment	0.339 ^c	0.456 ^c	-0.277 ^d	0.177 ^c
My illness has been a financial hardship to my family and me	0.307 ^c	0.407 ^c	-0.279 ^d	0.143 ^c
My out-of-pocket medical expenses are more than I thought they would be	0.268 ^c	0.332 ^c	-0.199 ^d	0.113 ^e
I feel in control of my financial situation	-0.200 ^d	-0.141 ^d	0.178 ^c	0.006 ^e

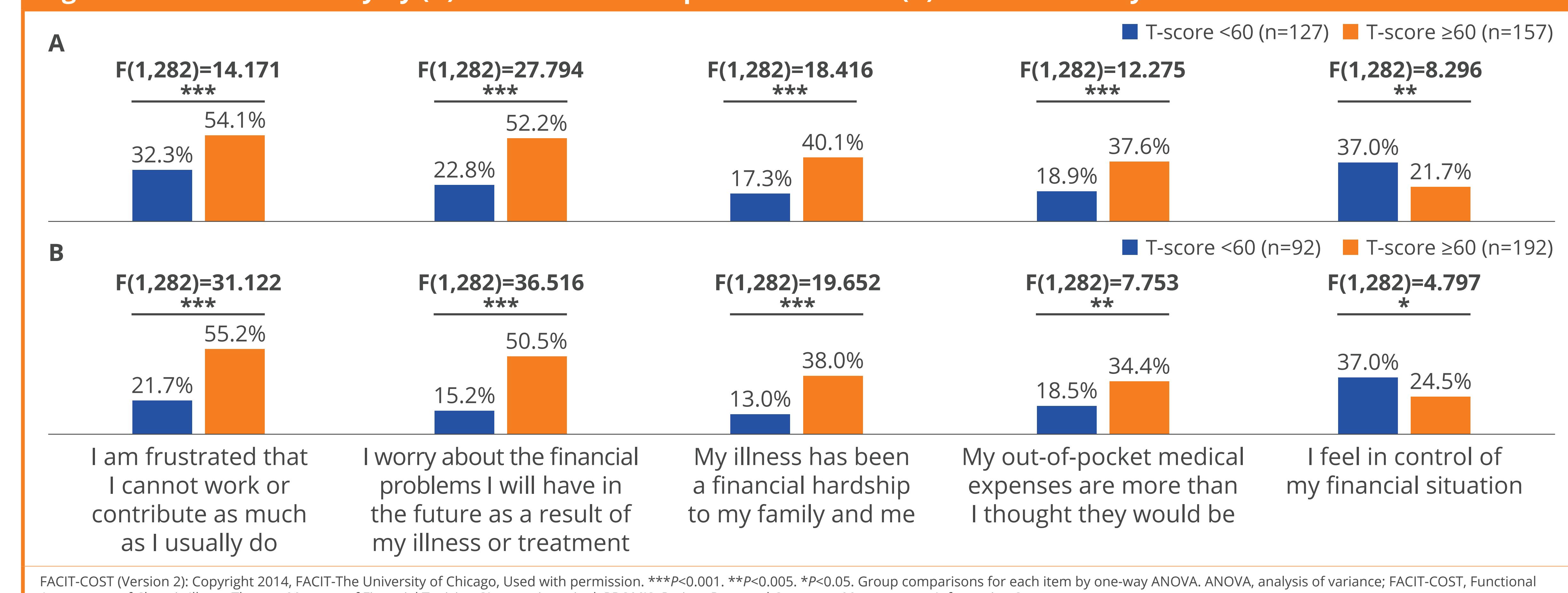
FACIT-COST (Version 2): Copyright 2014, FACIT-The University of Chicago, Used with permission. ^aIBS symptom control assessed by level of agreement or disagreement with this statement. ^bIBS episode frequency assessed by response to, "Within the past year, how frequently have you experienced IBS episodes?" Participants could select Daily, Weekly, Monthly, or Every few months or less often. ^cSignificant positive correlation. ^dSignificant negative correlation. ^eNot significant. FACIT-COST, Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity; GI, gastrointestinal; IBS, irritable bowel syndrome; IBS-C, irritable bowel syndrome with constipation; PROMIS, Patient-Reported Outcomes Measurement Information System.

Table 3: Overall Financial Toxicity by Each IBS Symptom Severity Item: Results From Multivariate Analyses

	PROMIS GI Constipation Scale T-score	PROMIS GI Belly Pain Scale T-score	My IBS is well controlled with my current treatment plan	Frequency of IBS-C episodes
FACIT-COST items	Pillai's Trace=0.114 F=7.1685 df=(5,278); P<0.001	Pillai's Trace=0.167 F=11.155 df=(5,278); P<0.001	Pillai's Trace=0.101 F=6.2716 df=(5,278); P<0.001	Pillai's Trace=0.0472 F=2.7532 df=(5,278); P<0.05

For the FACIT-COST items, the top 3 responses (somewhat, quite a bit, or very much) were used for the multivariate model except for the statement "I feel in control of my financial situation," for which the bottom 3 responses (not at all, a little bit, or somewhat) were used. FACIT-COST, Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity; GI, gastrointestinal; IBS, irritable bowel syndrome; IBS-C, irritable bowel syndrome with constipation; PROMIS, Patient-Reported Outcomes Measurement Information System.

Figure 2: Financial Toxicity by (A) PROMIS GI Constipation Scale and (B) PROMIS GI Belly Pain Scale T-Scores



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