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ORIGINAL RESEARCH

Validation of a Questionnaire for Assessing the Emotional Impact of Treatment for Type 2 Diabetes

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Background: Emotional reactions to treatment could affect treatment adherence and treatment outcomes, and it is therefore important to assess the emotional impact of treatment and consider this impact in clinical decision-making. The Emotional Impact of Diabetes Treatment Questionnaire – Status version (EIDTQ-Status) was developed based on qualitative research with patients as the first patient-reported outcome measure to assess both the positive and negative emotional impacts of type 2 diabetes (T2D) and its treatment. This study assessed the psychometric properties of the EIDTQ-Status.

Methods: Participants with T2D treated with a range of medications were recruited from eight clinical sites in the United States. Analysis of the EIDTQ-Status focused on item performance, subscale identification (including exploratory factor analysis), development of a scoring algorithm, test-retest reliability (intraclass correlation coefficients in a third of the participants who were randomized to attend a second visit), internal consistency reliability (Cronbach's alpha), and construct validity (via comparisons to previously validated generic and diabetes-specific instruments).

Results: The sample included 250 participants (mean age = 59.7 years old; 54.4% female). Based on item performance and exploratory factor analysis, 14 items were retained and grouped into three subscales: (1) positive emotions, (2) negative emotions, and (3) sense of control over diabetes, eating, and weight, as well as a total score. The EIDTQ-Status demonstrated good internal consistency reliability (Cronbach's alphas of the three subscales and total score: 0.92, 0.88, 0.85, 0.77). Test-retest reliability was acceptable with no significant differences between administrations 7+2 days apart among stable participants (n=37; intraclass correlation coefficients: 0.85, 0.67, 0.62, and 0.88). Construct validity was supported via significant correlations with validated instruments ($P<0.0001$). The EIDTQ-Status distinguished among participants who differed in reports of emotional well-being. Exploratory analysis suggests the EIDTQ-Status may differentiate between treatments. Compared with injectable semaglutide (n=47), tirzepatide-treated participants (n=58) reported a significantly greater sense of control over diabetes, eating, and weight ($P=0.025$).

Conclusion: The EIDTQ-Status had strong factor structure with three subscales and a total score that demonstrated good reliability and validity. This questionnaire may be useful in clinical trials and observational research assessing the emotional impact of treatment for T2D.

Keywords: Emotional Impact of Diabetes Treatment Questionnaire - Status version, EIDTQ-Status, type 2 diabetes, psychometric validation, patient-reported outcomes

Introduction

Type 2 diabetes (T2D) has been shown to have an emotional and psychological impact on patients, including diabetes-related distress, anxiety, and depressive symptoms.[1–11] People with T2D typically require chronic treatment, and previous research has found treatment-related differences in emotional impact, with insulin-treated patients often reporting the most significant distress.[12–16] Emotional reactions to treatment could affect treatment adherence and treatment

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outcomes,[17,18] and it is therefore important to assess the emotional impact of treatment and consider this impact in clinical decision-making. Previously developed diabetes-specific measures that assess emotional impact, such as the Problem Areas in Diabetes Survey, Treatment-Related Impact Measures for Diabetes (TRIM-D), Diabetes Therapy-Related Quality of Life, and Diabetes Symptom Checklist-Revised, have included items focusing on diabetes-related distress and negative emotions.[19–22] However, no previous measures were designed to assess the potential positive emotional impact of treatment.

In addition, the newer treatments for T2D, such as glucagon-like peptide-1 (GLP-1) receptor agonists and a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 receptor agonist, have different treatment benefits than insulin, such as the potential for weight loss.[23] The outcomes of these new treatments, including substantial weight loss, may have a positive emotional impact on patients.[24] No previous patient-reported outcome (PRO) measure has been designed and validated to assess the potential positive emotional impact specifically associated with these treatments. To address these measurement gaps, the Emotional Impact of Diabetes Treatment Questionnaire – Status version (EIDTQ-Status) was developed to assess both the positive and negative emotional impact of a patient's current treatment for T2D.[25] The instrument was developed based on qualitative research with patients receiving a range of treatments for T2D, including GLP-1 receptor agonists and a dual GIP/GLP-1 receptor agonist. Therefore, the EIDTQ-Status includes items assessing constructs that are specifically relevant to these patients, including a sense of control related to eating and weight.

The content validity of the EIDTQ-Status has been previously demonstrated among patients with T2D.[25] The purpose of this study was to perform a psychometric validation of the EIDTQ-Status in a larger sample of people receiving treatment for T2D. The analyses focused on item performance, possible item reduction, subscale identification, development of a scoring algorithm, and assessment of reliability and validity.

Materials and Methods

Study Design

People with T2D were recruited from eight clinical sites across the United States (US), including three endocrinology sites (two sites in Houston, TX; one site in Fresno, CA) and five general practice sites (two sites in Miami, FL; one site in Fargo, ND, Gretna, LA, and McAllen, TX) between June and November 2023 to examine the measurement properties of the EIDTQ-Status. Participants were identified through clinical site chart review and in-person clinic visits. All participants completed the instruments on paper during an in-person clinic visit (visit 1), and approximately one-third were randomly selected to participate in a visit 2 assessment 7±2 days later to gather data for test-retest reliability. The study protocol, all study materials, and clinic sites were approved by an independent review board (Salus IRB, study number 23069). Participants provided written informed consent during visit 1 and received remuneration for their time. Data analysis began with descriptive statistics and examination of factor structure to inform subscale identification for the EIDTQ-Status. Then, reliability and validity were assessed for the subscales and total score.

Participants

To be eligible, participants were required to meet the following criteria: (1) currently residing in the US; (2) at least 18 years old at the time of enrollment; (3) diagnosed with T2D by a recognized medical professional at least 6 months prior to enrollment; (4) treated with their current prescription medication for T2D for at least 4 months; (5) previously treated with a medication for T2D different from their current medication; (6) able and willing to give written informed consent prior to study entry; and (7) able to complete protocol requirements (eg, complete study questionnaires in person in the English language). Participants were excluded from the study if they were healthcare professionals who treat patients with diabetes or if they had been diagnosed with latent autoimmune diabetes or gestational diabetes.

Measures

To characterize the study sample, the clinical sites completed a clinical form for each participant, and the participants completed a sociodemographic form. Participants also completed the following questionnaires.

EIDTQ-Status: This 14-item PRO measure was developed to assess the emotional impact of current T2D medications on patients in the past week.[25] Respondents rate the frequency of experiencing each emotion on a 5-point scale ranging from "never" to "almost always."[25] All items, except those focused on negative emotions (items 12–14) are scored on a 5-point scale ranging from 0 ("never") to 4 ("almost always"). The negative emotion items are reverse-scored (ie, the response option of "never" is scored as 4, while the response option of "almost always" is scored as 0) so that higher scores on all items always indicate better emotions.

Simplicity of Diabetes Treatment Questionnaire (Sim-Q): This 10-item PRO measure was developed to assess the simplicity and complexity of a patient's current treatment for T2D.[26] Respondents rate the simplicity or complexity of each treatment attribute on a 5-point scale ranging from "very complex" to "very simple."[26] Eight items contribute to a scale score representing treatment simplicity, and two global items assess the simplicity of treatment for diabetes and the simplicity of overall diabetes management. Higher scores indicate greater simplicity.

Treatment-Related Impact Measure – Diabetes (TRIM-D): This 28-item PRO measure assesses five domains: treatment burden, daily life, diabetes management, compliance, and psychological health.[19] Only the psychological health domain and individual items from the diabetes management domain were used for the current analysis. Higher scores indicate better health.[19]

Diabetes Treatment Satisfaction Questionnaire (DTSQ-Status): This measure was developed to assess patients' satisfaction with their diabetes treatment. Six items measure treatment satisfaction, and the sum of these items produces the DTSQ-Status treatment satisfaction scale total. The remaining two items assess the frequency of hyperglycemia and hypoglycemia and were not included in the current analysis. Higher scores indicate greater satisfaction with treatment.[27]

Short Form (36) Health Survey (SF-36v2): The SF-36v2 assesses overall health-related quality of life using a 1-week recall period and norm-based scoring (from the US general population) with a mean of 50 and a standard deviation (SD) of 10.[28] Only the physical and mental component scores were included in the current analysis.

Global Impression of Emotional Health: The global impression of emotional health item asks participants to choose the response that best describes their emotional health over the past week on a 5-point Likert scale ranging from "excellent" to "poor." For visit 2, participants are asked to describe the overall change in their emotional health since the previous visit on a 5-point Likert scale ("much better" to "much worse") and if their treatment changed since the last visit.

Statistical Analysis Procedures

Descriptive statistics (eg, mean, median, SD, range, frequency) were used to summarize participants' responses to the PRO measures and to characterize the sample in terms of sociodemographic and clinical variables. Missing data were handled as indicated in the instructions from the instrument developers. All statistical analyses were conducted using data from visit 1, except the analysis of test-retest reliability, which was conducted in a subset of participants with data from both visit 1 and visit 2. Statistical analyses were conducted using SAS 9.4 (Cary, NC).

Item Reduction and Subscale Identification

EIDTQ-Status items were not necessarily deleted based on any individual statistical criterion or cutoff. Instead, decisions about item reduction were based on consideration of all the following criteria: (1) ceiling or floor effect (ie, items where more than 50% of the sample endorsed the highest or lowest response options); (2) greater than 5% missing responses; (3) redundancy as indicated by a particularly high correlation with another item ($r > 0.85$); (4) lack of relationship to other items as indicated by Cronbach's alpha with the item deleted (ie, if alpha increased by >10% upon deletion of an item, then that item would have been considered for possible exclusion); and (5) items with insufficient factor loading (ie, <0.40) or loading on multiple factors in the factor analysis described below. Additionally, when deciding whether to delete any item, the patient perspective was considered based on qualitative research conducted to generate items for the questionnaire prior to this psychometric study.[25]

Exploratory factor analyses (EFAs) with orthogonal (assumes factors are not correlated) and oblique (assumes factors are correlated) rotations were used to examine the underlying structure among the items using the principal axis extraction method. The number of potential factors was determined based on eigenvalues using Kaiser's criterion (factor

loadings ≥1.0) as an approximate cutoff value and examination of the scree plot.[29] Subscales were determined based on consideration of the number of factors that emerged from the EFAs, factor loadings of each item, and consideration of whether any items met criteria for deletion. The scoring of subscales, including the strategy for handling missing data, was finalized after item reduction and subscale identification were completed.

Psychometric Evaluation

Internal consistency reliability of the EIDTQ-Status was assessed for each subscale and the total score using Cronbach's coefficient alpha. Cronbach's alpha ≥0.70 and ≤0.95 was considered acceptable.[30,31]

The test-retest reliability of the EIDTQ-Status was assessed using data from the subgroup of participants who were randomized to visit 2, completed the visit within the required timeframe (ie, 7 ± 2 days after visit 1), and had no change in diabetes medication or their self-reported emotional state between the two visits. To assess change in self-reported emotional state, participants were asked at visit 2 to respond to a single item assessing change in overall emotional health between the two visits. To be included in the test-retest analysis, participants were required to select "no change" as a response. Intraclass correlation coefficients (ICCs) were used to evaluate the degree of association between scores at visit 1 and visit 2 for the EIDTQ-Status. An ICC between 0.5 and 0.75 was considered to indicate moderate agreement between the two administrations.[32] In addition, paired *t* tests were used to evaluate whether there were statistically significant score changes between visit 1 and visit 2. It was hypothesized that there would be no statistically significant change between the two visits.

Construct validity of the EIDTQ-Status was evaluated via Spearman correlations with questionnaires assessing related concepts. To assess validity, the DTSQ-Status treatment satisfaction scale total, TRIM-D psychological health subscale, and SF-36v2 physical and mental component scores were used as the comparator measures with the hypothesis that there would be a relatively high positive correlation between scales assessing similar constructs. The following criteria were applied for the interpretation of the strength of the correlations: small ($|r|<0.30$), moderate ($0.30\leq |r| <0.50$), or large ($|r| \geq 0.50$).[33]

Known-groups validity was assessed by examining the ability of the EIDTQ-Status to discriminate between groups of participants who differed with regard to known factors. *T* tests (for comparisons between two groups) and analysis of variance (ANOVA) with Scheffé's post hoc pairwise comparisons (for comparisons between more than two groups) were used to compare EIDTQ-Status scores among these groups. For example, participants were categorized based on their response to an item assessing their global impression of emotional health on a 5-point scale ranging from "excellent" to "poor." It was expected that participants reporting better overall emotional health would have higher scores on the EIDTQ-Status. Participants were also categorized based on their responses to the two global items from the Sim-Q assessing simplicity of medication for diabetes and simplicity of overall diabetes management. It was expected that participants reporting greater simplicity on these items would have higher scores on the EIDTQ-Status. An exploratory analysis was conducted to examine whether the EIDTQ-Status was able to differentiate among treatments that could differ with regard to emotional impact. For this analysis, *t* tests were used to compare EIDTQ-Status scores between tirzepatide-treated participants and injectable semaglutide-treated participants. This exploratory analysis was conducted to generate potential hypotheses for exploration in future studies.

Results

Sample Description

The sociodemographic and clinical characteristics are shown in Table 1. The 250 participants (54.4% women) had a mean age of 59.7 years (SD=11.7 years). The majority of participants were White, and over half of the participants were Hispanic or Latino (57.6%). Most participants were either employed full- or part-time (51.6%) or retired (28.4%). Just over a quarter of the sample (25.6%) had a college/university or post-graduate degree. The most common comorbid conditions were hypertension (48.4%), arthritis (28.4%), and diabetic retinopathy (16%).

Seventy percent of the sample received some type of oral medication for treatment of T2D, including biguanides (31.2%), sulfonylureas (29.6%), sodium-glucose cotransporter 2 inhibitors (20.0%), and oral semaglutide (8.4%).

Table 1 Demographic and Clinical Characteristics

Characteristics	Descriptive Statistics (N=250)
Age (years), mean (SD)	59.7 (11.7)
Sex, n (%)	
Male	114 (45.6%)
Female	136 (54.4%)
Highest Education Level, n (%)[a]	
Less than high school	25 (10.0%)
Secondary/high school/GED	92 (36.8%)
Associate degree, technical, or trade school	63 (25.2%)
College/university degree	51 (20.4%)
Post-graduate degree	13 (5.2%)
Other	6 (2.4%)
Ethnic Background, n (%)	
Hispanic or Latino	144 (57.6%)
Not Hispanic or Latino	103 (41.2%)
Missing	3 (1.2%)
Racial Background, n (%)[b]	
American Indian or Alaska Native	3 (1.2%)
Asian or Asian American	5 (2.0%)
Black or African American	40 (16.0%)
White	177 (70.8%)
Other	24 (9.6%)
Not reported	1 (0.4%)
Duration of T2D Diagnosis (years), mean (SD)[c]	12.1 (10.1)
Current Diabetes Medication, n (%)[d]	
Oral	176 (70.4%)
Insulin	83 (33.2%)
Injectable GLP-1 receptor agonist	96 (38.4%)
Injectable dual GIP/GLP-1 receptor agonist	60 (24.0%)
Injectable combination insulin and GLP-1 receptor agonist	6 (2.4%)
Most Recent HbA1c Level, %, mean (SD)[e]	7.3% (1.5)
BMI, kg/m^2, mean (SD)	32.8 (7.1)

Notes: [a]"Associate degree + other" counted under "other" (n=1); "high school + associate degree" counted under "associate degree" (n=1). [b]"American Indian or Alaska Native + White" counted under "other" (n=1). [c]N=2 (0.8%) missing. [d]Not mutually exclusive. [e]N=10 (4.0%) missing.

Abbreviations: BMI, body mass index; GED, general education development; GIP, glucose-dependent insulinotropic polypeptide; GLP-1, glucagon-like peptide-1; HbA1c, glycated hemoglobin; SD, standard deviation; T2D, type 2 diabetes.

Approximately a third of the sample (33.2%) was receiving insulin, while 38.4% were treated with GLP-1 receptor agonists. The most common non-insulin injectable medications were tirzepatide (24.0%), injectable semaglutide (22.0%), and dulaglutide (10.8%).

Item Reduction and Subscale Identification

Decisions regarding item reduction and subscale identification were made for the EIDTQ-Status based on item performance, item-to-item correlations, and EFAs, as well as Cronbach's alpha for proposed subscales. Mean scores for the 11 individual items that were not reverse-scored (items 1–11) ranged from 2.8 to 3.3, and mean scores for the three reverse-scored items (items 12–14) ranged from 0.8 to 1.0. For each item, participants used the full range of the scale, with responses ranging from 0 ("never") to 4 ("almost always"). Responses often reflected positive emotions associated with diabetes treatment. For each of the items, 33.3% to 51.4% of participants selected the response at the upper range of the response scale. Still, none of the items had a ceiling effect substantial enough to justify item deletion. Missing data were minimal for all items.

All items were found to be strongly correlated (range: absolute value of r = 0.47 to 0.78) with each other (all P <0.01), except item 12 ("fearful") and item 1 ("hopeful"), which had a weak but significant correlation of r= −0.13 (P <0.05). While some items were closely related to each other, no item-to-item correlations were large enough (ie, >0.85) to suggest an item should be dropped because of redundancy.

EFAs of the EIDTQ-Status were run with oblique (PROMAX) rotations to inform decision-making about subscale structure. The first EFA did not specify the number of factors to be included in the solution. In this run, the first four eigenvalues were 7.03, 1.37, 0.77, and 0.27, suggesting a two- and three-factor solution.

The two-factor solution resulted in the three negative emotion items (items 12–14) loading separately from all other items (items 1–11). The three-factor solution yielded three subscales that were clearly distinct from each other: items 1 to 8 assessing positive emotions, items 12 to 14 assessing negative emotions, and items 9 to 11 assessing a sense of control. The items within each of these three factors had factor loadings (standardized regression coefficients emerging from the PROMAX rotation) ranging from 0.58 to 0.82 for the positive items, 0.76 to 0.87 for the negative items, and 0.61 to 0.86 for the control items (Table 2). There was no cross-loading across factors for any of the items, supporting the three-factor solution as the optimal solution based on the factor loadings and factor content. Thus, the EIDTQ-Status was finalized as three subscales (positive emotions, negative emotions, and sense of control) as well as a total score.

Scoring and Interpretation of the EIDTQ-Status

After reverse-scoring the negative emotion items (as described above in the Methods section), responses to items within each of the three subscales are summed: the positive emotions subscale (items 1–8), the negative emotions subscale (items 12–14), and the subscale titled sense of control over diabetes, emotions, and weight (items 9–11). For the total

Table 2 EIDTQ-Status Descriptive Statistics and Exploratory Factor Analysis

EIDTQ-Status[a]	N	Mean (SD)	Floor n (%)[b]	Ceiling n (%)[b]	Missing n (%)	Exploratory Factor Analysis[c]		
						Factor 1	Factor 2	Factor 3
Item 1: Hopeful	250	3.1 (1.0)	6 (2.4%)	112 (44.8%)	0 (0.0%)	0.75		
Item 2: Optimistic	250	3.1 (0.9)	2 (0.8%)	108 (43.2%)	0 (0.0%)	0.81		
Item 3: Happy	249	3.2 (0.9)	3 (1.2%)	114 (45.8%)	1 (0.4%)	0.79		
Item 4: Relieved	247	3.1 (0.9)	4 (1.6%)	95 (38.5%)	3 (1.2%)	0.82		
Item 5: Self-confident	249	3.2 (0.9)	5 (2.0%)	113 (45.4%)	1 (0.4%)	0.78		
Item 6: Good about myself	247	3.3 (0.8)	2 (0.8%)	127 (51.4%)	3 (1.2%)	0.74		
Item 7: Motivated	250	3.1 (0.9)	3 (1.2%)	105 (42.0%)	0 (0.0%)	0.76		
Item 8: Energetic	249	2.8 (1.0)	3 (1.2%)	83 (33.3%)	1 (0.4%)	0.58		
Item 9: In control of my diabetes	250	3.1 (0.9)	1 (0.4%)	108 (43.2%)	0 (0.0%)		0.61	
Item 10: In control of my eating	249	2.8 (1.0)	3 (1.2%)	87 (34.9%)	1 (0.4%)		0.86	
Item 11: In control of my weight	247	2.8 (1.1)	7 (2.8%)	83 (33.6%)	3 (1.2%)		0.83	
Item 12: Fearful	247	0.8 (1.0)	115 (46.6%)	6 (2.4%)	3 (1.2%)			0.79
Item 13: Frustrated	248	1.0 (1.1)	109 (44.0%)	7 (2.8%)	2 (0.8%)			0.76
Item 14: Worried	248	1.1 (1.1)	100 (40.3%)	8 (3.2%)	2 (0.8%)			0.87
Positive Emotions Score	250	78.23	0 (0.0%)	60 (24.0%)	0 (0.0%)			
Negative Emotions Score	248	75.80	5 (2.0%)	79 (31.9%)	2 (0.8%)			
Sense of Control Over Diabetes, Eating, and Weight Score	250	73.08	1 (0.4%)	65 (26.0%)	0 (0.0%)			
Total Score	249	76.54	0 (0.0%)	33 (13.3%)	1 (0.4%)			

Notes: [a]The EIDTQ-Status asks participants to think about how their current diabetes medication affects them emotionally, "Because of your current diabetes medication, how often have you felt the following?" Response scale ranges from 0 ("Never") to 4 ("Almost always"). [b]These percentages represent the proportion of responses at the lowest response option (floor) and the highest response option (ceiling). [c]An exploratory factor analysis (oblique rotation) was conducted with a three-factor solution: Factor 1 is the positive emotions subscale; Factor 2 is the sense of control over diabetes, eating, and weight subscale; Factor 3 is the negative emotions subscale.
Abbreviations: EIDTQ-Status, Emotional Impact of Diabetes Treatment Questionnaire – Status version; SD, standard deviation.

score, responses to all 14 items are summed. Finally, to generate scores on a 100-point scale, each of the raw sum scores are transformed by multiplying the mean raw score by 100 and dividing by 4 (range of raw scores). To be scored, at least 50% of items within any subscale or the total score must be answered (eg, at least four items for the eight-item positive emotions subscale). If a respondent does not answer the minimum number of items within a subscale or the total score, the score should not be calculated and presented.

Scores can be interpreted as follows: higher scores on the positive emotions subscale indicate more positive emotions associated with the treatment being rated, whereas higher scores on the negative emotions subscale reflect fewer negative emotions. Higher scores on the subscale assessing sense of control over diabetes, eating, and weight indicate a greater sense of control. Higher total scores indicate more overall positive emotions associated with treatment. In sum, higher scores represent more positive and less negative emotions than lower scores on all three subscales and the total score. Descriptive statistics for the three subscale scores and total score are presented in Table 2.

Reliability

The positive emotions, negative emotions, and sense of control subscales, as well as the total score, demonstrated good internal consistency reliability with Cronbach's alphas of 0.92, 0.88, 0.85, and 0.77, respectively. Dropping any individual item did not substantially increase or decrease the alpha for any of the subscales or total score.

Of the 92 participants who completed visit 2, 37 participants reported no change in their diabetes treatment or emotional health between the two visits and were included in the test-retest reliability analysis. In this subgroup, paired *t* tests found no significant change in the EIDTQ-Status subscales or total score between visits 1 and 2. The EIDTQ-Status demonstrated good test-retest reliability with an ICC of 0.85 for the positive emotions subscale, 0.67 for the negative emotions subscale, 0.62 for the sense of control subscale, and 0.88 for the total score.

Validity

All three EIDTQ-Status subscales demonstrated construct validity, as indicated by statistically significant (P <0.0001) correlations in the moderate-to-large range with the DTSQ-Status treatment satisfaction scale total, TRIM-D psychological health subscale, and the SF-36v2 mental component score (Table 3). Correlations with the SF-36v2 physical component score were somewhat lower in magnitude but still statistically significant (Table 3).

The EIDTQ-Status demonstrated known-groups validity by distinguishing between subgroups that differentiated on other indicators. Participants were categorized into five groups based on their self-reported overall emotional health status: excellent, very good, good, fair, and poor (Table 4). All EIDTQ-Status scales differentiated between groups. Participants who reported better overall emotional health tended to have more positive emotions, fewer negative

Table 3 Construct Validity of the EIDTQ-Status: Spearman Correlations[a] with Other Measures

Measures		EIDTQ-Status Scales			
		Positive Emotions	Negative Emotions	Sense of Control Over Diabetes, Eating, and Weight	Total Score
DTSQ-Status Treatment Satisfaction scale	r	0.48****	0.40****	0.52****	0.56****
	N	250	248	250	249
TRIM-D Psychological Health subscale	r	0.59****	0.58****	0.56****	0.69****
	N	250	248	250	249
SF-36v2 Physical Component score	r	0.35****	0.30****	0.37****	0.41****
	N	250	248	250	249
SF-36v2 Mental Component score	r	0.48****	0.47****	0.36****	0.53****
	N	250	248	250	249

Notes: [a]Spearman rank-order correlation coefficients; ****P<0.0001.

Abbreviations: DTSQ, Diabetes Treatment Satisfaction Questionnaire; EIDTQ-Status, Emotional Impact of Diabetes Treatment Questionnaire – Status version; SF-36v2, Short Form (36) Health Survey; TRIM-D, Treatment-Related Impact Measure – Diabetes.

Table 4 Known-Groups Validity: EIDTQ-Status Scores by Overall Rating of Emotional Health Over the Past Week (N=250)

EIDTQ-Status[a] Scores	Overall Rating of Emotional Health Over the Past Week[a]					Overall F Value	*P* Value	Significant Pairwise Comparisons[c]
	Excellent (n=67) Mean (SD)	Very good (n=96) Mean (SD)	Good (n=50) Mean (SD)	Fair (n=32) Mean (SD)	Poor (n=5) Mean (SD)			
Positive Emotions	86.60 (13.64)	81.22 (17.82)	76.65 (14.29)	58.83 (19.18)	48.50 (11.81)	21.06***	<0.0001	A*, B***, C***, D***, E***, F***, G**
Negative Emotions[b]	83.99 (18.87)	78.42 (22.13) (N=95)	72.35 (24.96) (N=49)	62.27 (25.18)	36.50 (26.84)	9.62***	<0.0001	B***, C***, D*, E**, G*
Sense of Control Over Diabetes, Eating, and Weight	81.12 (19.01)	75.08 (21.99)	70.70 (20.35)	59.69 (22.91)	36.50 (19.41)	9.89***	<0.0001	B***, C***, D*, E**, G*
Total score	84.63 (12.35)	79.42 (15.84) (N=95)	74.35 (14.78)	59.69 (16.87)	43.00 (10.81)	22.89***	<0.0001	A**, B***, C***, D***, E***, F**, G***

Notes: [a]Participants rated their overall emotional health in response to the following question: "Please choose the response below that best describes your emotional health over the past week." [b]The EIDTQ-Status Negative Emotions score could not be calculated for two participants due to missing data. [c]Scheffé post-hoc pairwise comparisons: A: Excellent vs Good; B: Excellent vs Fair; C: Excellent vs Poor; D: Very good vs Fair; E: Very good vs Poor; F: Good vs Fair; G: Good vs Poor. *P<0.05; **P<0.01; ***P<0.001.

Abbreviations: EIDTQ-Status, Emotional Impact of Diabetes Treatment Questionnaire – Status version; SD, standard deviation.

emotions, a greater sense of control, and a total score indicating better overall emotions compared with participants who reported worse overall emotional health.

Treatment simplicity was also hypothesized to be associated with emotional impact. All EIDTQ-Status scales were shown to differentiate between two groups of participants, categorized based on whether they reported their current medication to be simple or complex on a global item of the Sim-Q (Table 5). Participants who reported that their diabetes medication was simple had significantly greater scores on all EIDTQ-Status scales than participants who reported that their diabetes medication was complex (all P values <0.01).

Similar analyses examining known-groups validity were conducted with two items from the TRIM-D. Participants who reported less satisfaction with their medication's ability to control their diabetes and their weight (TRIM-D items 4a and 4d) had significantly lower EIDTQ-Status scores (all P values <0.0001).

Exploratory Analysis: Differences in EIDTQ-Status by Current Diabetes Treatment

To provide an initial indication of whether the EIDTQ-Status can differentiate between treatments, two groups receiving different treatments were compared. Participants currently taking tirzepatide (n=58) had a significantly greater sense of control over diabetes, eating, and weight (P=0.025) and a significantly higher EIDTQ-Status total score (P=0.028) than

Table 5 Known-Groups Validity: EIDTQ-Status Scores by Simplicity of Medication Treatment for Diabetes (N=249)

EIDTQ-Status Scores	Simplicity of Medication Treatment for Diabetes[a]		Overall F Value	Sim-Q Item 9 *P* Value
	Simple[b] (n=205) Mean (SD)	Complex[b] (n=44) Mean (SD)		
Positive Emotions	80.28 (17.20)	68.18 (21.80)	16.21***	<0.0001
Negative Emotions[c]	77.61 (23.60) (N=204)	66.63 (23.57) (N=43)	7.69**	0.0060
Sense of Control Over Diabetes, Eating, and Weight	75.88 (21.56)	59.43 (21.55)	21.09***	<0.0001
Total score	78.60 (16.65)	66.16 (16.28) (N=43)	19.97***	<0.0001

Notes: [a]Participants were categorized based on responses to Sim-Q Item 9: "How simple or complex is your medication treatment for diabetes?" [b]Simple includes participants who selected Simple or Very Simple. Complex includes participants who selected Very Complex, Complex, or A Little Complex. [c]The EIDTQ-Status Negative Emotions score could not be calculated for two participants due to missing data. **P<0.01; ***P<0.001.

Abbreviations: EIDTQ-Status, Emotional Impact of Diabetes Treatment Questionnaire – Status version; SD, standard deviation; Sim-Q, Simplicity of Diabetes Treatment Questionnaire.

Table 6 Comparison of EIDTQ-Status Scores: Tirzepatide-Treated Participants vs Injectable Semaglutide-Treated Participants

EIDTQ-Status Scores	Tirzepatide (n=58)	Injectable Semaglutide (n=47)	Between-Group Difference	*t* test	
	Mean (SD)	Mean (SD)	Mean (SD)	*t* statistic	*P* Value
Positive Emotions	81.90 (15.77)	77.07 (15.51)	4.82 (15.66)	1.6	0.120
Negative Emotions	81.29 (22.87)	73.62 (23.80)	7.68 (23.29)	1.7	0.096
Sense of Control Over Diabetes, Eating, and Weight	83.71 (19.18)	75.32 (18.41)	8.39 (18.84)	2.3	0.025
Total score	81.94 (15.15)	75.59 (13.79)	6.35 (14.56)	2.2	0.028

Abbreviations: EIDTQ-Status, Emotional Impact of Diabetes Treatment Questionnaire – Status version; SD, standard deviation.

those taking injectable semaglutide (n=47). There were no statistically significant between-group differences on the positive and negative emotions subscale scores (Table 6).

Discussion

While previous PRO measures have included items assessing diabetes-related distress and negative emotions associated with T2D, no previous measures have been designed to assess positive emotional reactions to diabetes treatment. The EIDTQ-Status was designed to address this gap as the first questionnaire to assess both the positive and negative emotional impact of treatment for T2D. The items were developed and refined based on qualitative research with patients, many of whom were treated with GLP-1 receptor agonists or a dual GIP/GLP-1 receptor agonist.[24,25] Therefore, while this questionnaire was designed to apply across treatments for T2D, it is well-suited for assessing and comparing the emotional impact of these non-insulin injectable medications. Based on the initial qualitative research,[24] the subscale assessing sense of control over diabetes, eating, and weight may be particularly relevant to patients treated with the newer medication classes that tend to be associated with weight loss.

The current analyses build on the previous qualitative research supporting the content validity of the EIDTQ-Status.[24,25] Based on item performance and EFA, all 14 items were retained and categorized into three subscales: positive emotions (eight items), negative emotions (three items), and sense of control over diabetes, eating, and weight (three items). These three subscales and a total score demonstrated good internal consistency reliability, test-retest reliability, convergent validity, and known-groups validity. These psychometric results suggest that the instrument is appropriate for evaluating the emotional impact of treatment for T2D. The EIDTQ-Status may be useful in a wide range of clinical and observational research to provide additional insight into patients' experiences using medication. In addition, the questionnaire could be implemented in clinical settings to help clinicians better understand how prescribed medications are affecting their patients.

The EIDTQ-Status may be used in clinical trials to compare two treatments that are hypothesized to differ in emotional impact. The current study focused on psychometric analyses and was therefore not powered to detect significant differences in treatment effect. However, exploratory analysis was conducted to compare tirzepatide and injectable semaglutide, two treatments that have demonstrated significant benefits for blood glucose control and weight reduction.[23] On the EIDTQ-Status, participants generally reported a positive emotional experience with both of these treatments. Despite the small sample sizes of individual treatment groups in this study (tirzepatide, n=58; injectable semaglutide, n=47), there was some indication that the EIDTQ-Status may be able to differentiate between treatments (Table 6). For example, compared with injectable semaglutide-treated participants, tirzepatide-treated participants (n=58) reported a significantly greater sense of control over diabetes, eating, and weight, as well as a higher total score (P=0.03). Further research with larger samples is needed to examine the extent to which the EIDTQ-Status can differentiate between treatment groups.

There are also situations when it would be useful to compare two treatments received by the same patients. For example, crossover studies can be conducted in which every patient receives the same two treatments in sequence. Other studies may employ a "switch" design in which patients are switched from a previous treatment to the study treatment.

For these situations, a second version of the EIDTQ has been developed, called the EIDTQ-Comparison.[25] This version includes the same 14 items as the EIDTQ-Status but asks respondents to directly compare the emotional impact of their current treatment and their previous treatment. The EIDTQ-Comparison has demonstrated content validity in qualitative research,[25] but it was not validated in the current study because the sample did not include a sufficient number of participants with consistent experience switching from one treatment to another. Future research is needed to examine the validity of the comparison version of the EIDTQ with a sample of participants who can directly compare two treatments for T2D. Current results suggest that patients often have a positive emotional reaction to treatment, which could lead to ceiling effects. If the EIDTQ-Status cannot differentiate between two treatments because of ceiling effects, the comparison version may be useful.

Study limitations should be acknowledged. While results provide initial support for the psychometric properties of the EIDTQ-Status, confidence in any PRO instrument develops with repeated use across multiple samples. Further research is required to provide broader support for the instrument's reliability and validity. If the EIDTQ-Status is administered at multiple timepoints in a clinical trial, analyses can also be conducted to examine its responsiveness to change. Additional research is also needed to provide insight into the magnitude of difference scores or change scores that would be considered meaningful to patients. Future analyses following a clinimetric approach, such as a Rasch analysis,[34] could provide further information on the functioning of the EIDTQ-Status items.

Characteristics of the current sample have both strengths and limitations. The sample was recruited to reflect the broad range of treatments available to patients with T2D because the EIDTQ-Status was designed to be applicable across treatments. The sample reflected substantial educational diversity, including over 70% of the sample without a college degree. The participants were also diverse with regard to racial and ethnic background, including 70.8% of the sample reporting race as White and 16.0% of the sample reporting race as Black or African American. In addition, 57.6% of the sample reported a Hispanic or Latino ethnic background. While this diversity can be considered a strength of the current sample, this relatively high rate of Hispanic/Latino participants is not representative of the overall US population. It should also be noted that the generalizability of these results to countries other than the US is unknown. It is hoped that the EIDTQ-Status will be used and validated in additional samples within and outside the US.

Conclusions

In sum, the EIDTQ-Status has a strong factor structure with three subscales and a total score that demonstrated good reliability and validity. This questionnaire may be useful in clinical trials and observational research assessing the emotional impact of treatment for T2D. Qualitative research suggests that the improved blood glucose and weight management associated with newer non-insulin injectable treatments may lead to a positive emotional impact.[24] The EIDTQ-Status can quantify these emotional benefits and complement clinical measures to provide a broader picture of the overall impact of these treatments.

Abbreviations

DTSQ-Status, Diabetes Treatment Satisfaction Questionnaire – Status version; EFA, exploratory factor analysis; EIDTQ-Status, Emotional Impact of Diabetes Treatment Questionnaire – Status version; GIP, glucose-dependent insulinotropic polypeptide; GLP-1, glucagon-like peptide-1; ICC, intraclass correlation coefficient; PRO, patient-reported outcome; SD, standard deviation; SF-36, Short Form (36) Health Survey; Sim-Q, Simplicity of Diabetes Treatment Questionnaire; TRIM-D, Treatment-Related Impact Measures for Diabetes; T2D, type 2 diabetes; US, United States.

Data Sharing Statement

For permission to reproduce or use the EIDTQ-Status, please contact copyright@lilly.com. After permission is obtained, there is no fee for using this instrument. The data analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics Approval and Informed Consent

All methods, materials, and clinical sites participating in the study were approved by an independent review board (Salus IRB, study number 23069). The study complies with the Declaration of Helsinki, and all participants provided informed consent before engaging in study procedures. The consent form informed participants that their data may be published, but they would not be personally identified in any publications.

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Consent for Publication

All participants were informed of and approved the use of their published data.

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References

1. Azadbakht M, Taheri Tanjani P, Fadayevatan R, Froughan M, Zanjari N. The prevalence and predictors of diabetes distress in elderly with type 2 diabetes mellitus. *Diabetes Res Clin Pract*. 2020;163:108133. doi:10.1016/j.diabres.2020.108133
2. Celik A, Forde R, Racaru S, Forbes A, Sturt J. The impact of type 2 diabetes on women's health and well-being during their reproductive years: a mixed-methods systematic review. *Curr Diabetes Rev*. 2022;18(2):e011821190403. doi:10.2174/1573399817666210118144743
3. Gomez-Pimienta E, Gonzalez-Castro TB, Fresan A, et al. Decreased quality of life in individuals with type 2 diabetes mellitus is associated with emotional distress. *Int J Environ Res Public Health*. 2019;16(15):2652. doi:10.3390/ijerph16152652
4. Jones A, Olsen MZ, Perrild HJ, Willaing I. The psychological impact of living with diabetes: descriptive findings from the DAWN2 study in Denmark. *Prim Care Diabetes*. 2016;10(1):83–86. doi:10.1016/j.pcd.2015.03.008
5. McInerney AM, Lindekilde N, Nouwen A, Schmitz N, Deschenes SS. Diabetes distress, depressive symptoms, and anxiety symptoms in people with type 2 diabetes: a network analysis approach to understanding comorbidity. *Diabetes Care*. 2022;45(8):1715–1723. doi:10.2337/dc21-2297
6. Owens-Gary MD, Zhang X, Jawanda S, Bullard KM, Allweiss P, Smith BD. The importance of addressing depression and diabetes distress in adults with type 2 diabetes. *J Gen Intern Med*. 2019;34(2):320–324. doi:10.1007/s11606-018-4705-2
7. Perrin NE, Davies MJ, Robertson N, Snoek FJ, Khunti K. The prevalence of diabetes-specific emotional distress in people with type 2 diabetes: a systematic review and meta-analysis. *Diabet Med*. 2017;34(11):1508–1520. doi:10.1111/dme.13448
8. Peyrot M, Rubin RR, Lauritzen T, Snoek FJ, Matthews DR, Skovlund SE. Psychosocial problems and barriers to improved diabetes management: results of the cross-national diabetes attitudes, wishes and needs (Dawn) study. *Diabet Med*. 2005;22(10):1379–1385. doi:10.1111/j.1464-5491.2005.01644.x
9. Semenkovich K, Brown ME, Svrakic DM, Lustman PJ. Depression in type 2 diabetes mellitus: prevalence, impact, and treatment. *Drugs*. 2015;75(6):577–587. doi:10.1007/s40265-015-0347-4
10. Spencer MS, Kieffer EC, Sinco BR, et al. Diabetes-specific emotional distress among African Americans and Hispanics with type 2 diabetes. *J Health Care Poor Underserved*. 2006;17(2 Suppl):88–105. doi:10.1353/hpu.2006.0095
11. Trief PM, Uschner D, Tung M, et al. Diabetes distress in young adults with youth-onset type 2 diabetes: TODAY2 study results. *Diabetes Care*. 2022;45(3):529–537. doi:10.2337/dc21-1689
12. Delahanty LM, Grant RW, Wittenberg E, et al. Association of diabetes-related emotional distress with diabetes treatment in primary care patients with type 2 diabetes. *Diabet Med*. 2007;24(1):48–54. doi:10.1111/j.1464-5491.2007.02028.x
13. Egede LE, Zheng D. Independent factors associated with major depressive disorder in a national sample of individuals with diabetes. *Diabetes Care*. 2003;26(1):104–111. doi:10.2337/diacare.26.1.104
14. Peyrot M, Rubin RR. Persistence of depressive symptoms in diabetic adults. *Diabetes Care*. 1999;22(3):448–452. doi:10.2337/diacare.22.3.448

15. Tanenbaum ML, Kane NS, Kenowitz J, Gonzalez JS. Diabetes distress from the patient's perspective: qualitative themes and treatment regimen differences among adults with type 2 diabetes. *J Diabetes Complications*. 2016;30(6):1060–1068. doi:10.1016/j.jdiacomp.2016.04.023
16. Yang W, Zhuang X, Li Y, et al. Improvements in quality of life associated with biphasic insulin aspart 30 in type 2 diabetes patients in China: results from the A1chieve(R) observational study. *Health Qual Life Outcomes*. 2014;12:137. doi:10.1186/s12955-014-0137-9
17. Kalra S, Jena BN, Yeravdekar R. Emotional and psychological needs of people with diabetes. *Indian J Endocrinol Metab*. 2018;22(5):696–704. doi:10.4103/ijem.IJEM_579_17
18. Minton AR, Young NA, Nievera MA, Mikels JA. Positivity helps the medicine go down: leveraging framing and affective contexts to enhance the likelihood to take medications. *Emotion*. 2021;21(5):1062–1073. doi:10.1037/emo0000798
19. Brod M, Hammer M, Christensen T, Lessard S, Bushnell DM. Understanding and assessing the impact of treatment in diabetes: the treatment-related impact measures for diabetes and devices (TRIM-Diabetes and TRIM-Diabetes Device). *Health Qual Life Outcomes*. 2009;7:83. doi:10.1186/1477-7525-7-83
20. Grootenhuis PA, Snoek FJ, Heine RJ, Bouter LM. Development of a type 2 diabetes symptom checklist: a measure of symptom severity. *Diabet Med*. 1994;11(3):253–261. doi:10.1111/j.1464-5491.1994.tb00268.x
21. Ishii H. Development and psychometric validation of the Diabetes Therapy-Related QOL (DTR-QOL) questionnaire. *J Med Econ*. 2012;15 (3):556–563. doi:10.3111/13696998.2012.665111
22. Polonsky WH, Fisher L, Earles J, et al. Assessing psychosocial distress in diabetes: development of the Diabetes Distress Scale. *Diabetes Care*. 2005;28(3):626–631. doi:10.2337/diacare.28.3.626
23. Frias JP, Davies MJ, Rosenstock J, et al. Tirzepatide versus semaglutide once weekly in patients with type 2 diabetes. *N Engl J Med*. 2021;385 (6):503–515. doi:10.1056/NEJMoa2107519
24. Matza LS, Stewart KD, Lando LF, Patel H, Boye KS. Exit interviews examining the patient experience in clinical trials of tirzepatide for treatment of type 2 diabetes. *Patient*. 2022;15(3):367–377. doi:10.1007/s40271-022-00578-8
25. Boye KS, Stewart KD, Matza LS. Development of a patient-reported outcome (PRO) measure to assess emotional impact of treatment for type 2 diabetes. *Diabetes Ther*. 2023;14(9):1451–1470. doi:10.1007/s13300-023-01426-0
26. Stewart KD, Matza LS, Patel H, Boye KS. Development of a patient-reported outcome (PRO) measure to assess patient perceptions of simplicity and complexity of treatment for type 2 diabetes. *J Patient Rep Outcomes*. 2023;7(1):89. doi:10.1186/s41687-023-00614-7
27. Bradley C, Lewis KS. Measures of psychological well-being and treatment satisfaction developed from the responses of people with tablet-treated diabetes. *Diabet Med*. 1990;7(5):445–451. doi:10.1111/j.1464-5491.1990.tb01421.x
28. Ware J, Kosinski M, Bjorner J, Turner-Bowker D, Gandek B, Maruish M. *Development of User's Manual for the SF-36v2® Health Survey*. Lincoln (RI): QualityMetric Incorporated; 2007.
29. Kaiser HF. The application of electronic computers to factor analysis. *Educational and Psychological Measurement*. 1960;20(1):141–151. doi:10.1177/001316446002000116
30. Hays RD, Anderson RT, Revicki D. Assessing reliability and validity of measurement in clinical trials. *Quality of Life Assessment in Clinical Trials: Methods and Practice*. 1998;169–182.
31. Nunnally JC, Bernstein IH. *Psychometric Theory*. 3rd ed. McGraw-Hill; 1994.
32. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation coefficients for reliability research. *J Chiropr Med*. 2016;15 (2):155–163. doi:10.1016/j.jcm.2016.02.012
33. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Lawrence Erlbaum Associates Inc; 1988.
34. Christensen KS, Cosci F, Carrozzino D, Sensky T. Rasch analysis and its relevance to psychosomatic medicine. *Psychother Psychosom*. 2024;93 (2):88–93. doi:10.1159/000535633