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The development of a new computer adaptive test to evaluate anxiety in caregivers of individuals with traumatic brain injury: TBI-CareQOL Caregiver-Specific Anxiety

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Abstract

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Objective—To design a new measure of caregiver-specific anxiety for use in caregivers of individuals with TBI, the TBI-CareQOL Caregiver Specific-Anxiety item bank.

Design—Cross-sectional survey study.

Setting—Three TBI Model Systems rehabilitation hospitals, an academic medical center, and a military medical treatment facility.

Participants—344 caregivers of civilians with TBI and 216 caregivers of service members/veterans with TBI.

Interventions—Not applicable.

Main Outcome Measures—TBI-CareQOL Caregiver-Specific Anxiety Item Bank

Results—The retention of 40 caregiver-specific anxiety items was supported by exploratory and confirmatory factor analyses. Graded response model (GRM) and differential item functioning analyses supported the retention of 33 items in the final measure. Expert review and GRM calibration data was used to select a 6-item static short form, and GRM calibration data was used to program the TBI-CareQOL Caregiver-Specific Anxiety computer adaptive test (CAT).

Conclusions—Established, rigorous measurement development standards were used to develop the new TBI-CareQOL Caregiver-Specific Anxiety CAT and corresponding 6-item short form. This measure is the first patient-reported outcome measure (PRO) designed to assess caregiver-specific anxiety in caregivers of individuals with TBI. The measure exhibits strong psychometric properties.

Keywords

Health-related quality of life; PROMIS; TBI-CareQOL; traumatic brain injury; caregiver; anxiety; patient reported outcome

Many persons with moderate to severe traumatic brain injury (TBI) face challenges with long-term cognition, functional activities, and societal participation. After discharge from inpatient rehabilitation, a person with a TBI may rely on an informal caregiver, such as a family member or someone else in the social network of the person with TBI, for their day-to-day functioning.^{1–4} These caregivers play a key role in the rehabilitation process and recovery following an injury, as they provide essential patient supports to social participation, emotional and physical well-being, and functional independence.^{4,5} However, the challenges associated with caregiving make caregivers vulnerable to significant distress, including anxiety and mood issues, social difficulties, and diminished quality of life.^{6–13} This distress is present regardless of the relationship type between the caregiver and the person with the TBI (e.g., spouses, parents, and friends).^{14–16}

Although generalized anxiety is a common emotional experience among caregivers with TBI,^{14–18} caregivers also have anxiety that is specific to caring for a person with TBI. This can include concerns about reinjury, the unpredictable behavior of the person with the TBI, and/or the future of the person with the TBI.^{19,20} Moreover, anxiety can also be specific to the caregiver role and include concerns about the mastery of duties and level of burden experienced.^{19,20} Furthermore, between 20 and 70% of caregivers of people with TBI

experience clinically significant emotional difficulties, which is substantially higher than in the general population.^{1,7–13,21} In fact, some studies have reported that people who provide care and support to a person with moderate to severe TBI experience more emotional distress than caregivers who care for persons with other chronic disabilities, such as mobility impairments or developmental intellectual disabilities.^{22,23} The level of burden of care, the degree of social support that the caregiver experiences, and the presence of neurobehavioral disturbance in the person with TBI have been shown to influence the emotional well-being of the caregiver.^{16,18} These findings indicate that individuals who provide care to a person following a TBI might experience unique stressors in their caregiving role.

The impact and implications for these emotional reactions in caregivers is broad and far reaching. Research has demonstrated that the well-being and functioning of the caregiver directly affects their willingness and ability to support the individual with TBI, which ultimately affects the functioning and rehabilitation outcomes of the person with TBI.^{4,24–32} Caregiver distress may result in strained relationships, poor family adjustment, a shifting of roles and communication within the support system, decreased community integration and participation, and a decreased ability of caregivers to care for the person with the injury. The emotional status of the caregiver is important not only for their own quality of life, but also for the family or support system, and for the person with TBI. These findings highlight the importance of clinical care systems that address the needs of caregivers and the person with the TBI in the long term. Such systems will require a reliable and valid way of measuring the emotional experiences of caregivers in order to guide and evaluate treatments.

No consensus measure for evaluating emotional distress in caregivers of persons with TBI currently exists. Measures that have been used clinically or in research have typically focused on caregivers' perceived burden^{33,34} or are generic measures of anxiety and emotional distress.^{14,16} There are few well-developed assessment tools that specifically measure the anxiety and emotional strain of those who care for persons with TBI. To address this shortcoming, we have developed a new PRO measure of self-reported HRQOL for caregiver-specific anxiety using established methodology.³⁵ Data summarizing this process are included below.

Methods

Study Participants

Five hundred and sixty caregivers of individuals with mild, moderate, severe, or penetrating TBI participated in this study; this included 344 caregivers of civilians with TBI and 216 caregivers of service members/veterans (SMVs) with TBI. Of these participants, 25.9% (n=56 civilian and n=89 SMV) completed a retest survey. Participants were recruited from existing medical treatment centers, TBI caregiver databases, community outreach, and medical record data capture systems.³⁶ Participating data collection sites included: TIRR Memorial Herman (civilian), Rehabilitation Institute of Michigan (civilian), the Kessler Foundation (civilian), the University of Michigan (civilian and SMV), and Walter Reed National Military Medical Center (WRNMMC; SMV). In order to be eligible to participate, participants needed to be 18 years old, able to read and understand English, and be caring for an individual with a TBI that was sustained after age 15, at least 1-year post-injury (i.e.,

those caring for someone less than 1-year post injury were not eligible^{37–48}), and have medically documented injury that met either TBI model system criteria⁴⁹ (civilian) or was verified by a Department of Defense or Veteran Affairs treatment facility (SMV). Caregivers who provided assistance in physical, financial, or emotional forms to the individual with TBI were eligible for participation in the study. Prior to their participation in the study, participants provided informed consent. We collected data according to the guidelines of local institutional review boards.

Study Measures

TBI-CareQOL Caregiver-Specific Anxiety Item Pool Development—As described in Carlozzi and colleagues⁵⁰ items were designed according to established measurement methodology³⁵ to evaluate how caregiver-specific anxiety affects HRQOL. The final Caregiver-Specific Anxiety item pool (81 items) was administered to study participants. Items examined feelings of anxiety/worry related to the caregiver role and concern/worry about the behavior and well-being of the person with TBI.

Measure Administration and Data Collection

PROs were administered on a personal or publicly-available computer with internet access via a publicly-available online data capture system (<https://www.assessmentcenter.net>); for participants who had limited access to the computer/internet, PROs were administered at a designated research visit computer. Typically, the initial study survey was completed within a 2-week time period. The test-retest survey (conducted only at University of Michigan) was completed within a 3-week time period of the initial survey.

Statistical Analyses

Sample size considerations for this study are reported elsewhere in this issue.⁵⁰

Overview—Following established guidelines,³⁵ we identified a unidimensional item set and conducted item response theory-based (IRT) analyses to estimate item parameters (thresholds and slopes) for scoring and CAT administration.⁵¹ IRT was used because each individual item of a measure can be used to estimate an individual's "true score" (in contrast to classical test theory, which requires successful completion of all test items to estimate a "true score"⁵²), and because IRT has the advantage of CAT administration (which allows for the administration of only the most informative items for each individual participant).^{53,54}

Exploratory Factor Analysis (EFA)/Confirmatory Factor Analysis (CFA)

Modeling, Initial Item Performance Assessments—Dimensionality was examined using an iterative process that included both statistical analyses (EFA and CFA) and information gained from clinical input.^{55–57} For EFA, unidimensionality was suggested if the ratio of eigenvalue 1 to eigenvalue 2 was greater than 4, and the proportion of variance accounted for by eigenvalue 1 exceeded 0.40. Next, if items had sparse cells (at least one response category with fewer than 10 respondents), the item-adjusted total score correlation was less than 0.40, or if observed responses were non-monotonic, such items were removed from the item pool. The assumption of monotonicity was tested using item-rest plots and expected score by latent trait plots derived by using a non-parametric IRT model

(Testgraf⁵⁸). Next, CFA screened out items that had either low factor loadings ($\lambda < 0.50$) or evidence suggestive of local dependence (residual correlation > 0.20 ; correlated error modification index > 100).^{55–57} To include or exclude items from locally dependent item pairs or triplets, we sought clinical input to identify more vs. less relevant item content.^{55–57} Additional CFA modeling was conducted to establish evidence of unidimensionality. EFA and CFA analyses were conducted in Mplus (version 7.4).⁵⁹

IRT Modeling, Final Item Performance Assessments, Differential Item Functioning (DIF) Studies, Final CFA Modeling

An IRT model was fit to the data after identification and refinement of an essentially unidimensional item set. We estimated item parameters using Samejima's graded response model (GRM),⁶⁰ using IRTPRO (version 3.1).⁶¹ In this analysis, we retained items that demonstrated good model fit, and excluded items that displayed significant misfit ($S-X^2$, $p < 0.01$). Next, a hybrid IRT ability score-ordinal logistic regression framework⁶² in the R package LORDIF (Version 0.3.2), was used to examine DIF for age, education, and caregiver civilian vs. military status.^{63,64} DIF analyses can be used to examine potential item bias (i.e., an item that unexpectedly performs differently for different groups, systematically providing better or worse scores for a specific group; e.g., men versus women). Criteria for exclusion from the final item set were items that showed impactful DIF (Nagelkerke pseudo- R^2 change > 0.20 , plus $> 2\%$ of DIF-corrected vs. uncorrected score differences exceeding uncorrected score standard errors). After excluding items identified using DIF, we ran a final CFA model to assess overall model fit to the item response data, using recommended fit criteria and cutoffs: comparative fit index (CFI) > 0.95 , Tucker-Lewis index (TLI) > 0.95 , and root mean square error of approximation (RMSEA) < 0.15 .^{65–68}

CAT Simulation, Short Form Development—CAT simulation (conducted using Firestar⁶⁹ and IRTPRO 2.1 software⁶¹) was used to simulate CAT scores for the Caregiver-Specific Anxiety item bank and examine the frequencies and patterns of item usage. Item calibrations and calibration-related statistics (e.g., item slope, thresholds, average item difficulty, and item information), combined with clinical experts' input on item content, were then used to select a 6-item Caregiver-Specific Anxiety short form. Please note that IRT scores are on a theta metric with a mean of 0 and a SD of 1.

Results

Study Participants

A detailed description of the study sample is reported elsewhere.⁵⁰ Briefly, five hundred sixty caregivers ($n = 344$ civilian; $n = 216$ SMV) of persons with mild, moderate, severe, or penetrating TBI were included in our sample. On average, caregivers were 46.1 years of age ($SD = 14.1$). Caregivers were also predominantly female (85.5%; $n = 477$) and Caucasian (77.2%); 13.8% were African American, and 10.6% indicated that they were of Hispanic or Latino descent. The majority of caregivers had at least some college (42%), followed by 39.5% that had a college degree; 18.6% indicated an educational attainment of high school or less. Caregivers primarily reported being the spouse (58.2%), parent (22.9%), or child/other family member (12.9%) of the person with TBI for whom they cared. Study

participants indicated they had been functioning in a caregiver role for an average of 5.8 years (SD=5.4).

The majority of the civilian group (56.1%) were caring for a person with severe TBI; 20.9% were caring for a person with moderate TBI, and 17.7% were caring for a person with complicated mild TBI. For the SMV group, 19.2% were caring for a person with mild TBI, 15.4% were caring for 'equivocal' mild, 1.9% complicated mild, 2.3% moderate, 1.9% severe, and 1.4% were caring for persons with penetrating TBIs (TBI severity data were unavailable for the 57.9% of the SMV group that was recruited through the University of Michigan). Given that the participants within the SMV group were recruited from the community, it can be reasonably assumed that the vast majority of this group (i.e., >80%) falls in the mild TBI classification.⁷⁰

Unidimensional Modeling and Analyses

EFA/CFA Modeling, Initial Item Performance Assessments—We tested 81 Caregiver Specific Anxiety items. Unidimensionality of these items was supported by the initial EFA analyses. Several items were deleted based on CFA misfit analyses (Table 1) or because of sparse cells. An examination of item-rest plots and expected score by latent trait plots also supported the assumption of monotonicity (Table 1). This resulted in a reduced set of 31 Caregiver-Specific Anxiety items.

IRT Modeling, Final Item Performance Assessments, DIF Studies, Final CFA Modeling—An additional four items were deleted due to poor model fit (Table 1). No items were flagged for potential age-related DIF, education-related DIF, or caregiver status-related (civilian vs. military) DIF (Table 1).

Final Item Bank Criteria

The final Caregiver-Specific Anxiety item bank contained 27 items. A final CFA model was run after DIF studies. The results of this model (Table 2) suggested good overall model fit. The item bank's response pattern (marginal) reliability and Cronbach's alpha (internal consistency) reliability were both excellent (Table 2). Table 3 shows estimates of final item bank item parameters. Score-level test information was excellent from $\theta = -1.6$ to $+2.8$, with expected score-level reliability .90 (Figure 1).

CAT Simulation, Short Form Development

The correlation between full item bank and Caregiver Specific Anxiety estimated CAT scores was 0.97. This high correlation suggests that CAT administration of the Caregiver Specific Anxiety item bank produced scores similar to those derived from the full 27-item bank. The standard deviation of the differences between full item bank and CAT scores was 0.24, and the root mean square deviation (RMSD) of the two score sets was also 0.24 (both statistics in the theta metric). The most common number of items administered in the CAT was four items ($n = 368$, 65.9%). Thetas ranged from -0.67 to $+1.70$ for 4-item CATs. Twelve items ($n=60$, 10.8%) were the second-most frequent CAT length. Observed thetas for 12-item CATs were bimodal: Low thetas ranged from -2.21 to -1.16 , while high thetas ranged from $+2.51$ to $+3.06$. Five items ($n = 40$, 7.2%) were the third-most frequent CAT

length. Thetas for 5-item CATs ranged from -0.77 to $+1.87$. The fourth-most frequently occurring CAT length was 6 items ($n = 34$, 6.1%), with thetas ranging from -0.95 to $+2.08$. CATs between seven to 11 items long were the least common ($n = 56$, 10.0%). Note that 12-item CATs occurred when extreme low and extreme high levels of Caregiver-Specific Anxiety were measured.

The number of CAT items administered at varying standard deviation units is shown in Figure 2. The maximum of 12 items from the item bank were used by the CAT at roughly -1 SD units and $+2$ SD units; the CAT tended to use the minimum of four items from the item bank from approximately -1 to $+2$ SD units.

The content, representativeness, and range of coverage of the six-item short form of the Caregiver-Specific Anxiety scale was approved by a panel of clinical experts (including experts in TBI and caregivers of persons with TBI, and experts in measurement development; $n=11$ Ph.D. and $n=3$ masters'-level investigators). The reliability for this SF was examined on a measurement continuum from $\theta=-2.8$ ($T\text{-score} = 22$) to $+2.8$ ($T\text{-score} = 78$). For the θ range from -0.8 to $+2.0$, expected score-level reliability was excellent ($.90$); for the extended θ range from -1.2 to $+2.4$, score-level reliability was very good or excellent (i.e., $.80$), and for the further extended θ range from -1.6 to $+2.8$, score-level reliability was good, very good, or excellent (i.e., $.70$). The short form also had good three-week test-retest reliability ($r = 0.86$). A summed score to T score conversion table is shown in Table 4.

Discussion

This paper presents the development of a new patient reported outcomes measure specific to caregivers of persons with TBI that assesses feelings of anxiety/worry related to the caregiver role and concern/worry about the behavior and well-being of the person with the TBI. Analyses supported the development of an item bank that can be administered as either a CAT or a 6-item short form. Both assessment types are scored using a T metric, with a mean of 50 and standard deviation of 10 (higher scores indicate more caregiver-specific anxiety). In this manner, scores of 60 or greater suggest that clinical follow-up may be warranted; that is, the caregiver is experiencing more anxiety related to the caregiving role than 84% of other caregivers of individuals with TBI. Similarly, scores of 70 or greater suggest clinically significant anxiety; that is, these caregivers are reporting more distress than 95.5% of their caregiving peers. In this manner, scores can be used to make clinical referrals for mental health treatment for anxiety; however, the scale is not a screen for clinical anxiety per se, and other assessments developed for diagnostic purposes should be conducted as follow-up.

Preliminary data from this study provide strong support for the measure's reliability and validity. First, reliability was supported by excellent response pattern reliability for the CAT ($r = .97$),⁵⁰ and good 3-week test-retest reliability for the 6-item static short form ($r = .86$). In addition, construct validity was supported by a unidimensional set of items (supported by both exploratory and confirmatory factor analyses). The final item set was also free of bias for age, education, and caregiver type (civilian vs. military caregiver). Finally, CATs were

generally more efficient (i.e., 4-item CATs were administered to 65.9% of the sample, for those individuals scoring between -1 and $+2$ SD units) than short form administrations, which were six items in length and represented excellent reliability for scores from -0.8 to $+2.0$ and adequate or better reliability for scores -1.6 to $+2.8$.

Study Limitations

While this study has a number of strengths, it is also important to acknowledge limitations. First, the small number of parent and male caregivers did not allow for an examination of item bias relative to spouse or female caregivers. Additionally, the University of Michigan sample did not have access to military medical records (including details that could be used to determine TBI severity) for the military sample, resulting in a large number of unknown TBI severity cases in the military cohort. Finally, longitudinal studies are needed to establish test-retest reliability, validity, and responsiveness to change for this measure over time.

Conclusions

Taken together, this is the first comprehensive measure of caregiver-specific anxiety developed to capture feelings of anxiety/worry related to both the caregiver role and the behavior and well-being of the person for whom this individual is providing care. In addition, although these measures were developed for use in caregivers of individuals with TBI, they may also have utility in other caregiving populations that include behavioral changes (e.g., caregivers of individuals with frontotemporal dementia, multiple sclerosis, or schizophrenia). Future efforts should focus on examining the sensitivity of these measures to change over time, as well as responsiveness to clinical interventions. Future work is also needed to examine the clinical utility of this measure in other caregiver populations.

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List of Abbreviations

CAT	Computer Adaptive Test
CFA	Confirmatory Factor Analysis

CFI	Confirmatory Fit Index
DIF	Differential Item Functioning
EFA	Exploratory Factor Analysis
GRM	Graded Response Model
HRQOL	Health-Related Quality of Life
PRO	Patient-Reported Outcome
PROMIS	Patient-Reported Outcomes Measurement Information System
RMSD	Root Mean Square Deviation
RMSEA	Root Mean Squared Error of Approximation
SE	Standard Error
SF	Short Form
SMV	Service Member/Veteran
TBI	Traumatic Brain Injury
TBI-CareQOL	Traumatic Brain Injury Caregiver Quality of Life
TLI	Tucker Lewis Index

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Highlights

- Caregivers of persons with traumatic brain injury often have heightened anxiety
- A new self-report measure of caregiver-specific anxiety was developed
- This new measure can help identify caregivers with significant anxiety

Figure 1.

Caregiver-Specific Anxiety Test Information Plot

Caption: In general, we want total information to be 10 and standard error to be 0.32 (this provides a reliability of 0.9). This figure shows excellent total information and standard error for Specific Anxiety scale scores between -1.60 and +2.8.

Figure 2.

Caregiver-Specific Anxiety Number of CAT Items by CAT Theta

Caption: This figure shows the number of CAT items used for different scale scores in standard deviation units: at -1 SD units, the CAT tended to use the maximum of 12 items from the item bank; from -1 to $+2$ SD units, the CAT tended to use the minimum number of 4 items from the item bank; and at $+2$ units the CAT tended to use the maximum of 12 items from the item bank.

Table 1**Unidimensional Modeling and Analyses for Caregiver-Specific Anxiety Item Pool**

Domain	Unidimensional Modeling						Initial Item Performance			IRT Modeling		
	Item pool	EFA EI/E2 ratio (criterion >4)	Proportion of variance for E1 (criterion >0.40)	1-factor CFA loading (criterion <.50)	1-factor CFA residual correlation (criterion >.20)	1-factor CFA modification index (criterion >100)	Item-adjusted total score correlations (Criterion <.40)	Sparse cells (criterion<10)	Problems with monotonicity	IRT item misfit	DIF	Final item bank
Caregiver-Specific Anxiety	81 items	6.26	0.47	2 items	22 items	18 items	0 items	8 items	0 items	4 items	0 items	27 items

Note. CFA = Confirmatory Factor Analysis; EFA = Exploratory Factor Analysis, IRT = Item Response Theory

Table 2

Caregiver-Specific Anxiety Final Item Parameters

Domain	Item Bank	CFI (criterion .95)	TLI (criterion .95)	CFA-based RMSEA (criterion < .15)	Cronbach's Alpha Reliability (criterion > .80)	IRT-based RMSEA (criterion < .15)	Response Pattern Reliability (criterion > .80)
Caregiver-Specific Anxiety	27 items	.95	.95	.10	.97	.05	.97

Note. CFI = Comparative Fit Index, TLI = Tucker-Lewis Index, RMSEA = Root Mean Square Error of Approximation

Table 3

TBI-CareQOL Specific Anxiety Parameters

Item	Slope	Threshold 1	Threshold 2	Threshold 3	Threshold 4
I worry I might make the person I care for angry.	2.48	-1.03	-0.40	0.63	1.14
I cannot enjoy myself because I am worried about the person I care for.	2.60	-0.62	0.15	1.13	1.79
I worry that something small will irritate the person I care for.	2.81	-0.95	-0.38	0.56	1.13
I worry that something small will cause the person I care for to become violent.	1.94	0.02	0.88	1.85	2.19
I worry that the person I care for might behave inappropriately.	2.40	-0.92	-0.15	0.91	1.36
My worry for the person I care for interferes with my social activities.	2.42	-0.27	0.43	1.23	1.84
My worry for the person I care for makes me feel drained.	2.87	-0.63	-0.06	0.96	1.57
I cannot focus on other activities because of my worry for the person I care for.	2.75	-0.40	0.36	1.42	2.03
I feel drained due to my anxiety about how the person I care for might act.	3.83	-0.32	0.26	1.19	1.63
I feel drained because of the person with the injury's unpredictable behavior.	4.55	-0.37	0.18	1.08	1.53
I worry that something small will cause the person I care for to feel anxiety.	2.35	-0.87	-0.21	0.83	1.47
I feel anxiety about the unpredictable mood swings of the person I care for.	3.44	-0.60	-0.04	0.75	1.24
I feel anxiety about the possibility of the person I care for becoming verbally abusive in public.	2.48	0.00	0.61	1.47	1.74
I am bothered by the unpredictable behavior of the person I care for.	3.24	-0.24	0.35	1.26	1.77
I am bothered about the worry I have for the person I care for.	2.52	-0.37	0.29	1.29	1.91
I worry about the person with the injury's relationships with other people.	1.91	-1.06	-0.31	1.04	1.71
I am less effective at work (including work at home) because I worry about the person I care for.	2.18	-0.43	0.27	1.17	1.92
I get nervous when I have to tell the person I care for that they cannot do something.	2.47	-0.52	0.08	0.88	1.51
I worry about the mental health of the person I care for.	1.78	-1.67	-0.96	0.13	0.81
I worry that the person I care for will say something inappropriate to a stranger.	1.73	-0.55	0.25	1.17	1.76
I feel like I have to choose my words carefully around the person I care for.	2.79	-0.75	-0.16	0.77	1.33
I have to make sure the person I care for is being treated fairly.	1.05	-1.64	-0.90	0.42	1.20
I am on edge around the person I care for.	2.77	-0.04	0.63	1.48	2.04
I do not want to come home because I am nervous about what kind of mood the person I care for will be in.	2.95	0.24	0.87	1.77	2.10
I am afraid to set boundaries with the person I care for.	2.15	0.04	0.78	1.81	2.54
I feel frightened that the person I care for might behave inappropriately.	2.28	0.34	0.96	1.90	2.45
I worry that I cannot retire because of the injury.	1.42	0.21	0.77	1.80	2.30

Note. Items that are indicated in bold were selected for inclusion on the 6-item Caregiver-Specific Anxiety short form

Table 4

Caregiver Specific-Anxiety Short-Form Summed Score to t Score Conversion Table

Raw Score	T-score	SE *
6	33.92	5.26
7	39.00	3.71
8	41.28	3.43
9	43.35	3.07
10	45.05	2.91
11	46.62	2.78
12	48.07	2.72
13	49.45	2.69
14	50.81	2.68
15	52.14	2.70
16	53.46	2.70
17	54.74	2.71
18	56.00	2.71
19	57.24	2.71
20	58.49	2.70
21	59.75	2.70
22	61.02	2.69
23	62.32	2.70
24	63.66	2.75
25	65.06	2.82
26	66.57	2.97
27	68.16	3.13
28	70.10	3.45
29	72.02	3.68
30	75.57	4.50

*
SE = Standard error