

PATIENT-REPORTED OUTCOMES: DEVELOPMENT & JUST-IN-TIME ADAPTIVE INTERVENTIONS: FROM DEVELOPMENT TO APPLICATION

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WHAT IS A PATIENT REPORTED OUTCOME (PRO) MEASURE?



WHAT IS HEALTH-RELATED QUALITY OF LIFE?



PHYSICAL
HEALTH



MENTAL
HEALTH



SOCIAL
HEALTH



NEW MEASURES...



<https://www.healthmeasures.net/explore-measurement-systems/promis>



<https://www.healthmeasures.net/explore-measurement-systems/neuro-qol>



THE PROMIS BUFFET

<https://www.healthmeasures.net/search-view-measures>

COMPUTER ADAPTIVE TESTING (CAT)

Items answered by students

● Correct response ● Incorrect response



ITEM BANK

- DOMAIN = MENTAL HEALTH
- SUBDOMAIN = DEPRESSION
- ITEM BANK (50 ITEMS)
- IN THE PAST 7 DAYS...
 - I FELT SAD.
 - I FELT DEPRESSED.
 - I FELT LIKE A FAILURE.
 - I FELT WORTHLESS.
 - I FELT THAT NOTHING COULD CHEER ME UP.
 - [AND SO ON...]

1 = Never

2 = Rarely

3 = Sometimes

4 = Often

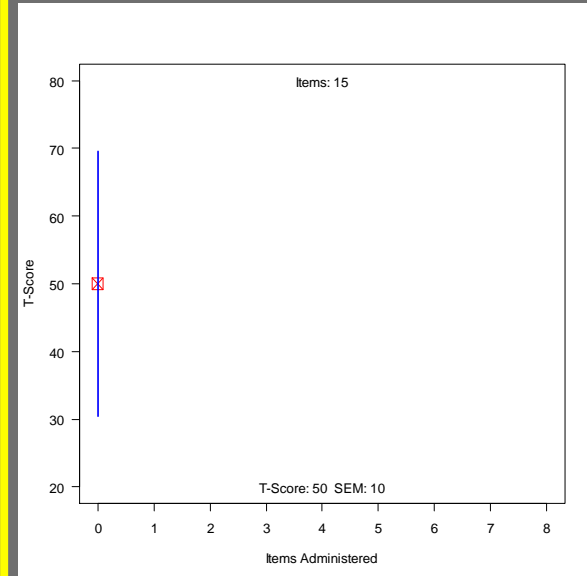
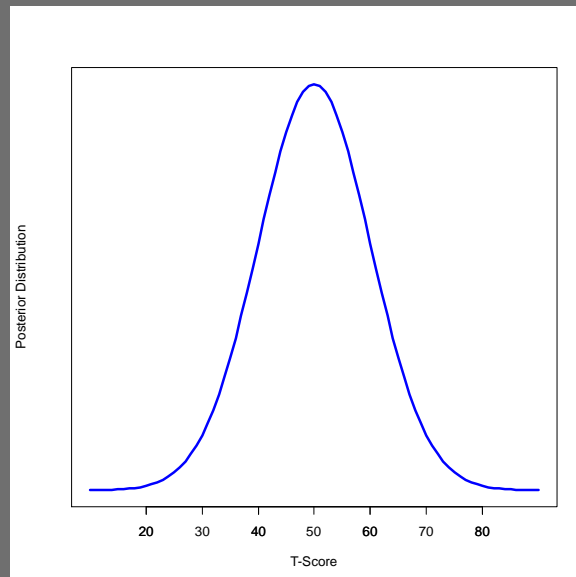
5 = Always

I felt sad:

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

T-Score = 50

SE = 10



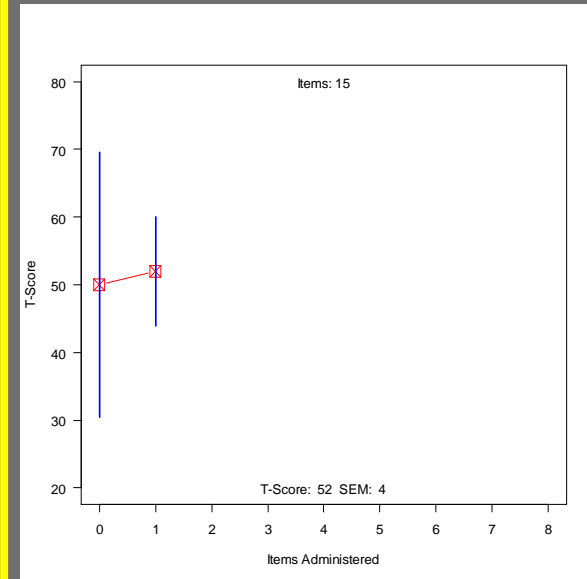
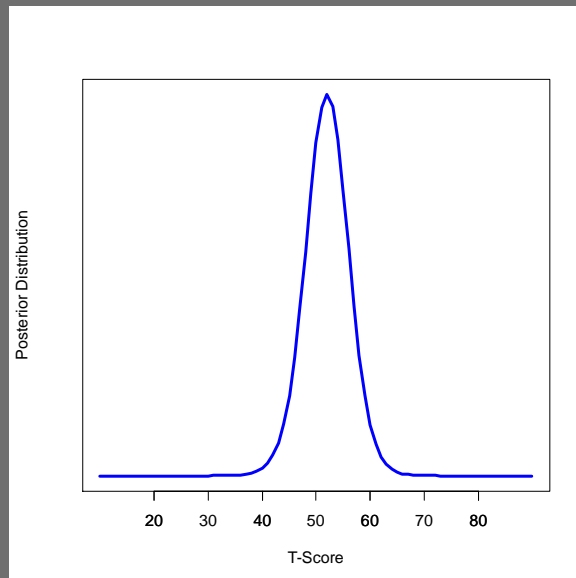
Next Best Item:
I felt depressed

I felt depressed

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

T-Score = 52

SE = 4



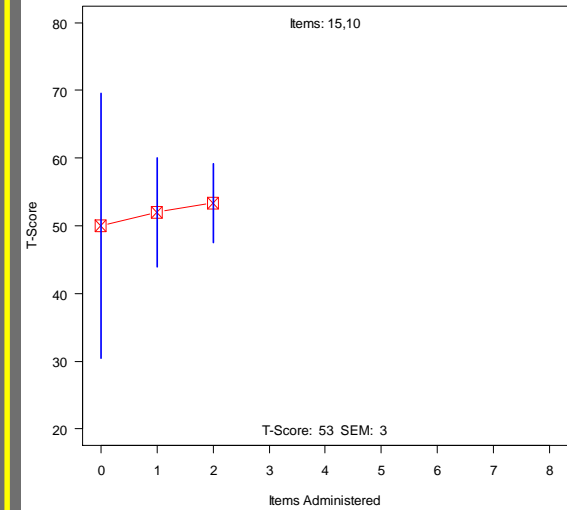
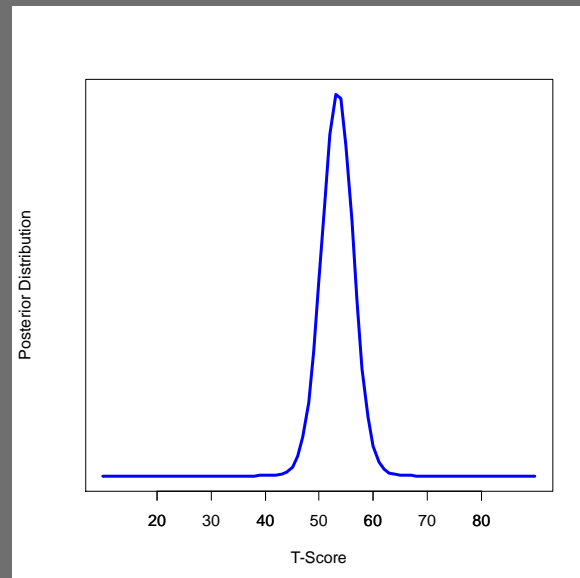
Next Best Item:
I felt like a
failure

I felt like a failure

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

T-Score = **53**

SE = **3**

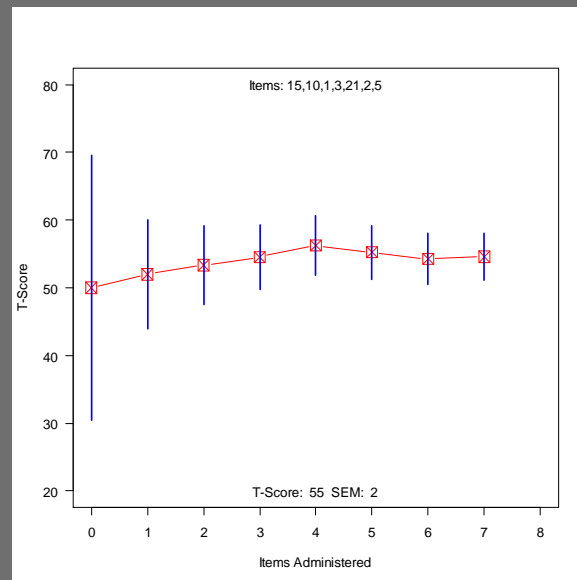
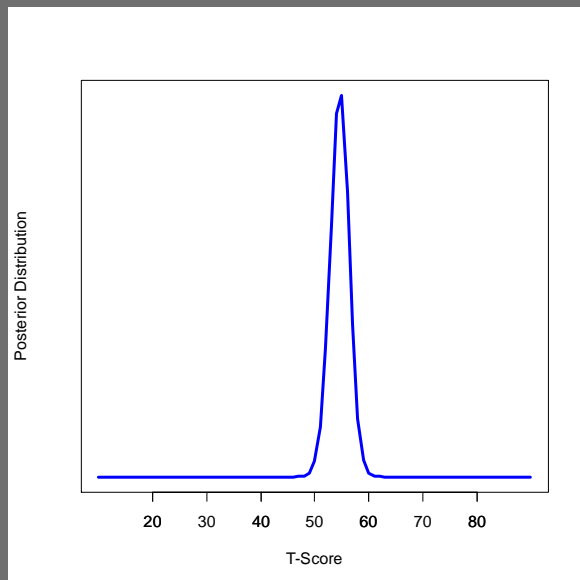


I felt that nothing could cheer me up

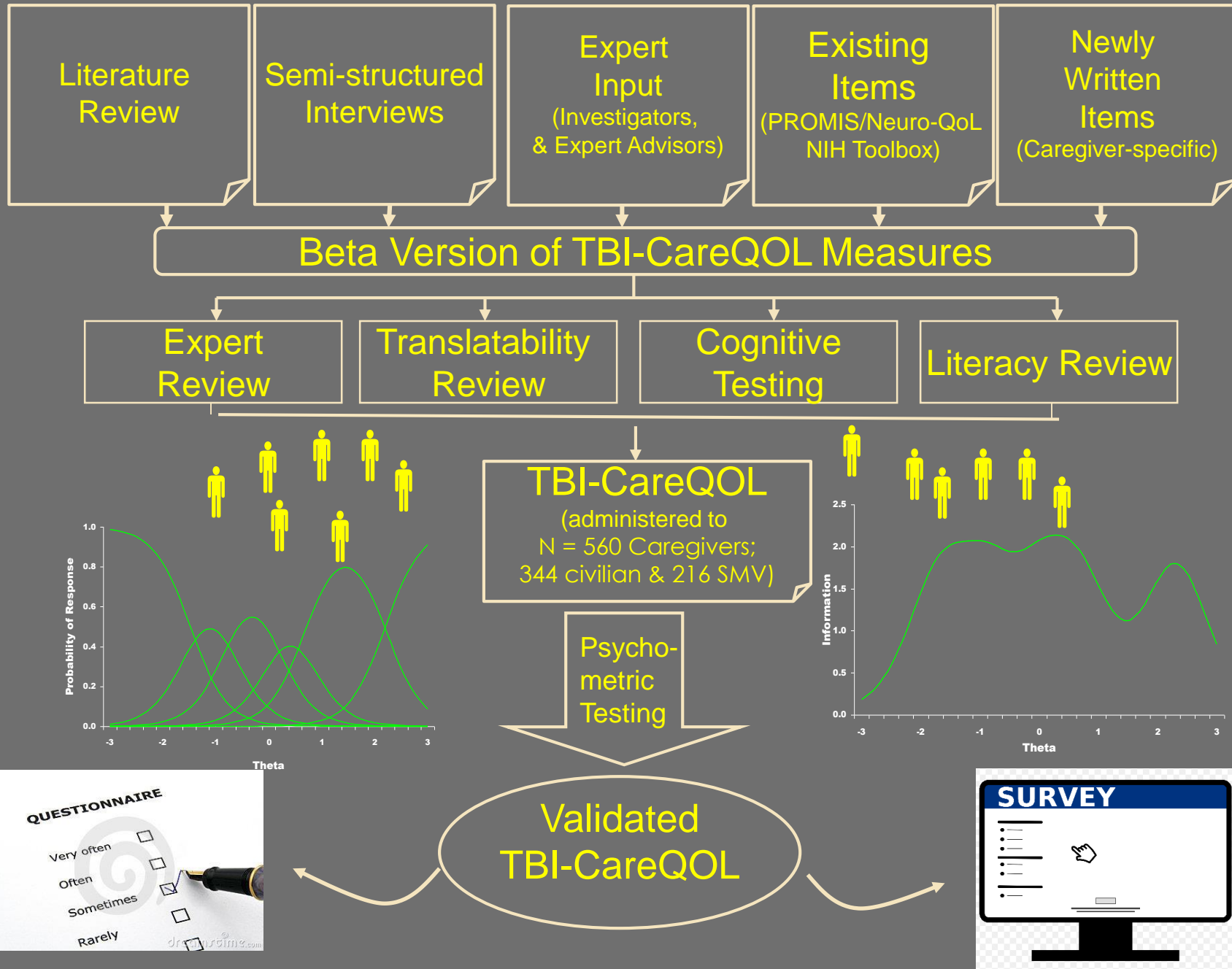
1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

T-Score = **55**

SE = **2**



**PRO DEVELOPMENT PROCESS
ACCORDING TO ESTABLISHED
STANDARDS**



PRO DEVELOPMENT PROCESS ACCORDING TO ESTABLISHED PROMIS STANDARDS

- STAGE 1:
 - QUALITATIVE STUDY TO IDENTIFY THE MOST IMPORTANT ASPECTS OF HRQOL FOR A GIVEN POPULATION
- STAGE 2
 - QUANTITATIVE STUDY TO FIELD TEST THE NEWLY DEVELOPED ITEMS (N = 500-600 PARTICIPANTS)
- STAGE 3
 - QUANTITATIVE VALIDITY STUDY

STAGE 1: PARTICIPANT DEMOGRAPHICS

9 CIVILIAN & 9 SMV FOCUS GROUPS

Variable	Civilian Focus Groups	SMV Focus Groups
N	55	45
Female - %	76	93
Age - M(SD)	46.1 (14.1)	45.9 (13.7)
Race		
Caucasian - %	78	84
African American - %	13	2
Hispanic - %	15	9
Relationship to PW TBI		
Spouse - %	36	73
Parents - %	58	4
Child - %	--	16
Average Time in Caregiver Role - M(SD)	6.5 (4.8)	4.4 (2.5)

Negative HRQOL

doctors don't communicate
suppressing emotions
breaks your heart
hardest thing
leave my job
am I going crazy
scavenger hunt
resentment
isolated
life on hold
anger
tired
cry
scream
anxiety
exhausted
cant function
denied
stress
depressed
situation seems impossible
foggy
loneliness
on guard
not helpful
scared
its not your life anymore
upset
they dont understand
drowning
worried
weight gain
give up
frustration
my world is ending
not making ends meet
I feel trapped
walk on eggshells
fallen through the cracks
changed forever
tense

THEMES

resilience
family disruption
caregiver strain
sleep disturbance
informational support
anxiety
caregiver-specific anxiety
ability to participate in social activities
frustration with military health care services
satisfaction with social activities
fatigue
sleep
emotional suppression
grief/loss
caregiver vigilance
self-efficacy
emotional support
feeling trapped
Feelings of loss
perceived stress
depression
anger
impairment

Positive HRQOL

counseling
top-notch care
grateful
understand
helpful
cope
proud
amazing
respite
caregiver services
support



**Generic Domains
(Neuro-QoL & PROMIS)**

- Anxiety
- Anger
- Depression
- Emotional & Behavioral Dyscontrol
- Positive Affect and Well-being
- Lower Extremity Function/Mobility
- Upper Extremity Functions/ADLs
- Applied Cognition Executive Function
- Applied Cognition-General Concerns
- Stigma
- Ability to Participate in Social Roles and Activities
- Satisfaction with Social Roles and Activities

TBI Caregiver- Specific Domains

- Caregiver-Specific Anxiety
- Caregiver Strain
- Feelings of Loss
- Feeling Trapped
- Emotional suppression
- Caregiver vigilance
- Anger Regarding Services

ITEM BANK DEVELOPMENT

Domain	Item Pool	Expert Review	Expert Review	Cognitive Interviews	Translation review	Literacy review	Consensus Meeting	Final Items
Caregiver Strain	75 items	(- 16 + 8) 67 items	(- 13 + 28) 82 items	(- 6 1R) 76 items	(- 10 39R) 66 items	(N/C) 66 items	(2R) 66 items	66 items
Caregiver-Specific Anxiety	75 items	(- 39 + 36) 72 items	(- 18 + 28) 82 items	(+ 18) 100 items	(- 19, 50R) 81 items	(N/C) 81 items	(8R) 81 items	81 items
Feeling Trapped	75 items	(- 50) 25 items	(- 1 + 9) 33 items	(- 5 1R) 28 items	(15R) 28 items	(N/C) 28 items	(N/C) 28 items	28 items
Feelings of Loss	75 items	(- 14 + 11) 72 items	(- 1 + 60) 131 items	(- 4 14R) 127 items	(- 29 75R) 98 items	(N/C) 98 items	(2R) 98 items	98 items
Caregiver Suppression	45 items	(- 8 + 9) 46 items		(- 3 9R) 43 items	(1R) 43 items	(N/C) 43 items	(N/C) 43 items	43 items
Caregiver Vigilance	41 items	(- 16 + 8) 33 items		(2R) 33 items	(- 1) 32 items	(N/C) 32 items	(N/C) 32 items	32 items
Family Disruption	6 items	(- 3 + 1) 4 items		(N/C) 4 items	(N/C) 4 items	(N/C) 4 items	(N/C) 4 items	4 items
Caregiver Frustration with Services	81 items	(- 20 + 19) 80 items		(- 8 10R) 72 items	(- 3 9R) 69 items	(- 5 1R) 64 items	(N/C) 64 items	64 items

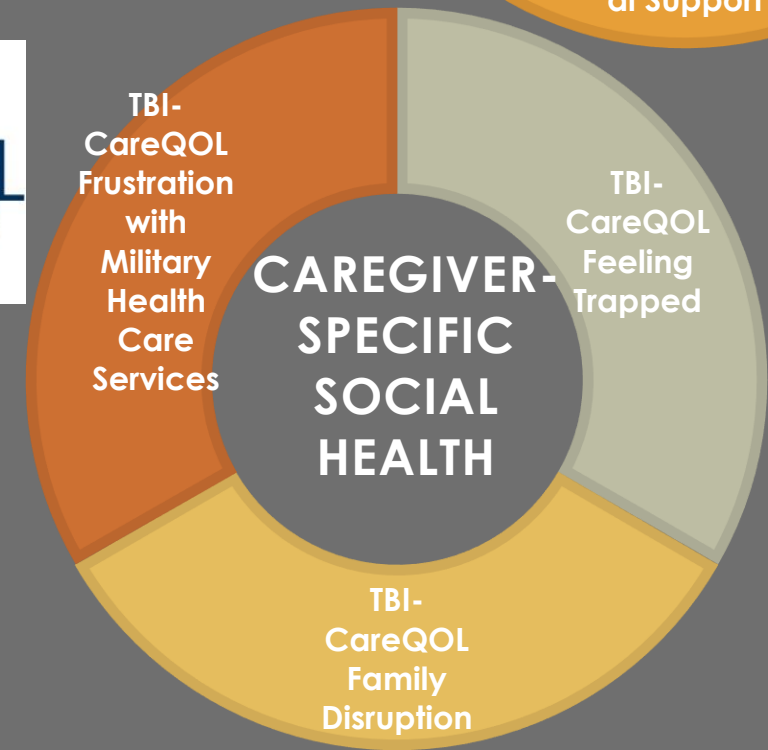
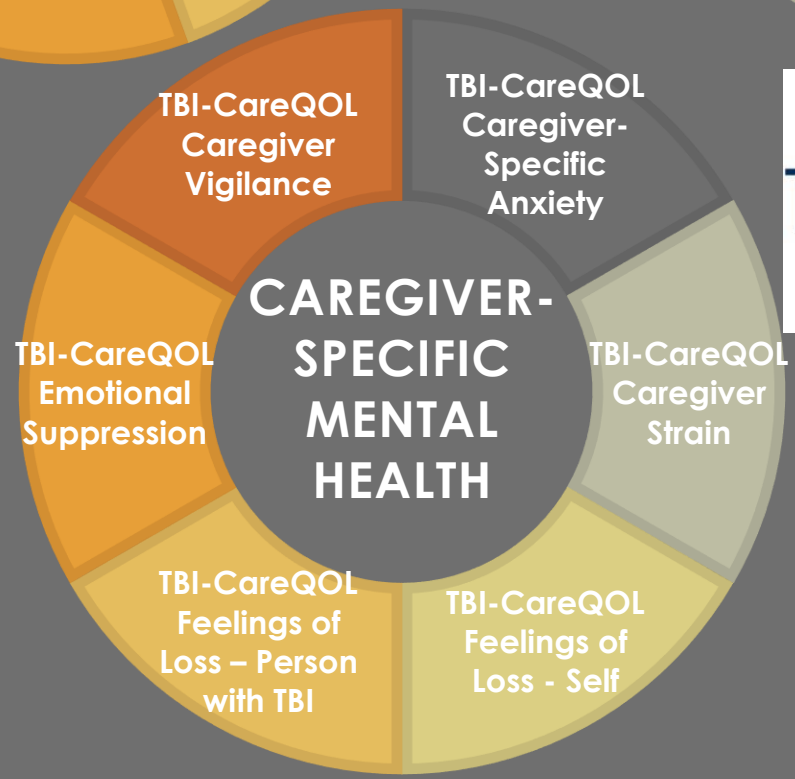
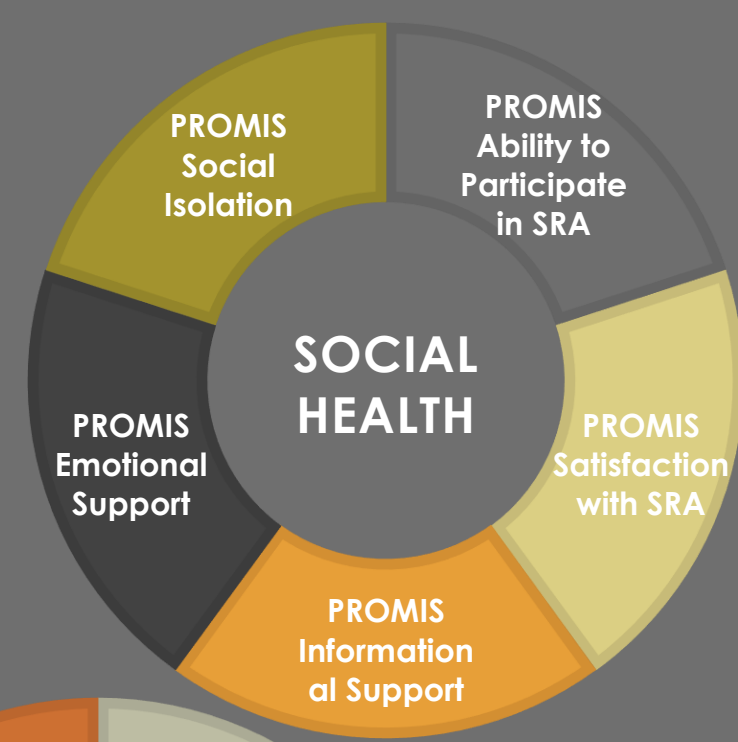
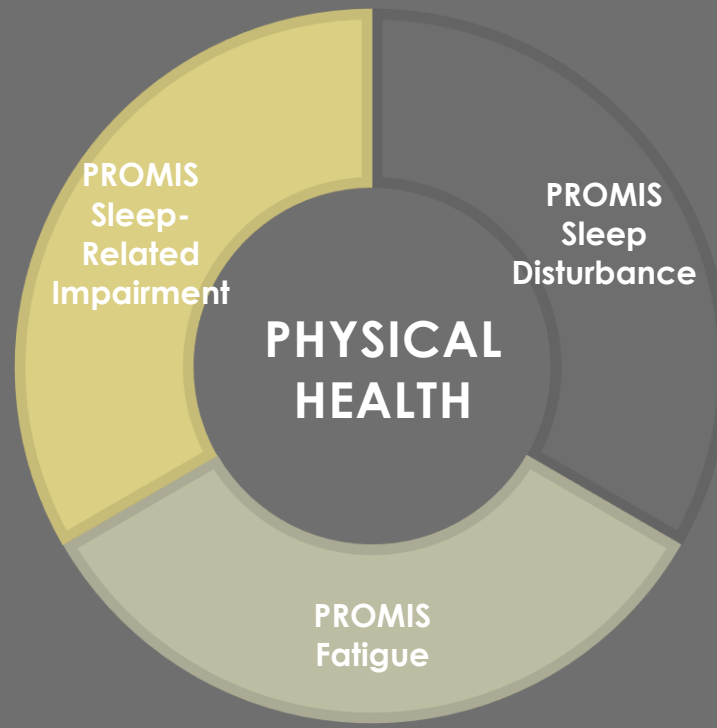
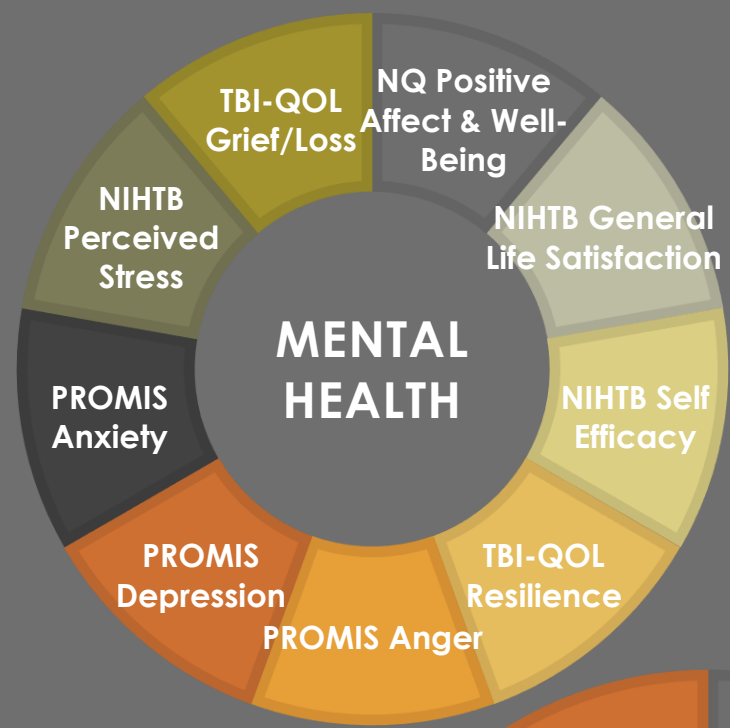


PRO DEVELOPMENT PROCESS ACCORDING TO ESTABLISHED PROMIS STANDARDS

- STAGE 1:
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- STAGE 2
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- STAGE 3
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STAGE 2: PARTICIPANT DEMOGRAPHICS

- N = 560 CAREGIVERS (344 CIVILIAN & 216 SMV)
- 85.4% FEMALE
- AVERAGE AGE = 47.4 YEARS (SD=14.6)
- 76% CAUCASIAN; 14% AFRICAN AMERICAN
- 10.5% HISPANIC
- 58.3% SPOUSES; 23.0% PARENTS; 7.7% OTHER FAMILY MEMBERS
- AVERAGE TIME IN CAREGIVER ROLE = 5.9 YEARS (SD = 5.1; RANGE 0 TO 59)



PRO DEVELOPMENT PROCESS ACCORDING TO ESTABLISHED PROMIS STANDARDS

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 - STAGE 3
 - QUANTITATIVE VALIDITY STUDY
- 

STAGE 2: PARTICIPANT DEMOGRAPHICS

Variable	Phase 2A Field Testing	Phase 2B Field Testing
N	558 (344 civilian; 214 SMV)	533 (218 civilian; 315 SMV)
Female - %	85.5	87.6
Age - M(SD)	46.1 (14.1)	45.9 (13.7)
Race		
Caucasian - %	77.2	78.4
African American - %	13.8	11.4
Hispanic - %	10.6	9.4
Relationship to PW TBI		
Spouse - %	58.2	56.8
Parents - %	22.9	24.6
Child - %	12.9	12.8
Average Time in Caregiver Role - M(SD)	5.8 (5.4)	7.1 (4.2)

RELIABILITY AND VALIDITY FOR TBI-CAREQOL MEASURES

- INTERNAL CONSISTENCY RELIABILITY
- TEST-RETEST STABILITY
- FLOOR AND CEILING EFFECTS
- ADMINISTRATION TIMES
- CONVERGENT AND DISCRIMINANT VALIDITY
- KNOWN GROUPS VALIDITY
- CLINICAL IMPAIRMENT RATES

**STAGE 3:
CONVERGENT & DISCRIMINANT VALIDITY**

Caregivers of Civilians					
	N	Internal consistency (> .70)	Test-retest stability (> .70)	Floor % (< 20)	Ceiling % (< 20)
CAREGIVER-SPECIFIC MEASURES					
TBI-CareQOL Caregiver-Specific Anxiety CAT	218	.92	.91	7	0
TBI-CareQOL Caregiver Strain CAT	218	.92	.90	8	0
TBI-CareQOL Feeling Trapped CAT	218	.90	.90	22	0
TBI-CareQOL Feelings of Loss-Self CAT	218	.90	.92	16	0
Emotional Suppression CAT	218	.91	.90	1	5
Caregiver Vigilance CAT	218	.90	.86	1	13
Family Disruption SF	218	.87	.85	30	1
MENTAL HEALTH					
Anger CAT	335	.91	.76	0	4
Anxiety CAT	335	.92	.68	0	5
Depression CAT	335	.92	.79	0	13
TBI-QOL Grief/Loss SF	218	.93	.86	25	0
NIH Toolbox Perceived Stress CAT	218	.86	.91	1	0
TBI-QOL Resilience SF	218	.91	N/A	9	0
NIH Toolbox Self-Efficacy CAT	218	.90	.77	7	0
Neuro-QoL Positive Affect and Well Being CAT	218	.96	.84	6	0
NIH Toolbox General Life Satisfaction CAT	218	.93	.86	3	0
PHYSICAL HEALTH					
Fatigue CAT	335	.94	.78	0	1
Sleep Disturbance CAT	335	.92	.86	0	2
PROMIS Sleep Related Impairment CAT	218	.92	.85	2	0
SOCIAL HEALTH					
Emotional Support CAT	235	.92	.77	0	10
Informational Support CAT	235	.93	.75	1	8
Social Isolation CAT	235	.86	.83	0	12
Ability to Participate in SRA CAT	235	.91	.67	0	10
Satisfaction with SRA CAT	235	.91	.77	0	8

**STAGE 3:
CONVERGENT & DISCRIMINANT VALIDITY**

Caregivers of Civilians					
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TBI-CareQOL Feeling Trapped CAT	218	.90	.90	22	0
TBI-CareQOL Feelings of Loss-Self CAT	218	.90	.92	16	0
Emotional Suppression CAT	218	.91	.90	1	5
Caregiver Vigilance CAT	218	.90	.86	1	13
Family Disruption SF	218	.87	.85	30	1
MENTAL HEALTH					
Anger CAT	335	.91	.76	0	4
Anxiety CAT	335	.92	.68	0	5
Depression CAT	335	.92	.79	0	13
TBI-QOL Grief/Loss SF	218	.93	.86	25	0
NIH Toolbox Perceived Stress CAT	218	.86	.91	1	0
TBI-QOL Resilience SF	218	.91	N/A	9	0
NIH Toolbox Self-Efficacy CAT	218	.90	.77	7	0
Neuro-QoL Positive Affect and Well Being CAT	218	.96	.84	6	0
NIH Toolbox General Life Satisfaction CAT	218	.93	.86	3	0
PHYSICAL HEALTH					
Fatigue CAT	335	.94	.78	0	1
Sleep Disturbance CAT	335	.92	.86	0	2
PROMIS Sleep Related Impairment CAT	218	.92	.85	2	0
SOCIAL HEALTH					
Emotional Support CAT	235	.92	.77	0	10
Informational Support CAT	235	.93	.75	1	8
Social Isolation CAT	235	.86	.83	0	12
Ability to Participate in SRA CAT	235	.91	.67	0	10
Satisfaction with SRA CAT	235	.91	.77	0	8

STAGE 3:

CONVERGENT & DISCRIMINANT VALIDITY

Caregivers of Civilians					
	N	Internal consistency (> .70)	Test-retest stability (> .70)	Floor % (< 20)	Ceiling % (< 20)
CAREGIVER-SPECIFIC MEASURES					
TBI-CareQOL Caregiver-Specific Anxiety CAT	218	.92	.91	7	0
TBI-CareQOL Caregiver Strain CAT	218	.92	.90	8	0
TBI-CareQOL Feeling Trapped CAT	218	.90	.90	22	0
TBI-CareQOL Feelings of Loss-Self CAT	218	.90	.92	16	0
Emotional Suppression CAT	218	.91	.90	1	5
Caregiver Vigilance CAT	218	.90	.86	1	13
Family Disruption SF	218	.87	.85	30	1
MENTAL HEALTH					
Anger CAT	335	.91	.76	0	4
Anxiety CAT	335	.92	.68	0	5
Depression CAT	335	.92	.79	0	13
TBI-QOL Grief/Loss SF	218	.93	.86	25	0
NIH Toolbox Perceived Stress CAT	218	.86	.91	1	0
TBI-QOL Resilience SF	218	.91	N/A	9	0
NIH Toolbox Self-Efficacy CAT	218	.90	.77	7	0
Neuro-QoL Positive Affect and Well Being CAT	218	.96	.84	6	0
NIH Toolbox General Life Satisfaction CAT	218	.93	.86	3	0
PHYSICAL HEALTH					
Fatigue CAT	335	.94	.78	0	1
Sleep Disturbance CAT	335	.92	.86	0	2
PROMIS Sleep Related Impairment CAT	218	.92	.85	2	0
SOCIAL HEALTH					
Emotional Support CAT	235	.92	.77	0	10
Informational Support CAT	235	.93	.75	1	8
Social Isolation CAT	235	.86	.83	0	12
Ability to Participate in SRA CAT	235	.91	.67	0	10
Satisfaction with SRA CAT	235	.91	.77	0	8

**STAGE 3:
CONVERGENT & DISCRIMINANT VALIDITY**

Combined Sample					
	Convergent Validity	Discriminant Validity			
		Rand 12 Physical Health	CAS Satisfaction	CAS Ideology	CAS Mastery
CAREGIVER-SPECIFIC MEASURES					
Caregiver-Specific Anxiety CAT	Anxiety 0.63	-0.21	-0.40	0.07	-0.31
Caregiver Strain CAT	CAS Burden -0.79	-0.24	-0.24	0.07	-0.37
Feeling Trapped CAT	Social Isolation 0.68	-0.21	-0.14	0.15	-0.31
Feelings of Loss-Self CAT	Grief/Loss 0.75	-0.28	-0.30	0.11	-0.33
Emotional Suppression CAT	Social Isolation 0.51	0.21	0.21	0.16	0.28
Caregiver Vigilance CAT	Social Isolation 0.57	0.20	0.20	0.22	0.31
Family Disruption SF	MCSI Social Strain 0.68	NA	-0.31	0.08	-0.29
Military HealthCare Frustration**	Anger with the services that the <u>person you care for receives...</u> .67	NA	-0.22	0.03	-0.32

**STAGE 3:
CONVERGENT & DISCRIMINANT VALIDITY**

Combined Sample					
	Convergent Validity	Discriminant Validity			
		Rand 12 Physical Health	CAS Satisfaction	CAS Ideology	CAS Mastery
CAREGIVER-SPECIFIC MEASURES					
Caregiver-Specific Anxiety CAT	Anxiety 0.63	-0.21	-0.40	0.07	-0.31
Caregiver Strain CAT	CAS Burden -0.79	-0.24	-0.24	0.07	-0.37
Feeling Trapped CAT	Social Isolation 0.68	-0.21	-0.14	0.15	-0.31
Feelings of Loss-Self CAT	Grief/Loss 0.75	-0.28	-0.30	0.11	-0.33
Emotional Suppression CAT	Social Isolation 0.51	0.21	0.21	0.16	0.28
Caregiver Vigilance CAT	Social Isolation 0.57	0.20	0.20	0.22	0.31
Family Disruption SF	MCSI Social Strain 0.68	NA	-0.31	0.08	-0.29
Military HealthCare Frustration**	Anger with the services that the <u>person you care for</u> receives... .67	NA	-0.22	0.03	-0.32

STAGE 3: KNOWN GROUPS VALIDITY & CLINICAL IMPAIRMENT RATES

	Caregiver of High-Functioning Individual		Caregiver of Low-Functioning Individual		t	p
	Mean (SD)	%Impaired	Mean (SD)	%Impaired		
CAREGIVER-SPECIFIC MEASURES						
TBI-CareQOL Caregiver-Specific Anxiety CAT	50 (10)	14	55 (7)	23	-3.48	0.001
TBI-CareQOL Caregiver Strain CAT	45 (10)	6	56 (10)	35	-4.81	<.0001
TBI-CareQOL Feeling Trapped CAT	44 (8)	3	55 (6)	19	-6.87	<.0001
TBI-CareQOL Feelings of Loss-Self CAT	45 (10)	6	56 (9)	42	-5.19	<.0001
Emotional Suppression CAT	47 (10)	7	53 (8)	23	3.40	0.001
Caregiver Vigilance CAT	44 (9)	3	52 (8)	12	4.40	<.001
Family Disruption SF	46 (9)	5	56 (7)	27	5.49	<.0001
Military Healthcare Frustration*	42 (8)	0	53 (8)	22	8.95	<.0001
MENTAL HEALTH						
Anger CAT	50 (10)	20	57 (8)	41	3.93	<.001
Anxiety CAT	52 (9)	20	57 (8)	41	3.50	0.001
Depression CAT	50 (9)	13	55 (9)	26	3.49	0.001
TBI-QOL Grief/Loss SF	43 (9)	2	51 (9)	12	-4.43	<.0001
NIH Toolbox Perceived Stress CAT	47 (11)	12	55 (10)	23	-3.25	0.001
TBI-QOL Resilience SF	49 (9)	16	46 (9)	19	1.67	0.10
NIH Toolbox Self-Efficacy CAT	50 (10)	17	50 (10)	15	0.06	0.95
Neuro-QoL Positive Affect and Well Being CAT	53 (8)	4	49 (5)	4	3.32	0.002
NIH Toolbox General Life Satisfaction CAT	50 (9)	13	41 (8)	50	4.40	<.0001

STAGE 3: KNOWN GROUPS VALIDITY & CLINICAL IMPAIRMENT RATES

	Caregiver of High-Functioning Individual		Caregiver of Low-Functioning Individual		t	p
	Mean (SD)	%Impaired*	Mean (SD)	%Impaired*		
PHYSICAL HEALTH						
Fatigue CAT	51 (9)	17	56 (11)	41	3.24	0.001
Sleep Disturbance CAT	51 (9)	15	56 (9)	29	3.31	0.001
PROMIS Sleep Related Impairment CAT	51 (11)	23	59 (9)	35	-3.42	0.0008
SOCIAL HEALTH						
Emotional Support CAT	50 (9)	10	48 (11)	29	1.64	0.10
Informational Support CAT	51 (11)	17	47 (11)	29	2.10	0.04
Social Isolation CAT	47 (9)	7	53 (9)	19	4.10	<.0001
Ability to Participate in SRA CAT	53 (9)	24	44 (10)	33	5.64	<.0001
Satisfaction with SRA CAT	49 (9)	11	43 (9)	38	4.15	<.0001

PROS: TAKE AWAYS

- **PROMIS CATs AND SHORT FORMS:**
 - **PROVIDE USEFUL MEASURES OF GENERIC (“UNIVERSAL”) PHYSICAL, EMOTIONAL AND SOCIAL HEALTH HAVE LOW RESPONDENT BURDEN**
- **COMBINING GENERIC AND TARGETED PROs CAN FACILITATE A BETTER UNDERSTANDING OF HRQOL**

FOOD FOR THOUGHT

- DO YOU KNOW WHAT ASPECTS OF HRQOL ARE IMPORTANT TO PATIENTS?
- YOU HAVE DISEASE-SPECIFIC MEASURES—IS THIS SUFFICIENT?
 - MORE THOROUGH REVIEW OF PSYCHOMETRICS WOULD BE IMPORTANT
- WOULD GENERIC MEASURES ADD VALUE?
- WOULD THE ADVANTAGES OF CATs (BREVITY/SENSITIVITY) BE OUTWEIGHED BY PRAGMATIC CONCERNS (ASSESSMENT PLATFORMS)?
- WHAT RELIABILITY/VALIDITY DATA IS STILL NEEDED (IF ANY)?
- WHAT ARE THE QUESTIONS YOU WANT TO ANSWER?
 - PREDICTING PROGNOSIS?
 - DETERMINING EFFICACY

JUST-IN-TIME ADAPTIVE INTERVENTIONS (JITAI)



THE RIGHT AMOUNT OF SUPPORT FOR THE RIGHT PERSON AT THE RIGHT TIME

JITAI: EFFICACY DATA

SIGNIFICANT IMPROVEMENTS IN BEHAVIORAL OUTCOMES FOR:

- PHYSICAL ACTIVITY (DECREASE SEDENTARY BEHAVIOR)
- ALCOHOL USE (STOP DRINKING)
- SMOKING CESSATION (STOP SMOKING)
- MENTAL HEALTH (IMPROVED MOOD)

APPLICATION OF A JITAI TO FAMILY CAREGIVERS

TWO SEPARATE STUDIES:

1) THE ACCELERATING SYNERGY (AS) STUDY

(MOBILE TECHNOLOGY AND DATA ANALYTICS TO IDENTIFY REAL-TIME PREDICTORS OF CAREGIVER WELL-BEING)

2) THE NIH STUDY

(IMPROVING OUTCOMES FOR CARE PARTNERS OF PERSONS WITH TRAUMATIC BRAIN INJURY)

WHY CARE PARTNERS?

- CARE PARTNERS EXPERIENCE:
 - DEPRESSION
 - ANXIETY
 - FAMILY STRESS
 - DECREASED MARITAL SATISFACTION
 - DIVORCE
 - SOCIAL ISOLATION
 - ALCOHOL & DRUG ABUSE



CARE PARTNERS IMPACT CARE RECIPIENTS

- CARE PARTNER OUTCOMES ARE ASSOCIATED WITH POORER OUTCOMES FOR THE CARE RECIPIENT
 - POORER FUNCTIONAL ABILITY
 - POORER COGNITION
 - LESS PSYCHOSOCIAL WELL-BEING
 - LESS SOCIAL INTEGRATION
 - POORER WORK PRODUCTIVITY AND EMPLOYABILITY
 - POORER ADJUSTMENT TO DISABILITY



CARE PARTNERS OF 4 DISTINCT POPULATIONS

THE FEASIBILITY (AS) STUDY

- ALLOGENEIC HEMATOPOIETIC CELL TRANSPLANTATION [HCT]
 - EPISODIC CANCER CONDITION THAT REQUIRES INTENSE, PROLONGED INPATIENT AND OUTPATIENT TREATMENT
- SPINAL CORD INJURY
 - CHRONIC CONDITION CAUSED BY A TRAUMATIC EVENT
- HUNTINGTON DISEASE
 - PROGRESSIVE, FATAL NEURODEGENERATIVE DISEASE

THE EFFICACY (NIH) STUDY

- TRAUMATIC BRAIN INJURY
 - CHRONIC CONDITION CAUSED BY A TRAUMATIC EVENT



OVERALL STUDY DESIGN

Randomization

AS:

10/10 HC

10/10 SCI

10/10 HD

NIH:

120/120 TBI

Baseline Assessment

PROs & Training

Home-Monitoring Period

AS: 3 months

NIH: 6 months

Real-time PROs

End of month PROs

Fitbit monitoring

JITAI (intervention group only)

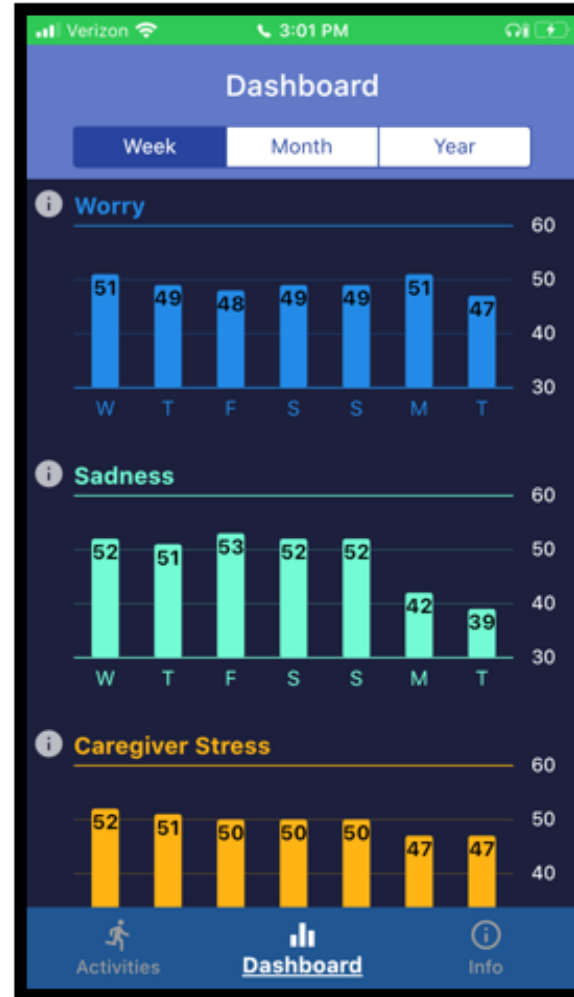
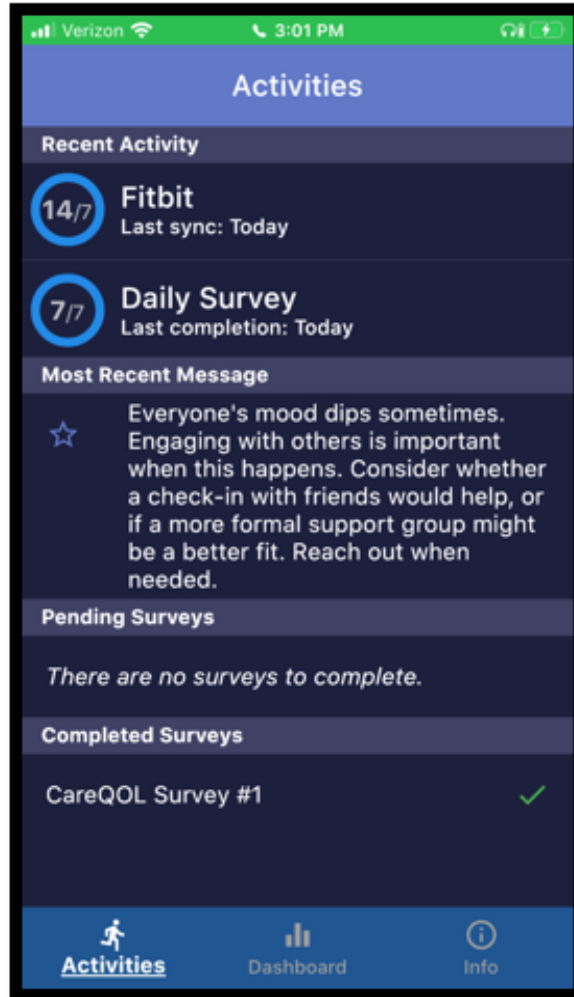
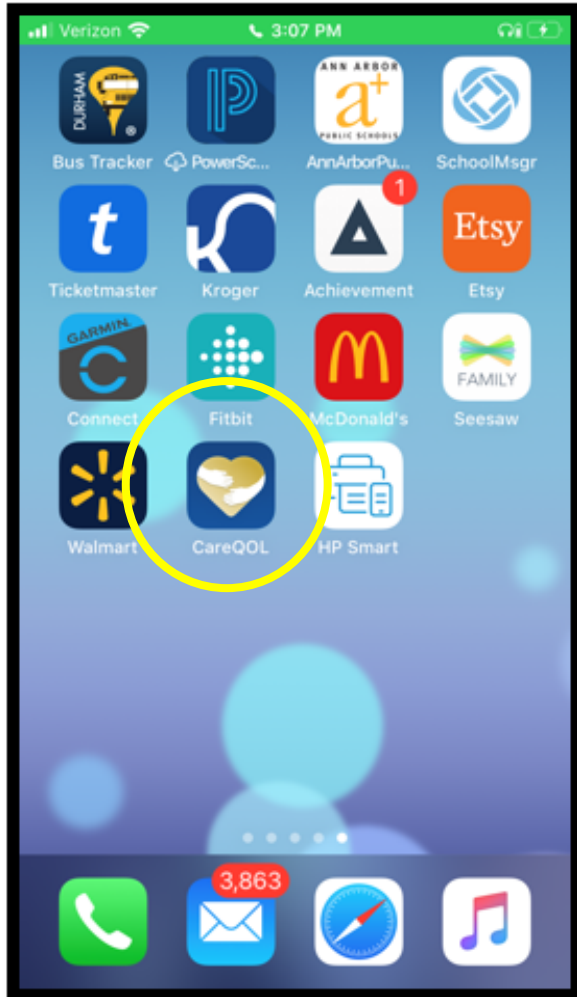
Post-Intervention

NIH only

PROs

Schedule of events	Baseline	Daily*	Monthly	End of study	+3m & +6m Follow-ups
Caregiver Strain SF	X		X	X	X
Caregiver-Specific Anxiety SF	X		X	X	X
Sleep-Related Impairment SF	X		X	X	X
Fatigue SF	X		X	X	X
Anxiety SF	X		X	X	X
Depression SF	X		X	X	X
Anger SF	X		X	X	X
Self-Efficacy SF	X		X	X	X
Positive Affect & Well-Being SF	X		X	X	X
Perceived Stress	X		X	X	X
Ability to Participate in SRAs SF	X		X	X	X
Global Health	X		X	X	X
COVID HRQOL	X		X	X	X
Single-item Caregiver Strain		X			
Single-item Anxiety		X			
Single-item Depression		X			
MedHistory/Medications/Treatment/COVID	X		3m only	X	X
Adverse event status			3m only	X	X
Feasibility and acceptability			AS only		

THE INTERVENTION



THE INTERVENTION PROMPTS

- PROMPTS ARE AIMED AT:
 - PROMOTING HEALTHY BEHAVIORS (PHYSICAL ACTIVITY AND GOOD SLEEP HYGIENE)
 - IMPROVING MOOD (ANXIETY, DEPRESSION, CAREGIVER STRAIN)
- 50/50 CHANCE OF RECEIVING A PROMPT EACH DAY
 - PROMPT PULLED AT RANDOM FROM THE FULL BANK OF POTENTIAL PROMPTS
- PROMPTS INCLUDE:
 - DATA FEEDBACK (E.G. THIS PAST MONTH YOU AVERAGED 8756 DAILY STEPS)
 - FACT (E.G. YOUR PHONE'S LIGHT CAN SHIFT YOUR BODY'S CIRCADIAN CLOCK)
 - TIP (E.G. FOR A BOOST ON BAD DAYS, CRANK UP THE VOLUME ON YOUR FAV PLAYLIST & TAKE A MINUTE TO DANCE IT OUT)
 - SUPPORT (E.G. FALLING ASLEEP CAN BE FRUSTRATING, EVEN WHEN YOU'RE TIRED)

JITAI TAILORING

<u>Feedback Domain</u>	<u>Intervention Options:</u> Example Low Level (below average performance/problems)	<u>Intervention Options:</u> Medium Level (average performance/problems)	<u>Intervention Options:</u> High Level (above average performance/problems)
Mental Health (depression)	Your average sadness rating over the last week was XX. Next time you're feeling low, watch your favorite funny movie. Laughter is the best medicine!	Your average sadness rating over the last week was XX. When you're feeling low, why not watch your favorite funny movie? Laughter is the best medicine!	Your average sadness rating over the last week was XX. If you're ever feeling low, watch your favorite funny movie. Laughter is the best medicine!
Mental health (anxiety)	When you start to feel overwhelmed by your worries, a few deep breaths can steady and calm you. Breathe in slowly and deeply through your nose, hold the breath for a moment, then exhale slowly through your mouth. Repeat until you feel better!	When you start to feel overwhelmed by your worries, a few deep breaths can steady and calm you. Breathe in slowly and deeply through your nose, hold the breath for a moment, then exhale slowly through your mouth. Repeat until you feel better!	If you ever feel overwhelmed by your worries, a few deep breaths can steady and calm you. Breathe in slowly and deeply through your nose, hold the breath for a moment, then exhale slowly through your mouth. Repeat until you feel better!
Mindfulness	Take a few minutes every day to wind down. Even if you don't feel stressed all the time, meditating can relieve built up tension.	Take a few minutes every day to wind down. Try meditating to relieve built up tension.	Take a few minutes every day to wind down. Even if you don't feel stressed right now, meditating can relieve any built-up tension.
Physical Activity	This past week, your average daily step count has been XX. Try to maintain this level, or even increase it more if you can	This past week, your average daily step count has been XX. Try to increase this if you can!	This past week, your average daily step count has been XX. Great job! Try to maintain this level.
Sleep	You aren't quite getting the recommended 7-8 hours of sleep per night. Try moving bedtime up by 5-10 minutes each night to get closer to this goal.	You're having a hard time getting the recommended 7-8 hours of sleep per night. We all struggle to get to sleep sometimes. Try moving bedtime up by 5-10 minutes each night.	If you ever having a hard time getting the recommended 7-8 hours of sleep per night, try moving bedtime up by 5-10 minutes each night.

AS: FINDINGS

- N=73 ENROLLED
- N=70 COMPLETERS
 - N=30 HCT
 - N=19 SCI
 - N=21 HD
- 3 DROPOUTS ALL SCI

Protocol Compliance by Caregiver Group					
Domain	N	Minimum	Maximum	Mean	SD
Daily Surveys					
• HD	21	45%	100%	90%	12%
• SCI	19	51%	100%	86%	14%
• HCT	30	64%	100%	92%	8%
Daily Steps					
• HD	21	92%	100%	98%	2%
• SCI	19	38%	100%	90%	18%
• HCT	30	91%	100%	99%	2%
Daily Sleep					
• HD	21	8%	100%	82%	29%
• SCI	19	8%	100%	80%	27%
• HCT	30	4%	100%	90%	21%

Note. Caregiver groups included: HD = Huntington disease; SCI = spinal cord injury; HCT = hematopoietic cell transplantation

AS: FINDINGS - FITBIT®

Acceptability data (N=70 care partner respondents)						
Fitbit®						
	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Agree + Strongly Agree (>80%)
Instructions for the Fitbit® were easy to understand.	1%	6%	3%	36%	54%	90%
The Fitbit® was easy to set up.	1%	6%	1%	39%	52%	91%
The Fitbit® was easy to use.	0%	3%	10%	48%	39%	87%
The Fitbit® was comfortable to wear.	0%	6%	10%	41%	43%	84%
The Fitbit® was easy to sync with my phone.	0%	3%	12%	35%	51%	86%
I was confident using the Fitbit®	0%	3%	10%	48%	39%	87%

AS: FINDINGS – CAREQOL APP

CareQOL App Acceptability data (N=70 care partner respondents)						
CareQOL app						
	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Agree + Strongly Agree (>80%)
The instructions for the CareQOL app set up were easy to understand.	0%	3%	1%	38%	58%	96%
The CareQOL app was easy to set up.	0%	3%	3%	41%	54%	94%
The CareQOL app was easy to use.	0%	1%	1%	35%	62%	97%
I was confident using the CareQOL app	0%	1%	1%	33%	64%	97%
I am confident that I was using the CareQOL app correctly.	0%	3%	3%	38%	57%	94%
	Poor	Fair	Good	Very Good	Excellent	Very Good + Excellent (>80%)
What is your overall rating of the design of the screens on the app, including the colors and layout?	0%	1%	14%	48%	36%	84%

AS: FINDINGS – DAILY QUESTIONS

Acceptability data (N=69 care partner respondents)						
Daily Questions						
	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Agree + Strongly Agree (>80%)
The daily questions on the app were easy to understand.	1%	0%	4%	33%	61%	94%
The daily questions on the app were easy to answer.	0%	3%	7%	36%	54%	90%
Answering the daily questions fit easily into my routine.	0%	0%	10%	30%	59%	90%
The number of daily questions to answer on the app was reasonable.	0%	0%	0%	26%	74%	100%

AS: FINDINGS – MONTHLY QUESTIONS

Acceptability data (N=70 care partner respondents)						
Monthly Surveys						
	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Agree + Strongly Agree (>80%)
The monthly surveys on the app were easy to understand.	0%	1%	3%	33%	62%	96%
The monthly surveys on the app were easy to answer.	0%	1%	7%	30%	61%	91%
Answering the monthly surveys fit easily into my routine.	0%	0%	6%	28%	67%	94%
The number of questions in the monthly surveys was reasonable.	0%	1%	7%	42%	49%	91%

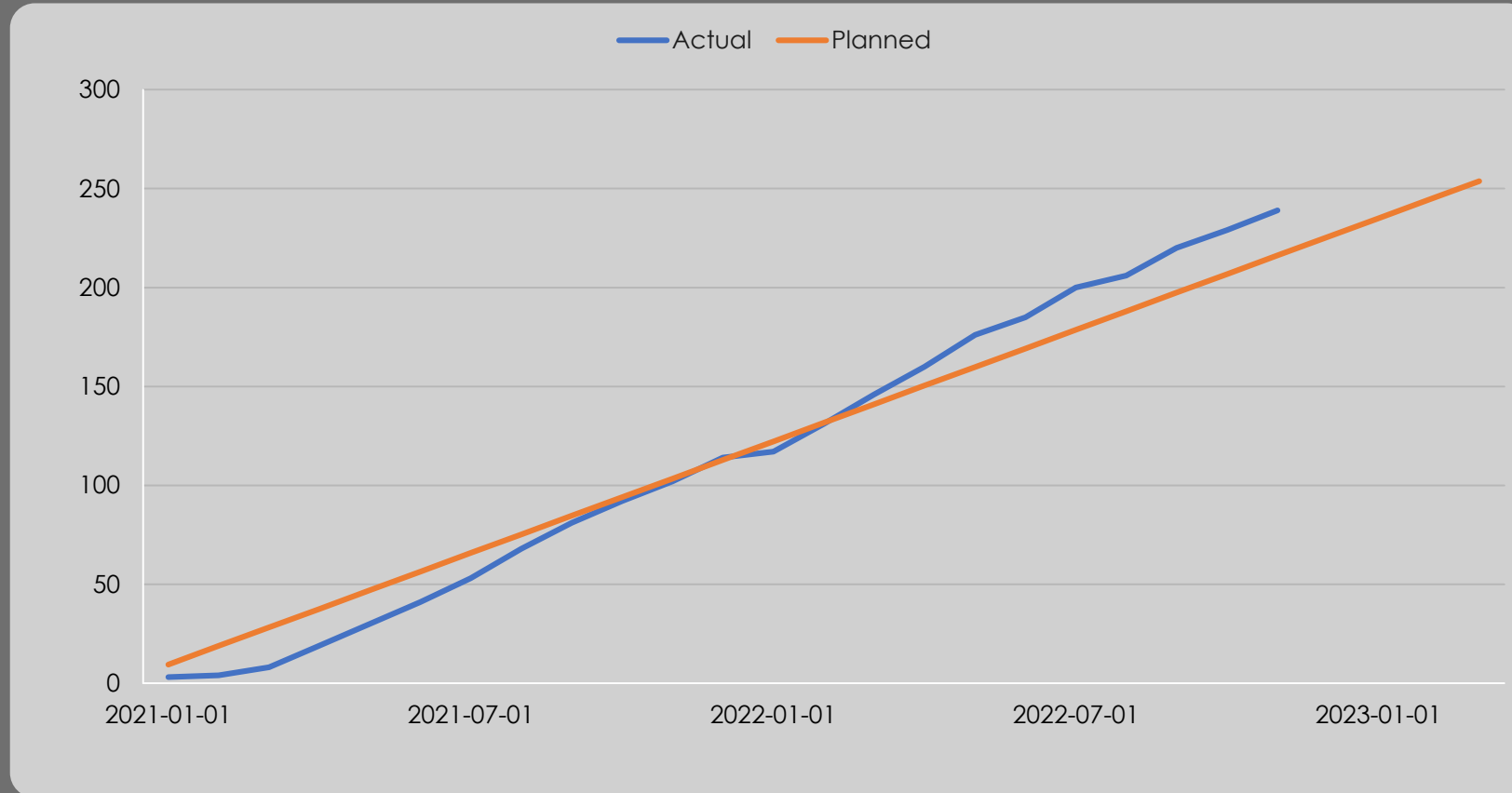
AS: FINDINGS – FUTURE PARTICIPATION

Acceptability data (N=69 care partner respondents)						
How likely would you be to participate in a study that lasted...						
	Extremely unlikely	Unlikely	Neutral	Likely	Extremely	Likely + Extremely (>80%)
1 month?	0	0	4.3	21.7	73.9	97%
3 months?	0	1.4	7.2	23.2	68.1	97%
6 months?	1.4	5.8	15.9	24.6	52.2	76%
9 months?	4.3	7.2	20.3	21.7	46.4	73%
1 year?	7.2	8.7	18.8	23.2	42.0	70%
Other Acceptability Questions						
	A lot worse	A little worse	About the same	A little better	A lot better	About the same + A little better + A lot better (>80%)
Compared to what you expected, how you would rate your experience in participating in this research study?	0	1.4	34.8	26.1	37.7	99%

AS: FINDINGS

Univariate analysis of the effect of JITAI on HRQOL (controlling for baseline HRQOL)						
	Control (n=33)		JITAI (n=36)		Significance	Effect Size
	Pre	Post	Pre	Post		
Caregiver Strain	47.8 (7.9)	49.1 (10.9)	49.7 (6.5)	47.1 (10.7)	F(1, 66)=7.9, p=.007	.107
Anger	49.0 (9.3)	46.7 (9.1)	51.6 (11.2)	46.8 (13.3)	F(1, 66)=1.5, p=.230	.022
Anxiety	52.7 (7.6)	53.2 (7.7)	53.2 (9.2)	53.2 (9.9)	F(1, 66)=.04, p=.834	.001
Depression	47.8 (7.8)	50.4 (7.5)	52.4 (8.2)	50.4 (9.6)	F(1, 66)=4.5, p=.037	.064
Fatigue	48.4 (9.9)	50.5 (11.1)	51.8 (9.6)	51.0 (10.6)	F(1, 66)=2.0, p=.162	.029
General Physical Health	50.8 (7.6)	50.1 (8.3)	50.5 (7.2)	51.0 (8.5)	F(1, 66)=.61, p=.439	.009
General Mental Health	47.3 (9.6)	47.8 (10.1)	49.4 (8.3)	49.7 (10.9)	F(1, 66)=.00, p=.987	.000
Perceived Stress	48.2 (11.6)	46.6 (12.5)	49.5 (11.7)	46.8 (12.7)	F(1, 66)=.20, p=.655	.003
Positive Affect	53.5 (5.0)	54.2 (6.4)	53.2 (7.0)	52.8 (9.4)	F(1, 66)=.48, p=.490	.007
Social Role Ability	48.4 (8.5)	47.5 (9.5)	46.8 (8.5)	47.7 (10.0)	F(1, 66)=.71, p=.404	.011
Sleep-Related Impairment	50.2 (9.5)	50.4 (9.4)	53.8 (9.5)	49.1 (11.1)	F(1, 66)=5.7, p=.020	.079

NIH STUDY : PROGRESS TO DATE



NIH STUDY: PROTOCOL COMPLIANCE

REPORTED AS PERCENTAGE OF DAYS WITH DATA OVER NUMBER OF DAYS IN STUDY THROUGH 8/31/2022 OR THEIR 6M VISIT

Domain	n	Min	Max	M (SD)
Daily Surveys	208	13	100	86 (14)
Daily Steps	208	0	100	91 (18)
Daily Sleep	208	0	100	74 (31)

Reflects data collected through 8/31/2022

PROTOCOL COMPLIANCE

BASELINE AND MONTHLY SURVEY COMPLETION RATE, REPORTED AS A PERCENTAGE
(EXCLUDES WITHDRAWALS)

Domain	n	n Complete	% Complete
Baseline	208	208	100
Month 1	197	197	100
Month 2	186	184	98.9
Month 3	175	173	98.9
Month 4	166	163	98.2
Month 5	149	144	96.6
Month 6	136	136	100
Month 9	109	104	95.4
Month 12	78	75	96.2

Reflects data collected through 8/31/2022

JITAI: TAKE AWAYS

- THIS INTENSIVE STUDY DESIGN IS FEASIBLE AND ACCEPTABLE
- THERE IS SOME SIGNAL TO SUGGEST THAT THE JITAI IS ASSOCIATED WITH HRQOL IMPROVEMENTS...

QUESTIONS?

ACKNOWLEDGEMENTS:

- 1R01NR013658: NINR
- 2R01NR013658: NINR
- R01HL146354: NHLBI
- UL1TR002240: NCATS