Coping, Symptoms, and Insomnia among People with Heart Failure during the Covid-19 Pandemic

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Abstract

Aim: Increases in stress, symptoms of anxiety and depression and sleep problems have been reported during the Covid-19 pandemic, and people with chronic medical conditions such as heart failure (HF) are especially vulnerable. The purpose of this study was to examine the extent to which sleep characteristics, sleep-related cognitions, anxiety, depression, perceived stress, and changes in these phenomena over time predict ways of coping with pandemic-related stress among participants in the HeartSleep study, a randomized controlled trial of the effects of cognitive behavioral therapy for insomnia (CBT-I) in people with HF.

Methods: Participants completed questionnaires to elicit sleep characteristics, daytime symptoms, mood and stress at baseline, six-months after the intervention and during the Covid-19 pandemic. We added measures of coping during the pandemic (June-August 2020).

Results: The sample included 112 participants (M age = 63 + 12.9 years; 47% women; 13% Black; 68% NY Heart Class II or III). Participants (43%) reported pandemic-related stressors and most often used secondary control coping. Insomnia severity, anxiety, depression, perceived stress, and sleep-related cognitions predicted secondary control coping (positive thinking, cognitive restructuring, acceptance, distraction), involuntary engagement (physiological arousal, rumination) and involuntary disengagement (emotional numbing).

Conclusions: Insomnia and mood disturbance are important determinants of coping and responses to stress. Improving sleep and symptoms among people with HF may improve coping during stressful events, and CBT-I may have protective effects.

Keywords: Covid-19, heart failure, insomnia, sleep, coping, stress, cognitive behavioral therapy.

Background

Increases in stress, anxious and depressive symptoms, and sleep problems were reported during the Covid-19 pandemic.[1,2] People with pre-existing chronic conditions are at high risk for these problems[3] and reported greater stress and anxiety during the pandemic compared to healthy counterparts.[4] People with heart failure (HF) experienced anxiety about interrupted healthcare.[5] Stress,[6] depression,[7] insomnia, and sleep disturbance[8] may exacerbate HF symptoms.

Stress and Coping Theory[9] posits that stress occurs when people assess a circumstance as personally relevant and threatening (primary appraisal) and beyond what they believe they have resources to deal with (secondary appraisal). Coping involves cognitive and behavioral strategies used to alleviate stress.[9] Stress was associated with dysfunctional coping strategies (e.g., denial) among people with chronic conditions during the pandemic.[10] Adequate sleep may reduce stress and improve coping;[11] however, there are several pandemic-specific precipitating (e.g., worry about contracting the virus) and perpetuating factors (e.g., not being able to see loved ones) that the 3P model of insomnia[12] suggests could increase insomnia during this time.[13] Behavioral treatments may have protective effects on these perpetuating factors as well as coping. Healthy adults who received cognitive behavioral therapy for insomnia (CBT-I) compared to a control condition had less insomnia, depression, stress, and pandemic-related cognitive intrusions.[14] Although the effects of CBT-I were not examined among people with HF during the pandemic, it improved insomnia, sleep duration and quality, sleep onset, and dysfunctional sleep related cognitions at six-months post-treatment prior to the pandemic.[15] There were smaller improvements on these outcomes among people receiving HF self-management education. Anxious and depressive symptoms decreased in both groups, but there were no group-by-time effects.[15]

The purpose of this study was to examine the extent to which sleep characteristics, sleep-related cognitions, anxiety, depression and perceived stress prior to insomnia treatment and changes in these phenomena predicted ways of coping with pandemic-related stress among participants in a study of the effects of CBT-I compared with HF self-management education in people with HF.[15]

Methods

Design. We report data from participants in the HeartSleep Study, a randomized controlled trial of CBT-I, compared with HF self-management education among adults with stable HF (NCT 02660385).[16] We obtained human subjects' approval and written informed consent. We used the STROBE cross sectional reporting guidelines.[17]

Setting. We conducted the study in June-August 2020 in a U.S. northeastern state that was undergoing phased reopening after "all in-person functions" were prohibited in non-essential businesses. We collected data electronically via REDCap[18] or by mail.

Participants. HeartSleep study participants were adults with stable HF and mild to severe insomnia (scored >7 on the Insomnia Severity Index[19]). Exclusions were: more than mild untreated sleep apnea, severe sleepiness, seizure disorders, restless legs syndrome, narcolepsy, end stage renal failure, severe mental illness, current illicit drug use, and shift work.[16]

Procedures. We collected data from participants at three timepoints: baseline (prior to participation in CBT-I or HF self-management intervention/attention control condition); 6 months following completion of the intervention; and during the pandemic (June-August 2020). Participants reported sleep characteristics, daytime symptoms, mood, and perceived stress at each timepoint, with the addition of measures of coping with stress during the pandemic. HeartSleep Study enrollment spanned 48 months and participants were followed for six months; therefore, data collection dates varied. The time between six-month follow-up and the pandemic ranged from 6-48 months. We provided $25 gift cards for completing surveys during the pandemic and stipends in earlier phases of the study.[16]

Variables and Measures

Demographic and clinical characteristics. We collected self-reported demographic data (age, sex, race/ethnicity, marital and work status, education) and used medical records to elicit the New York Heart Association Functional Classification (NYHA), ejection fraction, body mass index and health history. We used the Charlson Comorbidity Index.[20]

Sleep characteristics. We used the Insomnia Severity Index (ISI), an internally consistent (0.74 – 0.88) and sensitive[19] measure and the Pittsburgh Sleep Quality Index (PSQI) to measure

perceived sleep quality, efficiency, duration, and latency (Alpha coefficient = 0.72). We measured daytime dysfunction using the PROMIS Sleep Related Impairment Scale[21] (Coefficient alpha = .90), sleep related beliefs and cognitions with the Sleep Disturbance Questionnaire (SDQ)[22] (e.g., restlessness, agitation, worry about the consequences of insomnia) (Coefficient alpha= 87), and the Dysfunctional Beliefs and Attitudes About Sleep scale (DBAS)[23] to measure maladaptive beliefs about sleep (e.g., worry about sleep, consequences of poor sleep) (Coefficient alpha = .87).

Mood and Stress. We used the reliable and valid 10-item Perceived Stress Scale (PSS)[24] (Coefficient alpha = .91) and PROMIS Anxiety and Depression scales[25] (Coefficient alpha = .94).

Covid-19 Related Measures

The Response to Stress Questionnaire (RSQ)- [COVID-19-19] (SR-A)[26] presents participants with a list of stressors commonly experienced during the Covid-19 pandemic and asks for respondents to consider the level of stress each has caused them; this exercise is used to prime respondents for responding to items about coping with Covid-19 related stress (and is not considered a measure of stress). The instrument elicits five characteristics of coping and involuntary stress responses: primary control engagement coping (problem solving, emotional expression, emotional modulation); secondary control engagement coping (positive thinking, cognitive restructuring, acceptance, distraction); disengagement coping (avoidance, denial, wishful thinking); involuntary engagement (physiological arousal, rumination); and involuntary disengagement (emotional numbing). The scores are calculated as the ratio of the total items in each subscale to the total of all items. The RSQ was used in clinical populations.[26] Reliability was adequate (Coefficient alpha = 0.83).

Statistical Analysis

We computed descriptive statistics and imputed missing data using the Markov Chain Monte Carlo (MCMC) algorithm when the missing response rate was less than 30%. We calculated summary scores with observed and imputed data. We computed the cross-sectional correlations between the sleep, mood, and stress variables and coping with Pearson coefficients and partial Pearson coefficients, controlling for covariates. We examined whether insomnia,

anxiety, depression, perceived stress, and sleep-related cognitions at baseline and change from 6 months post-treatment predicted types of coping, after controlling for comorbidity using the Generalized Linear Model (GLM). All variables were standardized for zero means and one standard deviation before running GLM. The residuals were assessed for normality. Multicollinearity was checked using variance inflation (VIF) and tolerance for each GLM. VIFs and tolerance scores indicated the absence of multicollinearity.

Results

One hundred and twelve (74%) of the 152 participants who completed the parent study agreed to participate, including 52 (46%) who completed the HF self-management intervention and 60 (54%) who completed CBT-I. The mean age was 63 (12.9) years, 53% were male, 13% were Black/African American and approximately half were married/partnered (52%) and college educated (54%). Most had HF with preserved ejection fraction and NYHA functional class II (experiencing HF symptoms with moderate physical exertion) or III (experiencing HF symptoms with minimal physical exertion). The mean Charlson Comorbidity Index score was 2.5 (1.8).

Descriptive statistics and the changes in sleep characteristics, sleep impairment, anxiety, depression, and dysfunctional beliefs and attitudes about sleep from the six-month follow-up to the pandemic have been previously reported [27]. In brief, at baseline, participants had poor sleep quality (PSQI) [M= 9.82 (3.84)], prolonged sleep latency (minutes) [M = 36.07 (41.32)] and low sleep efficiency (%) [M = 77.68 (14.64)], and clinical levels of insomnia (ISI) [M = 15.11 (4.87)]. They scored higher than the T-score of 50 (the population norms) on anxiety [M = 51.30 (8.64)] and sleep impairment [M = 53.49 (8.55)], but not depressive symptoms [M = 49.68 (8.10)]. Stress levels were moderate (PSS) [M = 14.39 (7.19)]. Mean sleep disturbance (SDQ) was 5.18 (1.52) and mean dysfunctional beliefs/attitudes about sleep (DBAS) was 2.92 (0.70). During the pandemic timepoint, there were no statistically significant differences between groups of participants who received CBT-I and those who received HF self-management intervention (on any variables); therefore, we combined groups for these analyses.

As previously reported,[15] there were statistically significant improvements in all outcomes at six-month follow-up from baseline and all outcomes were related to sleep variables. From six-months post treatment to the pandemic timepoint (June-August 2020) insomnia severity improved (ISI) [-1.05 (5.30)] and levels of sleep disturbance, quality, efficiency, latency

and dysfunctional beliefs about sleep, perceived stress, anxiety and depression remained consistent with measurements at six-month follow-up. Sleep duration became shorter (.59 hours), and there was an increase in the sleep impairment [M = 6.77 10.41)].[27]

The most frequently endorsed pandemic-related stressors included inability to spend time with friends and family (64%) and participate in regular activities (69%), needing to cancel plans (54%) and uncertainty about when the pandemic would end (57%) (see Table 1). Fifty-seven (51%) participants thought of "different ways to change or fix the situation." They suggested taking expert advice (wear masks, etc.) (n=10; 18%), finding new ways to access food (n=8; 14%) and socialize (n=6; 11%), keeping busy (n=6; 11%) and keeping in touch with healthcare providers.

Secondary control coping (positive thinking, cognitive restructuring, acceptance, distraction) was the most frequently used coping style. Mean (SD) coping scores were: Primary Control Coping (problem solving, emotional expression and modulation) 0.18 (0.04); Secondary Control Coping (positive thinking, cognitive restructuring, acceptance, distraction) 0.29 (0.06); Disengagement Coping (avoidance, denial, wishful thinking) 0.15 (0.03); Involuntary Engagement (physiological arousal, rumination) 0.22 (0.04) and Involuntary Disengagement (emotional numbing) 0.17 (0.03). Correlations between sleep and mood variables and RSQ scales at the Covid survey timepoint appear in table 2. The sleep, perceived stress (Perceived Stress Scale) or mood variables were not associated with primary control (problem solving, emotional expression and modulation) or disengagement coping (avoidance, denial, wishful thinking). Therefore, we did not include these in further multivariable analyses. Comorbidity was negatively associated with primary (problem solving, emotional expression and modulation) (r=-0.16; p=.09) and secondary control coping (positive thinking, cognitive restructuring, acceptance, distraction), (r=-0.27; p=.004) and positively associated with involuntary engagement (physiological arousal, rumination) (r=0.20; p=.04) and involuntary disengagement (emotional numbing) (r=0.36; p=.0001). There were small to moderate statistically significant negative relationships between insomnia severity, poor sleep quality, anxiety, depression, sleep impairment, perceived stress, dysfunctional beliefs and cognitions about sleep and secondary control coping (positive thinking, cognitive restructuring, acceptance, distraction), controlling for comorbidity. These variables had positive correlations with involuntary engagement

(physiological arousal, rumination). Anxious and depression symptoms, perceived stress, sleep impairment and dysfunctional sleep-related beliefs and cognitions were associated with involuntary disengagement coping (avoidance, denial, wishful thinking).

Table 3 presents the data on the extent to which baseline insomnia severity, anxiety, depression, perceived stress, and sleep-related beliefs and cognitions and the changes in these variables from six-months to the pandemic (post-treatment) predicted coping during the pandemic, while controlling for comorbidity. Baseline levels predicted secondary control coping (positive thinking, cognitive restructuring, acceptance, distraction), involuntary engagement (physiological arousal, rumination), and involuntary disengagement (emotional numbing). Changes in perceived stress and dysfunctional beliefs and cognitions (SDQ) from six-months to the pandemic period were significantly associated with these coping strategies. Improvements of all predictors were associated with secondary control coping (positive thinking, cognitive restructuring, acceptance, distraction). Improvements in perceived stress and sleep related cognitions predicted involuntary engagement (physiological arousal, rumination), and improved anxiety, perceived stress, and sleep related cognitions predicted involuntary disengagement (emotional numbing). There was a trend suggesting that improvements in anxiety predicted involuntary engagement (physiological arousal, rumination) ($p = .0655$).

Discussion

Our findings suggest that insomnia, anxiety, and depressive symptoms are important determinants of coping and responses to stress in people with HF, with more severe insomnia symptoms associated with involuntary coping behaviors and lower levels associated with control-oriented coping. These findings align with research suggesting that people with insomnia are more likely than those without insomnia to use maladaptive coping strategies.[28] Baseline levels of dysfunctional beliefs and cognitions about sleep, important psychological mechanisms for insomnia, also predicted coping outcomes. Although there were no differences in coping outcomes between the HF self-management and CBT-I groups, both treatments may have improved these outcomes or prevented deterioration; in the parent study both groups experienced statistically significant improvements on several important outcomes (insomnia severity, depression, and dysfunctional beliefs and attitudes about sleep), although improvements were smaller in the HF self-management group.[15]

Like others, [29] participants experienced pandemic-related stressors including social isolation, inability to participate in usual routines, uncertainty about when Covid-19 will end, and a commonly reported stressor, "watching or hearing distressing news reports." Additional stressors may be particularly salient for people with HF. For example, fear of dying from Covid was a significant source of emotional distress[30] among people with comorbid conditions and may be especially important to people with HF who were at very high risk due to exposure to Covid-19. Although others with HF reported that obtaining care was a source of anxiety,[5] only 18% of our sample reported this concern. Although the reasons for this are not clear, the HF, cardiology, and primary care providers in our area were early adopters of telehealth approaches. This may have alleviated some of these concerns.

The 3P model of insomnia[12] posits that there are predisposing (e.g., prior insomnia), precipitating (e.g., stressful life events) and perpetuating factors (thoughts and behaviors that maintain insomnia) that together lead to chronic insomnia. Cox and Olatunji[13] explain the impact of the pandemic on sleep using the 3P Model[12] and identified pandemic specific predisposing, precipitating and perpetuating factors, many of which were experienced by participants in this study. Study participants had a history of chronic insomnia, multiple comorbidities (predisposing factors) and the majority reported several Covid-related stressors that may be considered both precipitating (e.g., worry about self or others contracting the virus) and perpetuating factors (e.g., inability to spend time with loved ones). Given these factors, we expected that study participants would experience increased insomnia during the pandemic, despite the improvements made during their participation in the main study. Instead, participants maintained the significant improvements in insomnia severity, depression, and dysfunctional beliefs and attitudes about sleep achieved during the main study. It is possible that CBT-I and HF self-management education exert protective effects, but future research is needed in a prospective study.

In a prior study, stress was associated with use of dysfunctional coping strategies (e.g., denial, behavior disengagement) among people with chronic conditions during the pandemic.[10] Studies suggest that obtaining adequate sleep may reduce stress and increase use of adaptive coping strategies,[11,31,32] and this may have occurred for the people in our study, given that participation both the treatment and control conditions decreased insomnia and improved sleep quality.[15] People with insomnia, mood disturbance and higher pre-pandemic stress, including people with HF,[6] are at higher risk for difficulty with coping. While the ratio of secondary

control coping (positive coping method) was higher compared to the other stress responses, the lower proportion scores of all 5 RSQ factors, suggest that participants use both positive and negative coping strategies or used coping strategies and responded to stress in ways not measured with the RSQ.

Our findings align with research showing significantly lower levels of positive attitude and optimism among people with HF compared to people without a chronic condition.[33] Coping has important implications for HF outcomes. For example, there was a significant relationship between emotion-focused coping strategies (similar to disengagement coping) and poor physical and psychological health-related quality of life among people with HF. In contrast to the lack of association between sleep, symptoms or sleep related cognitions with primary control coping in our study, problem-focused coping strategies (similar to primary control coping) were associated with fewer depressive symptoms, better self-care, and diminished HF-related physical symptoms.[34]

The findings of our study suggest the critical role of insomnia, anxiety, and depression to coping among people with HF, especially during a stressful time such as a pandemic. Screening and identifying people with HF for these symptoms will help to determine the need for early intervention to strengthen coping. Although our study was not designed a priori to evaluate the effects of CBT-I on coping and pandemic related stress, our finding of an association between improved dysfunctional beliefs and cognitions about sleep and coping suggest that insomnia treatment focused on these cognitive factors may have beneficial effects. However, future studies are needed.

Strengths of the study include the use of standardized, valid and reliable measures and long-term follow-up. However, the study also had limitations. There are potential threats to internal and external validity. For example, the average age of participants in this study is younger than the average age of people with HF; this may limit generalizability. Lack of baseline data on coping, reliance on secondary analysis and varying times between the 6 month and pandemic period follow-ups may also have biased the results. We are unable to draw conclusions about whether participating in the main study (developing new behavioral skills and changing negative sleep related cognitions) led to greater resilience and better coping during the pandemic. Our study included only people with chronic HF and insomnia, and it is possible that the findings of our study are similar to the experiences of other people with insomnia and in insomnia

treatment. However, to our knowledge, no comparable data are available. Future studies are needed to uncover the extent to which are findings are unique to the HF population.

Conclusions

Improving sleep and symptoms (stress, anxiety, depression) among people with HF has the potential to improve clinical outcomes and contribute to positive ways of coping with stressful life events. Future prospective studies are needed to further examine the extent to which improving sleep and symptoms among people with HF contributes to coping with stressful events, and whether CBT-I or HF self-management education exert protective effects. Efforts to assure maintenance of treatment effects after behavioral interventions may be especially important.

Data Availability Statement

The data underlying this article will be shared on reasonable request to the corresponding author.

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Table 1. Covid-19 Related Stressors

Stressor	Not at all Or A little N (%)	Somewhat or Very N (%)
Financial problems because of COVID-19 (e.g., reduced income, job loss, difficulty paying monthly expenses)	86 (79%)	23 (21%)
Unable to spend time in person with close friends or family because of COVID-19	40 (37%)	69 (63%)
Unable to participate in normal routines and activities because of COVID-19 (e.g., spiritual services, shopping, dining at restaurants, going to the gym)	34 (31%)	75 (69%)
Having to change, postpone, or cancel important plans or events because of COVID-19 (e.g., family events, travel, or vacation, work related events)	50 (46%)	59 (54%)
Challenges at home or with others because of COVID-19 (e.g., conflicts, lack of privacy, lack of personal space)	87 (80%)	22 (20%)
Trouble obtaining groceries or other needed supplies because of COVID-19 (e.g., food, medicine, household goods)	81 (74%)	28 (26%)
Watching or hearing distressing news reports about COVID-19	59 (54%)	50 (46%)
Uncertainty about myself or someone close to me getting COVID-19, including being unable to access testing	61 (56%)	48 (44%)
Myself or someone close to me experiencing symptoms or being diagnosed with COVID-19	83 (76%)	26 (24%)
Trouble getting medical care or mental health services because of COVID-19	89 (82%)	20 (18%)
Uncertainty about when COVID-19 will end or what will happen in the future	47 (43%)	62 (57%)
Difficulty completing my work responsibilities remotely because of COVID-19	92 (84%)	17 16%)
Unable to complete educational or work requirements because of COVID-19	96 (88%)	13 (12%)
Needing to take on greater family and/or work responsibilities because of COVID-19	98 (90%)	11 (10%)

Table 2. Partial Correlations Between insomnia, sleep quality, mood, perceived stress, and dysfunctional beliefs and cognitions and coping after controlling for CCI

	Primary Control Coping	Secondary Control Coping	Disengagement Coping	Involuntary Engagement Coping	Involuntary Disengagement Coping
	Partial Correlation after controlling for CCI				
Insomnia Severity index	0.07 (.4449)	**-0.35 (.0002)**	0.01 (.8887)	**0.26 (.0057)**	0.22 (.0238)
Poor Sleep Quality	0.06 (.5664)	**-0.24 (.0119)**	-0.02 (.8704)	**0.19 (.0506)**	0.17 (.0862)
Anxiety (PROMIS)	0.06 (.5068)	**-0.57 (<.0001)**	0.06 (.5553)	**0.43 (<.0001)**	**0.42 (<.0001)**
Depression (PROMIS)	0.01 (.9478)	**-0.51 (<.0001)**	0.11 (.2463)	**0.42 (<.0001)**	**0.35 (.0002)**
Sleep Impairment (PROMIS)	0.00 (.9814)	**-0.46 (<.0001)**	0.06 (.0958)	**0.36 (.0001)**	**0.35 (.0002)**
Perceived Stress (PSS)	-0.07 (.4792)	**-0.67 (<.0001)**	0.16 (.0958)	**0.59 (<.0001)**	**0.50 (<.0001)**
DBAS	-0.06 (.5416)	**-0.42 (<.0001)**	0.14 (.1383)	**0.38 (<.0001)**	**0.29 (.0027)**
SDQ	0.00 (.9673)	**-0.41 (<.0002)**	0.02 (.8674)	**0.39 (<.0001)**	**0.28 (.0031)**

Note--Correlations are at Covid survey timepoint except CCI.

Definitions. Primary Control Coping: problem solving, emotional expression, emotional modulation; Secondary Control Coping: positive thinking, cognitive restructuring, acceptance, distraction; Disengagement Coping: avoidance, denial, wishful thinking; Involuntary Engagement: physiological arousal, rumination; Involuntary Disengagement: emotional numbing

Table 3. Prediction of Coping Scales at the COVID Survey with Insomnia and mood changes from 6 months after controlling for CCI

Predictor Variables		**Outcome Variables**		
		Prediction ***of Secondary Control Coping*** at Covid Survey	Prediction of ***Involuntary Engagement Coping*** at Covid Survey	Prediction of ***Involuntary Disengagement Coping*** at Covid Survey
Insomnia Severity	Change from 6 months	-0.19±0.10 (.0488)	0.10±0.10 (.3299)	0.03±0.10 (.8072)
	Baseline	-0.24±0.10 (.0157)	0.21±0.10 (.0455)	0.08±0.10 (.3765)
	CCI	-0.21±0.10 (.0408)	0.16±0.10 (.1282)	0.34±0.10 (.0008)
	Model Fit: F-Test	F=5.63, p=.0014	F=2.85, p=.0415	F=4.58, p=.0049
Anxiety	Change from 6 months	-0.29±0.10 (.0026)	0.19±0.10 (.0655)	0.25±0.10 (.0064)
	Baseline	-0.30±0.10 (.0020)	0.21±0.10 (.0418)	0.25±0.10 (.0061)
	CCI	-0.18±0.10 (.0553)	0.14±0.10 (.1711)	0.29±0.10 (.0019)
	F-Test	F=9.50, p<.0001	F=3.93, p=.0109	F=10.65, p<.0001
Depression	Change from 6 months	-0.20±0.10 (.0420)	0.16±0.10 (.1164)	0.14±0.10 (.1350)
	Baseline	-0.34±0.10 (.0008)	0.30±0.10 (.0039)	0.24±0.10 (.0131)
	CCI	-0.15±0.10 (.1293)	0.10±0.10 (.3203)	0.28±0.10 (.0131)
	F-Test	F=7.99, p<.0001	F=5.16, p=.0024	F=7.60, p=.0001
Perceived Stress	Change from 6 months	-0.31±0.09 (.0009)	0.26±0.09 (.0067)	0.18±0.09 (.0504)
	Baseline	-0.43±0.09 (<.0001)	0.44±0.09 (<.0001)	0.35±0.09 (.0002)
	CCI	-0.14±0.09 (.1374)	0.08±0.09 (.4167)	0.27±0.09 (.0008)
	F-Test	F=14.18, p<.0001	F=11.26, p<.0001	F=7.33, p=.0002
DBAS	Change from 6 months	-0.32±0.10 (.0017)	0.30±0.10 (.0040)	0.14±0.10 (.1468)
	Baseline	-0.45±0.10 (<.0001)	0.44±0.10 (<.0001)	0.35±0.10 (.0004)
	CCI	-0.24±0.09 (.0090)	0.16±0.09 (.0772)	0.36±0.09 (.0001)
	F-Test	F=11.19, p<.0001	F=8.50, p<.0001	F=10.45, p<.0001
SDQ	Change from 6 months	-0.45±0.10 (<.0001)	0.42±0.11 (.0001)	0.28±0.10 (.0077)
	Baseline	-0.46±0.10 (<.0001)	0.42±0.10 (.0001)	0.34±0.10 (.0017)
	CCI	-0.19±0.09 (.0385)	0.12±0.09 (.2088)	0.30±0.09 (.0014)
	F-Test	F=11.97, p<.0001	F=8.39, p<.0001	F=9.40, p<.0001

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Disclosure Statement

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