

Current pain severity and electronic cigarettes: an initial empirical investigation

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Received: September 21, 2018 / Accepted: November 19, 2018 / Published online: November 28, 2018
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Abstract The present study examined past-month pain severity in relation to e-cigarette dependence, perceived barriers for quitting e-cigarettes, and beliefs about risks associated with using e-cigarettes. Participants were 322 e-cigarette users from the United States (60.2% female, $M_{age} = 36.78$ years, $SD = 10.62$). Results indicated that pain severity was significantly and positively related to e-cigarette dependence, perceived risks of e-cigarette use, and perceived barriers to quitting e-cigarettes. The observed effects were evident above and beyond the variance accounted for by sex, age, education, income, dual cigarette use, frequency of e-cigarette use, and perceived health status. The present study provides novel empirical evidence that pain experience is related to a moderate, yet clinically-meaningful, proportion of the variance in e-cigarette dependence, perceived barriers for quitting e-cigarettes, and beliefs about e-cigarette risks. These findings suggest there is merit to exploring the role of pain experience in the onset and maintenance of e-cigarette use.

Keywords Electronic cigarette · Tobacco · Pain · Pain severity · Dependence · Beliefs

Introduction

Electronic cigarettes (e-cigarettes) are battery operated nicotine delivery devices that mimic the experience of conventional cigarettes (Cobb et al., 2010). The ubiquitous adoption of e-cigarettes among adults in the United States is unprecedented (Levy et al., 2017) and poses a serious threat to public health. Although often employed to aide with combustible cigarette cessation (Dawkins et al., 2012), the overwhelming majority of adult e-cigarette users are or become dual users (i.e., use both combustible and e-cigarettes; Etter & Bullen, 2011; King et al., 2015). From an additive risk perspective, such behavioral patterns complicate health treatment and have the potential to worsen conditions. Indeed, although e-cigarettes may be relatively less dangerous than combustible cigarettes (Farsalinos & Polosa, 2014), even when used in isolation, e-cigarettes present health-related risks, including respiratory illness and toxin exposure (Callahan-Lyon, 2014; Ogunwale et al., 2017; Pisinger & Døssing, 2014). Moreover, the long-term health effects associated with e-cigarette use remain largely unknown and may not be known for years (Dinakar & O'Connor, 2016).

Emerging evidence suggests that specific subgroups of the population may be more vulnerable to e-cigarette use (Hartwell et al., 2017). For example, initial investigations have found that e-cigarette use is more common among persons with psychiatric symptoms and disorders, and among those who recently quit using combustible cigarettes (Cummins et al., 2014; Delnevo et al., 2015). Unfortunately, the recent development and introduction of

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e-cigarettes has not allowed adequate time to conduct studies aimed at understanding *why* certain subpopulations may be at greater risk for use. It may be that, for example, individuals with the greatest difficulty achieving or maintaining abstinence from traditional tobacco cigarettes, such as those with mental illness or recent cigarette quitters, perceive e-cigarettes as a ‘bridge’ to long term cessation (Ghosh & Drummond, 2017; Prochaska & Grana, 2014). Another, although not mutually exclusive, possibility is that there are certain biopsychosocial factors that predispose individuals to risk of e-cigarette uptake and persistent use (Hartwell et al., 2017). Although work to elucidate biosocial predictors of e-cigarette use is growing (e.g., age; Hartwell et al., 2017), far less research has been devoted to understanding the role of psychological/emotional constructs within models of e-cigarette use. To date, this work has exclusively focused on psychopathology and mood symptoms (Cummins et al., 2014). It is possible that co-occurring pain represents an important individual difference factor that is relevant to e-cigarette use.

Pain had garnered recognition as a complex phenomenon that is influenced by a myriad of biopsychosocial factors (Keefe & France, 1999). Research across a wide range of sophisticated designs, including experimental, cross-sectional, and controlled trials, has documented a reciprocal relation between combustible cigarette use and pain, such that they frequently co-occur and influence one another (Ditre & Brandon, 2008; Ditre et al., 2011; Parkerson et al., 2013). For example, combustible cigarette use has been implicated in the onset of chronic pain (Shiri et al., 2010) and identified as a risk factor for worsened pain (Andersson et al., 1998; Oleske et al., 2004; Riley et al., 2004; Scott et al., 1999). Conversely, more severe pain experience has been related to the maintenance of combustible cigarette use (Deyo & Bass, 1989), and cigarette smokers who experience pain symptoms or clinical pain disorders showcase more severe tobacco dependence (Fertig et al., 1986).

The degree to which pain-combustible cigarette use relations generalize to e-cigarette users remains largely uninvestigated. One recent study found that, among a large sample of adolescents, e-cigarette use was associated with greater risk of tooth damage and a greater probability of tongue or cheek pain compared to non-users (Cho, 2017). Despite emerging evidence to suggest e-cigarette use may relate to physical pain symptoms, to our knowledge, no previous study has explored pain experience in relation to e-cigarette use or beliefs about use. Drawing from the combustible tobacco-pain literature (Ditre et al., 2011), and evidence that e-cigarette use is related to bone or tissue damage (Cho, 2017; Hwang et al., 2016), inflammation (Ji et al., 2016), and exposes users to an array of toxins that may harm the body and contribute to pain (Meo & Al Asiri,

2014), there is reason to explore whether e-cigarette-pain relations operate similarly to combustible cigarette-pain relations. Thus, initial work is warranted to evaluate whether current severity of pain experience is related to e-cigarette dependence or beliefs about e-cigarette use. Understanding these relations from a dynamic perspective has the potential to inform evolving theoretical models of e-cigarette use and potential treatment options.

The present study sought to explore current pain intensity among adult e-cigarette users in relation to several clinically-relevant variables, including e-cigarette dependence, perceived risks of e-cigarette use, and perceived barriers to quitting e-cigarettes. It was hypothesized that greater pain intensity would be associated with greater e-cigarette dependence, perceived risks of e-cigarette use, and perceived barriers to quitting e-cigarettes. These hypotheses were informed by research documenting complex interrelations between pain experience and combustible tobacco cigarette dependence and its clinical correlates (Ditre et al., 2011; Parkerson et al., 2013).

Methods

Participants

The present study included 322 e-cigarette users (60.2% female, $M_{age} = 36.78$ years, $SD = 10.62$). Participants were recruited via an online survey, panel program. Study eligibility criteria included being 18–65 years old, e-cigarette use within the past 30 days, reporting pain on at least one area of the body, and being able to provide informed consent. Exclusion criteria included being younger than 18 years, older than 65 years, being a non-English speaker (to ensure comprehension of the study questions), and inability to give informed and voluntary consent to participate.

The present sample consisted of predominately White/Caucasian (78.0%) individuals, followed by 14.3% Black/African American, 3.7% Asian, 1.9% Native American/Alaska Native, and 2.2% other. Regarding education, 26.1% of the participants received a high school diploma or equivalent, 24.5% completed some college, 13.4% earned an associate degree, 16.8% earned a bachelor’s degree, 2.2% completed at least some graduate school, and 4.3% did not graduate high school or earn an equivalent diploma. More than half of the sample indicated they were married or living with someone (62.7%). The median income bracket fell within the range of \$35,000 to \$49,999.

Most participants reported daily e-cigarette use (60.9%), and on average, participants reported using an e-cigarette 7.8 ($SD = 10.1$) times per day. A low level of e-cigarette dependence was observed in the present sample ($M = 7.0$,

$SD = 4.0$; Foulds et al., 2014). Additionally, more than three-fourths of the participants (76.0%) reported concurrent tobacco cigarette use. Among those who reported concurrent cigarette use, participants reported smoking an average of 12.4 ($SD = 8.4$) cigarettes per day, being 16.0 ($SD = 4.6$) years old when they started smoking cigarettes daily, and being a daily cigarettes smoker for an average of 17.2 ($SD = 11.0$) years. In terms of pain severity, 1.5% of participants endorsed no pain, 19.9% reported mild pain, 48.1% reported moderate pain, and 30.6% indicated severe pain.

Measures

Demographics Questionnaire

Participants reported sex (0 = Male, 1 = Female), race, marital status (1 = Married or Living with someone, 2 = Widowed, 3 = Separated, 4 = Divorced/Annulled, 5 = Never Married), age, educational level (1 = Grade 6 or less to 8 = Graduate or professional degree), and annual income (1 = \$0–\$4999 to 8 = \$75,000 or higher).

Electronic Cigarette Smoking History Questionnaire

The Electronic Cigarette Smoking History Questionnaire (EC-SHQ) is a 28-item self-report measure that assess e-cigarette use history (Zvolensky et al., 2018). This questionnaire includes items pertaining to frequency of use (e.g., Think about your e-cig use during the last month, how many days did you use an e-cig?), age at onset, concurrent tobacco use (e.g., Do you currently use cigarettes? [1 = Yes, 2 = No]), and number of e-cigarette quit attempts. The EC-SHQ has been successfully used in previous e-cigarette studies (Zvolensky et al., 2018).

SF-12 Health Survey

The SF-12 Health Survey is a 12 item self-report questionnaire used to assess an individual's view of their personal health (Ware Jr et al., 1996). The current study utilized the first question of this questionnaire (e.g., in general, would you say your health is: [1 = excellent to 5 = poor]).

Hunter Integrated Pain Service-Brief Pain Inventory

The Brief Pain Inventory (BPI) is used to evaluate an individual's self-reported pain severity and pain-related interference with daily functioning (Cleeland & Ryan, 1994). Respondents indicate areas of their body where they experience pain, and rate the severity of their pain from 0

(No Pain) to 10 (Pain as bad as you can imagine). Participants then rate the level of pain-related interference on a scale from 0 (Does not interfere) to 10 (Completely interferes). The Brief Pain Inventory has demonstrated strong reliability, and construct validity in previous studies (Poquet & Lin, 2016). Within the current study, current level of pain severity was utilized as a predictor variable and demonstrated good consistency ($\alpha = .74$).

Penn State Electronic Cigarette Dependence Index

The Penn State Electronic Cigarette Dependence Index is a 10-item self-report questionnaire used to assess e-cigarette dependence (Foulds et al., 2014). Participants are asked to provide information on the strength of urges to use (e.g., Do you ever have strong cravings to smoke?), waking and night use (e.g., Do you sometimes awaken at night to have a e-cigarette?), number of times that an individual uses an e-cigarette (e.g., How many times a day to you usually smoke?), difficulty quitting (e.g., Did you feel more irritable because you couldn't smoke?), and experience of craving and withdrawal symptoms (e.g., Is it hard to keep from smoking?) are measured. Previous work supports the total score as a valid and reliable index of e-cigarette dependence (Foulds et al., 2014).

Risks and Benefits of E-Cigarettes Questionnaire

The Risks and Benefits of E-Cigarettes Questionnaire is a 30-item self-report measure that assess perceived risks (e.g., E-cigarettes contain toxic chemicals) and benefits (e.g., E-cigarettes are safe) of e-cigarettes use (Copeland et al., 2017). Each item is assessed on a Likert-type scale ranging from 1 (Totally Disagree) to 7 (Totally Agree). The questionnaire contains 2 subscales: risks (16 items) and benefits (14 items). The RABE has demonstrated sound psychometric properties and reliability (Copeland et al., 2017). The Risks subscale was utilized in the present study and demonstrated excellent internal consistency (Risks: $\alpha = 0.92$).

E-Cigarette Barriers of Cessation Scale

The E-Cigarette Barriers of Cessation Scale (E-BCS) is a 19-item questionnaire that was modified from the original Barriers of Cessation Scale (BCS; Garey et al., 2017; Macnee & Talsma, 1995). The E-BCS assesses perceived barriers to or stressors resulting from using electronic cigarettes (e.g. No encouragement or help from friends). Responses are scored on a 4-point Likert scale with items ranging from a 0 (Not a barrier) to 3 (a large barrier). The

E-BCS total score was used for the present study and demonstrated excellent internal consistency ($\alpha = 0.96$).

Procedure

Participants were recruited nationally via Qualtrics Inc. Interested participants were screened for eligibility and directed to the online, anonymous survey. Prior to completing the survey, participants provided informed consent. The survey took approximately 30 min to complete, and participants were compensated with credit through their Qualtrics account commensurate to their participation. Although each participant was given the option to choose their preferred form of compensation, the total amount for completing the survey remained the same (\$8.50). The study protocol was approved by the Institutional Review Board at the institution supporting this research.

Analytic strategy

Analyses were conducted using SPSS version 25. First, sample descriptive statistics and bivariate correlations among study variables were examined. Second, to evaluate the effect of pain severity after controlling for covariates, three separate hierarchical regression analyses were conducted for dependent variables: e-cigarette dependence, perceived risks of e-cigarette use, and perceived barriers to quitting e-cigarettes. Covariates were entered in the first step of each model and included sex, age, education, income, dual cigarette use, frequency of e-cigarette use, and perceived health status. Covariates were selected based on prior research (Dawkins & Corcoran, 2014; Zvolensky et al., 2018). Current level of severity was entered on the second step of each model.

Results

Descriptive statistics

Descriptive statistics and bivariate correlations are presented in Tables 1 and 2, respectively. Pain severity correlated significantly and positively with all three criterion variables (r 's range = .14 to .34; p 's range = .01 to < .001). All dependent variables significantly correlated (r 's range = .27 to .54; all p 's < .001).

Primary analyses

For e-cigarette dependence, covariates entered in the first step accounted for significant variance ($F[7, 314] = 8.22$, $p < .001$, $R^2 = .14$). Dual cigarette use, e-cigarette use frequency, and perceived health status emerged as signifi-

cant predictors. Step two accounted for significantly more variance in cigarette dependence ($\Delta R^2 = .06$, $p < .001$). Pain severity significantly predicted e-cigarette dependence after controlling for covariates. See Table 3.

Regarding perceived risks of e-cigarette use, covariates entered in the first step accounted for significant variance ($F[7, 314] = 3.52$, $p = .001$, $R^2 = .05$). Age was the only significant covariate. Step two accounted for significantly more variance in the outcome ($\Delta R^2 = .02$, $p = .01$). Pain severity significantly predicted perceived risks of e-cigarette use after controlling for covariates (Table 3).

Model inspection for perceived barriers to quitting e-cigarettes indicated that the covariates entered in the first step accounted for significant variance ($F[7, 314] = 6.33$, $p < .001$, $R^2 = .10$). Age, education, dual cigarette use, and e-cigarette use frequency emerged as significant predictors. Step two accounted for significantly more variance in perceived barriers to quitting e-cigarettes ($\Delta R^2 = .10$, $p < .001$). Pain severity significantly predicted the dependent variable after controlling for covariates (Table 3).

Discussion

There is a long history of pain experience being centrally related to combustible cigarette use and dependence (Ditre et al., 2011). However, there is highly limited data on the potential relevance of pain experience in terms of e-cigarette use and processes. The purpose of the present investigation was therefore to examine current pain severity in relation to e-cigarette dependence, perceived risks of e-cigarette use, and perceived barriers to quitting e-cigarettes.

Consistent with prediction, current pain severity was significantly related to e-cigarette dependence, perceived risks of e-cigarette use, and perceived barriers to quitting e-cigarettes.

The size of observed effects were small to moderate, ranging from 2 to 10% of variance; however, effects were observed above and beyond the variance accounted for by sex, age, education, income, dual cigarette use, frequency of e-cigarette use, and perceived health status. These novel data provide preliminary evidence that individual differences in the severity of experienced pain is related to a range of clinically-significant e-cigarette variables, among a large sample of current, adult e-cigarette users. These findings are broadly consistent with pain-combustible cigarette models that emphasize the role of pain experience as a core explanatory construct in negative reinforcement processes related to cigarette use (Ditre et al., 2011). Based on the present data, it can be inferred that purported pain-combustible cigarette models may be applicable to developing empirical and theoretical models of e-cigarette use.

Table 1 Descriptive statistics

	Mean/n	SD/%
<i>Demographic variables</i>		
Sex (Female)	194	60.20%
Age	36.78	10.62
Race		
White/Caucasian	251	78.00%
Black/African American	46	14.30%
Asian	12	3.70%
Native American/Alaska Native	6	1.90%
Other	7	2.20%
Education	4.67	1.73
Income	5.66	2.05
<i>Other variables</i>		
Dual Cigarette Use (% Dual User)	244	75.80%
E-cig Use Frequency	16.86	10.13
Perceived Health Status	2.90	1.06
Pain Severity	5.14	2.23
PSECDI	7.01	4.02
Perceived Risks	4.96	1.08
Perceived Barriers to Quitting	20.33	15.06

N = 322

E-cig use frequency: Electronic Cigarette Smoking History Questionnaire (Zvolensky et al., 2018); PSECDI: Penn State Electronic Cigarette Dependence Index (Foulds et al., 2014)

Table 2 Correlations among variables

	1	2	3	4	5	6	7	8	9	10	11
1. Sex (% female)	–										
2. Age	– .01	–									
3. Education	– .21***	– .12*	–								
4. Income	– .19**	– .08	.54***	–							
5. Dual Cigarette Use (% Dual User)	– .07	.02	– .02	– .04	–						
6. E-cig Use Frequency	– .02	.09	.01	.06	– .04	–					
7. Perceived Health Status	.26***	.23***	– .36***	– .28***	– .03	.10	–				
8. Pain Severity	– .05	.07	– .04	– .09	.19**	– .05	.17**	–			
9. PSECDI	– .03	.001	.16**	.17**	.16**	.28***	– .15**	.22***	–		
10. Perceived Risks	– .05	.20***	.08	.08	.09	.08	– .07	.14*	.27***	–	
11. Perceived Barriers to Quitting	– .09	– .12*	.18**	.09	.24***	.12*	– .11*	.34***	.54***	.33***	–

N = 322

Sex: 0 = Male, 1 = Female; Educational Level: 1 = Grade 6 or less to 8 = Graduate or professional degree; Annual Income: 1 = \$0–\$4999 to 8 = \$75,000 or higher; Dual Cigarette: 0 = E-cig use only, 1 = Dual use (combustible cigarettes and e-cigarettes); E-cig Use Frequency: Electronic Cigarette Smoking History Questionnaire (Zvolensky et al., 2018); Perceived Health Status: 1 = Excellent to 5 = Poor (Ware Jr et al., 1996); Pain Severity: Hunter Integrated Pain Service-Brief Pain Inventory (Cleeland & Ryan, 1994); PSECDI: Penn State Electronic Cigarette Dependence Index (Foulds et al., 2014); Perceived Risks: Risks and Benefits Questionnaire (Copeland et al., 2017); Perceived Barriers to Quitting: E-Cigarette Barriers of Cessation Scale Total: modified from Barriers of Cessation Scale (Macnee & Talsma, 1995)

***p <.001; ** p <.01; *p <.05

Indeed, to our knowledge, this is the first study provide evidence that pain may be pertinent to e-cigarette use and beliefs. Additional work is needed to replicate the present

findings on an independent sample of current, adult e-ci-garette users.

Table 3 Regression coefficients

	<i>b</i>	<i>SE</i>	<i>t</i>	<i>p</i>	<i>sr</i> ²	<i>R</i> ² change
<i>Model 1: E-cigarette Dependence</i>						
Step 1						.16***
Sex	.48	.45	1.07	.29	.003	
Age	.01	.02	.37	.71	.0004	
Education	.17	.15	1.14	.26	.003	
Income	.18	.12	1.49	.14	.01	
Dual Cigarette Use	1.61	.49	3.30	.001	.03	
E-cig Frequency	.12	.02	5.56	< .001	.08	
Perceived Health Status	− .53	.22	− 2.38	.02	.02	
Step 2						.06***
Pain Severity	.47	.09	4.93	< .001	.06	
<i>Model 2: Perceived Risks of E-cigarette Use</i>						
Step 1						.07**
Sex	.02	.13	.12	.90	< .0001	
Age	.02	.01	3.96	< .001	.05	
Education	.04	.04	.88	.38	.002	
Income	.02	.03	.60	.55	.001	
Dual Cigarette Use	.23	.14	1.65	.10	.01	
E-cig Frequency	.01	.01	1.32	.19	.01	
Perceived Health Status	− .10	.06	− 1.53	.13	.01	
Step 2						.02**
Pain Severity	.07	.03	2.57	.01	.02	
<i>Model 3: Perceived Barriers to Quitting E-cigarettes</i>						
Step 1						.12***
Sex	− .95	1.71	− .56	.58	.001	
Age	− .16	.08	− 2.03	.04	.01	
Education	1.47	.57	2.59	.01	.02	
Income	− .21	.47	− .45	.65	.001	
Dual Cigarette Use	8.68	1.86	4.66	< .001	.06	
E-cig Frequency	.21	.08	2.60	.01	.02	
Perceived Health Status	− .44	.85	− .51	.61	.001	
Step 2						.10***
Pain severity	2.28	.35	6.51	< .001	.10	

N = 322

E-cigarette Dependence: Penn State Electronic Cigarette Dependence Index (PSECDI; Foulds et al., 2014); Pain Severity: Hunter Integrated Pain Service-Brief Pain Inventory (Cleeland & Ryan, 1994); Perceived Risks: Risks and Benefits Questionnaire (Copeland et al., 2017); Perceived Barriers to Quitting: E-Cigarette Barriers of Cessation Scale Total: modified from Barriers of Cessation Scale (Macnee & Talsma, 1995)

****p* < .001; ***p* < .01; **p* < .05

Although not primary study aims, some additional observations warrant brief comment. First, at the bivariate level, age was negatively associated with perceived barriers for quitting e-cigarettes and positively related to perceived risk of using e-cigarettes. These data highlight age as an explanatory factor for e-cigarette beliefs, an issue that is increasingly important given the large number of younger persons initiating e-cigarette use (Gilreath et al., 2016). Future research could usefully explore the relevance of age as a moderator of pain-e-cigarette use relations using

alternative research designs to better elucidate how these factors may interplay with one another. Second, for e-cigarette dependence, it is noteworthy that dual cigarette use and perceived health status were each significant predictors. These data add to a growing literature that suggests e-cigarette use is highly associated with combustible cigarette use (Barrington-Trimis et al., 2016; Huh & Leventhal, 2016) and provides novel evidence that pain and perceived health may play an important role in the maintenance of e-cigarette dependence. Future research should

seek to develop integrated models of e-cigarette use that consider a wider range of factors, including concurrent substance use and psychological variables related to this addictive behavior (LaRowe et al., 2018). It is important to consider that the majority of participants within the current sample endorsed moderate (48.1%) and severe (30.6%) levels of pain. Thus, future research may seek to evaluate relations between pain severity and e-cigarette use behavior over time.

Clinically, these findings suggest that pain experience may contribute to several e-cigarette-related behaviors and use processes. For example, e-cigarette use may be negatively reinforced via acute pain-reducing effects of nicotine (Ditre et al., 2016) and alleviation of nicotine deprivation-induced exacerbation of pain (Ditre et al., 2018), which in turn may strengthen e-cigarette and nicotine-related expectancies/perceptions (Ditre et al., 2017). Indeed, e-cigarette users who increasingly rely on nicotine to cope with pain may come to perceive greater barriers to quitting e-cigarettes, and ultimately be less likely to quit and more likely to experience deleterious pain outcomes. There may also be utility in using pain reduction methods (e.g., graded pain exposure, acceptance-based approaches) to address the clinical needs of e-cigarette users (Dahl et al., 2004; Kabat-Zinn, 1982) with co-occurring pain. For instance, cognitive-behavioral and pharmacological tactics for pain management (Eccleston et al., 2009; Vlaeyen & Morley, 2005) could help mitigate the impact of pain on e-cigarette use and beliefs.

Limitations to the present study should be noted. First, results were based upon a cross-sectional study design and therefore do not address causal relations. Future study is needed to better understand the current observed relations, especially laboratory and longitudinal designs. Second, the sample was comprised of primarily White/Caucasian adult e-cigarette users. Additional work is needed to evaluate the proposed relations across a more ethnically diverse sample and among adolescent e-cigarette users. Third, as the study was conducted via an online platform, it may not generalize to e-cigarette users that do not have internet access. Future research could therefore benefit by using complimentary sampling tactics to better gauge the relative generalizability of these findings. Finally, although the sample reported experiencing current moderate and severe pain, they were not recruited as a clinical pain sample. Therefore, future research should replicate and extend these findings to e-cigarette users who present with clinical pain disorders.

Overall, there is highly limited empirical knowledge regarding pain experience among e-cigarette users. The present findings indicate that pain severity may play a role in terms of e-cigarette dependence, risks, and perceived barriers for quitting e-cigarettes. Based on these data, future work is needed to better understand the nature of

relations between pain experience and e-cigarette use (e.g., expectancies, coping motives).

Funding This study was not supported by any grant funding.

Compliance with ethical standards

Conflict of interest Michael J. Zvolensky, Lorra Garey, Nubia A. Mayorga, Andrew H. Rogers, Michael F. Orr, Joseph W. Ditre, and Natalia Peraza declare that they have no conflict of interest.

Human and animal rights and Informed consent All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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