ISSN: 0893-164X

2023, Vol. 37, No. 7, 829-840 https://doi.org/10.1037/adb0000940

# Randomized Trial of Mindfulness- and Reappraisal-Based Regulation of Craving Training Among Daily Cigarette Smokers

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**Objective:** Craving predicts smoking, yet existing interventions may not adequately target regulation of craving. We evaluated two versions of regulation of craving-training (ROC-T), a computerized intervention with intensive practice of strategies when exposed to smoking-related images. Method: Ninety-two nicotine-dependent daily smokers were randomized to mindfulness-based therapy (MBT) ROC-T focusing on mindful acceptance, and cognitive behavioral therapy (CBT) ROC-T focusing on reappraisal or no intervention control. The ROC task was administered pre- and postintervention to assess changes in cueinduced craving and mindfulness- and reappraisal-based regulation of craving. Results: MBT and CBTversus control-showed significantly greater reductions in smoking during the intervention phase (baseline to Week 4), corresponding to large (d = -1.08, 95% CI [-1.64, -0.52]) and medium-to-large effect sizes (d = -0.69, 95% CI [-1.22, -0.15]), respectively. During follow-up (Week 4–16), CBT showed significant increases in smoking, whereas MBT and control did not. For the entire study (baseline to Week 16), MBT showed significantly greater reductions in smoking compared to control (d = -1.6, 95% CI [-2.56, -0.66]) but CBT was not significantly different than control (d = -0.82, 95% CI [-1.77, 0.13]). There were no effects on smoking when directly comparing MBT and CBT. Quit rates were low across the sample, with no difference among conditions. MBT and CBT-versus control-significantly reduced cue-induced craving. CBT (but not MBT)-versus control-significantly improved reappraisal-based regulation of craving. Both MBT and CBT-versus control-significantly improved mindfulness-based regulation of craving. Conclusions: MBT- and CBT-ROC-T may reduce cue-induced craving and smoking, and MBT may be more durable than CBT.

#### Public Health Significance Statement

Innovative behavioral interventions for cigarette smoking are needed to reduce relapse rates. We evaluated brief, computerized, mechanism-focused interventions targeting craving, a core mechanism underlying smoking. Findings are promising and suggest that such interventions may play an important role in improving smoking reduction treatment outcomes.

Keywords: cigarette smoking, randomized trial, regulation of craving, mindfulness, reappraisal

Supplemental materials: https://doi.org/10.1037/adb0000940.supp

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This research was supported by grants funded by the National Institutes of Health, to HK (P50DA009241, Project 3). Writing included support for CRR (K23AT011342-03), and support for NRH (T32 DA022975). The authors declare no known conflicts of interest to disclose.

This study's design and outcomes were preregistered with https:// ClinicalTrials.gov at https://clinicaltrials.gov/ct2/show/NCT02153749? term=kober&draw=2&rank=5. Data reported in this article are publicly available at https://osf.io/vjfqw/. Corey R. Roos played a lead role in formal analysis, visualization, writingoriginal draft, and writing-review and editing and a supporting role in software, supervision, and validation. Nicholas R. Harp played a supporting role in formal analysis, validation, visualization, writing-original draft, and writing-review and editing. Nilofar Vafaie played a lead role in data curation, investigation, and software and a supporting role in project administration, and writing-review and editing. Ralitza Gueorguieva played a supporting role in conceptualization, formal analysis, investigation, methodology, and writingreview and editing. Tami Frankforter played a lead role in data curation and a supporting role in methodology, project administration, resources, and writing-review and editing. Kathleen M. Carroll played a lead role in funding acquisition and a supporting role in conceptualization, and

Kathleen M. Carroll is deceased.

Substance use disorders (SUDs) are the most costly and prevalent psychiatric disorders (National Institute of Mental Health [NIMH], 2007; Substance Abuse and Mental Health Services Administration, 2015). In particular, smoking is the leading preventable cause of disease (e.g., cardiovascular, pulmonary disease) and death in the United States (Center for Disease Control and Prevention [CDC], 2022) and costs an estimated \$600 billion in health care and lost productivity (CDC, 2022). Hence, reducing smoking is of crucial importance. Despite advances in strategies for treating nicotine use disorder, including pharmacological (Rigotti et al., 2022) and behavioral therapies (Lindson-Hawley et al., 2015), there remain high rates of relapse (Piasecki, 2006). Innovative interventions are needed, particularly those targeting core mechanisms underlying smoking and relapse.

One mechanism contributing to the high rates of smoking relapse is smoking craving, defined as the strong desire for cigarettes. Indeed, meta-analytic evidence shows that craving—including cue-induced craving—strongly predicts subsequent relapse to smoking (Vafaie & Kober, 2022). The importance of craving led to its addition as a diagnostic criterion for SUDs in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (American Psychiatric Association, 2013). As such, there is a need for interventions that directly target regulation of craving, including craving in response to cues (i.e., people smoking, lighter, etc.).

Empirical evidence supports the notion that craving can be regulated via cognitive strategies (Roos et al., 2020). Cognitive reappraisal of craving involves thinking about the negative consequences of smoking (i.e., bad breath, spending money, risk of cancer, etc.). Training in cognitive reappraisal is a hallmark of multicomponent cognitive behavioral therapy (CBT), which demonstrates modest efficacy for nicotine use disorder (Carroll, 1998; Kober, 2014). In laboratory settings, the use of cognitive reappraisal decreases momentary self-reported cravings to smoking cues (Kober, Kross, et al., 2010; Kober, Mende-Siedlecki, et al., 2010). Our team's pilot study on regulation of craving-training (ROC-T; described in more detail below), which involves targeted training in cognitive reappraisal for craving, resulted in decreases in cue-elicited craving and smoking over time (Lopez et al., 2022). Moreover, studies suggest that cognitive reappraisal leads to reduced neural activity in craving-related regions (Kober, Mende-Siedlecki, et al., 2010). Further, the neural mechanism underlying effectiveness of cognitive reappraisal for downregulating craving and craving-related neural activity may depend on recruitment of the prefrontal cortex and thus an effortful "top-down" cognitive control mechanism (Buhle et al., 2014; Kober, Mende-Siedlecki, et al., 2010).

Another strategy for regulating craving is mindful acceptance, defined as present-moment awareness coupled with acceptance of one's experience as it is (Bishop et al., 2004). Mindful acceptance of craving involves noticing and accepting craving as it is and letting it be (sometimes referred to as "surfing" or "riding out" the craving; Marlatt & Gordon, 1985). Training in mindful acceptance of craving is a core component of mindfulness-based therapies (MBT) for smoking, which demonstrate modest efficacy (Brewer et al., 2011; Goldberg et al., 2018). In laboratory settings (Westbrook et al., 2013), mindful acceptance reduced momentary self-reported cravings to smoking cues, and the neural mechanism underlying this effect appeared to be reduced activity in craving-related regions in the absence of recruitment of the prefrontal cortex—and thus a "bottom-up" mechanism of reduced reactivity (Kober et al., 2017; Westbrook et al., 2013).

Altogether, both cognitive reappraisal and mindful acceptance may be promising strategies-which may work via distinct mechanisms-for regulating smoking craving, a central factor driving smoking relapse. Although existing behavioral therapies for nicotine use disorder include some training in these strategies, there may be some limitations to these therapies. First, CBT and MBT typically are multicomponent interventions in which training in regulation of smoking craving is just one component. Therefore, the dose of training in regulation of craving may not be adequate. Second, the nature of training in regulation of craving in CBT and MBT may be limited. For example, CBT and MBT therapy sessions often rely on rehearsal of a strategy during an imagined situation (i.e., role-play or imaginal exposure), which does not involve direct presentation of external cues (i.e., images of people smoking) known to elicit strong momentary craving. Thus, individuals may not receive adequate practice during therapy sessions in using regulatory strategies when experiencing strong craving following presentation of a conditioned cue. Given these limitations in existing behavioral therapies for nicotine use disorder, our team developed ROC-T, a computerized intervention that involves intensive, repeated practice of strategies to regulate craving during exposure to a series of images of smoking cues (i.e., other people smoking, a lit cigarette). We developed two versions of ROC-T, one that focuses on using cognitive reappraisal (the CBT version) to regulate craving and another that focuses on mindful acceptance (the MBT version). As noted above, preliminary data on CBT-ROC-T for reducing smoking is promising (Lopez et al., 2022). However, we have not yet tested MBT-ROC-T for reducing smoking. Ultimately, there has not yet been a full-scale randomized controlled trial testing the efficacy of the CBT and MBT versions of ROC-T in reducing craving and smoking.

Accordingly, the aim of the present study was to compare the efficacy of the CBT– and MBT–ROC-T interventions, relative to an inactive control condition (CTL), in the context of a randomized controlled trial among individuals who were nicotine-dependent daily smokers. We hypothesized: (a) compared to control, both CBT and MBT would reduce frequency of smoking per day from baseline through the end of the intervention phase (i.e., 4 weeks postrandomization), as well as through the follow-up phase (i.e., 16 weeks postrandomization); (b) compared to control, both CBT and MBT would reduce cue-induced craving (pre- to postintervention); (c) compared to control and MBT, CBT would improve

II The data are available at https://osf.io/vjfqw/.

supervision. Hedy Kober played a lead role in conceptualization, funding acquisition, investigation, methodology, project administration, resources, software, supervision, validation, visualization, and writing–review and editing, and a supporting role in data curation, formal analysis, and writing–original draft.

The preregistered design is available at https://clinicaltrials.gov/ct2/ show/NCT02153749?term=kober&draw=2&rank=5.

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reappraisal-based regulation of craving (pre- to postintervention); and (d) compared to control and CBT, MBT would improve mindfulness-based regulation of craving.

## Method

#### **Participants**

Participants were recruited from the New Haven area in Connecticut between 2014 and 2019. Inclusion criteria: (a) ages of 18-60, (b) smoking  $\geq 10$  cigarettes/day, (c) score  $\geq 4$  on the Fagerström test for nicotine dependence (FTND; Heatherton et al., 1991), (d) motivated to quit or reduce smoking (>6 on a 10-point scale), (e) fluent in English, (f) can commit to the study protocol, and (g) willing to be randomized. Exclusion criteria: (a) current severe psychiatric disorder or SUD, other than nicotine, (b) use of psychoactive medications that have not been at a stable dose for 6 months or that affect blood flow or use of smoking cessation medications (e.g., varenicline), (c) current serious medical condition, (d) current use of an investigational drug, (e) conditions contraindicated for magnetic resonance imaging (e.g., claustrophobia, ferromagnetic metal in the body), and (f) pregnancy. This study received approval from the Yale School of Medicine institutional review board. All participants provided informed consent. Figure 1 presents the Consolidated Standards of Reporting Trials diagram with details on study recruitment, randomization, and participant flow.

## Procedure

This randomized controlled trial (https://ClinicalTrials.gov Identifier NCT02153749) included a 4-week intervention phase and 12-week follow-up phase. Assessments were at baseline (preintervention), 1-2 times per week during the intervention phase (for six assessment visits total in this phase), at postintervention, and 1- and 3-month follow-ups. Participants were randomized to a treatment condition at the beginning of the first weekly assessment in the intervention phase. Individuals randomized to CBT or MBT proceeded to complete the first training session. For participants in the CTL, they did not receive any training and only completed study assessments at each of the weekly assessment visits during the intervention period. All study visits were in person. Participants were compensated for completing study activities in the present study and could earn up to \$785. Specifically, participants were paid \$25/hr for functional magnetic resonance imaging (fMRI) sessions and \$20/hr for all other study sessions.

#### Interventions

The CBT–ROC-T and MBT–ROC-T interventions both included six computerized training sessions, each about 60 min and including three parts (described further below). The computerized training sessions included written text, question prompts, and images but did not include any videos. The strategies were taught to participants primarily through text-based instruction, question prompts, and brief rehearsal of the strategies while viewing smoking-related images before engaging in formal intensive strategy practice (Part 2 described below). Participants came to the lab and completed all ROC-T sessions on a study laptop. A research assistant was available to answer questions, while participants completed the computerized sessions on the laptop. Of note, neither CBT nor MBT instructed participants to set a quit date.

## **CBT-Based ROC-T**

Part 1 (Learn the Strategy and Initial Practice). Participants were trained in cognitive reappraisal or thinking about the negative consequences associated with smoking. Question prompts had participants identify and type a list of their own personally relevant negative consequences from smoking, including consequences they have experienced or are worried they could experience in the future. Participants were instructed to think of these personally relevant negative consequences during the training. Then, participants engaged in initial practice of the strategy while viewing a brief set of smoking-related images. Part 2 (Intensive Strategy Practice). Participants engaged in intensive practice of reappraisal while viewing smoking-related images. For each training session, there were 135 trials total and each image appeared for 6 s. When the instruction "NEGATIVE" appeared on screen before the smoking cue (75% of the trials), they practiced reappraisal, whereas when "LOOK" appeared (25% of the trials), they simply looked at the image. After each image disappeared, participants rated their craving from 1 = not at all to 5 = very much. A total of 75 of the same images were shown across each of the six training sessions. However, at each training session, participants saw 30 novel images, which were presented twice each within a given training session. Part 3 (Implementation Plan). Participants identified 10 situations in which they usually smoked or in which they thought they might smoke in the coming days and created a plan for using reappraisal during these situations (Osch et al., 2010).

## **MBT-Based ROC-T**

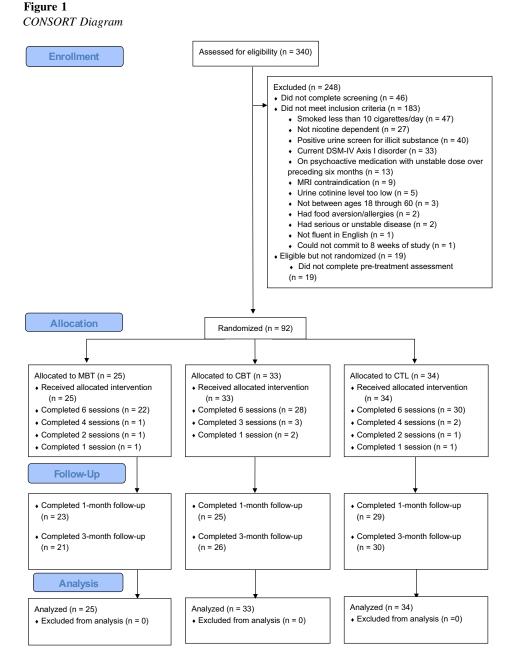
The procedures were the same as CBT except for the strategy being trained. In Part 1 (Learn the Strategy and Initial Practice), participants were trained in mindful acceptance, which was described as "noticing craving and accepting the feeling without judgment or reaction." Additionally, question prompts in the web program had participants identify and generate their own descriptions of acceptance-based responses to craving (e.g., "I can just sit here and notice this. I can ask myself: Can I be ok with this feeling?"). Participants were subsequently instructed to practice those acceptance-based responses when they saw the instruction "ACCEPT" during the practice of strategies with cue exposure.

# CTL

This condition did not receive any intervention and only completed assessments during the study, which included the six assessments during the intervention phase.

#### Measures

Cigarette smoking was assessed at every study visit with the calendar-based time line follow-back method (Sobell & Sobell, 1992). At every study visit, expired carbon monoxide (CO) was assessed. Abstinence from smoking was confirmed with an expired CO cutoff of <10 ppm (Benowitz et al., 2002). This CO cutoff was not prespecified in the clinical trials preregistration.



*Note.* CONSORT = Consolidated Standards of Reporting Trials; DSM-IV = Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition; MRI = magnetic resonance imaging; MBT = mindfulness-based therapy; <math>CBT = cognitive behavioral therapy; CTL = control condition. See the online article for the color version of this figure.

At baseline and postintervention, cue-induced craving, mindfulnessbased regulation of craving, and reappraisal-based regulation of craving were assessed with the ROC task, a validated lab-based assessment tool designed to assess craving and its regulation (Kober, Kross, et al., 2010; Kober & Mell, 2015; Kober, Mende-Siedlecki, et al., 2010). For clarity, the ROC task was similar, yet distinct from the ROC-T training interventions described above. The ROC task was similar to other lab-based assessments measuring emotion and its regulation (Buhle et al., 2014; Kober et al., 2019). Although the ROC task (described further below) included instruction on using strategies to regulate craving, it was presented to participants as an assessment not an intervention. The ROC task was distinct from the ROC-T intervention in that the ROC task provided briefer initial instruction in using both mindfulness and reappraisal as strategies, whereas ROC-T provided more detailed instruction in using a single strategy (mindfulness or reappraisal). Further, the ROC task did not involve some intervention components of ROC-T described above, such as the generation of plans to apply

the strategies in personally relevant smoking-related situations (in Part 3). In this study, the ROC task was administered via computer using the E-Prime software program. For the ROC task, participants first received brief instruction in both the strategies of reappraisal and mindfulness to regulate smoking craving, which were in the form of written descriptions on the E-Prime program. Research assistants were available to answer any questions from the participant. Then, participants completed a series of trials, each with a unique smoking-related image, and each image preceded by a one-word instruction to either use mindfulness (one third of trials), use reappraisal (one third of trials), or just look at the image (one third of trials). After each image was presented, participants rated their smoking craving from 1 = not at all to 5 = very much. Mean craving scores on mindfulness trials measure mindfulness-based regulation of craving, and mean craving scores on reappraisal trials measure reappraisal-based regulation of craving (with lower scores indicating greater regulation of craving). Mean craving scores on nonregulation trials measure cue-induced craving. Of note, in the current trial, the ROC task was administered, while participants were being scanned with fMRI. In this article, we focus on behavioral findings from the ROC task and not imaging findings.

At baseline, nicotine dependence was assessed with the FTND (Heatherton et al., 1991), and psychiatric diagnoses were assessed with the Mini-International Neuropsychiatric Interview (Sheehan et al., 1998). At baseline, depression was measured using Beck's Depression Inventory–Short Form (Beck & Beck, 1972), which showed good internal consistency ( $\alpha = .85$ ). At baseline, trait anxiety was measured using the State–Trait Anxiety Inventory (Spielberger et al., 1983), which also showed good internal consistency ( $\alpha = .88$ ).

## Statistical Analyses

A priori power analysis indicated that a sample size of at least 92 would provide 80% power to detect a medium (d = .60) betweencondition effect size for changes in the primary outcome of cigarettes smoked per day from baseline through postintervention. We used SPSS Version 28 for descriptive analyses, and Mplus Version 8.5 (Muthén & Muthén, 1998/2017) for all inferential analyses. To test the effect of treatment condition on change over time (by week) in average cigarettes smoked per day, we conducted piecewise multilevel regression models (Raudenbush & Bryk, 2002) with time (Level 1) nested within individual (Level 2) and with random intercepts and slopes. Piecewise models are ideal for estimating two separate slopes and are commonly used in clinical trials with intervention and follow-up phases (Segal et al., 2020). All analyses were conducted on the intent-to-treatment sample. For the piecewise model, the first piece captured change from baseline (Week 0) to Week 4 (i.e., the intervention phase), whereas the second piece captured change from Week 4 to 16 (i.e., the follow-up phase). Treatment condition was dummy-coded. We used the R software to generate plots that included confidence intervals for the model-estimated trajectories (Howard, 2021). Effect sizes for between-condition differences in changes in smoking over time were computed as Cohen's d using the Feingold approach (Feingold, 2009). To test the effect of treatment condition on changes in cue-induced craving, mindfulness-based regulation of craving, and reappraisal-based regulation of craving, we conducted regression analyses with postintervention scores as the dependent variables and treatment condition and preintervention scores as the predictors. For all regression models, we used all available data and estimated parameters with full information maximum likelihood with robust standard errors (MLR estimator in Mplus). As exploratory analyses, we conducted Fisher's exact tests to assess differences among treatments in 1-week point prevalence CO-confirmed abstinence (<10 ppm) at posttreatment and follow-ups. Data reported in this article are publicly available at https://osf.io/vjfqw/ (Roos et al., 2023).

#### Results

#### **Descriptive Statistics**

Demographic variables and clinical characteristics are reported in Table 1. Descriptive data for smoking over time are reported in Table 2. Mean (*SD*) of number of completed training sessions was 5.56 (1.29) for MBT and 5.42 (1.44) for CBT.

## Changes in Smoking Over Time in the Full Sample

As shown in Table 3, across the full sample, there were significant reductions in smoking during the intervention phase (Week 0–4; b = -1.23, SE = 0.15, p < .001) but no significant changes during the follow-up phase (Week 4–16; b = 0.01, SE = 0.05, p = .86).

#### **Treatment Effects on Changes in Smoking Over Time**

## Intervention Phase

As shown in Table 4, each treatment condition had significant reductions over time in cigarettes smoked per day during the intervention phase (MBT: -7.53, CBT: -5.67; CTL: -2.42). Importantly, we found significant effects (Table 3) for the Treatment (MBT vs. CTL)  $\times$  Time (Intervention Phase) interaction (b = -1.28, SE = 0.34, p < .001) and the Treatment (CBT vs. CTL) × Time (Intervention Phase) interaction (b = -0.81, SE = 0.32, p = .01). Individuals in MBT and CBT had significantly greater reductions in smoking than CTL during the intervention phase, which corresponded with large (MBT vs. CTL: d = -1.08, 95% CI [-1.55, -0.60]) and medium-to-large (CBT vs. CTL: d = -0.69, 95% CI [-1.14, -0.24]) between-condition effects (Table 4). We did not find a significant Treatment (MBT vs. CBT) × Time (Intervention Phase) interaction (b = -0.46, SE = 0.38, p = .23), indicating no significant difference in changes in smoking between MBT and CBT during the intervention phase.

Figure 2 provides a visual depiction of the piecewise multilevel models. The confidence intervals for MBT and CBT at Week 4 (the intervention termination point) do not overlap with the confidence interval of CTL, indicating that individuals in MBT and CBT, relative to CTL, smoked significantly less when focusing on the point estimate of smoking at the end-of-intervention time point.

#### Follow-Up Phase

As shown in Table 4, individuals in MBT showed no significant change (.50), CBT showed a significant increase (1.75), and CTL showed a significant decrease (-1.6) in cigarettes smoked per day during the follow-up phase. As shown in Table 3, we did not find a significant Treatment (MBT vs. CTL) × Time (Follow-Up Phase)

Participant Demographics and Clinical Characteristics

Measure	Full sample $(n = 92)$	MBT $(n = 25)$	CBT $(n = 33)$	CTL $(n = 34)$
Age, M (SD)	41.71 (11.55)	37.20 (12.19)	40.18 (11.59)	46.50 (9.39)
Gender, no. (%)				
Women	49 (53.26)	14 (56.00)	16 (48.48)	19 (55.88)
Men	43 (46.74)	11 (44.00)	17 (51.52)	15 (44.12)
Race, no. (%)				
African American	45 (48.91)	12 (48.00)	13 (39.39)	20 (58.82)
Asian	3 (3.26)	1 (4.00)	2 (6.06)	0 (0.00)
Multiracial	7 (7.61)	1 (4.00)	3 (9.09)	3 (8.82)
Native American	1 (1.09)	0 (0.00)	1 (3.03)	0 (0.00)
Pacific Islander	1 (1.09)	0 (0.00)	0 (0.00)	1 (2.94)
White	30 (32.61)	9 (36.00)	14 (42.42)	7 (20.59)
Other	2 (2.17)	0 (0.00)	0 (0.00)	2 (5.88)
Hispanic only	3 (3.26)	2 (8.00)	0 (0.00)	1 (2.94)
Ethnicity, no. (%)				
Hispanic/Latino	12 (13.04)	6 (24.00)	4 (12.12)	2 (5.88)
Not Hispanic/Latino	80 (86.96)	19 (76.00)	29 (87.88)	32 (94.12)
Education		· · · · ·		· · · · ·
Less than high school	8 (8.70)	2 (8.00)	4 (12.12)	2 (5.88)
High school or GED	37 (40.22)	11 (44.00)	11 (33.33)	15 (44.12)
Some college or associate degree	32 (34.78)	8 (32.00)	13 (39.39)	11 (32.35)
Bachelor's degree or higher	15 (16.30)	4 (16.00)	5 (15.15)	6 (17.65)
Employment		· · · · ·		· · · · ·
Working	38 (41.30)	7 (28.00)	16 (48.48)	15 (44.12)
Not working	54 (58.70)	18 (72.00)	17 (51.52)	19 (55.88)
Baseline cigarettes per day, $M$ (SD)	14.85 (4.53)	15.05 (5.27)	14.60 (4.38)	14.93 (4.20)
Baseline FTND total score, $M$ (SD)	6.26 (1.43)	6.32 (1.41)	6.33 (1.51)	6.15 (1.40)
Age of first daily cigarette use, $M(SD)$	18.18 (7.08)	18.76 (6.86)	16.61 (4.42)	19.29 (9.00)
Years of cigarette use, $M(SD)$	22.71 (12.13)	17.92 (11.31)	21.39 (12.94)	27.50 (10.38)
Depression, item-level $M(SD)$	0.21 (0.28)	0.30 (0.32)	0.20 (0.29)	0.15 (0.20)
Trait anxiety, item-level $M$ (SD)	1.71 (0.47)	1.89 (0.44)	1.65 (0.45)	1.63 (0.49)
Completed posttreatment assessment, no. (%)	81 (88.04%)	22 (88.00%)	27 (81.82%)	32 (94.12%)
Completed 1-month follow-up assessment, no. (%)	77 (83.70%)	23 (92.00%)	25 (75.76%)	29 (85.29%)
Completed 3-month follow-up assessment, no. (%)	77 (83.70%)	21 (84.00%)	26 (78.79%)	30 (88.24%)

*Note.* MBT = mindfulness-based therapy; CBT = cognitive behavioral therapy; CTL = control condition; GED = General Education Development Diploma; FTND = Fagerström test for nicotine dependence. All reported means in this table are based on observed data. One participant was missing baseline smoking data. For trait anxiety, item responses ranged from 1 = almost never to 4 = almost always. For depression, item responses ranged from 0 to 3, with higher values indicating more severity.

interaction (b = 0.17, SE = 0.13, p = .17) or Treatment (MBT vs. CBT) × Time (Follow-Up Phase) interaction (b = -0.11, SE = 0.11, p = .32), indicating no significant difference in changes in smoking for the MBT versus CTL and the MBT versus CBT contrasts during the follow-up phase. However, there was a significant Treatment (CBT vs. CTL) × Time (Follow-Up Phase) interaction (b = 0.28, SE = 0.13, p = .03). Specifically, individuals in CBT had greater increases in smoking than CTL during the follow-up phase, which corresponded with a large (CBT vs. CTL: d = 1.56, 95% CI [0.41, 2.72]) between-condition effect (Table 4).

In Figure 2, the confidence interval for MBT at Week 8 (1-month follow-up) does not overlap with the confidence interval of CTL, indicating that MBT, relative to CTL, had significantly less cigarette smoking when focusing on the point estimate of smoking at the 1-month follow-up time point. Of note, when conducting a separate post hoc single-level regression model, MBT had significantly less cigarette smoking at Week 8 than CTL (b = -4.28, SE = 1.67, p = .01). The confidence interval for CBT at Week 8 (1-month follow-up) overlaps with the confidence interval of CTL, indicating that CBT, relative to CTL, did not have significantly different cigarette smoking when focusing on the point estimate of smoking at the 1-month follow-up time point.

Furthermore, at Week 16 (the 3-month follow-up), the confidence intervals for all treatment conditions were overlapping, suggesting that there were not significant differences in cigarette smoking among treatment conditions when focusing on the point estimate of smoking at the 3-month follow-up time point.

When considering the entire study period (Week 0–16), all conditions showed significant reductions in smoking (Table 4). However, MBT showed significantly greater reductions in smoking than CTL during the entire study period, which corresponded with a large effect size (d = -1.61, 95% CI [-2.56, -0.66]). There were no significant differences for MBT versus CBT and CBT versus CTL for changes in smoking during the entire study period.

# Treatment Effects on Cue-Induced Craving and Mindfulness- and Reappraisal-Based Regulation of Craving

Compared to CTL, both MBT and CBT had significantly greater reductions in cue-induced craving (see Table 5), which corresponded with large between-condition effect sizes (MBT vs. CTL: d = -1.31, 95% CI [-0.65, -1.95]; CBT vs. CTL: d = -1.14, 95%CI [-0.54, -1.72]). There was no significant difference between

 Table 2

 Descriptive Statistics for Cigarette Smoking Over Time

Time/week	Phase	Full sample $(n = 92)$	MBT ( $n = 25$ )	CBT $(n = 33)$	CTL $(n = 34)$	Missing data rat
Baseline (Week 0)	Intervention	14.85 (4.53)	15.05 (5.27)	14.60 (4.38)	14.93 (4.20)	1.09%
Week 1	Intervention	11.77 (5.51)	11.83 (5.82)	9.63 (5.08)	13.60 (5.13)	4.35%
Week 2	Intervention	9.87 (5.72)	8.22 (5.48)	7.76 (4.99)	12.98 (5.24)	5.43%
Week 3	Intervention	9.50 (5.73)	7.40 (5.27)	7.66 (5.12)	12.58 (5.31)	7.61%
Week 4	End of intervention	9.24 (5.84)	7.19 (5.31)	7.53 (5.17)	12.30 (5.64)	10.87%
Week 5	Follow-up	8.88 (6.30)	6.52 (5.35)	7.48 (6.10)	11.88 (6.12)	10.87%
Week 6	Follow-up	8.59 (6.46)	6.22 (5.03)	7.40 (6.51)	11.42 (6.49)	10.87%
Week 7	Follow-up	8.49 (6.77)	6.80 (4.96)	7.31 (6.74)	10.90 (7.48)	11.96%
Week 8	Follow-up	8.41 (6.94)	6.36 (5.14)	7.38 (6.87)	10.88 (7.58)	13.04%
Week 9	Follow-up	9.43 (7.01)	7.11 (5.42)	8.85 (7.24)	11.55 (7.40)	17.39%
Week 10	Follow-up	9.09 (6.80)	6.83 (4.91)	8.47 (7.00)	11.20 (7.33)	16.30%
Week 11	Follow-up	8.88 (6.84)	6.38 (4.88)	8.42 (6.95)	11.02 (7.41)	16.30%
Week 12	Follow-up	9.13 (7.16)	6.93 (6.15)	8.66 (7.10)	11.09 (7.55)	16.30%
Week 13	Follow-up	9.05 (7.15)	7.07 (6.21)	8.58 (7.27)	10.84 (7.45)	16.30%
Week 14	Follow-up	8.82 (7.05)	7.22 (6.38)	8.81 (7.35)	9.96 (7.23)	16.30%
Week 15	Follow-up	8.94 (7.10)	7.05 (5.56)	9.11 (7.61)	10.10 (7.54)	16.30%
Week 16	Follow-up	8.70 (7.21)	6.35 (5.82)	9.18 (7.59)	9.92 (7.57)	16.30%

*Note.* MBT = mindfulness-based therapy; CBT = cognitive behavioral therapy; CTL = control condition.

MBT and CBT on changes in cue-induced craving. Compared to CTL, both MBT and CBT had significantly greater improvements in mindfulness-based regulation of craving, which corresponded with large between-condition effect sizes (MBT vs. CTL: d = -1.12, 95% CI [-0.49, -1.75]; CBT vs. CTL: d = -1.01, 95% CI [-0.42, -1.59]). There was no significant difference between MBT and CBT on mindfulness-based regulation of craving. Compared to CTL, CBT had significantly greater improvements in reappraisal-based regulation of craving, which corresponded with a medium-to-large between-condition effect size (d = -0.64, 95% CI [-0.07, -1.20]). There were no significant differences when comparing MBT to CBT and to CTL on reappraisal-based regulation of craving.

# Treatment Effects on 1-Week Point Prevalence CO-Confirmed Abstinence

As shown in Table 6, rates of 1-week point prevalence CO-confirmed abstinence were low across treatment conditions and time points. There were no significant differences among the treatment conditions in 1-week point prevalence CO-confirmed abstinence at any time point.

## Discussion

We conducted a randomized controlled trial evaluating two versions of ROC-T for smoking, a computerized six-session intervention with intensive, repeated practice of strategies when exposed to images of smoking cues (e.g., people smoking). A total of 92 participants who were nicotine-dependent daily smokers were randomized to either a MBT version of ROC-T that focused on mindful acceptance, a CBT version of ROC-T that focused on cognitive reappraisal, or an inactive CTL that received no intervention (but completed all study assessments, including during the intervention period). As hypothesized, MBT and CBT showed greater reductions in cigarettes smoked per day during the intervention phase (Week 0–4), as compared to the CTL, corresponding with large and medium-to-large effect sizes, respectively. There were no significant differences between MBT and CBT on changes in smoking during the intervention phase. These results build upon our pilot work (Boswell et al., 2018; Kober, Kross, et al., 2010; Lopez et al., 2022; Suzuki et al., 2020) and provide further evidence that both the MBT and CBT versions of ROC-T may be effective for reducing smoking in the short term.

Notably, rates of CO-confirmed 7-day point prevalence were very low across the entire sample, and there were no significant differences among treatment conditions. Hence, while this study provides evidence that MBT and CBT can decrease cigarettes smoked per day, it does not provide evidence that MBT- and CBT-ROC-T help people quit smoking. Importantly, the versions of MBT and CBT used in this study did not ask people to set a quit date. Additionally, it is not clear that our entire sample wanted to quit. We only assessed participants' interest in "reducing or quitting" on a single scale, and we did not combine ROC-T with other behavioral intervention components (i.e., motivational counseling) or medications (i.e., nicotine replacement therapy [NRT]) to assist individuals in quitting. Thus, the present study provides an initial and precise estimate of how intensive training in regulation of cue-elicited craving itself (without being part of a multicomponent intervention) influences smoking behavior over time. Future studies could evaluate the MBT and CBT versions of ROC-T as adjunctive interventions that are added to current evidencebased treatment approaches for smoking cessation, such as the combination of NRT and counseling. The addition of MBT and CBT to NRT and counseling, for example, might increase quit rates by enhancing the ability to regulate strong cravings after the initial quit attempt. Furthermore, future studies can evaluate whether higher doses of ROC-T (e.g., 12 sessions instead of six) may result in greater reductions in smoking and quit rates.

When considering the follow-up phase (Week 4–16), results suggested that the effects of MBT may be more durable than CBT. Specifically, (a) CBT showed significant increases in smoking during

#### Table 3

Effects	Estimate	SE	p value
Unconditior	nal model		
Fixed effects			
Intercept	8.69	0.68	<.001*
Time (intervention phase)	-1.23	0.15	<.001*
Time (follow-up phase)	0.01	0.05	.86
Random effects			
Residual variance	5.38	0.77	<.001*
Random intercept variance (participant)	34.88	5.05	<.001*
Random slope for time (intervention phase) variance	1.41	0.30	<.001*
Random slope for time (follow-up phase) variance	0.19	0.04	<.001*
Model with control condi	tion as reference group		
Fixed effects			
Intercept	12.07	1.05	<.001*
Treatment (MBT vs. CTL)	-5.65	1.46	<.001*
Treatment (CBT vs. CTL)	-5.28	1.51	<.001*
Time (intervention phase)	-0.60	0.19	.001*
Time (follow-up phase)	-0.13	0.10	.20
Treatment (MBT vs. CTL) $\times$ Time (intervention phase)	-1.28	0.34	<.001*
Treatment (CBT vs. CTL) $\times$ Time (intervention phase)	-0.81	0.32	.01*
Treatment (MBT vs. CTL) $\times$ Time (follow-up phase)	0.17	0.13	.17
Treatment (CBT vs. CTL) $\times$ Time (follow-up phase)	0.28	0.13	.03*
Random effects			
Residual variance	5.37	0.77	<.001*
Random intercept variance (participant)	28.63	4.52	<.001*
Random slope for time (intervention phase) variance	1.18	0.26	<.001*
Random slope for time (follow-up phase) variance	0.18	0.04	<.001*
Model with CBT as	s reference group		
Intercept	6.78	1.09	<.001*
Treatment (MBT vs. CBT)	0.37	1.48	.80
Time (intervention phase)	-1.42	0.26	<.001*
Time (follow-up phase)	0.15	0.07	.04*
Treatment (MBT vs. CBT) $\times$ Time (intervention phase)	-0.46	0.38	.23
Treatment (MBT vs. CBT) $\times$ Time (follow-up phase)	-0.11	0.11	.32

*Note.* MBT = mindfulness-based therapy; CBT = cognitive behavioral therapy; <math>CTL = control condition; SE = standard error. \* Significant effect.

follow-up, whereas MBT did not; (b) CBT had significantly worse outcomes than the CTL during the follow-up phase; and (c) when considering the entire study period (baseline through Week 16), MBT showed significantly greater reductions in smoking compared to control

but CBT was not significantly different than control. These results are in line with other randomized trials that have demonstrated superior effects of MBT-based approaches than CBT-based approaches for smoking cessation (Brewer et al., 2011; Bricker et al., 2020) and for preventing

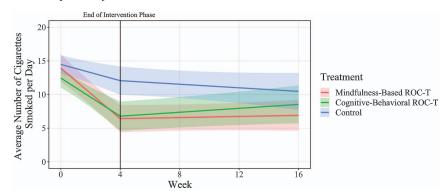
# Table 4

Effect Size Estimates of Treatment Effects

		in-condition change arettes per day, $M$	·		Between-con	ndition differences
Time period	MBT	CBT	CTL	Treatment comparison	M (SE)	Effect sizes Cohen's d [95% CIs]
Intervention phase (Week 0-4)	-7.53 (0.28)***	-5.67 (0.26)***	-2.42 (0.19)***	MBT versus CTL	-5.12 (0.34)***	-1.08 [-1.64, -0.52]
				CBT versus CTL	-3.26 (0.32)*	-0.69 [-1.22, -0.15]
				MBT versus CBT	-1.86 (0.38)	-0.39 [-1.03, 0.24]
Follow-up phase (Week 4–16)	0.50 (0.08)	1.75 (0.07)*	-1.60 (0.10)	MBT versus CTL	2.09 (0.13)	0.97 [-0.43, 2.38]
				CBT versus CTL	3.35 (0.13)*	1.56 [0.18, 2.93]
				MBT versus CBT	-1.26 (0.11)	-0.59 [-1.74, 0.56]
Total (Week 0–16)	-7.03 (0.29)***	$-3.92 (0.28)^{***}$	$-4.02 (0.17)^{***}$	MBT versus CTL	-3.01 (0.33)***	-1.61 [-2.56, -0.66]
				CBT versus CTL	0.10 (0.33)	-0.82 [-1.77, 0.13]
				MBT versus CBT	-3.11 (0.40)	-0.79 [-1.95, 0.37]

*Note.* The means for within-condition change and between-condition differences are model estimated (see Segal et al., 2020). The Cohen's *d* effect sizes are also model estimated, using the Feingold method (see Feingold, 2009). Of note, "total change" (Week 0–16) is computed by summing estimates from each piece of the piecewise model (e.g., intervention phase and follow-up phase). MBT = mindfulness-based therapy; CBT = cognitive behavioral therapy; CTL = control condition; SE = standard error; CIs = confidence intervals. \*  $p \le .05$ . \*\*\* $p \le .001$ .

**Figure 2** *Visual Depiction of Piecewise Multilevel Model* 



*Note.* The figure shows model-estimated trajectories for the mindfulness-based ROC-T (red), cognitive behavioral ROC-T (green), and control (blue). The shaded area around each trajectory is 95% CI. ROC-T = regulation of craving-training; CI = confidence interval.

relapse among individuals with alcohol and other drug use disorders (Bowen et al., 2014).

Consistent with hypotheses, we found that MBT and CBT, relative to the CTL, led to significant and large-sized reductions in cue-induced craving from pre- to postintervention, as measured by the ROC task. These findings provide initial empirical evidence that the MBT and CBT versions of ROC-T indeed target cue-induced craving. As expected, we also found that MBT, relative to the CTL, led to significant and large-sized improvements in mindfulnessbased regulation of craving. This provides initial evidence that MBT-ROC-T works as intended by improving the ability to use mindfulness to regulate smoking craving. Unexpectedly, however, we also found that CBT, relative to control, also led to significant and large-sized improvements in mindfulness-based regulation of craving. It is not clear why this finding emerged. It is possible that using reappraisal to regulate craving may to some extent also involve some mindfulness in the form of acknowledging a craving and letting it pass. Because individuals in the CBT condition were exposed to some instruction in mindful acceptance before the intervention period (in the baseline ROC task), it is also possible that individuals in the CBT condition continued to practice mindfulnessbased regulation of craving to some extent during ROC-T training sessions. Finally, CBT (but not MBT), relative to control, led to significant and large-sized improvements in reappraisal-based regulation of craving. This provides initial evidence that CBT-ROC-T may be successfully targeting the ability to use reappraisal to regulate smoking craving.

Further research is needed to explore underlying mechanisms that may explain differences in the effectiveness of MBT and CBT versions of ROC-T in general and among specific subpopulations. Our preliminary research suggests that mindful acceptance of craving may downregulate craving in a "bottom-up" fashion by reducing neural activation in subcortical craving regions of the brain (Westbrook et al., 2013), whereas cognitive reappraisal of craving may downregulate craving in a "top-down" fashion via cognitive control and recruitment of the prefrontal cortex (Kober, Mende-Siedlecki, et al., 2010; Suzuki et al., 2020). Our team is currently conducting additional analyses in new data sets to confirm these initial results. Additionally, further research is needed to test the hypothesis that the reason MBT may be more durable than CBT is because cognitive reappraisal may rely on "top-down" cognitive control, whereas mindful acceptance may not, and thus cognitive reappraisal may be less effective during situations (i.e., high stress) in which cognitive control is compromised. Another possibility that dovetails with the above is that the strategy of mindful acceptance in MBT may be easier to implement after the intervention phase has ended compared to the strategy of reappraisal in CBT. A final possibility is that the strategy of mindful acceptance in MBT may be more generalizable, such that individuals who learn this strategy can then apply it to a variety of situations that induce craving (e.g., stress, negative affect, pain), whereas the strategy of reappraisal in CBT may be more limited to situations in which they crave cigarettes. Further research is needed to explore these possibilities.

It is also important to note that we did not find any significant treatment effects on smoking when directly comparing MBT and CBT. Altogether, our results provide some initial indication that MBT could be more durable than CBT but more research is needed. The sample sizes the MBT (n = 25) and CBT (n = 33) conditions in this study were relatively small. Future research might involve a larger trial that is fully powered to detect small-to-medium-sized treatment effects when directly comparing the MBT and CBT versions of ROC-T.

This study has several limitations. First, the most distal follow-up was only 3 months and effects of ROC-T beyond this are unknown. Second, we recruited individuals who were motivated to reduce or quit smoking and thus cannot make conclusions about the effectiveness of ROC-T among individuals who are not motivated to reduce or quit smoking. Third, our sample included a relatively small proportion of individuals identifying as Hispanic, Asian, or multiracial. Fourth, we only recruited individuals living in Connecticut. Fifth, the inclusion of the ROC task at baseline may have affected the results of this study. For the ROC task, all conditions received some exposure to instruction in mindfulness- and reappraisal-based regulation of craving at baseline. It is possible that this brief exposure and use of the strategies at baseline during the ROC task in itself could have impacted subsequent regulation of craving and smoking. It is also possible that participants continued to use mindful acceptance

				Missinø		Between-condition comparisons	
Variable	MBT	CBT	CTL	data rate	MBT versus CTL	CBT versus CTL	MBT versus CBT
Cue-induced craving Pre $M(SD)$	3.49 (0.77)	3.57 (1.03)	3.67 (.97)	(1/92 (1.09%)			
Post $M$ (SD) 2.54 (0.96) Pre-post change $M$ (SD) -0.84 (0.70)			3.82 (.78) 0.05 (0.67)	21/92 (22.80%)	b = -1.50 SE = 0.26	b = -1.54 SE = 0.24	b = 0.39 SE = 0.27
- -		~			p < .001	<i>p</i> < .001	p = .15
					5 II = -1.31 [-0.65, -1.95]		
Mindfulness-based regulation of craving	on of craving	3 23 (0 07)	3 37 (1 02)	1/00/17/00/21		,	,
Post $M$ (SD)	2.21 (1.1)	2.03 (1.02)	3.36 (0.86)	21/92 (22.80%)	b = -0.90	b = -1.17	b = 0.27
Pre-post change $M$ (SD) -0.76 (0.58)	-0.76 (0.58)		-0.05(0.66)		SE = 0.25	SE = 0.23	SE = 0.26
					p < .001	p < .001	p = .29
						$\beta = -0.50$	$\beta = 0.11$
					d [95%  CI] = -1.12 [-0.49, -1.75]	d [95%  CI] = -1.01 [-0.42, -1.59] d [95%  CI] = 0.32 [0.03, -0.29]	d [95%  CI] = 0.32 [0.03, -0.29]
Reappraisal-based regulation of craving Pre $M$ (SD) 2.94 (0.95	n of craving 2.94 (0.95)	3.01 (1.08)	3.30 (1.05)				
Post $M$ (SD)	2.28 (1.0)	1.78 (0.95)	2.94 (1.01)	21/92 (22.80%)	b =46	b =93	b = 0.47
Pre-post change $M$ (SD) -0.66 (0.69)	-0.66 (0.69)		-0.39(0.96)		SE = 0.25	SE = 0.24	SE = 0.26
1					p = .07	p < .001	p = .07
					$\beta = -0.19$	$\beta = -0.41$	$\beta = 0.19$
					d [95%  CI] = -0.31 [0.28, -0.90]	d [95% CI] = $-0.64$ [ $-0.07$ , $-1.20$ ] $d$ [95% CI] = $0.42$ [ $1.03$ , $-0.19$ ]	d [95% CI] = 0.42 [1.03, -0.19]
<i>Note.</i> MBT = mindfulnes:	Iness-based therapy; CBT	; CBT = cognit	tive behaviora.	1 therapy; CTL =	Note. MBT = mindfulness-based therapy; CBT = cognitive behavioral therapy; CTL = control condition; $b$ = unstandardized regression coefficient; $SE$ = standard error; $d$ = Cohen's $d$ effect size for	regression coefficient; $SE =$ standard er	stror; $d = $ Cohen's $d$ effect size for

Effect of Treatment Condition on Pre–Post Changes in Cue-Induced Craving and Its Regulation Table 5

*Note.* MBT = mindfulness-based therapy; CBT pre-post change score; CI = confidence interval.

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		eek point prevale confirmed abstine				Fisher's exact tests	
Time point	MBT $(n = 25),$ n (%)	CBT $(n = 33),$ n (%)	CTL $(n = 34),$ n (%)	Missing data rate	MBT versus CTL	CBT versus CTL	MBT versus CBT
Posttreatment assessment 1-month follow-up 3-month follow-up	1 (4.00%) 0 (0.00%) 0 (0.00%)	2 (6.06%) 1 (3.03%) 1 (3.03%)	0 (0.00%) 0 (0.00%) 2 (5.88%)	11/92 (11.96%) 14/92 (15.22%) 14/92 (15.22%)	p = .41 p = 1.0 p = .50	p = .21 p = .47 p = 1.0	p = 1.0 p = 1.0 p = 1.0

 Table 6

 Rates of 1-Week Point Prevalence CO-Confirmed Abstinence

Note. MBT = mindfulness-based therapy; CBT = cognitive behavioral therapy; CTL = control condition; CO = carbon monoxide.

and/or reappraisal during treatment even if they were not randomized into the condition focused on the strategy. Future work might consider alternative ways to assess craving and its regulation (such as ecological momentary assessment) that do not involve instruction and practice of strategies, which may reduce potential crossover across conditions and enhance internal validity. Sixth, in this study, we assessed momentary craving and its regulation in a labbased environment, which may be substantially different than the natural contexts in which individuals experience craving. Future work can use ecological momentary assessment to assess craving and its regulation in individuals' natural daily contexts. Seventh, participants assigned to the active treatment conditions were compensated a greater amount than those in the CTL, given that participants in the active treatment conditions also completed training sessions during the weekly assessment visits, which involved \$20/hr compensation. This differential incentivization could have biased study results, and future studies should have equal incentivization across groups to reduce bias. Finally, the CTL was an inactive control that received no intervention, and hence, our data do not speak to the effects of ROC-T when compared to active CTLs or existing evidence-based interventions.

Despite potential limitations, inclusion of the ROC task in this study is also a strength because it enabled valid measurement of the mechanisms targeted by the interventions. Furthermore, a strength of the present study is the emphasis on targeted, mechanism-focused interventions. ROC-T is not a multicomponent intervention that necessitates complex unpacking to understand mechanisms. Instead, the ROC-T interventions provide precise training in the use of a single strategy to regulate craving. A mechanism-focused approach to intervention development may hold promise for promoting precision-based delivery in which specific interventions are matched to individuals based on their unique set of presenting vulnerabilities and needs (Nielsen et al., 2018).

The key finding from this study is that the MBT and CBT versions of ROC-T—both focusing on regulation of craving when provided alone maybe promising for reducing smoking. We also found preliminary data that MBT may be more durable than CBT. Future studies are warranted that evaluate the effects of additional ROC-T sessions, on a more diverse sample, and that evaluate ROC-T as adjunctive interventions to existing evidence-based approaches for smoking cessation.

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Received February 8, 2023 Revision received May 15, 2023 Accepted May 17, 2023