



## Mindfulness training for smoking cessation: Results from a randomized controlled trial

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### ABSTRACT

**Background:** Cigarette smoking is the leading cause of preventable death in the world, and long-term abstinence rates remain modest. Mindfulness training (MT) has begun to show benefits in a number of psychiatric disorders, including depression, anxiety and more recently, in addictions. However, MT has not been evaluated for smoking cessation through randomized clinical trials.

**Methods:** 88 treatment-seeking, nicotine-dependent adults who were smoking an average of 20 cigarettes/day were randomly assigned to receive MT or the American Lung Association's freedom from smoking (FFS) treatment. Both treatments were delivered twice weekly over 4 weeks (eight sessions total) in a group format. The primary outcomes were expired-air carbon monoxide-confirmed 7-day point prevalence abstinence and number of cigarettes/day at the end of the 4-week treatment and at a follow-up interview at week 17.

**Results:** 88% of individuals received MT and 84% of individuals received FFS completed treatment. Compared to those randomized to the FFS intervention, individuals who received MT showed a greater rate of reduction in cigarette use during treatment and maintained these gains during follow-up ( $F = 11.11$ ,  $p = .001$ ). They also exhibited a trend toward greater point prevalence abstinence rate at the end of treatment (36% vs. 15%,  $p = .063$ ), which was significant at the 17-week follow-up (31% vs. 6%,  $p = .012$ ).

**Conclusions:** This initial trial of mindfulness training may confer benefits greater than those associated with current standard treatments for smoking cessation.

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### 1. Introduction

Cigarette smoking along with other tobacco use is the leading cause of preventable death in the world, associated with approximately five million people annually, and accounting for 10% of all deaths (Jha et al., 2006). In the US, smoking costs more than \$193 billion in health care and lost productivity per year (Center for Disease Control, 2007). Although over 70% of smokers want to quit, fewer than 5% achieve this goal annually (Center for Disease Control, 2007).

As outlined in models previously (Baker et al., 2004; Curtin et al., 2006), acquisition as well as maintenance of nicotine dependence is a complex process, developed by associative learning mechanisms and perpetuated through positive and negative reinforcement.

Habitual smoking begins in part from the formation of associative memories between smoking and both positive (e.g., after a good meal), and negative (e.g., when "stressed") affective states (Bevins and Palmatier, 2004; Brown et al., 1996; Kandel and Davies, 1986; Leknes and Tracey, 2008; Piasecki et al., 1997). Subsequently, cues that are judged to be positive or negative can induce positive or negative affective states, which can then trigger craving to smoke (Baker et al., 2004; Brandon, 1994; Carter and Tiffany, 1999; Cox et al., 2001; Hall et al., 1993; Huston-Lyons and Kornetsky, 1992; Kassel et al., 2003; Perkins et al., 2010; Shiffman and Waters, 2004; Strong et al., 2009; Zinser et al., 1992). Though the centrality of craving remains controversial (Perkins, 2009; Tiffany, 1990; Tiffany and Carter, 1998; Tiffany and Conklin, 2000), evidence suggests that craving is strongly associated with smoking, which, mainly through the psychophysical properties of nicotine (Imperato et al., 1986), results in the maintenance or improvement of positive, or reduction of negative affective states (Cook et al., 2004; Perkins et al., 2010; Shiffman et al., 1997; Zinser et al., 1992). This sets up positive or negative reinforcement loops, respectively, by reinforcing associative memories between these affective states and smoking

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(Baker et al., 2004; Bevins and Palmatier, 2004; Brandon and Baker, 1991; Carmody et al., 2007; Carter et al., 2008; Carter and Tiffany, 2001; Cook et al., 2004; Hall et al., 1993; Hyman, 2007; Rose and Levin, 1991; Warburton and Mancuso, 1998).

Mainstay behavioral treatments for smoking have focused on teaching individuals to avoid cues, foster positive affective states, develop lifestyle changes that reduce stress (e.g., practice relaxation), divert attention from cravings, substitute other activities for smoking, learn cognitive strategies that reduce negative mood, and develop social support mechanisms (Fiore et al., 2000, 2008; Lando et al., 1990). These have shown modest success, with abstinence rates hovering between 20 and 30% over the past three decades (Law and Tang, 1995; Shiffman, 1993). This may be because triggers are often ubiquitous, and diversion of attention requires cognitive reserves, which are often depleted after strong negative affective states (Muraven and Baumeister, 2000). Also, substitutions (e.g., eating candy or carrot sticks) are not always available. The evidence for affective states and craving as perpetuators of smoking, coupled with the modest success of current treatments, highlights the need for innovative treatments (Niaura and Abrams, 2002).

Thus, recently developed smoking cessation treatments have begun to target components of the addictive process by helping patients tolerate negative affect and craving rather than avoiding cues or substituting other activities (e.g., “urge surfing” techniques in cognitive behavioral therapies) (Carroll, 2005; Marlatt and Donovan, 2005). Recent work has focused on recognition and tolerance of negative affect states. For example, in an uncontrolled trial, 16 participants who underwent distress tolerance training (six individual + nine group sessions + 8 weeks of nicotine patch), 1-week point prevalence abstinence was 31% at the end of treatment, but 0% at the 26-week follow-up (Brown et al., 2008). Acceptance and commitment therapy (ACT), which includes an emphasis on tolerance and “defusion” of aversive states has also shown preliminary efficacy for smoking cessation (Gifford et al., 2004; Hernandez-Lopez et al., 2009). Gifford and colleagues randomized 76 participants to nicotine replacement or ACT (seven individual + seven group sessions), and found 33% and 35%, respectively, achieved 24-h smoking abstinence in NRT and ACT after treatment, 11% and 23%, after 6 months, and 15% and 35% 1 year later (Gifford et al., 2004). Though preliminary, these studies suggest that targeting affective states may aid smoking cessation.

Thus, treatments that target both affective states and craving, such as mindfulness training (MT), may be helpful in smoking cessation (Brewer et al., 2009). Mindfulness approaches have been operationalized to include two components: (1) maintaining attention on the individual’s immediate experience and (2) maintaining an attitude of acceptance toward this experience (Bishop et al., 2004). Through these complementary components, MT has been hypothesized to not only bring habituated behaviors into consciousness such that they can be worked with effectively, but also target the associative learning process with an emphasis on affect and craving as critical components of positive and negative reinforcement loops (Brewer et al., 2010b). For example, similar to treatments such as ACT that place an emphasis on accepting one’s immediate experience, MT may help individuals learn “sit with” negative affect, cravings, and nicotine withdrawal without habitually reacting to these unpleasant states by smoking. Further, and perhaps somewhat unique to this practice, MT emphasizes the ability to perceive the selfless quality of affective/mind states in that it teaches individuals to recognize these as transient feelings and sensations in the mind and body rather than something that is happening to ‘them’. In doing so, individuals may learn to (literally) not take affective and withdrawal states personally, which also may help them quit smoking (Brewer et al., 2010a; Teasdale et al., 2002). Thus, MT may have the relative advantage of teaching a single technique that may lead to the dampening and eventual dismantling of

the complex interrelated associative processes of smoking rather than just removing stimuli that might propagate them.

Treatments that include MT have shown promise for a number of disorders, including anxiety and depression (Hofmann et al., 2010) and have recently been explored in the treatment of addictions (Bowen et al., 2009; Brewer et al., 2009; Zgierska et al., 2008). Data on the efficacy of these approaches remain rare: a recent review reported that of 22 published studies that included mindfulness, only one was a randomized control trial (as an add-on treatment) (Zgierska et al., 2009). Mindfulness approaches have only recently been extended to smoking (Bowen and Marlatt, 2009; Davis et al., 2007). For example, in an uncontrolled pilot study for smoking cessation, Davis and colleagues provided 8 weeks of mindfulness-based stress reduction and found 10 of 18 smokers were abstinent at a 6 week post-quit follow-up visit (Davis et al., 2007). These encouraging findings provide a basis for larger, controlled trials of MT for smoking cessation.

Though MT has been incorporated into other treatments, such as cognitive therapy (mindfulness-based cognitive therapy; Segal et al., 2002) and relapse prevention (mindfulness-based relapse prevention; Bowen et al., 2009; Brewer et al., 2009), as well as ACT, to our knowledge, its efficacy as a *stand-alone* treatment (i.e., not as a component of or combined with another form of treatment) for smoking cessation has not been compared to empirically based smoking cessation treatments.

In this report, we describe outcomes from a preliminary trial in which we evaluated the efficacy of MT compared to the American Lung Association’s freedom from smoking (FFS), a manualized, validated, widely disseminated treatment for smoking cessation (Addington et al., 1998; American Lung Association, 2010; Lando et al., 1990). The primary objective was to assess the efficacy of MT vs. FFS using 1-week point prevalence abstinence and number of cigarettes smoked/day as primary endpoints at treatment completion and a 17-week follow-up. As we have previously found positive relationships between homework completion and substance use outcomes with behavioral treatments (Carroll et al., 2005), our secondary objective was to assess correlations between the amount of completed home practice in both treatment arms and smoking outcomes. We hypothesized that MT would demonstrate at least similar efficacy as FFS with regards to smoking cessation and would show greater correlations between amount of home practice and these outcomes.

## 2. Methods

### 2.1. Study design

This study was a randomized, controlled pilot trial with a 4-week treatment and post-treatment follow-up interviews at 6, 12 and 17 weeks after treatment initiation. It was approved by the Yale University and Veteran’s Administration institutional review boards.

### 2.2. Study population

Participants were recruited through flyers and media advertisements offering behavioral treatment for smoking cessation. Those eligible were 18–60 years of age, smoked 10+ cigarettes/day, had fewer than 3 months of abstinence in the past year, and reported interest in quitting smoking. Participants were excluded if they currently used psychoactive medications, had a serious or unstable medical condition in the past 6 months, or met DSM-IV criteria for other substance dependence in the past year. After complete description of the study to the subjects, written informed consent

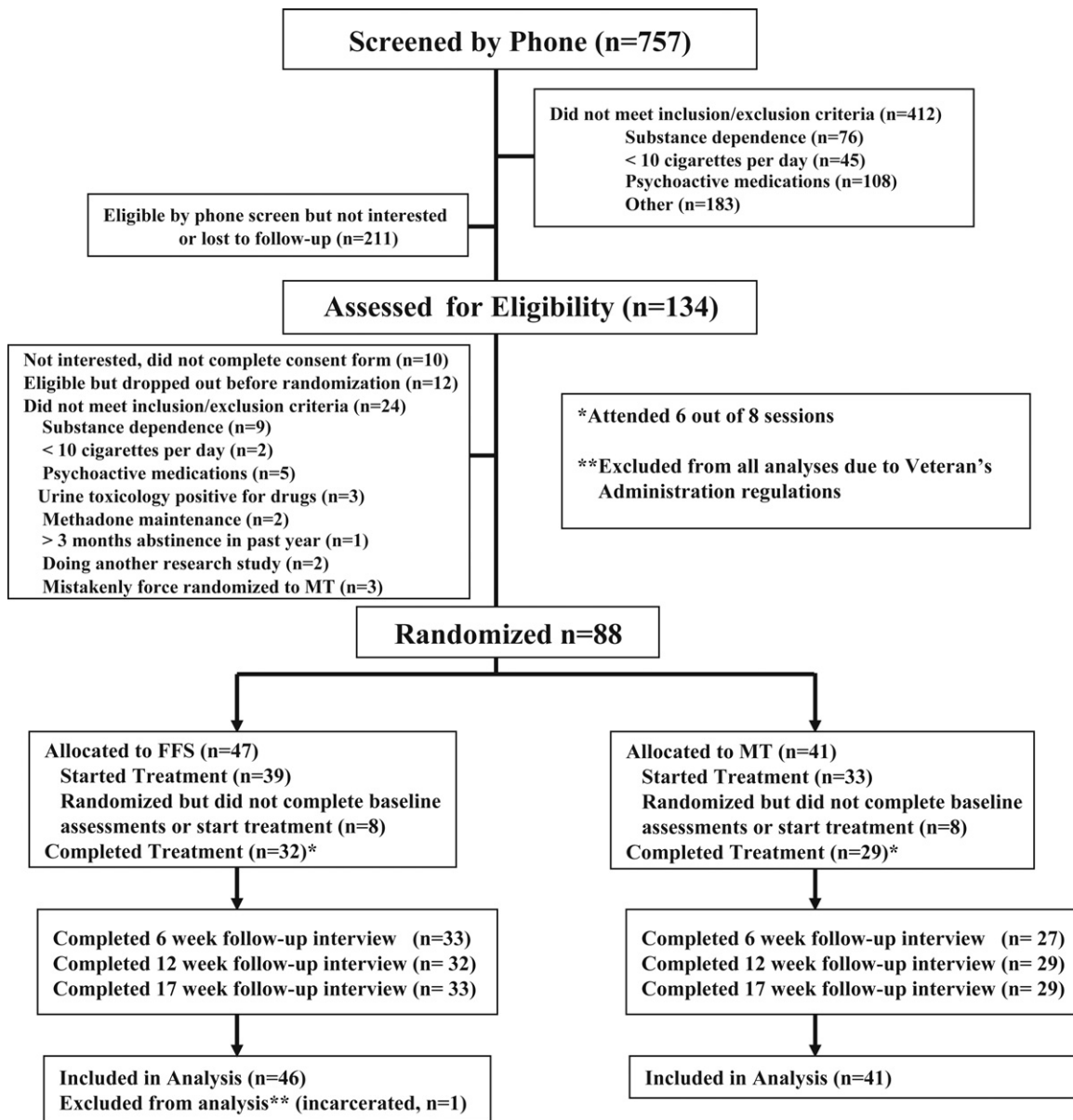


Fig. 1. CONSORT diagram.

was obtained. Of the 103 eligible individuals, 88 were randomized (see CONSORT diagram, Fig. 1).

### 2.3. Interventions

A computer-generated urn randomization program assigned participants to MT or FFS based on age (>40 years vs. ≤40 years old), sex, race (white vs. non-white), and cigarettes smoked/day (>20 vs. ≤20). All participants received twice weekly group sessions (eight total) that were manualized and delivered by instructors experienced in MT (a single therapist with >13 years of training in MT) or certified in FFS, respectively (2 therapists with masters (+) level of training in drug counseling/health psychology). FFS was chosen as an active 'standard treatment' comparison condition for several reasons: (1) it has demonstrated efficacy (Lando et al., 1990), (2) it is manualized and standards for training and certification of therapists are established, (3) it is widely available, and (4) it includes components that are well-matched with MT, but does not include hypothesized mechanism of MT. For example,

both MT and FFS had a quit date at the end of week 2 (session four), were matched for length (1.5 h/session) and delivered on the same days of the week (Monday and Thursday). In addition, home practice materials were matched in a number of ways, including the length (~30 min total) and number of tracks (five) on respective CDs. Participants were neither encouraged nor discouraged from using nicotine replacement in either group during active treatment or in the post-treatment follow-up phase.

**2.3.1. Mindfulness training.** The MT manual was adapted for active smoking cessation from a previous MT manual for drug relapse prevention (Bowen et al., 2009; Brewer et al., 2009). The overarching theme of momentary awareness and acceptance of cravings and affect (e.g., stress, anxiety, etc.) was introduced and reinforced in complementary ways throughout the training (Kabat-Zinn, 1982). The first session introduced participants to the concept of how smoking can become a habituated behavior triggered by an environmental, physical, or mental stimulus through associative learning. It also explored how cravings feel in the body and how

MT can help individuals become more aware of these processes. Session two examined how thoughts, emotions and body sensations become triggers for craving and smoking, and introduced a technique to ‘mindfully’ work with cravings (Recognize, Accept, Investigate and Note what cravings feel like as they arise, acronym: RAIN). Session three introduced how difficult emotions perpetuate smoking as well as a standard meditation technique called loving-kindness as a way to work with them (Gunaratana, 2002). Loving-kindness is practiced through directed well-wishing, typically by repetition of phrases such as ‘may X be happy’. Session four (quit date) taught participants how cravings thwart long-term goals, and reinforced mindfulness techniques as a way to help individuals disengage from habitual responding and realign with their goals. Session five introduced participants to mindfulness practice in everyday life, including “awareness of breath” meditation and mindful walking (“four modes of walking”, during which individuals practice systematically noting objects that they see, and then objects that they hear, then objects that they smell, and then tactile objects such as the pressure of their feet on the ground). Session six explored the automaticity of thought, and how thoughts can lead to habitual behaviors. Session seven reinforced the concept of acceptance and its role in changing habits. It also explored how both mental and physical actions can “plant seeds” for future actions and habits. Session eight summarized the course tools and explored ways of maintaining these in the future. Home practice was suggested after each session as a combination of formal MT meditations (the “body scan” which teaches individuals to systematically pay attention to different parts of their bodies as a way to reduce habitual mind-wandering and strengthen their attentional capacities, loving-kindness, and awareness of breath, which through focused attention on the breath also is intended to help individuals retrain their minds from habitually engaging in self-related pre-occupations – such as thinking about the past or future, or reacting to stressful stimuli – to more present moment awareness), and informal practices (four modes of walking, mindfulness of daily activities, mindfulness of smoking, RAIN). Each participant received a meditation practice CD.

**2.3.2. Freedom from smoking.** FFS was delivered as previously described (Lando et al., 1990), with the exception that sessions were delivered over 4 weeks (twice weekly) instead of 8 weeks. Briefly, the program covered behavior modification, stress reduction, and relapse prevention, and was divided into three stages: preparation, action, and maintenance. In the preparation stage (sessions 1–3), participants examined smoking patterns through self-monitoring, identified triggers, and developed a personalized quit plan. On quit day (session 4), participants affirmed their decision to quit and identified specific coping strategies. During the maintenance stage, participants identified ways to remain smoke-free and maintain a healthy lifestyle (e.g., weight management, exercise, and relapse prevention), and continued to discuss the importance of social support and relaxation strategies. Home practice was suggested after each session typically as a combination of formal (e.g., practicing guided relaxation techniques) and informal (e.g., “packtracks”) techniques. Each participant received a practice CD of cessation techniques.

#### 2.4. Smoking status

Self-reported smoking was assessed at in-person weekly visits by a research assistant who was not involved in treatment delivery via the timeline follow back (TLFB) method (Sobell and Sobell, 1992). Self-reported abstinence was assessed using TLFB and verified by an exhaled carbon monoxide (CO) measurement of  $\leq 10$  parts per million at each of the twice-weekly treatment and at follow-up visits. Participants who dropped out of treatment

were contacted to provide in-person assessments at follow-up time points (see CONSORT diagram) (Hollis and Campbell, 1999). All participants were financially compensated for assessment visits (10 USD per assessment visit during treatment and 20 USD per assessment visit at follow-up). Of 244 CO measurements taken for point prevalence confirmation, eight (3.3%) were unverified due to participants having moved out of the state or being assessed outside of the study timeframe, two (.8%) were confounded by marijuana use that day (Javors et al., 2005; Wu et al., 1988), and one (.4%) was unverified due to research assistant error. One CO measurement (.4%) was inconsistent with self-report and was considered to be non-abstinent.

#### 2.5. Study end points

The primary outcomes were 1-week point prevalence abstinence and average number of cigarettes smoked/day at 4 (treatment completion) and 17 weeks after treatment initiation.

#### 2.6. Statistical analysis

Longitudinal data were analyzed using intent-to-treat mixed effect regression models on the full sample of randomized subjects (minus one individual who was incarcerated after treatment and whose data were not allowed to be analyzed per Veteran’s Administration regulations) to evaluate change over time in cigarette use/week during treatment (1st phase) and during the follow-up period (2nd phase) as previously described (Ball et al., 2007; Singer and Willett, 2003). Longitudinal analyses are based on the continuous dependent variable “average number of cigarettes smoked per day by week”. ANOVA,  $\chi^2$  analysis and Pearson’s correlations were used where appropriate, using SPSS 18. Incomplete data were handled using casewise deletion, using all available data for parameter estimates (Hedeker et al., 2007). All tests of significance are reported as two-tailed, and error is reported as  $\pm$ standard deviation. Significance is reported as  $p \leq .025$  to take into account correction for multiple comparisons.

### 3. Results

#### 3.1. Participants

Baseline and demographic characteristics were comparable between treatment groups (see Table 1). Overall, 45% of participants were members of ethnic minority groups, and 63% were men. On average, participants were 46 years old, smoked 20 cigarettes/day, started smoking regularly at the age of 16, and had 5.2 previous quit attempts. Sixteen (eight in each group) did not complete baseline paperwork and were not exposed to treatment.  $\chi^2$  and ANOVA analyses revealed no differences between these individuals and those who started treatment ( $n = 33$  in MT,  $n = 38$  in FFS). Individuals in MT and FFS who started treatment attended  $6.7 \pm 1.7$  and  $6.2 \pm 2.2$  of eight sessions, respectively. The 6, 12, and 17-week follow-up completion rates were 27 (82% of treatment-exposed individuals) and 33 (87%), 29 (88%) and 32 (84%), and 29 (88%) and 33 (87%) for MT and FFS, respectively. No serious adverse events were reported in either treatment group.

#### 3.2. Effects of mindfulness training on smoking

Random effects regression analyses on the full intention to treat sample indicated participants in both groups reduced cigarette use from baseline through the 17-week follow-up (effect for time,  $F = 480.79$ ,  $df = 1, 1115$ ,  $p < .0001$ ). The rate of change during active treatment was significantly greater than the rate of change during post treatment (effect for phase, active vs. follow-up,

**Table 1**  
Baseline characteristics of participants.

	MT (n=41) N (%)	FFS (n=46) N (%)	Total (n=87) N (%)	F or $\chi^2$	df	p
Sex						
Male	27(65.9)	27(58.7)	54(62.1)	.472	1	.492
Female	14(34.1)	19(41.3)	33(37.9)			
Age	46.5 ± 8.7	45.3 ± 11.4	45.9 ± 10.2	.339	1	.562
Race						
White	24(58.5)	19(41.3)	43(49.4)	4.557	3	.207
Black	15(36.6)	19(41.3)	34(39.1)			
Hispanic	2(4.9)	7(15.2)	9(10.3)			
Other	0	1(2.2)	1(1.1)			
Education level						
College grad or more	12(29.3)	13(28.3)	25(28.7)	1.715	3	.634
Partial college	10(24.4)	15(32.6)	25(28.7)			
High school	17(41.5)	14(30.4)	31(35.6)			
Less than high school	2(4.9)	4(8.7)	6(6.9)			
Marital status						
Never married	20(48.8)	25(54.3)	45(51.7)	.376	3	.945
Married/cohabitating	8(19.5)	7(15.2)	15(17.2)			
Separated/divorced	12(29.3)	13(28.3)	25(28.7)			
Widowed	1(2.4)	1(2.2)	2(2.3)			
Employment status						
Full time	15(36.6)	13(28.3)	28(32.2)	.899	2	.638
Part time	5(12.2)	8(17.4)	13(14.9)			
Unemployed	21(51.2)	25(54.3)	46(52.9)			

	MT (n=41) Mean (±SD)	FFS (n=46) Mean (±SD)	Total (n=87) Mean (±SD)	F or $\chi^2$	df	p
Started smoking 3×/week (age)	16.7 + 4.8	15.6 + 4.0	16.1 + 4.4	1.402	1, 85	.240
Number of cigarettes/day	21.2 + 10.6	19 + 8.3	20.0 + 9.5	1.219	1, 85	.273
Number of smokers in house	.41 + .74	2.7 + 11.2	1.6 + 8.2	1.7	1, 85	.196
Number of prior quit attempts	6.0 + 9.1	4.4 + 4.8	5.2 + 7.2	1.037	1, 85	.311
Longest abstinence in life (months)	14.3 + 34.3	8.9 + 17.6	11.4 + 26.8	0.88	1, 85	.351
Longest abstinence in past year (months)	.07 + .35	.15 + .47	.11 + .42	0.782	1, 85	.379

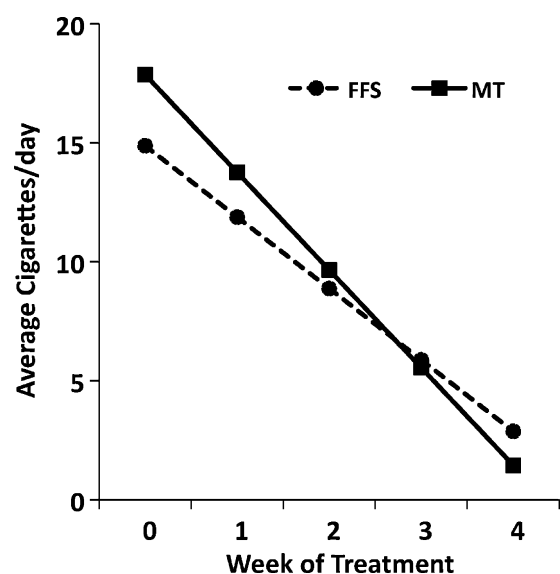
$F = 579.00$ ,  $df = 1, 1115$ ,  $p < .0001$ ). During active treatment, individuals receiving MT demonstrated a greater reduction in cigarette use than those receiving FFS, and maintained these treatment gains during the follow-up period (treatment group  $\times$  time,  $F = 7.01$ ,  $df = 1, 1115$ ,  $p = .008$ ). As subject expectancy of receiving treatment can have non-specific effects on smoking, we also analyzed cigarette use using the week before treatment initiation (as compared to baseline) in our regression model. When data from the treatment-exposed sample ( $n = 71$ ) was analyzed using the same model, individuals in the MT group again showed a greater rate of change in smoking compared to those in the FFS group, and maintained these treatment gains during the follow-up period (treatment group  $\times$  time,  $F = 11.11$ ,  $df = 1, 1082$ ,  $p = .001$ ; estimates from the regression analyses for the treatment-exposed sample are presented in Fig. 2). Individuals who received MT showed a trend toward greater 1-week point prevalence abstinence at the end of treatment (36% vs. 15%,  $\chi^2 = 3.45$ ,  $df = 1$ ,  $p = .063$ , see Fig. 3), which was statistically significant at the 17-week follow-up endpoint (31% vs. 6%,  $\chi^2 = 6.32$ ,  $df = 1$ ,  $p = .012$ ).

### 3.3. Medication use during and after treatment

Though participants were neither encouraged nor discouraged from using nicotine replacement, three participants (9%) who received MT and four (11%) who received FFS reported some type of nicotine replacement use during treatment (average of  $11.3 \pm 6.8$  and  $19.8 \pm 4.8$  days, respectively,  $F = 3.76$ ,  $df = 1, 5$ ,  $p = .110$ ). During follow-up, three participants (9%) who received MT and eight who received FFS (21%) reported nicotine replacement (average of  $17.3 \pm 27.4$  and  $35.4 \pm 22.1$  days, respectively,  $F = 1.30$ ,  $df = 1, 9$ ,  $p = .284$ ). No participants receiving MT reported other cessation medication use, while one participant receiving FFS reported using varenicline (24 days) and one reported using bupropion (12 days).

### 3.4. Effects of mindfulness training practice on outcomes

As home practice has been correlated with outcomes in studies of substance use (Carroll et al., 2008) and MT (Carmody and Baer, 2008), we also assessed links between home practice and treatment outcomes. Individuals receiving MT reported formal home practice an average of 18 min/day, 4.6 days/week and informal practice an



**Fig. 2.** Individuals receiving mindfulness training reduce cigarette smoking more than those receiving freedom from smoking. Mixed effect regression model estimates of cigarette smoking in mindfulness training (MT,  $n = 33$ ) and freedom from smoking (FFS,  $n = 38$ ) during the week before treatment initiation and the 4 weeks of treatment ( $F = 11.11$ ,  $df = 1, 1082$ ,  $p = .001$ ).

**Table 2**  
Correlations between MT home practice and treatment outcomes.

	Week 4		Week 6		Week 12		Week 17	
	<i>r</i>	<i>p</i>	<i>r</i>	<i>p</i>	<i>r</i>	<i>p</i>	<i>r</i>	<i>p</i>
<b>Point prevalence</b>								
Total formal practice	-.342	.075	-.323	.088	-.164	.395	-.280	.141
Body scan	-.270	.164	-.267	.162	-.136	.483	-.165	.393
Loving kindness	-.121	.546	-.083	.673	.031	.877	-.156	.429
Sitting meditation	-.584	.001	-.582	.001	-.400	.039	-.520	.005
Total informal practice	-.281	.147	-.310	.101	-.278	.144	-.214	.265
Setting aspiration	-.096	.628	-.068	.727	.026	.893	.020	.917
Daily activity	-.206	.294	-.222	.246	-.106	.584	-.104	.592
RAIN	-.283	.144	-.332	.078	-.406	.029	-.292	.124
<b>Average number of cigarettes/day</b>								
Total formal practice	-.442	.019	-.267	.162	-.190	.324	-.197	.305
Body scan	-.426	.024	-.212	.271	-.199	.300	-.195	.311
Loving kindness	-.296	.134	-.218	.264	-.193	.325	-.206	.293
Sitting meditation	-.508	.007	-.424	.027	-.071	.724	-.079	.696
Total informal practice	-.479	.010	-.373	.046	-.022	.911	-.008	.968
Setting aspiration	-.225	.251	-.085	.661	.087	.652	.086	.657
Daily activity	-.324	.093	-.249	.192	.105	.587	.125	.518
RAIN	-.499	.007	-.417	.024	-.170	.379	-.166	.388

Pearson correlations between formal practice (total minutes) and informal practice (total number of times) and smoking outcomes. *N* = 27–29. Significant correlations are in boldface. No significant correlations were found in the FFS group.

average of 4.8 times/day, 5.1 days/week during treatment. Those receiving FFS reported formal home practice (listening to a 30 min CD) 1.5 days/week, and informal practice (completing PackTracks®) an average of 3.2 days/week.

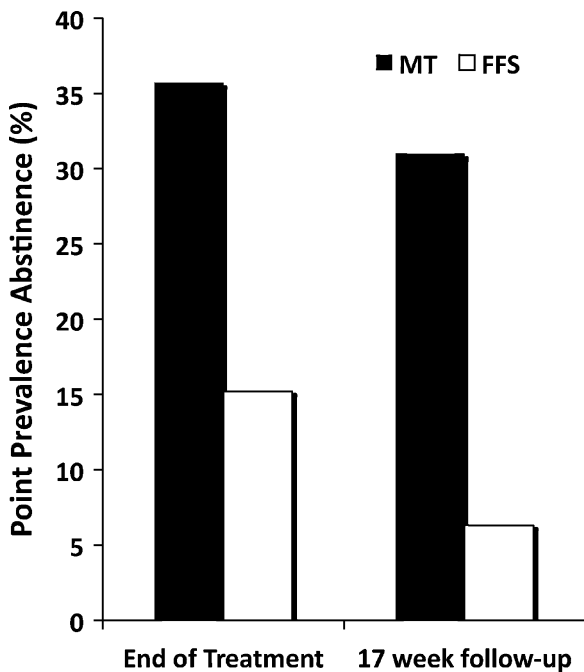
Within the MT group, more home practice correlated with less cigarette use for both formal (*r* = -.442, *df* = 26, *p* = .019, see Table 2) and informal practice (*r* = -.479, *df* = 26, *p* = .010) at the end of treatment. Although not statistically significant, this relationship was also seen for point prevalence abstinence (*r* = -.342, *df* = 26, *p* = .075). *Post hoc* analysis showed strong correlations between sitting meditation and point prevalence abstinence throughout the

follow-up period, and the use of the informal practice RAIN with average number of cigarettes at 4 and 6 weeks (see Table 2). No correlations were found between FFS home practices and outcomes (*df* = 29, all *p* > .315).

**4. Discussion**

This, to our knowledge, is the first randomized clinical trial to evaluate the efficacy of mindfulness training as a stand-alone treatment for smoking cessation compared to an active, empirically supported control condition. Despite comparable treatment retention and completion rates, we found that individuals who received MT demonstrated greater reductions in smoking, which were maintained through the 17-week follow-up interview. These findings are encouraging as behavioral treatments have shown little overall improvement in cessation rates over the past 30 years (Mottillo et al., 2009; Shiffman, 1993). For example, our 17-week point prevalence odds ratio of 6.75, is significantly larger than the average odds ratio of 1.76 found in a recent meta-analysis of previous studies of group counseling (Mottillo et al., 2009), though this may be in part a result of the relatively poor performance of FFS. It was also larger than the odds ratio of behavioral therapies as reported in the current clinical practice guidelines, such as those targeting negative affect (OR = 1.2, abstinence rate = 13.6%), social support (OR = 1.5, abstinence rate = 16.2%), practical counseling (OR = 1.5, abstinence rate = 16.2%), aversive smoking (OR = 1.7, abstinence rate = 17.7%) and medication + counseling (OR = 1.7, abstinence rate = 22.1%) (Fiore et al., 2008).

Though the underpinnings of the actions of MT are just beginning to be understood (Brewer et al., 2010b; Grabovac et al., 2011; Lutz et al., 2008), the results from this study suggest that teaching techniques that in theory, target core components of the addictive process (e.g., craving) may be more effective than teaching the avoidance of cues or fostering positive affective states that have been emphasized in previous treatments. This possibility is particularly relevant in light of evidence suggesting that pharmacotherapies may be more efficacious in targeting background rather than cue-induced craving (Ferguson and Shiffman, 2009). It is plausible that combining MT with a medication may improve both the initial efficacy as well as long-term abstinence rates as (1) the combination may target both background and cue-induced crav-



**Fig. 3.** Individuals receiving mindfulness training achieve greater point prevalence abstinence rates than those receiving freedom from smoking. One-week point prevalence abstinence rates for mindfulness training (MT) and freedom from smoking (FFS) at the end of treatment ( $\chi^2 = 3.45$ , *df* = 1, *p* = .063) and 17-week follow-up ( $\chi^2 = 6.32$ , *df* = 1, *p* = .012), *n* = 33 in MT and *n* = 38 in FFS.

**Table 3**  
Average home practice during treatment and follow-up.

Week(s)	MT				FFS			
	Formal home practice		Informal home practice		Formal home practice		Informal home practice	
	Days/week	Minutes/day	Days/week	Times/day	Days/week	Minutes/day	Days/week	Times/day
1–4	4.6	18.0	5.1	4.8	1.5	Not calc <sup>a</sup>	3.2	Not calc <sup>b</sup>
6	4.1	20.5	3.6	5.3	2.0	14.0	2.6	4.1
12	3.3	33.3	3.6	10.4	1.3	9.6	1.6	1.3
17	2.6	27.0	2.7	5.6	1.8	8.6	1.5	3.1

<sup>a</sup> Participants were instructed to listen to a 30 min CD but were not asked to report the actual number of minutes of listening.

<sup>b</sup> Participants were instructed to complete PackTracks<sup>®</sup> but were not asked to report the number of times/day of doing so.

ing concurrently and (2) MT may help to sustain medication effects after discontinuation through the “unlearning” of the addictive process. However, future studies are required to determine whether changes in craving, negative affect or other mechanisms mediate the effects of mindfulness training in smoking cessation. Additionally, as very few subjects in this study opted to use medications, no treatment by medication interactions or differences between groups was noted. Further trials combining MT with medications will help to answer whether there are indeed interactions therein and how these affect the addictive process.

We have previously shown positive relationships between homework completion and substance use outcomes (Carroll et al., 2005). Links between the amount of MT home practice and outcomes have also been studied in various populations, though have yielded mixed results, possibly due to methodological shortcomings (Vettese et al., 2009). Using careful matching for the type and amount of home practice between groups, we found no correlations between the amount of formal or informal homework in the FFS group, but strong correlations in the MT group. These findings help to control for the confounding effects of individuals being motivated to quit (i.e., motivated individuals would presumably do more home practice regardless of group), as well as non-specific effects of doing any type of home practice. Interestingly, many of the positive findings between home practice and outcomes in previous studies may be attributed to self-selection bias, familiarity with mindfulness, and/or treatment expectancies (Vettese et al., 2009). However, even when controlling for these factors (e.g., no mention of the type of treatment until after randomization, no previous mindfulness experience [data not shown], etc.), we still found strong correlations between home practice and outcomes. The correlations between sitting meditation and treatment outcomes are noteworthy as they may suggest that practicing to “sit” through difficult mind-states (including negative affect and craving) may train individuals to do the same when faced with an opportunity to smoke. Alternatively, sitting meditation may be a marker for individuals who are more likely to be able to utilize MT for smoking cessation, thus raising the prospect of individualizing treatment by using this at intake or early in treatment to determine if an individual may benefit from MT, or if other cessation strategies should be emphasized. Overall, these results suggest that MT may be a viable option for smoking cessation treatment for the general population, and given its group format and short treatment period, may prove to be cost effective as well (Table 3).

#### 4.1. Strengths and limitations

Strengths of this pilot trial include the random assignment from a diverse community sample, the presence of an active comparison group, and the use of intent-to-treat analysis of our sample using validated outcome measures. This study has several limitations as well. This study was performed at a single site, treatment was provided by only 1–2 therapists per condition, and treatment integrity was not formally assessed. Thus treatment effects may not

be generalized beyond the specific therapists in this trial (Crits-Christoph and Mintz, 1991). Also, it was of moderate size, and used an active comparison group, which typically limits the ability to detect differences between contrasts. Notwithstanding, we still found significant between-group differences, though these warrant replication before definitive conclusions may be drawn. Also, MT and FFS are typically delivered over 8 weeks as compared to 4 weeks. Despite significant overall reductions in smoking in both groups, it is possible that participants in both groups may have fared better with extended treatment. Further, the FFS group showed lower abstinence rates than those reported by self-quitters (11%) (Fiore et al., 2008), which may be due to selection inherent in clinical trials, though this bias should be distributed across both arms of this study due to randomization. In addition to the shorter 4-week format, FFS may have also fared unusually poorly as medication treatment was neither emphasized nor de-emphasized, rather than the usual emphasis that has been placed on combination treatment (this was specifically done to isolate the effects of these behavioral therapies, while not withholding proven medication treatment). In fact, the addition of 4–8 sessions of counseling to medication has been shown to produce greater abstinence rates (OR=1.3, abstinence rate=26.9%) than medication alone (OR=1.0, abstinence rate=21.8%) (Fiore et al., 2008). Given its pilot study nature, our 4-month follow-up period is shorter than the 6-month period that is standard in the field (Fiore et al., 2008). Finally, a limitation of this study is the exclusion of individuals using psychoactive medications (for example roughly 10% of the US population is currently prescribed selective serotonin reuptake inhibitors (Olsson and Marcus, 2009)). As the establishment of the efficacy of MT in the general population is an important first step, the next step will be to assess its effectiveness in individuals with psychiatric co-morbidities, especially with the high prevalence of smoking in individuals with psychiatric disorders (Ziedonis et al., 1994). Given shared features and possible common mechanisms between addictions and primary axis I psychiatric disorders (e.g., depression), it is possible that mindfulness training may benefit both concurrently (Brewer et al., 2010b).

In conclusion, results from this study suggest that MT may have promise as a brief, stand-alone treatment for smoking cessation. Larger studies that not only replicate these findings, but evaluate the psychological and neurobiological mechanisms of action of MT, as well as those combining MT with pharmacotherapies are warranted.

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## Contributors

Authors Brewer, Carroll and Rounsaville designed the study. Author Brewer wrote the protocol and conducted the study. Authors Brewer, Byrne, Deleone, Johnson, Kober, Mallik, Minnix-Cotton, and Weinstein collected data. Authors Babuscio, Brewer, Mallik and Nich analyzed the data. Authors Babuscio, Brewer, Carroll, Mallik, Nich, and Rounsaville interpreted the data. Author Brewer wrote the manuscript. Authors Babuscio, Carroll, Kober, Mallik, Nich, and Rounsaville edited the manuscript. All authors have approved the final manuscript (with the exception of Dr. Rounsaville, who approved an earlier version of the manuscript but passed away unexpectedly before its submission).

## Conflict of interest statement

None.

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