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Distress Tolerance Treatment for Weight Concern in Smoking Cessation Among Women: The WE QUIT Pilot Study

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Abstract

Fear of gaining weight after quitting cigarette smoking is a major barrier to smoking cessation among women. Distress tolerance, which refers to one's ability and willingness to tolerate physical and emotional discomfort, predicts successful behavior change. Novel interventions rooted in Acceptance and Commitment Therapy (ACT) have emerged that aim to increase distress tolerance and engagement in values-oriented behavior. In this study, we developed a 9-week, group-based distress tolerance intervention for weight concern in smoking cessation among women (DT-W). Using an iterative process, we piloted DT-W with two small groups ($n = 4$ and $n = 7$) of female weight-concerned smokers. Results indicated that we successfully established the feasibility and acceptability of DT-W, which was well-attended and well-received. Biochemically verified 7-day point-prevalence abstinence rates at post-intervention, 1, 3, and 6 months were 64%, 36%, 27%, and 27%, respectively. We are now evaluating DT-W in a randomized controlled trial.

Keywords

smoking cessation; tobacco cessation; Acceptance and Commitment Therapy; distress tolerance; weight

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Introduction

Cigarette smoking cessation is accompanied by weight gain for about 80% of quitters. The mean weight gain is 10 lb within the first year after quitting, with most of this weight gained within the first 6 months (Aubin, Farley, Lycett, Lahmek, & Aveyard, 2012). This weight is not typically lost; rather, weight gain continues at a slower rate. One study found that after 8 years, quitters had gained 19 lb compared with 5 lb for continuing smokers (Lycett, Munafò, Johnstone, Murphy, & Aveyard, 2011).

Women are much more likely than men to report that they smoke cigarettes as a means of weight control (Pinto et al., 1999; Weekley, Klesges, & Reylea, 1992; White, McKee, & O'Malley, 2007) and to be concerned about gaining weight after smoking cessation (Clark et al., 2006; Levine, Perkins, & Marcus, 2001). The majority of female smokers are concerned about post-cessation weight gain (Beebe & Bush, 2015; Jeffery, Hennrikus, Lando, Murray, & Liu, 2000; Pirie, Murray, & Luepker, 1991; Pomerleau, Zucker, & Stewart, 2001), with 75% reporting that they are unwilling to gain more than 5 lb, and 90% unwilling to gain more than 10 lb (Levine et al., 2001; Pomerleau & Kurth, 1996). In other studies, smokers were asked whether they would relapse if they gained weight up to 20 lb. Half of women said they would relapse, compared with only 25% of male smokers (Clark et al., 2004; Cooper, Dundon, Hoffman, & Stoeber, 2006). Caucasian and obese female smokers are most likely to be weight-concerned, but weight concern affects the majority of female smokers in all body mass index (BMI) categories except underweight and a significant proportion from all races and ethnicities (Beebe & Bush, 2015; Pomerleau, Zucker, Namenek Brouwer, Pomerleau, & Stewart, 2001; Pomerleau, Zucker, & Stewart, 2001). A national random-digit-dialing survey revealed that compared with female smokers who were “not at all” or “somewhat” weight-concerned, those who were “very” weight-concerned were less likely to have post-high school education, but did not differ in age or household income (Pomerleau, Zucker, & Stewart, 2001).

Female smokers report that their fear of gaining weight deters them from initiating quit attempts (Jeffery et al., 2000; Pomerleau, Zucker, & Stewart, 2001; Weekley et al., 1992) and decreases their confidence in their ability to quit (Bowen, McTiernan, Powers, & Feng, 2000). They also attribute past relapses to anticipated or actual weight gain (Jarry, Coombs, Polivy, & Herman, 1998; Pisinger & Jorgensen, 2007; Pomerleau, Zucker, & Stewart, 2001; Swan, Ward, Jack, & Javitz, 1993). Consistent with women's retrospective self-reports, weight concern is indeed associated with poor smoking cessation treatment outcomes, including more severe self-reported withdrawal symptoms (Pinto et al., 1999), failure to attend the first treatment session and treatment dropout (Copeland, Martin, Geiselman, Rash, & Kendzor, 2006; Mizes et al., 1998; Namenek Brouwer & Pomerleau, 2000), and relapse (Clark et al., 2006; Jeffery et al., 2000; Meyers et al., 1997).

Researchers have previously tested two types of adjunctive interventions to address weight concern in smoking cessation among women. The first type aims to prevent weight gain directly; approaches have included behavioral weight management treatment (e.g., reduced calorie diet) and pharmacotherapy. Reviews support a short-term benefit of behavioral weight management treatment in some studies but no long-term effects on smoking or

weight outcomes (Farley, Hajek, Lycett, & Aveyard, 2012; Parsons, Shraim, Inglis, Aveyard, & Hajek, 2009; Spring et al., 2009). Regarding pharmacotherapy, a recent meta-analysis revealed that nicotine replacement therapies, bupropion, and varenicline did not produce long-term effects on weight outcomes (Aubin et al., 2012). Furthermore, weight gain trajectories were similar regardless of use or non-use of medication (Aubin et al., 2012).

Perkins and colleagues developed an alternative cognitive-behavioral therapy (CBT) approach for weight-concerned female smokers intended to reduce negative affect associated with fear of weight gain and body dissatisfaction rather than to prevent weight gain directly. Women were encouraged to challenge their negative thoughts about weight and body image, whereas dieting was discouraged (Levine, Marcus, & Perkins, 2003; Levine et al., 2010; Perkins et al., 2001). An initial trial, which did not include pharmacotherapy, demonstrated a positive effect of this CBT relative to behavioral weight management treatment or smoking treatment only on both smoking and weight outcomes. Unexpectedly, however, no impact on weight concern was found, indicating that the mechanism of treatment was unclear (Perkins et al., 2001). A second trial revealed only a marginal effect of CBT relative to bupropion (Levine et al., 2010).

Perkins and colleagues' approach, which targeted negative affect associated with weight and body image concerns in the context of smoking cessation rather than actual weight, is consistent with theory and research implicating negative affect as a key factor in the maintenance of tobacco use (e.g., Baker, Piper, McCarthy, Majeskie, & Fiore, 2004; Khantzian, 1997; Leventhal & Zvolensky, 2015), a primary precipitant of relapse (Shiffman, Paty, Gnys, Kassel, & Hickcox, 1996), and a mediator of the relationship between body image dissatisfaction and craving to smoke (Lopez Khoury, Litvin, & Brandon, 2009). It might be expected that the severity or magnitude of negative affect experienced during a quit attempt would be a primary predictor of relapse. However, recent research has revealed that the extent of an individual's willingness and ability to tolerate aversive experiences such as physical or emotional distress (i.e., distress tolerance; Leventhal & Zvolensky, 2015) is an important contributor to outcomes in smoking cessation above and beyond the absolute severity or magnitude of distress (Brandon et al., 2003; Brown, Lejuez, Kahler, & Strong, 2002; Brown et al., 2009; Trujillo et al., 2015). A framework by Leventhal and Zvolensky posits that distress tolerance is a transdiagnostic emotional vulnerability such that individuals who are low in distress tolerance are particularly motivated to smoke to relieve or escape distress (Leventhal & Zvolensky, 2015) and therefore may be more likely to relapse when experiencing distress (e.g., nicotine withdrawal, cravings, general life stress). Similar models have been proposed to explain the influence of distress tolerance on weight management (Forman & Butryn, 2015; Lillis & Kendra, 2014).

Supporting these models, studies have shown that smokers are less persistent than non-smokers on physically or emotionally aversive tasks (e.g., breath-holding, mental arithmetic, tracing geometric figures from the perspective of a mirror; Brown et al., 2002; Quinn, Brandon, & Copeland, 1996) and that the duration of persistence on these tasks prospectively predicts successful cessation (Brandon et al., 2003; Brown et al., 2009). Furthermore, low distress tolerance is positively associated with indices of nicotine dependence after controlling for symptoms of negative affect (Trujillo et al., 2015), and

smokers who are low in self-reported distress tolerance believe that quitting smoking will be difficult because smoking serves as a primary method of affect regulation (Kraemer, McLeish, Jeffries, Avallone, & Luberto, 2013). Other recent research has focused on the related concept of experiential avoidance, which refers to efforts to control, suppress, or escape distress (e.g., nicotine withdrawal, craving). Reduction of experiential avoidance has been implicated in successful smoking cessation as well as weight management (Lillis, Hayes, & Levin, 2011; Minami, Bloom, Reed, Hayes, & Brown, 2015; Niemeier, Leahey, Palm Reed, Brown, & Wing, 2012), suggesting a common clinical pathway for smoking cessation and weight control (see Gifford & Lillis, 2009).

These findings have influenced the development of novel treatments intended to increase distress tolerance (e.g., Brown et al., 2013). Distress tolerance skills have been primarily derived from, and share many common elements with, Acceptance and Commitment Therapy (ACT; Hayes, Luoma, Bond, Masuda, & Lillis, 2006). The central focus of ACT is on teaching the practice of acceptance, defined as “the active and aware embrace” of uncomfortable or aversive thoughts and feelings “without unnecessary attempts to change their frequency or form” for the purpose of “increasing values-based action” (Hayes et al., 2006, pp. 7–8). The theoretical rationale for incorporating these skills is that behaviors such as smoking or eating are often used to reduce, avoid, escape, and/or cope with negative thoughts and feelings and interfere with engagement in values-oriented behaviors; individuals are taught that values-oriented behavior can be engaged in regardless of the presence or severity of distress (Hayes et al., 2006).

Promising results are now emerging for interventions that incorporate acceptance-based techniques in the areas of weight management (e.g., Forman et al., 2013; Katterman, Goldstein, Butryn, Forman, & Lowe, 2014), improving disordered eating and body image (e.g., Pearson, Follette, & Hayes, 2012), and increasing physical activity (e.g., Butryn, Forman, Hoffman, Shaw, & Juarascio, 2011), as well as in smoking cessation (e.g., Bricker, Mann, Marek, Liu, & Peterson, 2010; Hernández-López, Luciano, Bricker, Roales-Nieto, & Montesinos, 2009). The use of acceptance-based interventions for addressing negative affect associated with body dissatisfaction among non-eating disordered women is particularly compelling because the “pervasive yet subclinical nature of the problem” (Pearson et al., 2012, p. 182) across the life span may make it particularly resistant to change-based strategies (see also Juarascio, Forman, & Herbert, 2010). Furthermore, there is considerable support for theorized mechanisms of action for acceptance-based approaches and for a general relationship between distress tolerance and related constructs and mental and physical health (Ciarrochi, Billich, & Godsell, 2010). Among weight-concerned female smokers, two specific behaviors may be conceptualized as evidence of limited distress tolerance: (a) continuing to smoke (i.e., not initiating a quit attempt) to avoid fear of post-cessation weight gain and negative affect associated with body dissatisfaction more generally, and (b) after quitting, eating instead of smoking to reduce, avoid, escape, or cope with stress (Hudmon, Gritz, Clayton, & Nisenbaum, 1999).

In the current study, we developed and piloted a group-based intervention for weight-concerned female smokers that retained Perkins and colleagues’ focus on negative affect associated with fear of weight gain and body dissatisfaction but used an alternative distress

tolerance-based orientation. Our distress tolerance intervention for weight concern in smoking cessation among women (DT-W) promoted acceptance of negative weight-related thoughts and feelings, reduction of eating triggered by external and/or emotional cues, and increased engagement in values-oriented behaviors. DT-W also included all components of standard cognitive-behavioral smoking cessation treatment (Standard Treatment, ST; Brown, 2003) and an 8-week course of transdermal nicotine patch (TNP). The purpose of this pilot study was to establish the feasibility and acceptability of DT-W. We also piloted the assessment procedures for a planned future randomized controlled trial (RCT), including administration of primary outcome measures and several process measures that we hypothesized would be potential mechanisms of treatment efficacy.

Method

Participants

Two small groups of adult female smokers were recruited from the local community via online advertisements on Craigslist and Facebook, and paper flyers and brochures displayed throughout the study site and other public locations (e.g., grocery stores, mall). Advertisements for the study specifically targeted women who wanted to quit smoking and were concerned about gaining weight. The study was branded as the “WE QUIT” Study (*Women Engaging in Quitting Smoking Together*) in advertisements and participant materials (see Figure 1 for the logo that appeared on all advertisements and participant materials). All staff including group leaders referred to the study as “WE QUIT” and the treatment program as the “WE QUIT program” when communicating with participants. The term *DT-W* was not used with participants.

Eligible women were 18 to 65 years old, had smoked 10 cigarettes per day for 1 year, were motivated to quit, and were concerned about post-cessation weight gain, defined as a rating of at least 50 on at least one of two 100-point rating scales: “How concerned are you about gaining weight after quitting smoking” and “How concerned would you be if quitting smoking caused you to permanently gain 10–15 pounds?” (Levine et al., 2010, p. 544; Perkins et al., 2001, p. 605). Women were excluded if they were currently using other smoking cessation or weight loss treatments; used other tobacco products at least weekly; were pregnant or breast-feeding; had a medical condition that was a contraindication for the use of TNP; self-reported a current diagnosis of non-nicotine substance use disorder (SUD) or a lifetime diagnosis of eating, bipolar, or psychotic disorder; were taking psychotropic medication except for selective serotonin reuptake inhibitors (SSRIs); or scored above standard cutoffs on self-report screening measures of depression, eating disorder, or SUD symptoms (see “Measures” section below). Initially, we also excluded women with a BMI of >35 (Obesity Class II), with the rationale that a weight loss program was more appropriate (i.e., medically advisable) and desirable for these women. However, shortly after beginning recruitment for the first group, we eliminated this criterion after observing that women were interested who were otherwise eligible except for having a BMI >35. We realized that although it would be medically advisable for women with a BMI >35 to lose weight, other smoking cessation trials have not typically had BMI restrictions. Therefore, women with a BMI >35 would not typically receive a weight loss program as part of smoking cessation

treatment. Furthermore, we believed that the risk of our experimental intervention resulting in significantly *greater* weight gain than standard treatment (which could present a more significant health risk for women with BMI >35) was minimal. The participant flow diagram is shown in Figure 2. Sixteen ($n = 16$) women completed a baseline assessment, of whom 11 attended at least one group session of DT-W. The first group ($n = 4$) received DT-W in the spring of 2014 and the second group ($n = 7$) in the fall of 2014.

Procedure

Interested women were screened for preliminary eligibility via telephone by a research assistant or by completing an online survey created using Research Electronic Data Capture (REDCap; Harris et al., 2009). Those who met preliminary criteria were scheduled for an in-person baseline assessment during which they provided written informed consent and completed additional screening to confirm their eligibility, including a urine pregnancy test. When enough women had completed the baseline assessment to form a small group, their group began the intervention. Piloting of DT-W followed an iterative process, in which the original DT-W intervention was revised based on feedback received from participants in the first group, with additional revisions made based on the second group's feedback. This feedback is described in the "Results" section below.

DT-W intervention

Overview: Structure, clinicians, and treatment components—DT-W consisted of a 60-min individual counseling session followed by eight weekly, 90-min group counseling sessions, with quit date at Group Session 4, and a brief 20-min individual phone session between Group Sessions 4 and 5. Groups were co-led by two clinicians who followed a structured manual to ensure standardized intervention delivery. The spring 2014 ($n = 4$) group was co-led by a licensed clinical psychologist (E.L.B.) and a clinical psychology postdoctoral fellow (H.M.); the fall 2014 ($n = 7$) group was co-led by E.L.B. and a master's level nurse (J.H.). E.L.B. conducted weekly supervision with the other clinicians, both of whom had past experience in delivering similar ACT-based interventions. All sessions were audiotaped or videotaped to facilitate supervision. DT-W included three main components as described below.

ACT-based component of DT-W—Table 1 provides a description of the ACT-based treatment elements in DT-W and the sessions in which they appear in the final version. The ACT-based elements of DT-W were adapted from the following previous ACT-based treatment manuals, with permission from their authors: (a) distress tolerance treatment for smokers with a history of early lapse (Brown et al., 2008; Brown et al., 2013), (b) distress tolerance treatment for smoking cessation in a general population of smokers (manuscript under review, principal investigator [PI]: Richard A. Brown, PhD), (c) acceptance-based behavioral intervention for weight loss (Lillis et al., 2015), (d) ACT for body image dissatisfaction (Pearson et al., 2012; Pearson, Heffner, & Follette, 2010), and (e) Mindfulness and Acceptance-Based Group Therapy for Social Anxiety Disorder: A Treatment Manual (Fleming & Kocovski, 2009). The ACT-based content also incorporated concepts from *The Appetite Awareness Workbook* (Craighead, 2006), which was also used by Pearson et al. (2012).

The ACT-based content in DT-W specifically targeted weight concerns in the context of smoking cessation. This ACT-based content was “front-loaded” to motivate treatment retention, such that the first two group sessions included only ACT-based content targeting weight concerns, whereas the individual session and remaining group sessions (3–8) were split evenly between ACT-based content and Standard Treatment (ST) content (see description of ST components below). The ACT-based content covered all six core processes of ACT: values, acceptance, defusion, self as context, being present, and committed action (Hayes et al., 2006). ACT-based content in group sessions prior to quit date (Weeks 1–3) focused on “distress tolerance skills” for coping with the fear of anticipated weight gain. During the quit date (Week 4) and post-quit (Weeks 5–8) sessions, these distress tolerance skills were reinforced while new “values-oriented living skills” were introduced.

The distress tolerance skills content culminated in a mirror exposure exercise in Session 6 (Pearson et al., 2012). Participants were paired and each pair was sent to a different corner of the room where there was a full-length mirror on the wall. One member of each pair was asked to stand in front of the mirror and verbalize her thoughts about her body, starting at her head and moving down to her feet, while her partner wrote down each thought on an individual piece of paper. Then they switched roles. After all pairs had finished the exercise and returned to the table in the middle of the room, the group leaders collected all of the pieces of paper, shuffled them, and then distributed them evenly among the group. One at a time, each group member was asked to read the thoughts on her piece of paper to the rest of the group. After hearing all thoughts, the group was asked to discuss their reactions and also whether they could determine to whom each thought belonged. The goals of this exercise were practice in acceptance via exposure, and to notice the similarities among the thoughts, as well as how judgmental the thoughts were. Finally, participants were asked to rip up the pieces of paper, pick up a handful of the pieces, and “hold them lightly” (see Pearson et al., 2012, p. 192) as an exercise in cognitive defusion and self as context.

Values-oriented living skills in the post-quit date sessions focused on reducing eating triggered by external and/or emotional cues, a primary cause of excessive post-cessation weight gain (Hudmon et al., 1999). Participants were taught to become more aware of physiological sensations of hunger and fullness and to use those sensations rather than external or emotional triggers to guide decisions about when and how much to eat, following the appetite awareness training methods described in the *Appetite Awareness Workbook* (Craighead, 2006).

Standard smoking cessation treatment component of DT-W—Standard Treatment (ST) content in DT-W was based on a manual used in previous research (Brown, 2003), and was consistent with the most recent clinical practice guideline from the U.S. Department of Health and Human Services, *Treating Tobacco Use and Dependence: 2008 Update* (Fiore et al., 2008). The pre-quit date and quit date group sessions (Weeks 3 and 4) focused on preparation for quit date, reinforcement and support for quitting, discussion of past quit experiences, initiation of self-monitoring, identification of triggers and high-risk situations, development of coping strategies for triggers unrelated to weight and body image (three “As”: avoid, alter, alternative), enlisting social support, and instruction in use of TNP. During the quit date session (Week 4), participants engaged in extended discussion of

quitting experiences and coping strategies. After quit date, remaining sessions (Weeks 5–8) consisted of providing support and relapse prevention, including ongoing discussion of quitting experiences, anticipation of high-risk situations, developing social support, and making lifestyle changes that supported abstinence.

TNP component of DT-W—All participants were educated about the proper use of the patch at the group session immediately prior to quit date. On quit date, participants began with the label-recommended dose for their current smoking level (21 mg if >10 cigarettes per day, 14 mg if ≤10) and gradually tapered to 7 mg over an 8-week period.

Assessments and compensation—All assessment data were collected and managed using REDCap electronic data capture tools (Harris et al., 2009). In addition to the baseline assessment and brief assessments at the beginning of each group DT-W session, participants completed individual assessments at “pre-quit” (the week prior to quit date, between Group Sessions 3 and 4), post-treatment (at last group session or within 1 week afterward if missed last session), and 1, 3, and 6 months post-treatment. Shortly after completing DT-W (within about 1 week), participants were also interviewed individually about their experience in DT-W. Interviews were conducted by a research assistant or a study clinician who was not one of the participants’ group leaders, using a semi-structured interview guide. All participants were compensated US\$25 for the pre-quit assessment, US\$25 for the post-intervention interview, US\$25 for the 1-month assessment, and US\$50 each for the 3- and 6-month assessments, for a total of US\$175. All women in both groups were asked to provide breath samples for carbon monoxide (CO) testing to verify self-reported smoking abstinence (see “Measures” section below). Women in the first group who self-reported abstinence received an extra US\$25 at the 1-, 3-, and 6-month assessments for providing breath samples; we did not provide these extra payments to Group 2 because we realized they were unnecessary.

Measures

Screening to confirm eligibility—At the baseline assessment, after providing written informed consent, participants reported their *demographics* and completed additional screening to confirm their eligibility, including two items to screen for current major depressive disorder (MDD), the *Center for Epidemiological Studies–Depression Scale* (CES-D; excluded if ≥23; Radloff, 1977), the behavior items from the *Eating Attitudes Test* (EAT-26) to screen for eating disorder (excluded if above the cutoff for any behavior, available at www.eat-26.com; Garner, Olmsted, Bohr, & Garfinkel, 1982), the *Alcohol Use Disorders Identification Test* (AUDIT; excluded if ≥8; Babor, Higgins-Biddle, Saunders, & Monteiro, 2001), and the *Drug Abuse Screening Test* (DAST; excluded if ≥3; Skinner, 1982). Women who were not eligible based on these screenings were provided with referrals to other local smoking cessation programs; eligible women completed the rest of the baseline assessment.

Other baseline-only measures—Smoking History included current smoking pattern and quit attempt history and the *Fagerström Test for Nicotine Dependence* (FTND; Heatherton, Kozlowski, Frecker, & Fagerström, 1991).

The *Smoking-Related Weight and Eating Episodes Test* (SWEET; Adams, Baillie, & Copeland, 2011) is a 10-item measure that assessed the extent to which participants used smoking to manage weight and body image concerns.

The *Weight Concern Scale* (WCS; Borelli & Mermelstein, 1998) is a six-item measure that assessed concern about post-cessation weight gain, perceived likelihood of gaining weight after cessation, and perceived likelihood of resuming smoking if too much weight gain occurs.

Weight Gain Tolerance referred to how much post-cessation weight gain (in pounds) participants would be willing to tolerate.

DT-W program evaluations—Participants in both DT-W groups completed brief evaluations at the end of each group session on which they rated how helpful they perceived the session with regard to quitting smoking and how well they understood the session content on 5-point scales (from 1 = *not at all* to 5 = *extremely*). The second group additionally completed an end-of-treatment evaluation at the last group session that included helpfulness and comprehension ratings for DT-W as a whole, and helpfulness ratings for each of the major DT-W concepts and activities.

Post-treatment semi-structured interview—Interviewers first asked participants' for general feedback, including most and least useful concepts/activities, and participants' opinion about the program's structure, including the number, duration, and frequency of sessions, order of concepts/activities, proportion of content dedicated to coping with weight concerns versus general smoking cessation strategies, homework assignments, and the group leaders' style and skill. During the second portion of the interview, interviewers asked for participants' reactions to specific concepts and activities that they had not already mentioned spontaneously.

Primary outcomes—*Smoking behavior* was tracked from baseline through the 6-month follow-up using the *Timeline Followback* (TLFB) procedure at each assessment (Brown et al., 1998). The TLFB included assessment of e-cigarette and other tobacco product use. At follow-ups, we also assessed use of other smoking cessation treatments not provided by the study, including medications and counseling. At all time points, reports of past-week abstinence from smoking (i.e., 7-day point-prevalence abstinence) were biochemically verified by *expired CO* (4 ppm cutoff; Cropsey et al., 2014). At the 3- and 6-month follow-ups, self-reported past-week abstinence from nicotine (including cigarettes and other nicotine-containing products) was additionally verified by *saliva cotinine levels* (15 ng/ml cutoff; SRNT Subcommittee on Biochemical Verification, 2002).

Participants' *height* was measured at baseline. *Weight* was measured at baseline, the last group session (Week 8), and follow-ups using a calibrated medical scale. Height and weight measurements were used to calculate BMI ($\text{weight [lb]/(height)}^2 \text{ [in.]} \times 703$).

Process measures

Depressive symptoms and body dissatisfaction—The CES-D (Radloff, 1977; 20 items, score range = 0–60) and two brief 100-point *Visual Analogue Scales* (VAS) were administered at baseline, weekly during DT-W, and follow-ups to monitor depressive symptoms and state dissatisfaction with weight/size and body shape (0 = *none* to 100 = *extreme dissatisfaction*), respectively.

The *Three-Factor Eating Questionnaire* (TFEQ-R21; Karlsson, Persson, Sjöström, & Sullivan, 2000; Stunkard & Messick, 1985) was administered at baseline, end of treatment, and follow-ups to assess cognitive restraint (CR; tendency to consciously restrict food intake to control body weight; six items, score range = 6–24), emotional eating (EE; tendency to eat when experiencing negative mood states; six items, score range = 6–24), and uncontrolled eating (UE; tendency to overeat because of a perceived loss of control or hunger; nine items, score range = 9–36).

The *Body Image–Acceptance and Action Questionnaire* (BI-AAQ; Sandoz, Wilson, Merwin, & Kellum, 2013; 12 items, score range = 7–84) was administered at baseline, end of treatment, and follow-ups to assess self-reported cognitive flexibility (e.g., acceptance, willingness, commitment to values-oriented behavior) specific to body image concerns. The BI-AAQ is reverse scored, such that higher scores indicate less flexibility.

Results

Participant Characteristics

Demographics and baseline characteristics for the 11 participants who attended at least one DT-W group session versus the five dropouts (four dropped out after baseline and were never exposed to DT-W, one dropped out after the individual session and did not attend any group sessions) are in Table 2. Participants who attended at least one group session were significantly more likely to have a 4-year college degree or higher and had significantly higher baseline scores on the WCS than dropouts ($p < .05$), but there were no other significant differences.

Group Attendance and Retention

Participants ($n = 11$) attended a mean of 6.27 ($SD = 2.00$) of the eight group sessions. One participant attended only the first group session, while the other 10 attended at least five sessions. Follow-up retention was 91% (10/11) for the post-treatment (Week 8) assessment, including the interview, and for the 1-month and 3-month assessments, and 82% (9/11) for the 6-month assessment.

DT-W Program Evaluations

The mean of all individual session helpfulness ratings was 4.05 ($SD = 0.48$; 1–5 scale with 5 being *most helpful*), while the mean of all individual session comprehension ratings was 4.58 ($SD = 0.41$; 1–5 scale with 5 being *most well understood*). On the end-of-treatment evaluation (completed by $n = 6$ from the second group), the mean helpfulness rating for DT-W as a whole was 4.83 ($SD = 0.41$) and the mean rating for comprehension for DT-W as a

whole was 4.80 ($SD = 0.45$). Ratings for individual treatment components are shown in Table 3.

Common Themes From Post-Treatment Interviews (Groups 1 and 2)

Ten participants (four in Group 1, six in Group 2) completed the post-intervention interview. Both groups unanimously praised DT-W and said they would recommend it to other women. One common theme that emerged from their responses was that DT-W was more *effective* than and *different* from other treatments. Specifically, participants described DT-W as *effective* ($n = 3$) or a similar word or phrase (e.g., *instrumental in helping me quit, seems to be working*). In addition, participants described DT-W as *different*, in a positive way, from other smoking cessation treatments they had tried:

- It was something kind of out of my comfort zone, but that was okay. I think that's what I needed to actually quit.
- ... the whole program is so totally different from anything else I've ever tried ... it was more about you and ... it made you stop and experience who you are and what you want.
- I think this study by far was superior to anything I've experienced ... everything as regards to the paying attention to your life values—that was completely new to me. Explained in the way that it was. I had never thought to put the two together.

Another theme was that ACT-based content was applicable beyond weight and smoking. Although the ACT-based content was applied specifically to weight concern in the context of smoking cessation, participants in both groups readily applied this content more generally:

- It was helpful, I mean, not just for quitting smoking but for kind of managing so many things ... about, as women, how quickly we are to judge ourselves. How many thoughts we have in our head about what's not right, what's not perfect, what we might want to be better, what we might want to change. And understanding that those are just thoughts, and that they're not, in fact, facts, can really—I think this is the beginning of paving the way of just doing something differently. So I found it really, you know, profound.
- Prior to this program, having those negative self-thoughts, I almost gave it so much power over how I would react [to] or handle situations. And it's only because I gave it that much power that it, I don't want to say controlled my life, but in a way, it did. So knowing that those negative self-thoughts don't have to control our lives was awesome.
- And it's a change—not just the smoking part—but pretty much how you do everything else.

Participants did not complete written homework—Participants praised the homework worksheets and appreciated having them for future reference, but most admitted that they did not complete them.

Group 1 Feedback and Manual Revisions for Group 2

Overall, participants in Group 1 were satisfied with DT-W's structure, content, and group leaders' style. They noted that group leaders often had to rush to complete all exercises within the allotted session time and suggested adding additional sessions or reducing redundancy to provide more time for unstructured discussion time and facilitation of general social support. Participants described the quantity of handouts and homework assignments as appropriate. They reported that the most helpful and useful components were strategies for thought defusion and appetite awareness training. They were less enthusiastic about mindful eating (*strange*) and the mirror exposure exercise (*neutral*), but one participant noted the mirror exercise *may have been more helpful in a larger group*. For the second group, we streamlined the manual to reduce redundancy and detail instead of adding additional sessions, as DT-W was already lengthy at eight sessions and research suggests no additional benefit beyond eight sessions with respect to abstinence rates (Fiore et al., 2008). We retained mindful eating and the mirror exercise given the small number of participants who provided feedback on these components.

Group 2 Feedback and Manual Revisions for RCT

As with the first group, the second group provided positive feedback on the program structure, content, group leaders, handouts, and homework assignments. In this group, most participants thought that the eight-session length was sufficient. Concepts and activities most frequently named spontaneously as the most helpful or useful were an exercise in which participants practiced envisioning their thoughts and feelings as "leaves on a stream" that float in and out of consciousness, the mirror exposure exercise (*necessarily painful, powerful*), an ACT metaphor for thought defusion in which participants envisioned their thoughts and feelings as "passengers on a bus" for which they retained the power to determine the destination regardless of "passenger" requests, and appetite awareness training and mindful eating (*eye-opening*). There was no consensus about the least helpful components and very few suggestions for content to remove or add. Given that participants in the second group were very satisfied with the program, we made few additional changes to DT-W. We further streamlined the content, made some changes to the Appetite Monitoring forms that were intended to make them easier to understand and use, and instructed group leaders to put more emphasis on the option to complete monitoring forms electronically (e.g., on their smart-phone) instead of on the provided paper forms if it was more convenient.

Smoking Cessation and Weight Outcomes

CO-verified (and cotinine-verified when applicable) 7-day point-prevalence abstinence rates at end-of-treatment (last group session), 1, 3, and 6 months were 64% (7/11), 36% (4/11), 27% (3/11), and 27% (3/11), respectively. The same three participants were abstinent at 3- and 6-month follow-up. Notably, they were all from the first group and all self-reported continuous abstinence since quit date. The second group ended in mid-December, and at 1-month follow-up, some participants in that group attributed lapses to holiday-related events. Although none of the participants in Group 2 met our criteria for biochemically verified point-prevalence abstinence at 3- or 6-month follow-up, some were close (isolated lapses

only). Many remained actively engaged in efforts to quit smoking; at 6-month follow-up, only two reported returning to baseline smoking levels.

At the last group session, all nine participants who were weighed had gained weight since the baseline assessment ($M = 5.78$ lb). By the 6-month follow-up, six of the nine participants who were weighed had a higher weight than at baseline; their mean weight gain between baseline and 6-month follow-up was 11.67 lb. Among the three participants who self-reported continuous abstinence between quit date and the 6-month follow-up (all from the first group), the mean weight gain at 6 months was 12.17 lb.

Six of the 10 participants who completed at least one follow-up assessment reported use of another smoking cessation method or treatment not provided by the study at some point during their DT-W intervention or the follow-up period. One participant reported use of nicotine patches obtained from another source (not the patches we provided), four reported e-cigarette use, and one used an Internet program.

Process Measures

Formal statistical analyses were not conducted on process measures given the small sample size. However, a visual inspection suggests that depressive symptoms (CES-D) were low and relatively stable (see Figure 3). State body dissatisfaction (VAS) declined sharply on quit date but then gradually returned to baseline levels (see Figure 4). Regarding TFEQ scores, CR and EE were stable, but UE increased slightly after quit date and was stable thereafter (see Figure 5). Contrary to expectation, cognitive flexibility with respect to body image concerns (BI-AAQ) *decreased* (BI-AAQ is reverse scored) between baseline and quit date, but remained stable thereafter (see Figure 6).

Discussion

In the current study, we developed and piloted a novel group-based intervention to address women's concerns about gaining weight after smoking cessation called Distress Tolerance Treatment for Weight Concern in Smoking Cessation Among Women (DT-W). The goal of DT-W was to increase distress tolerance with respect to fear of weight gain prior to quitting and to reduce eating triggered by external and emotional cues that promotes weight gain after quitting, using concepts and metaphors derived primarily from ACT (Hayes et al., 2006) and the *Appetite Awareness Workbook* (Craighead, 2006). We were successful at establishing the feasibility and acceptability of DT-W. The 11 participants who initiated DT-W unanimously praised the intervention, describing it as more *effective yet different* from other smoking cessation treatments they had tried. On average, participants rated program sessions as "very" helpful on a quantitative evaluation, and five of six who completed the end-of-program evaluation rated the program as a whole as "extremely helpful," which compares favorably with past research in which similar rating scales were used (e.g., Brown et al., 2013; Napolitano, Lloyd-Richardson, Fava, & Marcus, 2011; Perkins et al., 2001). Based on participants' feedback, only minor changes were made to DT-W. We are now evaluating the finalized version of DT-W in an RCT.

Previous research has indicated that weight-concerned female smokers have high rates of failure to initiate smoking cessation treatment and treatment dropout (Copeland et al., 2006; Namenek Brouwer & Pomerleau, 2000). In our study, five of 16 participants who completed a baseline assessment for one of the two DT-W groups did not attend any group treatment sessions. However, the 11 women who initiated treatment had *more severe* weight concerns on the WCS than the five who dropped out. Therefore, we believe that we successfully retained weight-concerned participants. We speculate that the relatively high dropout rate may be partially attributable to loss of motivation and interest in quitting associated with a lengthy waiting time (1–2 months) for some participants between the completion of their baseline assessment and the beginning of their DT-W intervention.

Although this pilot study was not designed or powered to evaluate efficacy with respect to smoking or weight outcomes, smoking abstinence rates were comparable to other intensive treatments (Fiore et al., 2008) and promising, given that weight-concerned female smokers are considered a particularly treatment-resistant population. Weight gain among participants varied but was generally consistent with population means (Aubin et al., 2012). We also administered several process measures that could be potential mechanisms of treatment efficacy, including depressive symptoms, dissatisfaction with weight/size and body shape, cognitive flexibility with respect to body image concerns, and eating behavior (restrained, uncontrolled, and emotional). We would expect that in the absence of an intervention targeting weight concerns, depressive symptoms, body dissatisfaction, cognitive inflexibility related to body image, and all types of eating behavior would be likely to increase during the immediate pre-quit and/or post-quit period as weight concerns become activated and salient. The general pattern of scores in DT-W suggests that depressive symptoms, and restrained and emotional eating were fairly stable from baseline through the follow-up period. While cognitive inflexibility related to body image did increase between baseline and the pre-quit assessment, it remained stable thereafter. Uncontrolled eating increased slightly after quit date, as might be expected given that metabolism slows, appetite increases, and sense of smell and taste improve upon cessation of smoking (Audrain-McGovern & Benowitz, 2011). A randomized trial will be needed to determine whether DT-W has different effects on these process measures relative to standard treatment; for example, DT-W may prevent increases in depressive symptoms, body dissatisfaction, eating behaviors, and cognitive inflexibility.

Interestingly, four of the 10 participants who completed at least one follow-up assessment reported some use of e-cigarettes during the follow-up period, including all three participants from the first group who attended more than one group session and self-reported continuous abstinence from cigarettes between quit date and 6-month follow-up. Participant-initiated discussion of e-cigarette use, which occurred during the first group, may have influenced participants' behavior in that group. Although we did not assess reasons for e-cigarette use, we speculate that some women may try e-cigarettes because they believe that e-cigarette use could help prevent or minimize weight gain after smoking cessation. However, additional research is needed to determine the validity of this belief (Russo et al., 2016).

This study has several limitations. The purpose of this study was to establish the feasibility and acceptability of DT-W and pilot the assessment procedures for a future RCT. Although

we have reported the primary outcomes of smoking status and weight change and means on process measures, given the small sample size and lack of control group, we cannot make any conclusions about the efficacy of DT-W or the mechanisms of treatment efficacy. Second, the sample was primarily Caucasian, well-educated, and healthy (i.e., few physical or psychiatric comorbidities). Future research should evaluate the feasibility and acceptability of this treatment for a more diverse sample with regard to demographics and comorbidities.

In conclusion, we established the acceptability and feasibility of a novel intervention for weight-concerned female smokers intended to increase distress tolerance with respect to weight and body image concerns, and reduce eating triggered by external and emotional cues after quit date. Future research will evaluate the efficacy of this intervention in an RCT, as well as examine potential treatment mechanisms such as trajectories of depressive symptoms, body image dissatisfaction, cognitive inflexibility related to body image, and eating behavior.

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Figure 1.
The WE QUIT study logo that was used in advertisements and on participant materials.

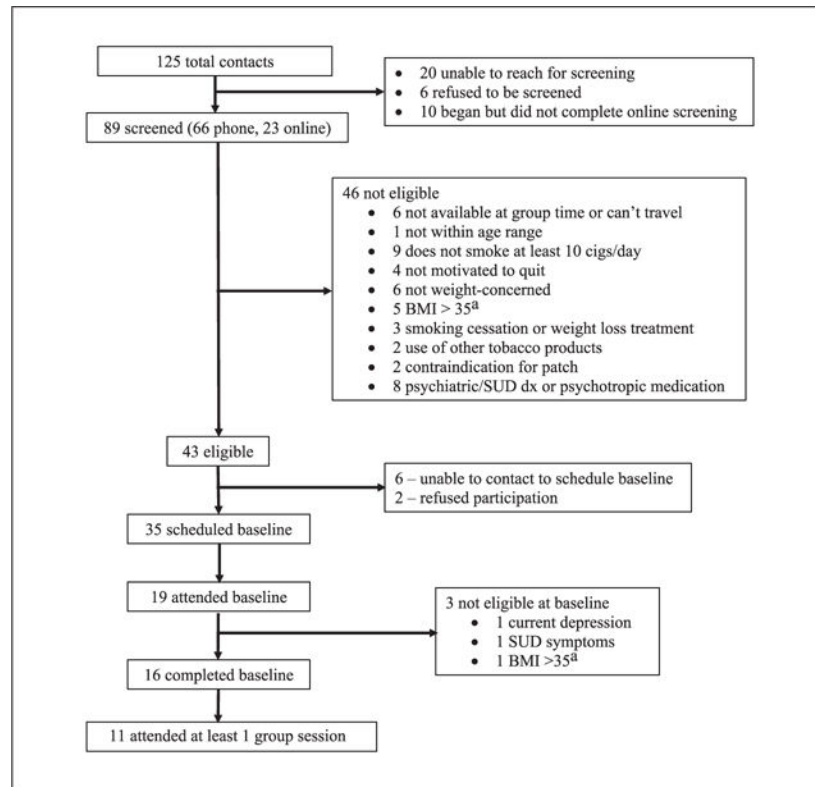


Figure 2.
Participant flow diagram.

Note. BMI = body mass index; SUD = substance use disorder.

^aThis criterion was eliminated partway through recruitment of the first group.

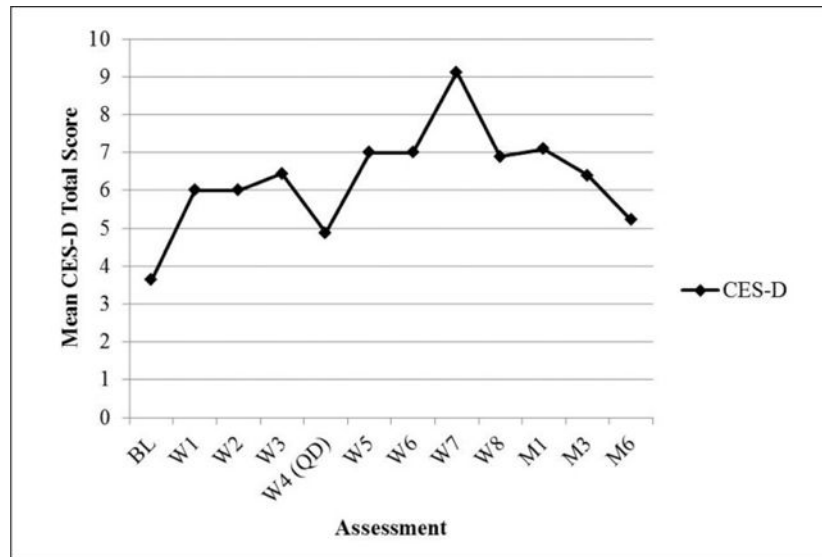


Figure 3.

Mean score on CES-D over time.

Note. CES-D = Center for Epidemiological Studies–Depression Scale; BL = baseline; W = week; QD = quit date; M1 = 1-month follow-up; M3 = 3-month follow-up; M6 = 6-month follow-up.

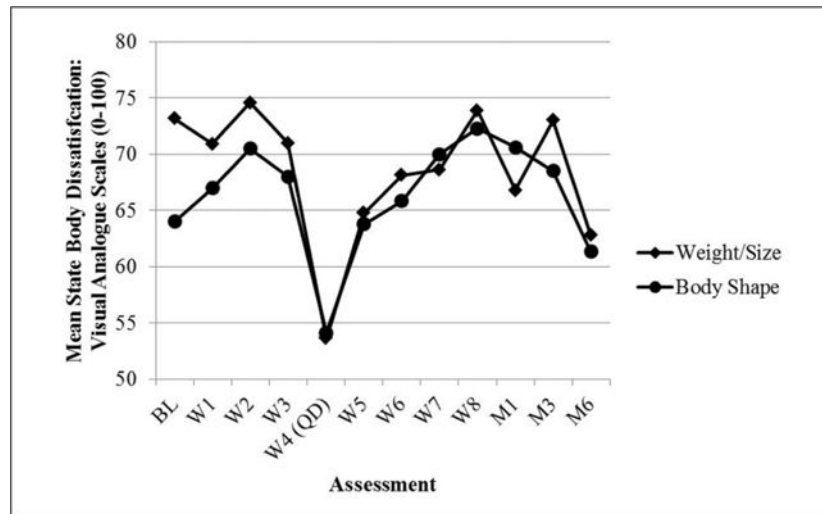


Figure 4.

Mean score on State Body Dissatisfaction over time.

Note. BL = baseline; W = week; QD = quit date; M1 = 1-month follow-up; M3 = 3-month follow-up; M6 = 6-month follow-up.

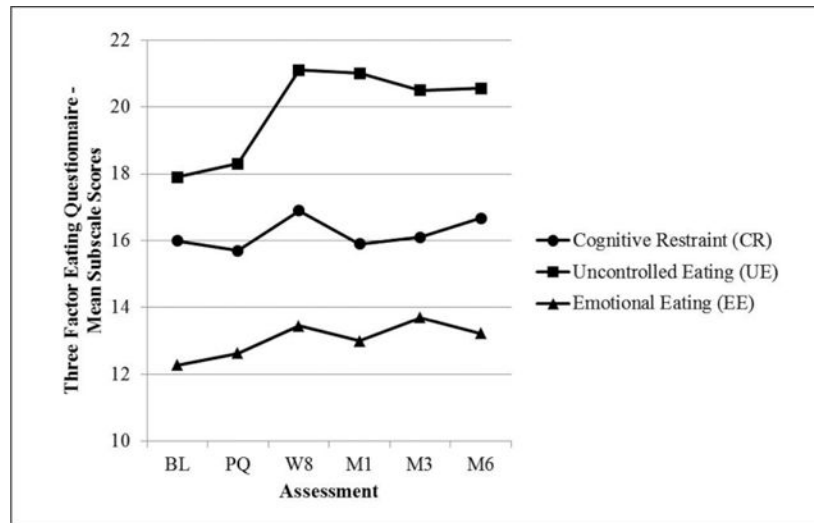


Figure 5. Mean score on Three Factor Eating Questionnaire (TFEQ) over time.
Note. BL = baseline; PQ = pre-quit (between Weeks 3 and 4); W = week; M1 = 1-month follow-up; M3 = 3-month follow-up; M6 = 6-month follow-up.

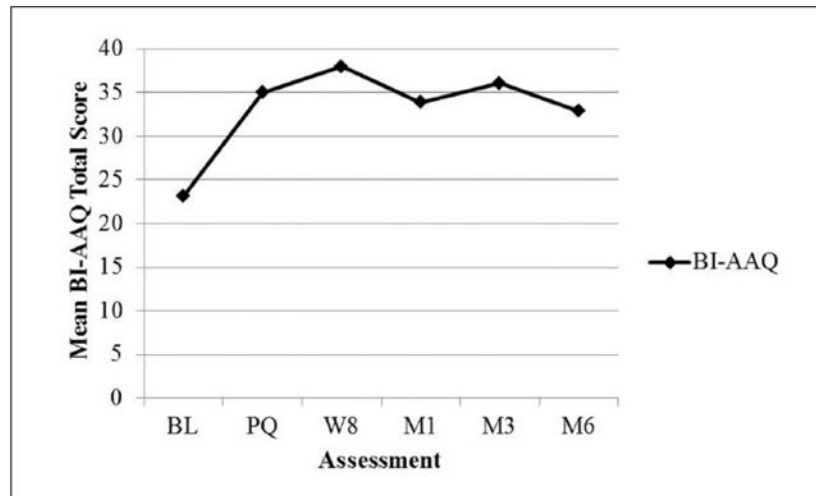


Figure 6.

Mean score on BI-AAQ over time.

Note. BI-AAQ = Body Image–Acceptance and Action Questionnaire (reverse scored, higher scores indicate greater inflexibility); BL = baseline; PQ = pre-quit (between Weeks 3 and 4); W = week; M1 = 1-month follow-up; M3 = 3-month follow-up; M6 = 6-month follow-up.

Table 1

Description of ACT-Based DT-W Elements Targeting Weight Concerns.

	Sessions	Description
Psychoeducation	1	History of the promotion of smoking as a weight control strategy, physiological effects of nicotine on weight, reasons for post-cessation weight gain
Distress tolerance skills		
Values	I, 1, 4, 7, 8	Identify and clarify life values as they relate to smoking vs. weight, differentiate values vs. goals
Weight concerns as triggers for smoking	I, 1	Differentiate external (e.g., people, places, situations) vs. internal (e.g., thoughts, feelings) triggers for smoking and eating, identify weight and body image concerns as internal triggers, discuss the role of these concerns in smoking cessation and relapse
Problems with efforts to control weight concerns	I, 2	Discuss past unsuccessful efforts to control or avoid weight concerns that led to resumption of smoking; understand why efforts to control/avoid weight and body image concerns are likely to maintain smoking
Acceptance	2, 6	Understand acceptance as an alternative to control/avoidance of weight concerns; participate in a mirror exposure exercise to experience these concerns fully without acting on them by smoking
Cognitive defusion	2, 6, 7	Learn to defuse weight concerns by viewing negative weight and body image thoughts as what they are (cognitive constructs that do not have to be reacted to or believed), with emphasis on weight-related rationalizations for smoking
Self as context	3	Practice taking a non-judgmental, observer perspective toward weight and body image concerns via exercises in which participants focused on breathing while observing thoughts and feelings
Values-oriented living skills		
Willingness	3	Commit to non-judgmental acceptance of negative thoughts and feelings related to weight and body image concerns; address tendency to set limits on weight gain tolerance. Commit to engaging in cessation-promoting, values-oriented behavior regardless of the presence of weight and body image concerns
Being present— Appetite awareness training	4–7	Identify that during past quit attempts, eating may have replaced smoking as a strategy to control or avoid negative emotions; practice increasing awareness and use of physiological hunger and satiety cues rather than external or emotional triggers to guide when and how much to eat; provide forms to practice monitoring appetite at home (Craighead, 2006)
Being present— Mindful eating	5–7	Practice (with a piece of candy) paying attention to the smell, taste, and texture of food while eating; eating slowly and noticing physical sensations of hunger and fullness; removing distractions while eating (e.g., TV)
Committed action	4, 8	Identify goals and barriers with respect to quitting smoking; link values to goals; make daily commitment to values-oriented healthy living behaviors. Participants generate their own behavioral goals, which could include activities such as increasing physical activity, increasing consumption of fruits and vegetables, self-esteem building hobbies, and so forth

Note. ACT = Acceptance and Commitment Therapy; I = individual session.

Table 2

Demographic and Baseline Characteristics.

	Attended DT-W (n = 11)	Dropped out (n = 5)
Age	46.45 (9.46)	43.00 (17.51)
Caucasian (n)	9	4
Married (n)	4	2
4-year degree or higher (n) *	7	0
Household income < US\$25,000	5	2
Cigarettes per day	16.09 (3.86)	18.60 (5.46)
Years smoked	25.00 (9.52)	24.80 (16.95)
FTND	5.55 (2.07)	4.60 (1.52)
BMI	29.87 (6.64)	31.89 (4.28)
SWEET	2.51 (1.04)	2.14 (0.38)
Weight gain tolerance (lb)	6.36 (4.39)	7.40 (2.51)
WCS **	7.55 (2.00)	5.07 (1.76)
CES-D	3.64 (3.41)	2.40 (2.30)

Note. Means and standard deviations unless specified. FTND = Fagerström Test for Nicotine Dependence; BMI = body mass index; SWEET = Smoking-Related Weight and Eating Episodes Test; WCS = Weight Concern Scale; CES-D = Center for Epidemiological Studies–Depression Scale.

*
 $p = .03$.

**
 $p = .03$.

Table 3

Helpfulness Ratings for DT-W Treatment Components (Means and Standard Deviations).

Treatment component	<i>M</i> rating (<i>SD</i>)
Values	4.83 (0.41)
Cognitive defusion	4.67 (0.82)
Acceptance	3.83 (0.75)
Willingness	3.83 (0.98)
Appetite awareness training	4.17 (0.41)
Mindful eating	3.83 (0.75)
Mirror exposure exercise	4.00 (0.89)

Note. All items were on 5-point scales with 5 being the *most helpful*.

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