Original Investigation

A Pilot Randomized Controlled Trial of Distress Tolerance Treatment for Weight Concern in Smoking Cessation Among Women

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Abstract

Introduction: The majority of women who smoke cigarettes report that concern about weight gain is a barrier to quitting. We developed an intervention incorporating distress tolerance, appetite awareness, and mindful eating skills to target concerns about post-cessation weight gain and emotional eating (DT-W). In the current study, we conducted a pilot randomized controlled trial of DT-W versus a smoking health education (HE) intervention.

Methods: Participants ($N = 69$ adult female, weight-concerned smokers) were recruited in cohorts of 4–11. Cohorts were randomized to DT-W or HE. DT-W and HE were matched on format (single individual session followed by eight group sessions), inclusion of cognitive behavioral therapy for smoking cessation (CBT) content, and pharmacotherapy (nicotine patches). Follow-up assessments occurred at 1-, 3-, and 6-months post-treatment.

Results: The recruitment goal was met; 61 of the 69 participants attended at least one group session. There were no significant differences between DT-W and HE in the number of group sessions attended (DT-W adjusted $M = 5.09$, HE adjusted $M = 5.03$, $p = .92$), ratings of treatment effectiveness or usefulness of skills, or retention at 6-month follow-up (79% in DT-W vs. 78% in HE) ($ps > .05$), but comprehension ratings were lower in DT-W than in HE ($p = .02$).

Conclusions: Overall, these results suggest that the study procedures and interventions were feasible and acceptable, but changes to the DT-W intervention content to improve comprehension should be considered prior to conducting a fully powered trial.

Implications: A distress tolerance-based treatment targeting fear of weight gain after smoking cessation and post-cessation emotional eating was feasible and acceptable relative to a smoking HE comparison condition, but changes should be considered before conducting a larger trial. Continued innovation in treatment development for weight-concerned smokers is needed.

Introduction

Nicotine is a stimulant that suppresses appetite and increases metabolism.¹ Most smokers gain weight after they quit, a mean of 10 pounds within 6–12 months.² However, weight gain after quitting smoking is associated with increased caloric intake that cannot be entirely explained by the reversal of nicotine's pharmacological effects.^{1,3} None of the FDA-approved medications for smoking cessation has been shown to consistently reduce long-term weight gain.^{2,4} Standard cognitive behavioral therapy (CBT) protocols for smoking cessation include only brief advice with respect to weight gain prevention.⁵ Combining CBT for smoking cessation with behavioral weight control treatment (eg, ^{6,7}) has produced short-term benefits in some studies but reviews indicate that this approach does not have long-term effects on smoking or weight gain outcomes.^{8–10}

Concern about anticipated post-cessation weight gain ("weight concern") is a barrier to quitting smoking for the majority of women who smoke cigarettes.^{11–13} Weight concern, rather than actual post-cessation weight gain, has been more strongly associated with poor smoking cessation treatment outcomes, including treatment dropout^{14–16} and relapse.^{17,18} Perkins and colleagues, therefore, tested an alternative CBT-based approach with a primary goal to reduce weight concern and improve body image rather than to prevent weight gain directly. Participants were advised to challenge negative thoughts about weight and body image, whereas dieting was discouraged.^{19–21} An initial trial in which participants did not receive pharmacotherapy revealed a positive effect of this alternative CBT compared to weight control treatment and standard CBT on both smoking and weight outcomes.²¹ However, in a second trial with a 2 × 2 factorial design (alternative vs. standard CBT, bupropion vs. placebo), abstinence rates were higher among those who received bupropion versus placebo, but there were no significant differences in abstinence rates or weight change between alternative versus standard CBT.²⁰

An experimental study in which participants received a manipulation (trying on a bathing suit) that increased both state body dissatisfaction and urges to smoke specifically for the purpose of reducing negative affect showed that the relationship between body dissatisfaction and urge to smoke was mediated by negative affect.²² This finding is consistent with theories that implicate negative affect more generally as a key factor in the maintenance of tobacco use (eg, ²³) and research demonstrating that general negative affect is a primary precipitant of relapse.²⁴ Furthermore, women who self-report engaging in eating to cope with negative affect are at higher risk of post-cessation weight gain.²⁵ The extent of an individual's willingness and ability to tolerate distressing thoughts and feelings (ie, distress tolerance) contributes significantly to treatment outcomes in smoking cessation (eg, ^{26–28}) and in weight loss.²⁹ Our team has developed treatment approaches for smoking cessation^{30,31} and weight loss^{32,33} that incorporate novel, distress tolerance skills into CBT. These skills are primarily derived from Acceptance and Commitment Therapy (ACT).³⁴ The theoretical rationale posits that individuals often engage in behaviors such as smoking and eating as a way to avoid or reduce distressing thoughts and feelings, which interfere with engagement in values-oriented behavior.³⁴

We reasoned that among weight-concerned female smokers, both (1) the fear of anticipated post-cessation body dissatisfaction and weight gain (a specific type of negative affect) and (2) actual post-cessation weight gain and the resulting increase in body dissatisfaction, which is attributable in part to replacing smoking with eating to cope with general negative affect,²⁵ could

be conceptualized as distress tolerance challenges. We previously developed a novel, group-based intervention for female weight-concerned smokers that incorporated distress tolerance skills to target the fear of anticipated post-cessation weight gain and facilitate initiation of abstinence, and appetite awareness and mindful eating skills to reduce post-cessation emotional eating (DT-W).³⁵ DT-W was adapted primarily from previous ACT-based treatments targeting weight loss^{32,33} and body dissatisfaction,^{36,37} with some limited influence from our prior ACT-based treatment for smoking cessation.³¹

The aim of the current study was to conduct a pilot randomized controlled trial of DT-W versus a smoking health education (HE) intervention that was matched to DT-W in total contact time, format, and inclusion of standard CBT elements and pharmacotherapy. We piloted all randomized controlled trial procedures, including data analysis techniques, to evaluate feasibility and acceptability and to influence the design of and to support a future fully powered randomized controlled trial. The study was not powered to detect statistically significant differences in abstinence rates between the two conditions. Our main hypothesis was that DT-W would be feasible and acceptable as indicated by comparable or superior session attendance and follow-up retention and treatment acceptability ratings relative to HE. We also hypothesized that the dual focus in DT-W on smoking cessation and weight concern/emotional eating would not have a negative impact on the primary intervention target of smoking cessation nor the hypothesized mechanisms of distress tolerance, weight concern, and eating behavior (cognitive restraint, uncontrolled eating due to hunger, and emotional eating).

Methods

Participants

Female participants (N = 69) were recruited from the local community via paper and electronic advertisements. Eligible women were at least 18 years of age, smoked 5 or more combustible cigarettes per day for at least the past year, motivated to quit, and concerned about post-cessation weight gain, defined as a score of at least 50 on a 100-point scale on at least one of the following two questions: "How concerned are you about gaining weight after quitting?" and/or "How concerned would you be if quitting smoking caused you to permanently gain 10–15 pounds?"^{20,21} Exclusion criteria were current smoking cessation or weight loss treatment; use of other non-cigarette combustible tobacco products at least weekly (e-cigarette use was not an exclusion); current substance use disorder (SUD) other than tobacco with substance use during the last 6 months; lifetime eating disorder, bipolar disorder, or psychotic disorder; current severe symptoms of depression (based on *Patient Health Questionnaire-9*³⁸ scores), pregnancy or breastfeeding, or other medical contraindication for the use of nicotine patch. The CONSORT flow diagram is shown in [Figure 1](#). The Institutional Review Board at Lifespan (parent corporation of Rhode Island Hospital) approved this study.

Procedure

Interested women who met preliminary eligibility criteria based on a brief online and/or telephone screening were scheduled for an individual baseline assessment at which written informed consent was obtained and additional screening measures were administered to

Figure 1. CONSORT flow diagram.

confirm eligibility. After the baseline assessment, participants initiated their intervention. Both DT-W and HE were 9-week interventions consisting of one 60-minute individual session followed by eight weekly 90-minute group sessions, with the target quit date at group session 4, and a 20-minute individual telephone session between group sessions 4 and 5 (ie, quit week). Participants also attended individual assessments within 1 week prior to the target quit date (ie, between group sessions 3 and 4, “pre-quit”), within 1 week after the end of the intervention (“post-treatment”), and at 1-, 3-, and 6-months post-treatment follow-up. REDCap was used for data collection and management.³⁹ Participants were compensated up to \$225 for completing all assessments.

Randomization occurred by cohort due to the group delivery of treatments. Cohort treatment assignments were randomly chosen without replacement from a fixed pool of 10 options (5 DT-W, 5 HE). Participants were informed of their treatment assignment (DT-W or HE) upon arrival to their first treatment session (an individual session, see below). Therefore, our intent to treat (ITT) sample ($N = 69$) consists of all participants who attended the individual treatment session (ie, all randomized participants).

Treatment Conditions

Format and Group Leaders (DT-W and HE)

Group sessions were co-led by two trained group leaders, including a physician, doctoral-level psychologists (including the first author, who was a group leader for five of the 10 groups), and clinical psychology doctoral students. All sessions were audiotaped to facilitate weekly supervision with the first author, who reviewed session tapes for fidelity and provided detailed feedback. All group leaders were trained to deliver both treatments (DT-W and HE) and had prior experience in at least some elements of both interventions. Training was tailored for each group leader based on prior experience and included online courses in smoking cessation treatment, reviewing

CBT and/or ACT books and manuals, individual supervision, reviewing recordings of previous sessions, and role-playing sessions.

Group sessions were “front-loaded” such that the first two group sessions included only content focused on weight concern (DT-W) or smoking health education (HE) as described below, whereas the individual session and group sessions 3–8 were split evenly between weight concern (DT-W) or smoking health education content and standard CBT for smoking cessation content (DT-W and HE). The standard CBT content was identical in DT-W and HE and was presented separately as either the first or second half of the session, with group leaders announcing the switch between the two halves.

Nicotine Patches (DT-W and HE)

All participants (DT-W and HE) received an 8-week course of nicotine patches. Participants who reported smoking more than 10 cigarettes per day used 21 mg patches for the first 4 weeks, then tapered to 14 mg for 2 weeks, and finally to 7 mg for the last 2 weeks. Those who reported smoking 10 or fewer cigarettes per day used 14 mg patches for the first 6 weeks and then tapered to 7 mg for the last 2 weeks. Participants were instructed to begin wearing the patch on the target quit date (group session 4).

Standard CBT Content (DT-W and HE)

CBT elements were based on manuals used in previous research⁵ and included preparation for quit date, reinforcement, and support for quitting, discussion of past and ongoing quit experiences, initiation of self-monitoring, identification of triggers and high-risk situations, development of coping strategies for triggers, obtaining social support, instruction in how to use nicotine patches, and relapse prevention. Recommendations for how to minimize weight gain were brief, de-emphasized, and consistent with standard CBT (eg, take a walk to cope with craving instead of smoking, eat low-calorie snacks).

Weight Concern Content (DT-W Only)

DT-W incorporated content adapted from previous ACT treatment manuals and other relevant manuals, with permission from their authors (J. E. Fleming, N. L. Kocovski, unpublished data, 2009).^{31–33,36,37,40} This content has already been described in detail³⁵; only minor changes were made for this study after previous pilot testing. In brief, during the individual session, group leaders engaged participants in a discussion of their life values with respect to quitting smoking and weight management, assessed the phenomenology of their smoking and past quit attempts with a specific focus on weight concern, and introduced the rationale for and the basic tenets of the distress tolerance model. During group session 1, participants were provided with psychoeducation about the relationship between smoking and weight, including the effects of nicotine on metabolism, reasons for weight gain, and health benefits of cessation versus consequences of weight gain. Distress tolerance skills (values clarification, identification of weight concern as a trigger for smoking, acceptance, cognitive defusion, observer-perspective skills) as a way to cope with fear of anticipated post-cessation body dissatisfaction and weight gain (these skills were *not* applied to coping with cravings or negative affect more generally) were introduced in sessions 1–3, and weight concern as a barrier to successful initiation of abstinence (ie, preparation for cessation) was addressed. Values-Oriented Living Skills, which targeted reduction of emotional eating after quitting smoking and were most relevant to relapse prevention after initiation of abstinence, were introduced in sessions 3–5 and included willingness, appetite awareness⁴⁰ and mindful eating skills, and committed action.

Smoking Health Education Content (HE Only)

The smoking health education content in HE was based on protocols used in previous research⁴¹ and consisted of didactic education about general health topics as they relate to the effects of smoking. As in previous research, we included this content to control for total time and attention in DT-W and did not expect this content to exert an independent effect on smoking cessation (ie, beyond the CBT content). Topics included effects on the cardiovascular and respiratory systems, cancer, oral health, sexual/reproductive health, digestive health, sleep, the immune system, and secondhand smoke. Eating a healthy diet and engaging in physical activity were mentioned as important strategies for health promotion and prevention of disease along with quitting smoking, but participants were not given any specific recommendations for how to change their diet or increase their physical activity.

Measures

Demographics and smoking history were collected at baseline and included current and past smoking behavior and *The Fagerström Test for Cigarette Dependence* (FTCD) (six items, $\alpha = .63$).⁴²

Attendance and Retention

We calculated the proportion of participants in each condition who attended at least one group session, the mean number of sessions attended by condition, and the proportion of participants in each condition who completed each follow-up assessment.

Treatment Acceptability

At post-treatment, participants completed an “end of program” evaluation, including ratings of effectiveness, usefulness of skills

taught, and how well they understood the content. These items were rated on 5-point scales, with 5 being the highest (ie, extremely effective/useful, understood extremely well).

Smoking Cessation Outcomes

Our primary smoking cessation outcome was 7-day point prevalence abstinence from combustible cigarette smoking, verified by expired breath carbon monoxide (CO) testing (≤ 6 ppm)⁴³ with a Bedfont Micro Smokerlyzer. Self-reported smoking behavior was assessed at all individual assessments and group treatment sessions using a *Timeline Followback* procedure.⁴⁴ Participants whose point prevalence abstinence data were missing were assumed to be smoking. The *Timeline Followback* also included assessment of daily use of study-provided nicotine patches as well as e-cigarettes and other tobacco products. Whenever possible, the PI or group leaders spoke to participants who had discontinued patch use and encouraged them to re-start if appropriate (eg, initiate another quit attempt if they stopped due to relapse, help them resolve side effects and/or change dose in consultation with the physician as needed). Participants were not given any instructions with regard to e-cigarette use (ie, were not encouraged to use them nor asked to stop using them if they reported e-cigarette use). Reports of past week e-cigarette use were rare (0 or 1 participant each at group sessions 4–8, three participants at the 1-month follow-up, one at 3-month follow-up, and four at 6-month follow-up).

Some participants completed their entire post-treatment assessment on the same day as the last group session (session 8, immediately following the end of that session), whereas others completed all or a portion of the post-treatment assessment at a separate individual appointment that occurred within 1 week after group session 8. In some cases, post-treatment point prevalence abstinence was collected twice (at group session 8 and at the later post-treatment assessment). In these cases, we included the “best” outcome in our analyses (ie, if the participant was abstinent at either group session 8 or her later post-treatment assessment, she was counted as abstinent at post-treatment).

Weight Outcomes

Participants were weighed on a calibrated medical scale at baseline, post-treatment, and 1-, 3-, and 6-month follow-ups.

Weight Concern

The *Weight Concern Scale* (WCS)⁴⁵ is a six-item measure that was administered at baseline ($\alpha = .87$) and pre-quit to assess 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.

Distress Tolerance

Self-reported distress tolerance skills (eg, acceptance, willingness, commitment to values-oriented behavior) were assessed at all individual assessments. The *Body Image - Acceptance and Action Questionnaire* (BI-AAQ)⁴⁶ (12 items, baseline $\alpha = .91$) assessed distress tolerance specific to weight and body image concerns. General distress tolerance skills were assessed with the *Acceptance and Action Questionnaire* (AAQ-II) (seven items, baseline $\alpha = .92$).⁴⁷ Higher scores on these measures indicate lower distress tolerance.

Eating Behavior

The *Three-Factor Eating Questionnaire (TFEQ)*⁴⁸ was administered at all individual assessments and was used to assess dietary restraint (“cognitive restraint”) (six items, baseline $\alpha = .71$), tendency to eat in response to negative affect (“emotional eating”) (six items, baseline $\alpha = .85$), and “uncontrolled eating” (due to very high levels of hunger or craving) (nine items, baseline $\alpha = .86$).

Negative Affect

The *Patient Health Questionnaire-9 (PHQ-9)* (nine items, baseline $\alpha = .76$) and the *Positive and Negative Affect Schedule (PANAS)* (baseline α for 10 negative affect items = .77) were administered at baseline, weekly during treatment, and at all follow up assessments to assess symptoms of depression and current negative affect severity, respectively.

Data Analysis

Sample Size and Power Analysis

We did not conduct a formal power analysis. Our sample size (target of $N = 60$ initiating treatment, 30 per condition) was selected based on Rounsaville et al.'s recommendations for behavioral intervention development (15 to 30 participants per condition).⁴⁹ We are aware of the dangers of relying on underpowered pilot trials to determine the promise of novel treatment approaches.⁵⁰ These trials produce effect size estimates that have a large standard error. Therefore, we did not expect to find significant differences in abstinence rates or weight change and did not plan to base our decision about next steps solely on potentially unstable effect sizes derived from this trial.

Analytic Plan

Analyses were conducted using SPSS and Stata/MP 16.0. We conducted chi-square analyses to compare DT-W versus HE on retention at each follow-up assessment (post-treatment, 1-, 3-, 6-months). In all other analyses, we used mixed models (mixed and melogit commands in Stata), specifying cohort as a random effect and the baseline value/score (if available) as a covariate. In longitudinal analyses of abstinence and weight change outcomes, we additionally specified participant as a random effect and age, Fagerström Test for Nicotine Dependence (FTND), timepoint, baseline weight, and any other variables on which the conditions differed at baseline as covariates. We also compared DT-W versus HE on hypothesized mechanisms, conducting a separate mixed model analysis for each mechanism rather than a simultaneous model given our limited sample size and ability to tease apart the relative contributions of related variables. A primary purpose in conducting the longitudinal analyses was to verify the validity of the analytic approach for a future fully powered trial.

Results

Participant Characteristics

Baseline characteristics for the 69 women (33 DT-W, 36 HE) who were randomized to treatment are shown in Table 1. DT-W and HE did not differ on any baseline variables except for the two measures of distress tolerance (AAQ and BI-AAQ). The mean score for DT-W was lower on both, indicating higher distress tolerance. Therefore, we included these variables (baseline AAQ and BI-AAQ) as additional covariates in longitudinal outcome analyses.

Table 1. Baseline Participant Characteristics

	DT-W (N = 33)	HE (N = 36)
Age	50.3 (13.8)	49.1 (11.2)
Race		
White	70%	78%
Black	15%	14%
Other race or more than one race	15%	8%
Hispanic	6%	8%
≥4-year degree	15%	17%
Income < \$25 000	42%	42%
Cigarettes per day	15.5 (8.0)	16.8 (5.8)
Years smoked	33.8 (14.6)	35.2 (11.4)
FTND	4.5 (2.5)	5.1 (2.1)
Body mass index (BMI)	31.0 (6.9)	31.8 (6.7)
Weight Concern Scale (WCS)	6.7 (1.8)	7.2 (2.3)
Acceptance and Action Questionnaire (AAQ)*	11.7 (5.2)	15.3 (9.3)
Body Image Acceptance and Action Questionnaire (BI-AAQ)*	26.7 (11.9)	33.8 (15.6)
Patient Health Questionnaire-9 (PHQ-9)	2.9 (3.3)	2.9 (3.1)
Positive and Negative Affect Scale (PANAS) – Negative Affect	13.6 (4.2)	15.4 (5.3)

FTND = Fagerström Test for Nicotine Dependence; DT-W: Distress Tolerance Treatment for Weight Concern; HE = smoking health education.

* $p < .05$.

Attendance at Group Sessions and Retention at Follow-up Assessments

We met our goal of 60 women initiating the group treatment; 61 of the 69 women attended at least one group session (four participants in each condition attended the individual session only). There were no significant differences between DT-W and HE in the mean number of group sessions attended (DT-W adjusted $M = 5.09$, standard error $[SE] = 0.44$; HE adjusted $M = 5.03$, $SE = 0.43$ [$b = -0.06$, 95% confidence interval $[CI]: -1.27, 1.14$, $p = .92$]). Also, there were no significant differences in retention at follow-up assessments ($ps > .05$); 79% in DT-W (26/33) attended each follow-up whereas follow-up attendance in HE ranged from 69% at 3 months (25/36) to 78% at 1- and 6-months (28/36) (Figure 1). If we exclude the eight participants who did not attend any group sessions, our retention rates were 90% in DT-W and 75%–84% in HE ($ps > .05$).

Treatment Acceptability

DT-W and HE did not differ on ratings of overall program effectiveness (DT-W adjusted $M = 4.29$, $SE = 0.19$; HE adjusted $M = 3.90$, $SE = 0.19$ [$b = -0.38$, 95% $CI: -0.91, 0.15$, $p = .16$]) or usefulness (DT-W adjusted $M = 4.25$, $SE = 0.16$; HE adjusted $M = 4.25$, $SE = 0.16$ [$b = 0.00$, 95% $CI: -0.45, 0.45$, $p = 1.0$]), but overall understanding of the program content was slightly lower in DT-W (DT-W adjusted $M = 4.14$, $SE = 0.17$; HE adjusted $M = 4.75$, $SE = 0.19$ [$b = 0.61$, 95% $CI: -0.11, 1.1$, $p = .02$]).

Smoking and Weight Outcomes

There were no significant effects of treatment condition on CO-verified abstinence (odds ratio $[OR] = 0.30$, 95% $CI: 0.02, 4.74$), self-reported abstinence ($OR = 0.22$, 95% $CI: 0.02, 2.17$), weight change outcomes ($b = -0.41$, 95% $CI: -6.11, 5.29$), or cigarettes smoked during the past week ($b = -3.06$, 95% $CI: -24.17, 18.04$) (all $ps > .05$, see Table 2). We also tested the interactions between

Table 2. Adjusted Smoking, Weight Change, and Treatment Mechanisms Outcomes

	DT-W (N = 33)	HE (N = 36)	OR/b and 95% CI
CO-verified point prevalence abstinence			OR = 0.30 (0.02, 4.74)
Post-treatment	17.6%	23.1%	
1 mo	12.7%	17.3%	
3 mo	11.3%	15.8%	
6 mo	12.7%	17.3%	
Self-reported point prevalence abstinence			OR = 0.22 (0.02, 2.17)
Post-treatment	18.9%	27.2%	
1 mo	13.8%	22.2%	
3 mo	13.8%	22.2%	
6 mo	13.8%	22.2%	
Weight Change (lbs): Mean (SE)			b = -0.41 (-6.11, 5.29)
Post-treatment	1.63 (2.12)	1.22 (2.11)	
1 mo	2.03 (2.13)	1.62 (2.11)	
3 mo	2.97 (2.12)	2.56 (2.13)	
6 mo	2.47 (2.13)	2.06 (2.13)	
Cigarettes smoked during past week: Mean (SE)			b = -3.06 (-24.17, 18.04)
Post-treatment	33.1 (8.3)	30.0 (7.7)	
1 mo	37.3 (8.3)	34.2 (7.7)	
3 mo	56.6 (8.3)	53.6 (7.7)	
6 mo	62.7 (8.4)	59.6 (7.8)	
Pre-Quit Weight Concern Scale	6.4 (0.31)	6.2 (0.30)	b = -0.18 (-1.03, 0.68)
Pre-Quit Acceptance and Action Questionnaire (AAQ)	16.0 (1.04)	15.2 (1.0)	b = -0.74 (-3.59, 2.11)
Pre-Quit Body Image Acceptance and Action Questionnaire (BI-AAQ)	35.4 (2.5)	30.8 (2.4)	b = -4.56 (-11.34, 2.21)
Post-Treatment adjusted Mean (SE)			
Three Factor Eating Questionnaire (TFEQ) - Cognitive restraint	15.5 (0.55)	14.6 (0.53)	b = -0.88 (-2.38, 0.63)
Three Factor Eating Questionnaire (TFEQ) - Uncontrolled eating*	19.5 (0.92)	15.9 (0.90)	b = -3.57 (-6.11, -1.02)
Three Factor Eating Questionnaire (TFEQ) - Emotional eating*	13.6 (0.67)	11.0 (0.65)	b = -2.55 (-4.39, -0.70)

CI = confidence interval; CO = expired breath carbon monoxide; HE = health education; OR = odds ratio; SE = standard error.

* $p < .05$.

Figure 2. Unadjusted abstinence rates by treatment condition (DT-W vs. HE).

condition and time, but they were also not significant. Unadjusted abstinence rates (self-reported and CO-verified) for DT-W versus HE are also shown in Figure 2. A qualitative examination of the data indicated that one HE cohort seemed to be an outlier with a high number of quitters compared to all other cohorts. There were four participants (one in DT-W and three in HE) for whom self-reported abstinence could not be verified by CO at one or more timepoints because of self-reported marijuana smoking, inability to travel to the laboratory to provide a breath sample, or retrospective reporting after a missed assessment (eg, missed 3-month assessment and reported at 6 months that she was abstinent at the time the 3-month assessment should have occurred).

Treatment Mechanisms

There were no significant differences between conditions in scores on weight concern (*Weight Concern Scale*) or distress tolerance (BI-AAQ, AAQ-II) at pre-quit or on the cognitive restraint subscale of the TFEQ at post-treatment (all $ps > .05$) (Table 2). However, DT-W participants had higher mean scores than HE participants on the emotional eating ($b = -2.55$, 95% CI: -4.39, -0.70, $p = .007$) and uncontrolled eating ($b = -3.57$, 95% CI: -6.11, -1.02, $p = .006$) subscales of the TFEQ at post-treatment. Adjusted mean scores on these measures by condition are shown in Table 2.

Discussion

In this pilot randomized controlled trial, we compared a novel distress tolerance treatment targeting weight concern in smoking cessation among women (DT-W) to a smoking health education (HE) treatment. DT-W and HE were matched on structure, duration, and inclusion of standard CBT elements and pharmacotherapy. A primary goal was to evaluate the feasibility and acceptability of the DT-W intervention relative to HE. There were no statistically significant differences in feasibility and acceptability outcomes, including attendance at group sessions, retention at follow-up assessments, or in participant ratings of program effectiveness and usefulness of the skills, suggesting that DT-W compared favorably to HE on these outcomes. Furthermore, attendance, retention, and participant ratings were all quite high/positive. This trial was not powered to detect statistically significant differences in abstinence rates or weight change outcomes, and indeed, we did not find significant differences between conditions. A fully powered trial would have required at

least 200 participants depending upon the estimated abstinence rates for the experimental versus control group and adjustment for clustering within cohorts. For example, if we predicted an abstinence rate of 30% in DT-W versus 20% in HE at 6-month follow-up, we would need at least 291 participants. If we predicted lower abstinence rates, we would need even more (eg, at least 480 participants for 22% vs. 15%).

Previous research indicates that interventions tailored for weight-concerned smokers have not generally produced superior outcomes relative to standard treatments without tailored weight concern-focused content.⁸⁻¹⁰ In the majority of these tailored interventions, smoking and eating-related behaviors have been addressed simultaneously (ie, participants were trying to change both behaviors at the same time) rather than sequentially. In two studies in which sequential treatment (smoking cessation followed by weight management) was compared to simultaneous treatment, some outcomes favored sequential treatment (weight gain,⁷ abstinence⁶), suggesting that attempting to change both of these behaviors at the same time may be more difficult than focusing only on one or the other. Given that DT-W targets smoking and eating behavior simultaneously, in a future trial we would plan to assess participants' perceptions regarding single versus multiple behavior change directly, as well as the extent to which they attempted to change each behavior. We would also carefully consider the timing of the content focused on eating behavior (eg, appetite awareness and mindful eating skills) in relation to smoking cessation.

Results of previous trials of ACT versus CBT-based treatments for weight loss and body dissatisfaction have been mixed^{33,51-53}; for the most part, outcomes have not been significantly different from CBT. Similarly, there were no significant differences in long-term abstinence rates in two recent large trials that compared ACT versus CBT-based group treatments for smoking cessation.^{31,54} Furthermore, neither of those trials identified significant differences between treatments on hypothesized mechanisms. Certain outcomes in one study seemed to favor standard CBT over ACT. For example, McClure et al.⁵⁴ reported that a higher proportion of participants assigned to CBT, relative to ACT, attended all group sessions, found their intervention useful for quitting smoking, completed end-of-treatment and 6-month follow-up assessments, and were abstinent at some timepoints. These results may be relevant to our finding that the DT-W group reported a somewhat lower level of understanding of their program's content compared to HE (81% of DT-W participants said they understood the content very or extremely well compared to 95% in HE). In a future trial, we would plan to revise the DT-W content with a goal of improving comprehension and assess comprehension in a more detailed manner.

DT-W was intended to reduce episodes of emotional and uncontrolled eating and increase appetite awareness, including eating when moderately hungry (ie, eating before getting too hungry such that binge eating would be likely to occur) and stopping when moderately full, and engagement in mindful eating. However, mean scores on emotional eating and uncontrolled eating subscales of the TFEQ were higher in DT-W than in HE at the end of treatment. These scores could suggest that DT-W did not affect these outcomes as intended; however, it is also quite possible that the higher scores among DT-W participants reflect a heightened awareness of these behaviors and attempts to practice appetite awareness. Moreover, appetite awareness and mindful eating skills were intended to be most relevant and applicable after initiation of smoking abstinence, but most DT-W participants did not quit smoking. In a future trial,

we would also consider incorporating content that targets emotion regulation or impulse control more generally, which some participants may find more relevant.

Limitations

We acknowledge that this study had a number of limitations. First, as already noted, this trial was not powered to detect statistically significant differences in abstinence rates. Second, we were only able to recruit and randomize one cohort at a time. Therefore, there may have been differences between cohorts associated with the time at which recruitment occurred. Third, in our effort to maximize generalizability, our eligibility criteria may have been too inclusive with regard to weight concerns and current weight loss efforts, resulting in enrollment of women for whom the weight concern-focused content in DT-W was not relevant. In a future trial, we would plan to assess throughout treatment the degree to which weight gain prevention remains a priority in the context of smoking cessation. Fourth, although the first author was a group leader for five of the 10 cohorts and listened to audiotapes of all other sessions to confirm fidelity and provide leaders with detailed written and verbal feedback, we did not complete any other formal assessments of treatment fidelity. Therefore, it is possible, but we believe unlikely, that lack of fidelity had an impact on outcomes. Despite these limitations, this study also had a number of strengths, including a rigorous experimental design (treatments matched exactly in total duration, format, and inclusion of evidence-based counseling and pharmacotherapy elements), well-trained therapists, and good treatment attendance and retention at follow-ups.

Conclusion

In conclusion, we found that a novel distress tolerance-based content targeting weight concern in smoking cessation among women (DT-W) appeared to be feasible and acceptable as compared to a smoking health education intervention (HE) intervention matched to DT-W in duration, format, and inclusion of standard CBT for smoking cessation elements and NRT. However, a number of issues should be considered prior to conducting a larger trial, including comprehension of DT-W content and alternative treatment mechanisms.

Supplementary Material

A Contributorship Form detailing each author's specific involvement with this content, as well as any supplementary data, are available online at <https://academic.oup.com/ntr>.

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Declaration of Interests

RAB has equity ownership in Health Behavior Solutions, Inc., which is developing products for tobacco cessation that are not related to this study. The terms of this arrangement have been reviewed and approved by the University of Texas at Austin in accordance with its policy on objectivity in research. The other authors have no interests to declare.

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