ORIGINAL INVESTIGATION

Randomized Trial of Telephone-Delivered Acceptance and Commitment Therapy Versus Cognitive Behavioral Therapy for Smoking Cessation: A Pilot Study

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ABSTRACT

Objective: We conducted a pilot randomized trial of telephone-delivered acceptance and commitment therapy (ACT) versus cognitive behavioral therapy (CBT) for smoking cessation.

Method: Participants were 121 uninsured South Carolina State Quitline callers who were adult smokers (at least 10 cigarettes/day) and who wanted to quit within the next 30 days. Participants were randomized to 5 sessions of either ACT or CBT telephone counseling and were offered 2 weeks of nicotine replacement therapy (NRT).

Results: ACT participants completed more calls than CBT participants ($M = 3.25$ in ACT vs. 2.23 in CBT; $p = .001$). Regarding satisfaction, 100% of ACT participants reported their treatment was useful for quitting smoking (vs. 87% for CBT; $p = .03$), and 97% of ACT participants would recommend their treatment to a friend (vs. 83% for CBT; $p = .06$). On the primary outcome of intent-to-treat 30-day point prevalence abstinence at 6 months postrandomization, the quit rates were 31% in ACT versus 22% in CBT (odds ratio [OR] = 1.5, 95% confidence interval [CI] = 0.7–3.4). Among participants depressed at baseline ($n = 47$), the quit rates were 33% in ACT versus 13% in CBT (OR = 1.2, 95% CI = 1.0–1.6). Consistent with ACT's theory, among participants scoring low on acceptance of cravings at baseline ($n = 57$), the quit rates were 37% in ACT versus 10% in CBT (OR = 5.3, 95% CI = 1.3–22.0).

Conclusions: ACT is feasible to deliver by phone, is highly acceptable to quitline callers, and shows highly promising quit rates compared with standard CBT quitline counseling. As results were limited by the pilot design (e.g., small sample), a full-scale efficacy trial is now needed.

Cigarette smoking among adults is the leading cause of preventable death, accounting for 440,000 deaths annually in the United States alone (Centers for Disease Control and Prevention, 2006). To address this serious public health issue, smoking cessation quitlines (QLs) are an important and cost-effective part of the U.S. tobacco control program (Fiore et al., 2008), serving over 500,000 smokers each year across all 50 states (North American Quitline Consortium, 2013). The QL-recommended standard of care is the combination of proactive counseling (i.e., calls initiated by the counselor) and nicotine replacement therapy (NRT) (Fiore et al., 2008).

Since their inception in early 1990s, QLs' primary counseling approach has been traditional cognitive behavioral therapy (CBT) (Fiore et al., 2008; Stead, Hartmann-Boyce, Perera, & Lancaster, 2013). CBT for smoking cessation combines techniques from traditional cognitive and behavioral treatments to teach skills to cope with cues to smoke. These skills

include exercises to avoid cravings and using cognitive restructuring to change thoughts that cue smoking (Perkins, Conklin, & Levine, 2008). Although certain studies of QLs' traditional CBT counseling with NRT have yielded higher results, their average 30-day point prevalence quit rate has consistently remained at 14% at 12 months postrandomization (Fiore et al., 2008; Stead et al., 2013). These low quit rates stifle the ability of QLs to have high population-level impact. To address this need, the current study tested a counseling model called acceptance and commitment therapy (ACT) (Hayes, Luoma, Bond, Masuda, & Lillis, 2006).

ACT: An Emerging Theory-Based Intervention

ACT focuses on increasing willingness to experience physical cravings, emotions, and thoughts that trigger smoking (i.e., acceptance) while making values-guided behavior changes (i.e., commitment).

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ACT is similar to traditional CBT in that it teaches skills to cope with cues to smoke, but the philosophy and content of those skills follow a fundamentally different paradigm. ACT is based on Relational Frame Theory (Hayes, Barnes-Holmes, & Roche, 2001), which posits that trying to control learned associations (e.g., between an urge and smoking) creates a paradox: New associations are formed that interfere with behavior change (e.g., distraction from urges leads to more urges). In contrast, traditional CBT is based on information processing theories, which posit that mental rules guide behavior such that applying illogical beliefs (e.g., smoking controls stress) lead to dysfunctional behavior (e.g., more smoking) (Newell, 1990).

Unlike traditional CBT, ACT does not focus on changing the *content* of thoughts (e.g., replacing an inaccurate thought with an accurate thought), but rather on changing one's *relationship* to thoughts via active awareness and observation of thoughts (Hayes et al., 2006). ACT focuses on increasing a person's willingness to experience urges to smoke (Bricker, 2011). In contrast, traditional CBT uses problem-solving skills to avoid and control urges to smoke (Perkins et al., 2008). ACT's second key innovation is promoting value-driven behavior change (Hayes, Strosahl, & Wilson, 1999; Luoma, Hayes, & Walser, 2007), whereas traditional CBT promotes reason-driven behavior change (Fiore et al., 2008; Perkins et al., 2008). For the change approach, ACT teaches skills primarily through metaphors and experiential exercises (Hernandez-Lopez, Luciano, Bricker, Roales-Nieto, & Montesinos, 2009; Luoma et al., 2007), whereas CBT teaches skills primarily through logical and literal explanation (Perkins et al., 2008). Moreover, ACT, but not traditional CBT, was mediated by increases in acceptance of internal triggers (Forman, Herbert, Moitra, Yeomans, & Geller, 2007; Lappalainen et al., 2007). Finally, ACT differs from mindfulness-based therapies in that: (a) being mindful is only one of numerous ACT strategies for increasing willingness to experience urges and (b) ACT, but not mindfulness, focuses on values (Herbert & Forman, 2011).

Promising evidence from three studies, albeit with methodological limitations (e.g., nonbehavioral comparison group, small Ns), suggests that face-to-face ACT for smoking cessation has 30%–35% quit rates at 12 months follow-up (Gifford et al., 2004, 2011; Hernandez-Lopez et al., 2009). For example, in a randomized trial of 302 smokers, Gifford and colleagues (2011) compared individual plus group therapy ACT with bupropion to bupropion only. In intent-to-treat 12-month follow-up analysis, the ACT intervention arm had a quit rate of 32% versus 18% in the comparison arm ($p < .05$). We compared group therapy ACT to CBT (both with no pharmacotherapy) for adult smoking cessation in a small ($N = 81$) nonrandomized trial (Hernandez-Lopez et al., 2009). The intent-to-treat 12-month 30-day point prevalence quit rate was 30% in the ACT group versus 13% in the CBT group (odds ratio [OR] = 2.86; $p = .05$).

Telephone-Delivered ACT for Smoking Cessation: Treatment Development Study

We adapted ACT into a telephone-delivered five-session (90-min total) treatment protocol and delivered the intervention (without pharmacotherapy) in a single-arm treatment development study of 14 adults (Bricker, Mann, Marek, Liu, & Peterson, 2010; Schimmel-Bristow, Bricker, & Comstock, 2012). Independent ratings of audio recordings of all telephone

counseling calls showed that intervention delivery was highly competent ($M = 4.81$, $SD = 0.39$, on a 1–5 scale) (Schimmel-Bristow et al., 2012). The study provided four initial receptivity and efficacy results: (a) Average number of calls completed (i.e., 3.5) was higher than the widely used traditional CBT QL intervention (i.e., 2.3; Hollis et al., 2007); (b) 93% said the intervention was useful for quitting smoking; (c) from baseline to posttreatment, there was an increase in acceptance of physical cravings, emotions, and thoughts that cue smoking, consistent with ACT's theory-based mechanism of change; (d) in intent-to-treat analyses, 29% had not smoked at all in the past 12 months at 12 months posttreatment.

Subgroups: Low Acceptance of Cravings, Heavy Smoking, and Depression

ACT may be especially helpful for smoking cessation in three subgroups: smokers low in acceptance, heavy smokers, and depressed smokers. The ACT model suggests that, in addition to being a key mechanism (i.e., mediator) of treatment, baseline acceptance is a moderator of treatment outcome (Hayes et al., 2006). Specifically, people who avoid their triggers to smoke (i.e., low acceptance) will benefit most from ACT because ACT teaches skills to overcome avoidance. We also posit that this focus on acceptance may be especially helpful for heavy smokers and those with mental health symptoms because physical, emotional, and cognitive cues to smoke are stronger for these individuals (Cui et al., 2012; Kushnir et al., 2013; Loeber et al., 2011; Weinberger, McKee, & George, 2012). Overall, exploration of comparative treatment effects in these subgroups can aid in the critical effort to improve quit rates for high-risk groups and thereby reduce tobacco-related health disparities (Baker et al., 2007; Marlatt, Curry, & Gordon, 1988; Wee, West, Bulgiba, & Shahab, 2011; Zhou et al., 2009).

Present Study

Stimulated by the results of this first study of telephone-delivered ACT, the overall goal of this study was to test telephone-delivered ACT plus NRT versus traditional CBT plus NRT for smoking cessation in a pilot randomized trial. To support this goal, the aims were to examine trial design feasibility (Aim 1), participant receptivity and satisfaction (Aim 2), compare quit rates overall and among three key baseline subgroups of smokers (specifically, low acceptance of cravings, heavy smoking, and depressed) (Aim 3), and ACT's impact on acceptance of cravings (Aim 4).

METHODS

Participants

Participants were uninsured callers to the South Carolina State Quitline (SCQL), operated by Seattle-based Alere Well-Being® (Alere). South Carolina was chosen for its substantial African American population (U.S. Census Bureau, 2008) and because its 22.3% adult smoking prevalence is higher than the national average (Centers for Disease Control and Prevention, 2007). To prevent potentially biasing participants in favor of one intervention over another, all recruitment communications stated that “the purpose of the study is to learn which of two

Randomized trial of ACT versus CBT

telephone coaching programs for quitting smoking works better.” They were informed that they would be randomly assigned to two different approaches to personalized coaching in (a) creating and acting on a plan for quitting smoking and (b) skills to cope with triggers to smoke. There were no references to ACT, CBT, or any other counseling intervention content. Eligibility criteria were (a) aged 18 and older; (b) smoked at least 10 cigarettes per day (to be eligible for NRT) for at least the past 12 months; (c) wanted to quit smoking in the next 30 days; (d) willing to be randomly assigned to either group; (e) willing and able to speak and read in English; (f) willing and medically eligible to use NRT; (g) resided in the United States and expected to continue for at least 12 months; (h) not participating in other smoking cessation interventions; and (i) had regular access to a telephone. Baseline characteristics of the randomized participants were similar to those of SCQL callers not enrolled in this study (South Carolina State Quitline, personal communication, November 13, 2013).

Sample Size

As Aim 1’s focus was on feasibility, the study’s sample size was powered to show differences in number of completed calls. The estimate of the number of calls completed was 3.5 ($SD = 1.3$) for ACT (Bricker et al., 2010) and 2.3 ($SD = 1.6$) for CBT (Hollis et al., 2007). Based on these estimates, there was 80% power to detect a significant difference in number of completed calls (60 per arm). In contrast, the study was not powered to show differences in quit rates, but rather to provide an estimate of the effect size for telephone-delivered ACT.

Recruitment

Alere QL staff advertised the study to the SCQL callers. Callers interested in the study ($N = 238$) were transferred to the Fred Hutchinson Cancer Research Center’s (FHCRC) research team members who administered on the phone the (a) Eligibility Phone Screener, (b) Verbal Consent, and (c) Baseline Survey. Those eligible ($N = 150$) were contacted by telephone 2 days later to confirm their interest in the study and, if confirmed, were randomly assigned to treatment ($N = 121$). Callers who were not enrolled in the trial were referred to the SCQL intervention program. The exclusions from initial screening through randomization are shown in Figure 1.

Randomization

To balance baseline variables between the two conditions, treatment assignment used an automated algorithm stratifying on these factors empirically known to predict smoking cessation: gender (male/female), quit attempts in past 12 months (yes/no), binge alcohol use in past 30 days (yes/no), and positive screen for depression in past 3 months (yes/no; Hughes & Kalman, 2006; Perkins et al., 2008; Shiffman et al., 1997; Zhu, Sun, Billings, Choi, & Malarcher, 1999). Randomized study arm assignments were computer generated and concealed from participants after eligibility was determined and consent for participation was obtained. Neither research staff nor participants had access to upcoming randomized study arm assignments. All study procedures were approved by the Institutional Review Board of the Fred Hutchinson Cancer Research Center and Western IRB. The ClinicalTrials.gov identifier was NCT01525420.

Interventions

Both the ACT telephone intervention and the traditional CBT telephone intervention were delivered as a five-session counseling protocol in combination with NRT. Participants in both groups were mailed a personalized letter with their quit plan, handouts specific to their assigned condition, and instructions for NRT use. The length of intervention was the same in both arms: the first call was 30 min, and each subsequent call was 15 min. Each intervention approach is described briefly below.

ACT Intervention

The ACT intervention content was previously described (Bricker et al., 2010). Briefly, the acceptance components taught skills in (a) increasing willingness to experience urges that cue smoking, (b) changing the function of smoking urges, and (c) responding differently to smoking urges (e.g., noticing and not acting on urges). The commitment components focused on helping individuals articulate the values guiding quitting (e.g., the love of one’s children) and taking actions to quit guided by those values.

CBT Intervention

The comparison was the standard CBT-based counseling intervention that is delivered by Alere and offered through the SCQL. Alere is the largest provider of telephone smoking cessation interventions in the United States, currently operating QLs for 28 states and numerous large health insurers and companies. This intervention met our criteria for a comparison intervention because (a) it follows Agency for Healthcare Research and Quality (AHRQ) clinical practice guidelines for smoking cessation (Fiore et al., 2008); (b) it has demonstrated efficacy (Bush et al., 2012; Hollis et al., 2007; Swan et al., 2003); (c) its traditional CBT approach is mediated by psychological processes that are different from those of ACT, providing a rigorous test of the hypothesized mediator (Forman et al., 2007; Hayes et al., 1999); and (d) the intervention is equal in length to the ACT intervention. Sessions focus on assisting participants to develop a quit plan and teaching skills in the avoidance of triggers through techniques such as distraction, stimulus control, and changing the content of thoughts about smoking.

Counselor Qualifications and Training

All counselors were bachelors or masters-level providers with at least 3 years of general counseling experience, consistent with prior QL (Hollis et al., 2007; Stead et al., 2013) and ACT intervention trials (Dahl, Wilson, & Nilsson, 2004; Forman et al., 2007; Lappalainen et al., 2007). Counselors completed at least 100 hr of training in the treatment approach that they delivered and, prior to beginning as a study counselor, demonstrated acceptable adherence to the intervention protocol using standardized rating procedures. Quality control procedures for both interventions included ongoing monitoring of protocol adherence and supervision. We followed the expert recommendation of having two teams of equally competent counselors each deliver only one of the treatment arms (Falkenstrom, Markowitz, Jonker, Philips, & Holmqvist, 2013; Markowitz, Kocsis, Christos, Bleiberg, & Carlin, 2008). This design, the alternative to having counselors deliver both treatment arms,

Figure 1. Participant flow diagram.

prevents biases, including the following: (a) allegiance to a given intervention treatment biases their delivery of the other treatment and (b) treatment contamination via using techniques from one treatment in the comparison treatment (Falkenstrom et al., 2013).

Nicotine Replacement

NRT provision is a recommended standard of care for QLs (Fiore et al., 2008) and thus was used in both interventions. All participants received a standard 2-week course of nicotine patch or gum (participant's choice)—consistent with SCQL procedures at the time of the trial enrollment. Counselors presented NRT as a tool for coping with smoking urges and nicotine withdrawal symptoms while participants are learning their respective therapy's behavioral skills. At every session,

participants were asked about their use of the NRT and/or the NRT handout that was mailed to them.

Counselor Competence Ratings

For counselor competence, we audiorecorded calls and rated counselors on adherence to each protocol. ACT and CBT calls were each independently rated by two trained raters. Interrater agreement was high and did not differ by arm (proportion of positive agreement = 0.91 for CBT; 0.99 for ACT; proportion of negative agreement = 0.00 for CBT; 0.00 for ACT). ACT calls were rated using the ACT Adherence Raters' Manual (modified from Gifford et al., 2004, 2011), whereas CBT calls were rated using the Alere Call Quality Management Tool used in multiple NIH-funded trials (Bush et al., 2012; Hollis et al., 2007; Swan et al., 2003).

Follow-up Data Collection and Retention

All follow-up survey data collection was conducted by an FHCRC team blind to treatment arm assignment. The follow-up data collection followed a timed protocol of online, telephone, and mailed versions of each survey. Participants were compensated \$20 for each follow-up survey that they completed.

Measures

Participant Demographics and Smoking Behaviors at Baseline
Participants reported at the baseline assessment a variety of demographics (e.g., marital status), depression, and smoking in the social environment.

Depression Symptoms at Baseline

Depressive symptoms at baseline were measured using the depression scale of the Anxiety and Depression Detector, a brief screener that has shown good sensitivity (0.85) and specificity (0.73) in correspondence with clinical interview diagnosis in a primary care settings (Means-Christensen, Sherbourne, Roy-Byrne, Craske, & Stein, 2006). The scale included the following item: “In the past three months, did you have a period of one week or more when you lost interest in most things like work, hobbies and other things you usually enjoyed?” A “yes” response was coded as a positive depression screen.

Nicotine Dependence at Baseline

Nicotine dependence at baseline was measured with the two-item Heaviness Smoking Index from the Fagerström Test for Nicotine Dependence (cutoff score: 4 or more) (Heatherton, Kozlowski, Frecker, & Fagerström, 1991).

Treatment Satisfaction

Treatment satisfaction at the 3-month follow-up was measured with a brief survey. A sample item was “How useful were your program’s skills exercises for quitting smoking?” Response choices ranged from *Not at all* (1) to *Very much* (5).

NRT Use

At the 6-month follow-up, participants were asked whether they had ever used NRT (nicotine gum, patch) since joining the study.

ACT Theory-Based Acceptance Process

The willingness to experience and not act on physical cravings to smoke (i.e., acceptance) was measured at baseline and 3-month follow-up using a nine-item subscale of the Avoidance and Inflexibility Scale (AIS; adapted from Gifford et al., 2004). The psychometric properties of the AIS have been previously reported in our research (Bricker, Wyszynski, Comstock, & Heffner, 2013). Scores were derived by averaging the items. Regarding assessment timing, the 3-month follow-up was when we expected acceptance to increase the most, as consistent with past ACT smoking cessation studies (Bricker et al., 2010, 2013).

Thirty-Day Point Prevalence Cessation Outcome at 6-Month Follow-Up

For scientific rigor and comparability with current QL trials (Hollis et al., 2007; Stead et al., 2013), the cessation outcome

was 30-day point prevalence abstinence (i.e., no smoking at all in the past 30 days) at the 6-month follow-up. Smoking status was self-reported. Due to cost and low demand characteristics for false reporting, the SRNT Subcommittee on Biochemical Verification recommends biochemical confirmation is unnecessary in population-based studies with limited face-to-face contact and studies where the optimal data collection methods are through the mail or telephone (Benowitz et al., 2002), and self-reported smoking is a standard method for assessing the efficacy of telephone-delivered interventions (Stead et al., 2013).

Statistical Analysis

Baseline sample characteristics were assessed for balance between study groups using two-sample *t* tests for continuous variables and Fisher’s exact test for categorical variables. The comparison of the smoking cessation outcome was a logistic regression comparing the intent-to-treat 30-day quit rates at 6-month follow-up. To be comparable with current smoking cessation QL trials, we used the missing = smoking imputation for the smoking cessation outcome variable (Stead et al., 2013). To test the extent to which ACT impacts acceptance of cravings to smoke, a linear regression model compared the two arms’ AIS acceptance scores at the 3-month follow-up, whereas a logistic regression model examined whether AIS acceptance scores at 3 months predicted the 30-day point prevalence smoking cessation at 6 months. (Note that this pilot study’s sample size of 121 provided inadequate power to determine whether acceptance of cravings mediates the impact of ACT on smoking cessation.) We considered, as covariates, any baseline variables that either significantly differed between the treatment groups or were predictive of the 6-month smoking cessation outcome. No variable met either of these criteria, and thus, no covariates were added. Analyses were conducted using STATA 12.0 and R 2.13.2.

RESULTS

Design Feasibility

Participant characteristics were balanced at baseline across the two treatment arms (see Table 1). As shown in Table 2, each counseling intervention was delivered to a high and similar level of competence. The data retention rates were 66% at 3-month follow-up and 67% at 6-month follow-up and did not differ significantly by treatment arm (all $p > .05$).

Receptivity and Satisfaction

ACT participants completed 1.1 more calls on average than CBT participants ($p < .001$). For every one call attempt, ACT participants completed a call 36% of the time compared with only 13% of the time for CBT participants ($p < .0001$). Regarding dose response, more calls predicted higher 30-day point prevalence abstinence at 6-month follow-up for ACT ($OR = 1.6$; 95% confidence interval [CI] = 1.1–2.6; $p = .03$), but not for CBT ($OR = 1.6$; 95% CI = 0.9–3.0; $p = .10$). Length of each completed call did not significantly differ by treatment arm ($M = 23.64$ min for ACT vs. 22.01 min for CBT; $p = .25$). Rates of NRT usage by participants did not significantly differ by treatment arm (67% for ACT vs. 73% for CBT; $p = .59$). As

Table 1. Baseline Characteristics of Trial Participants Randomized to Each Arm

	Overall (<i>N</i> = 121)	ACT (<i>n</i> = 59)	CBT (<i>n</i> = 62)	<i>p</i> value*
Demographics				
Age, <i>M</i> (<i>SD</i>)	39.08 (9.8)	39.6 (9.5)	38.6 (10.2)	.55
Female	69%	66%	73%	.40
Caucasian	73%	76%	69%	.39
Married	28%	27%	29%	.82
Working	37%	44%	31%	.13
HS or less education	55%	56%	53%	.77
Positive depression screen	39%	41%	37%	.83
Smoking behavior				
Smokes more than half pack per day	65%	58%	71%	.13
Nicotine dependent	71%	73%	68%	.54
Smoked for 10 or more years	75%	75%	76%	.88
Tried to quit in the last 12 months	45%	48%	42%	.67
Friend and partner smoking				
Close friends who smoke, <i>M</i> (<i>SD</i>)	3.1 (1.7)	3.0 (1.8)	3.1 (1.8)	.78
Living with partner who smokes	38%	41%	34%	.44
ACT theory-based acceptance, <i>M</i> (<i>SD</i>)				
Acceptance of cravings ^a	1.85 (0.48)	1.84 (0.43)	1.86 (0.52)	.87

Note. ACT = acceptance and commitment therapy; CBT = cognitive behavioral therapy; HS = high school.

^aResponse choices for each item ranged from not at all (1) to very willing (5). Scores were derived by averaging the items.

**p* values compare baseline variables between the ACT and CBT arms. The *p* values were generated from two sample *t* tests for continuous variables and Fisher's exact test for categorical variables.

Table 2. Comparison of ACT and CBT on Implementation, Satisfaction, and Cessation Outcomes

Outcomes	ACT		CBT		<i>p</i> value ^a
	<i>n</i>	Summary	<i>n</i>	Summary	
Counseling implementation, <i>M</i> (<i>SD</i>)					
Number of intervention calls completed	59	3.25 (1.94)	62	2.23 (1.34)	.001
Competence of intervention delivery ^b	38	4.92 (0.34)	12	4.58 (0.64)	.10
Participant satisfaction, % (<i>n</i>)					
Satisfied overall ^c	32	97% (31)	27	85% (23)	.10
Recommend to friend	34	97% (33)	30	83% (25)	.06
Useful skills for quitting ^c	32	100% (32)	31	87% (27)	.04
Cessation—30-day PPA at 6 months, % (<i>n</i>) ^d					
All participants	59	31% (18)	62	22% (14)	.32
Those reporting low acceptance	27	37% (10)	30	10% (3)	.02
Those reporting heavy smoking	25	36% (9)	18	17% (3)	.17
Those screening positive for depression	24	33% (8)	23	13% (3)	.11

Note. ACT = acceptance and commitment therapy; CBT = cognitive behavioral therapy; PPA = point prevalence abstinence.

^aTwo-sided *p* values calculated from unadjusted logistic regression models.

^bRatings ranged from 1 (not at all) to 5 (extensively).

^cResponses dichotomized as somewhat or very much versus not at all or a little.

^dCessation outcomes for missing values were imputed using the standard missing = smoking assumption.

shown in Table 2, ACT participants were generally more satisfied with their treatment than CBT participants.

Cessation Outcomes

The bottom four rows of Table 2 report the cessation outcomes. Among all randomized participants, the 6-month 30-day point prevalence quit rates were 31% in ACT versus 22% in CBT (*OR* = 1.5; 95% *CI* = 0.7–3.4; *p* = .32). Among the subgroup of participants who reported low acceptance of cravings (i.e., below the median on the acceptance scale) at baseline, the 30-day point prevalence quit rates at 6-month follow-up were

37% in ACT versus 10% in CBT—a significant difference (*OR* = 5.3; 95% *CI* = 1.3–22.0; *p* = .02). Among those reporting heavy smoking (i.e., at least a pack of smoking per day) at baseline, the quit rates were 36% in ACT versus 17% in CBT (*OR* = 2.8; 95% *CI* = 0.6–12.4; *p* = .17). Among those screening positive for depression at baseline, the quit rates were 33% in ACT versus 13% in CBT (*OR* = 1.2; 95% *CI* = 1.0–1.6; *p* = .10).

Acceptance of Cravings

At the 3-month follow-up, ACT participants had significantly higher levels of acceptance of cravings to smoke than CBT

participants ($M = 2.41$ for ACT vs. 2.13 for CBT; on a scale of 1–5; $p = .046$). In turn, higher levels of acceptance of cravings to smoke at the 3-month follow-up predicted a 4.6 times higher odds of quitting at the 6-month follow-up ($OR = 4.6$; 95% CI = 1.5–14.2; $p = .009$).

DISCUSSION

The goal of this study was to test telephone-delivered ACT plus NRT versus traditional CBT plus NRT for smoking cessation in a pilot randomized trial in order to examine trial design feasibility (Aim 1), participant receptivity and satisfaction (Aim 2), quit rates overall and among three key subgroups (Aim 3), and impact on acceptance of cravings (Aim 4). In general, the results supported all four aims. The fact these aims were achieved in an uninsured sample of smokers is encouraging because they are a generally challenging population to engage in research (e.g., low retention) and tend to have worse treatment outcomes than the insured (Bush et al., 2012; Schauer et al., 2013; Stead et al., 2013).

Design Feasibility

The enrollment source (i.e., SCQL) and eligibility criteria provided assurances that study enrollment was feasible and timely. The data collection protocol yielded overall retention rates that were higher than the 55% average rates for comparable general population telephone-delivered smoking cessation interventions (Bush et al., 2012; Schauer et al., 2013; Stead et al., 2013). Finally, the per-protocol implementation data demonstrated that ACT can be implemented with a QL population with high and similar competence as CBT.

Participant Receptivity and Satisfaction

As hypothesized, ACT participants completed more calls than CBT participants. Indeed, the observed number of completed calls in each arm closely correspond to those observed in the first ACT telephone study (Bricker et al., 2010) and prior CBT QL studies (Hollis et al., 2007). Encouragingly, the call completion yield for each ACT call attempt was 3 times higher than that of each CBT call attempt.

While high for both arms, participant satisfaction in the ACT arm was generally higher than that of the CBT arm. The high level of satisfaction for ACT is very similar to that reported in our first ACT telephone study (Bricker et al., 2010) and all three face-to-face studies of ACT for smoking cessation (Gifford et al., 2004, 2011; Hernandez-Lopez et al., 2009). This is an important finding because ACT asks smokers to do something counterintuitive—namely, to accept their cravings.

Quit Rates Overall and Among Three Key Subgroups

The 31% observed quit rate for ACT was similar to the 29% we obtained in our first trial of telephone-delivered ACT (Bricker et al., 2010) and the 30%–35% quit rates observed in all three face-to-face trials of ACT for smoking cessation (Gifford et al., 2004, 2011; Hernandez-Lopez et al., 2009). While each study had different designs and their own set of methodological limitations, the similarity of ACT quit rates across studies is noteworthy. The comparison of the ACT and CBT quit rates was underpowered because this was a pilot trial. Nonetheless, the

estimated difference of nine percentage points in absolute quit rates (31% vs. 22%) for the cessation outcome (number needed to treat [NNT] = 11; West, 2007) suggests that, if proven definitive in a future well-powered trial and then implemented broadly to the 500,000 smokers who use U.S. QLs annually, ACT could result in approximately 45,000 additional quitters per year.

The quit rate differences between ACT and CBT were more striking among the three subgroups we explored—descriptively ranging from 2 to 3 times higher quit rates. The effects among the low acceptance subgroup fit the ACT theoretical model, which suggests the treatment would be most beneficial for people who lack skills in accepting their cravings to smoke. While all three subgroups are important, results for heavy smokers and those screening positive for depression are especially important because these groups have very low quit rates, and thus, their morbidity and mortality rates are strikingly high (Fagan et al., 2004). These pilot results thus show the promise of telephone-delivered ACT in reducing these tobacco-related health disparities.

Impact on Acceptance of Cravings

The results on ACT's influence on acceptance of cravings are important for several reasons. First, from an intervention design perspective, they suggest that the ACT intervention protocol was impacting its intended clinical process target. Second, the results comport with the ACT theoretical model of acceptance as it applies to smoking cessation, namely that acceptance of cravings is an underlying process of smoking cessation. Finally, the results are highly consistent with our first trial of telephone-delivered ACT (Bricker et al., 2010) and all three face-to-face studies of ACT for smoking cessation (Gifford et al., 2004, 2011; Hernandez-Lopez et al., 2009).

Post Hoc Results on NRT

In post-hoc analyses of NRT, there was no evidence that use of NRT alone predicted cessation outcomes ($p = .30$) and no evidence of an interaction between NRT use and treatment group ($p = .63$). In addition, there was no evidence that NRT use explained smoking cessation outcome after accounting for treatment group ($OR = 1.8$; 95% CI = 0.6–5.5; $p = .30$). While the study was not designed to assess the added incremental impact of NRT, the lack of observed impact of NRT in this post-hoc analysis may have been limited by the fact the SCQL was only offering 2 weeks of NRT in the standard QL service during the time of trial enrollment. A longer duration of dosing is therefore advised.

Limitations

The study has important limitations. As pilot randomized trial, the study's sample size was not powered to detect statistically significant differences in quit rates or to conduct formal mediation analysis of hypothesized treatment effects. Moreover, there is substantial relapse that naturally occurs even after a 6-month follow-up (Hollis et al., 2007; Stead et al., 2013), and therefore, a longer term follow-up (e.g., 12 months) is recommended. Finally, we relied exclusively on self-reported abstinence in our estimate of 30-day point prevalence abstinence. However, expert consensus suggests that biochemical verification of abstinence is impractical and unnecessary in population-based studies that do not involve in-person contact and where the optimal data collection methods are through the mail or telephone (Benowitz et al., 2002).

Future Directions

This study suggests four lines of future research. *First*, in a well-powered trial, a definitive test of the effectiveness for smoking cessation of ACT telephone counseling compared with traditional CBT telephone counseling. *Second* demonstrate that the smoking cessation outcomes of ACT, *but not traditional CBT*, are formally mediated by acceptance of internal cues to smoke. *Third* determine the comparative cost-effectiveness of ACT telephone counseling versus traditional CBT telephone counseling. *Fourth* determine the effectiveness for smoking cessation of ACT versus traditional CBT among these baseline subgroups: (a) low acceptors of cues to smoking, (b) heavy smokers, and (c) smokers screening positive for a number of mental health symptoms, including depression.

CONCLUSIONS

ACT is feasible to deliver by phone, is highly acceptable to QL callers, and shows highly promising quit rates compared with standard CBT QL counseling. As results were limited by the pilot design (e.g., small sample), a full-scale efficacy trial is now needed.

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DECLARATION OF INTERESTS

In 2011 Dr. Heffner served as a consultant for Pfizer.

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