- There is a need for innovative and efficacious smoking cessation interventions.
- This trial compared behavioral support, ACT, and ACT combined with smartphone app.
- The combined intervention promoted smoking reduction at post-treatment.
- Acceptance and awareness improved in the combined group at post-treatment.
- The three groups displayed comparable smoking cessation outcomes.

Randomized controlled trial of a smartphone application as an adjunct to acceptance and commitment therapy for smoking cessation

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Data and recruitment materials used in this research are publicly available on the Open Science Framework: https://osf.io/xgesf/

Funding: This work was supported by an Irish Research Council Government of Ireland Postgraduate Scholarship awarded to Martin O'Connor.

Declarations of interest: none

Abstract

There is a major public health need for innovative and efficacious behavioral and cognitive interventions for smoking cessation. This randomized controlled trial evaluated the efficacy of an acceptance and commitment therapy (ACT) smartphone application in augmenting ACT group treatment for smoking cessation. One hundred fifty adults smoking 10 or more cigarettes per day were randomly assigned to six weekly group sessions of behavioral support, ACT, or ACT combined with the smartphone application. Access to the app was provided from the start of the in-person treatment until the six-month follow-up assessment. Participants were encouraged to make their quit attempts after the third session, and the post-treatment assessment occurred three weeks later. Measures of smoking status and ACT processes were obtained at baseline, post-treatment and six-month follow-up. Biochemically verified quit rates in the combined, ACT and behavioral support groups were 36% (p = .079 relative to ACT; p = .193 relative to behavioral support), 20% (p = .630 relative to behavioral support) and 24% at post-treatment, as compared with 24% (p = .630 relative to behavioral support), 24% (p = .630 relative to behavioral support) and 20% at follow-up. There was no significant difference (p = > .999) in the primary outcome of biochemically verified seven-day point-prevalence abstinence at six-month follow-up between the combined and ACT groups. The combined group reported significantly greater smoking reduction, acceptance and present-moment awareness than the behavioral support group at post-treatment, but not at follow-up. There were no significant differences between the groups in positive mental health. Contrary to hypotheses, the ACT group did not display significant improvements in positive mental health or ACT processes relative to the behavioral support group at post-treatment or follow-up. Implications and directions for future research are discussed.

Keywords: Acceptance and commitment therapy; eHealth; Smoking cessation; Randomized controlled trial.

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Smoking is a leading cause of preventable death globally, contributing to almost six million deaths per year (Centers for Disease Control and Prevention, 2018). For every person who dies as a result of smoking, at least 30 people live with the burden of a serious smoking-related illness such as cancer, heart disease, diabetes, or chronic obstructive pulmonary disease (World Health Organization, 2018). The global economic cost of smoking is estimated at €1.3 trillion (Goodchild, Nargis, & Tursan d'Espaignet, 2018). There are currently 1.1 billion adult smokers in the world (World Health Organization, 2018). Although the vast majority of smokers want to quit (Lebrun-Harris, Fiore, Tomoyasu, & Ngo-Metzger, 2015), the rates of successful abstinence are sobering. Approximately 3–5% of those who attempt to quit without assistance are successful (Hughes, Keely, & Naud, 2004). Consequently, there is a major public health need for efficacious and acceptable smoking cessation interventions. Systematic reviews have supported psychological interventions in promoting smoking cessation, including motivational interviewing (*RR* = 1.26; Lindson-Hawley, Thompson, & Begh, 2015), physician- (*RR* = 1.66; Stead, Buitrago et al., 2013), nurse- (*RR* = 1.29; Rice, Heath, Livingstone- Banks, & Hartmann- Boyce, 2017) and telephone-delivered (*RR* = 1.38; Stead, Hartmann- Boyce, Perera, & Lancaster, 2013) counselling interventions.

Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 2012) is a contextual cognitive behavioral therapy that has shown promise as a smoking cessation intervention (McCallion & Zvolensky, 2015). The psychological inflexibility model that underlies ACT proposes six coherently related processes that contribute to smoking maintenance and relapse: experiential avoidance (e.g., avoidance of cravings or urges to smoke; Roales-Nieto et al., 2016), rigid attachment to self-conceptualizations (e.g., "I have

no willpower"; Dupont et al., 2015), inflexible attention (e.g., attentional bias toward smoking cues; Chanon, Sours, & Boettiger, 2010), *fusion* with unworkable verbal rules (e.g., "I can have just one"), inaction or impulsivity (e.g., the smaller sooner reward of smoking holds more value than the larger later reward of better health; Barlow, McKee, Reeves, Galea, & Stuckler, 2017), and disconnection from personal values (e.g., loss of contact with value of healthy living; MacLean et al., 2017). ACT promotes smoking cessation by cultivating *psychological flexibility*: the ability to fully contact experiences in the present moment without needless defense, and persist in or change behavior when doing so serves one's values (Hayes, Luoma, Bond, Masuda, & Lillis, 2006; Hayes, Strosahl, Bunting, Twohig, & Wilson, 2004). Specifically, mindfulness processes (i.e., acceptance, flexible perspective taking, present-moment awareness, and defusion) are used to undermine the repertoire-narrowing effects of aversive control and broad, flexible, and effective repertoires under appetitive control are built through successively larger patterns of values-committed actions. Indeed, as experiential avoidance tends to narrow peoples' behavioral repertoires in key areas, ACT aims to counteract experiential avoidance by promoting mindful engagement and to broaden behavioral repertories by helping clients engage in and expand patterns of action that are aligned with their personal values (Hayes et al., 2012; Roemer, Orsillo, & Salters-Pedneault, 2008).

A growing body of research supports the efficacy of ACT for smoking cessation. Controlled trials have found face-to-face ACT to yield significantly higher smoking cessation rates than nicotine replacement therapy (Gifford et al., 2004; $N = 76$), treatment as usual (Davoudi, Omidi, Sehat, & Sepehrmanesh, 2017; $N = 70$), and cognitive behavior therapy (Hernandez-Lopez, Luciano, Bricker, Roales-Nieto, & Montesinos, 2009; $N = 81$). ACT has also been found to contribute to stop smoking medication outcomes, as a combination of the contextual cognitive behavior therapy and bupropion resulted in significantly higher seven-

day point-prevalence abstinence at one-year follow-up than bupropion-alone (Gifford et al., 2011; *N* = 303). In response to these encouraging findings, telephone-delivered (Bricker, Bush, Zbikowski, Mercer, & Heffner, 2014; *N* = 121) and web-based (Bricker, Wyszynski, Comstock, & Heffner, 2013; *N* = 222) adaptations of ACT for smoking cessation have been developed. Intention-to-treat smoking cessation rates from the longest available follow-up assessment within each of the aforementioned trials vary widely from 19.45% (Gifford et al., 2011) to 51.43% (Davoudi et al., 2017) for face-to-face interventions and 11.71% (Bricker et al., 2013) to 30.51% (Bricker, Bush et al., 2014) for alternative modes of intervention delivery. Thus, it is evident that while ACT interventions for smoking cessation are efficacious, there is scope for improving these treatments.

The smartphone application (app) is an innovative method of delivering therapeutic content that has the potential to contribute to face-to-face ACT interventions. Accordingly, 95% of practitioners surveyed by Pierce, Twohig, and Levin (2016) reported that ACT-related apps would improve their work with clients – both as an additional support between sessions and an ongoing support after face-to-face services have finished. Smartphone apps offer considerable advantages for clients: they can augment therapeutic content delivered in the clinic with on-the-spot assistance in the individual's natural environment; provide high treatment fidelity and consistency of care; feature visually engaging designs with audio-visual capabilities; and, unlike internet- or mobile phone-based interventions, can be accessed without an internet or cellular connection (Bricker, Mull et al., 2014; Vilardaga, Bricker, & McDonell, 2014). Consequently, smartphone apps for smoking cessation are used at an increasing rate around the world (Regmi, Kassim, Ahmad, & Tuah, 2017).

Although there are over 500 smartphone apps for smoking cessation on the market, few studies have evaluated their efficacy (Bricker, Mull et al., 2014; Vilardaga et al., 2018). A recent systematic review (Regmi et al., 2017) identified only three randomized controlled

trials of smoking cessation apps, one of which evaluated smartphone-delivered ACT. In that trial, Bricker, Mull et al. (2014) evaluated the efficacy of SmartQuit (2Morrow) – an ACT-based smartphone app – as a stand-alone smoking cessation intervention. Findings indicated promising quit-rates at two-month follow-up (10/98) compared to the National Cancer Institute's QuitGuide (7/98) – a smartphone app with content that follows the U.S. Clinical Practice Guidelines (Fiore et al., 2008). Although this difference was not statistically significant, there was a significant increase in acceptance of cravings to smoke in the SmartQuit (2Morrow) group, but not in the QuitGuide group. Moreover, the ACT-based app yielded higher engagement and satisfaction than the comparison intervention.

Leveraging such eHealth treatments in conjunction with face-to-face services may enhance smoking cessation outcomes (Dallery, Kurti, & Martner, 2015). In addition, if a portion of clinician-delivered therapeutic content is instead delivered via smartphone app, smoking cessation services may have the capacity to treat a larger number of clients (Marsch, 2015). Although calls have been made to combine smartphone apps with in-person interventions (Vilardaga et al., 2014), no study to date has investigated the efficacy of a smartphone app in augmenting face-to-face ACT for smoking cessation. The magnitude of human suffering and economic cost associated with smoking necessitate the development and evaluation of such innovations in behavioral medicine. Furthermore, numerous randomized controlled trials have evaluated the impact of ACT for smoking cessation on acceptance of cravings to smoke (Bricker et al., 2013; Bricker, Bush et al., 2014; Bricker, Mull et al., 2014; Gifford et al., 2004; Gifford et al., 2011), but no published randomized controlled trial has investigated the effects of such interventions on measures of other core ACT processes, such as defusion, present-moment awareness and valued action.

This randomized controlled trial evaluated the efficacy of an ACT-based smartphone app in augmenting ACT group treatment for smoking cessation. The primary aim was to

determine if the combined treatment would yield superior smoking cessation outcomes at post-treatment and six-month follow-up than ACT or behavioral support group treatment alone. The primary comparison was between the combined and ACT treatments, while the longest assessment period – six-month follow-up – was the primary endpoint (Lee, An, Levin, & Twohig, 2015; van den Brand et al., 2017). A secondary aim was to elucidate the effects of the treatments on the number of cigarettes smoked per day by non-abstinent participants. Furthermore, given that ACT takes a positive approach to mental health rather than an eliminative approach to narrowly defined problem behaviors (Hayes et al., 2006; Trompetter et al., 2013), another aim was to determine the effects of the treatments on positive mental health. The final aim was to evaluate the impact of the treatments on the core ACT processes of defusion, present-moment awareness, valued action and acceptance of cravings to smoke. All outcomes were pre-registered on a public registry (ClinicalTrials.gov ID NCT02901171). It was hypothesized that the combined treatment group would demonstrate significantly higher abstinence rates than the ACT or behavioral support groups. Similarly, it was expected that non-abstinent participants in the combined group would report significantly less cigarettes smoked per day than those in the ACT or behavioral support groups. In line with the psychological flexibility model, it was also predicted that the combined and ACT groups would display statistically significant improvements in positive mental health and the core ACT processes of defusion, present-moment awareness, valued action and acceptance of cravings to smoke relative to the behavioral support group. Additional exploratory analyses were conducted to investigate smartphone app adherence as a predictor of smoking cessation.

Method

Design

A multi-arm parallel-group randomized controlled trial was conducted in University College Dublin, Ireland. Assessments were completed prior to the treatment, immediately after the treatment, and at six-month follow-up. The trial is reported in accordance with the CONSORT guidelines (Schulz, Altman, & Moher, 2010). Ethical approval for the trial was provided by the University College Dublin Human Research Ethics Committee. All persons provided written informed consent prior to their inclusion in the trial.

Participants

Eligible participants were (a) aged 18 years or older, (b) smoking 10 cigarettes or more per day for the past 12 months or more, (c) interested in quitting smoking, (d) willing to engage in six weekly group treatment sessions, (d) daily access to a smartphone that was compatible with apps from iTunes or Google Play, and (f) not receiving any other treatment for quitting smoking. Ineligible individuals were provided with information on alternative smoking cessation support services. An a priori power analysis conducted in G*Power (Faul, Erdfelder, Buchner, & Lang, 2009) revealed that a total sample size of 150 was required to provide 80% statistical power at $\alpha = .05$ to detect the medium-sized effect ($OR = 3.5$) on quit rates suggested by previous studies of ACT for smoking cessation (Davoudi et al., 2017; Gifford et al., 2011). This sample size was pre-registered on a public registry (ClinicalTrials.gov ID NCT02901171). Participants were recruited from the community by self-selection between December 2016 and September 2017. The combined, ACT and behavioral support group treatments were delivered concurrently. As each treatment was delivered three times, participants were recruited in three waves to minimize the time between baseline assessment and start of treatment. The largest portion of participants were recruited through an online source: 23.33% specified Instagram ads, 11.33% Facebook ads, 9.33% Twitter ads, 5.33% Google AdWords and 15.33% other online sources. The remaining participants specified their recruitment source as word of mouth (12.66%), posters (12.00%),

radio ads (6.66%) and unknown (4.00%). Participant flow through the phases of the trial is shown in Figure 1.

Procedure

To safeguard against performance bias, the recruitment materials, study website and information sheets were formatted to ensure that participants were blinded to the experimental manipulations. The recruitment materials advertised a research study offering adults "free help to quit smoking." Individuals who expressed an interest in participating in the trial were directed to the study website to complete a screening survey. Eligible individuals were invited to attend an assessment session, during which baseline biochemical and self-report measures were administered. After completing baseline measures, participants were randomly allocated to the treatment groups. To reduce the risk of selection bias and ensure balance of the numbers in each trial arm, the allocation sequence was generated with random block sizes of 3, 6 and 9 by a researcher with no clinical involvement in the trial using an online randomization tool. This allocation sequence was concealed from the researcher (MOC) enrolling participants in sequentially numbered, opaque, sealed envelopes. The treatments were delivered to groups ranging in size from 14 to 21 participants. At post-treatment and six-month follow-up, outcome and process measures were again administered and self-reported abstinence was biochemically verified.

Interventions. A comprehensive manual was developed to standardize the ACT group treatment. The treatment was delivered in six weekly 90-min sessions. Each ACT session was delivered by both a psychology doctoral student with training in ACT (MOC) and a doctoral-level Peer Reviewed ACT Trainer (LMH). As previous research has shown that meditative practices can have unintended effects on participants (Kuijpers, van der Heijden, Tuinier, & Verhoeven, 2007; Shapiro, 1992), potential adverse effects were monitored by the psychologists facilitating the sessions. The first session focused on

promoting creative hopelessness and values-directed behavior. Guided meditations, exercises, metaphors and interactive inquiry cultivated the processes of present-moment awareness, experiential acceptance and cognitive defusion in sessions two, three and four, respectively. In session five, the treatment goals were to weaken participants' attachment to smoking-related self-conceptualizations and strengthen their connection with self-as-context. The final session focused on reviewing the aforementioned mindfulness and behavior change processes as well as developing values-based goals and action plans.

To safeguard against contamination, participants in the ACT condition were treated separately to those in the combined condition. The latter received the SmartQuit (2Morrow; Bricker, Mull et al., 2014) smartphone app in combination with the ACT group treatment. Each participant in the combined group was given a unique access code to activate the app after downloading it from iTunes or Google Play. This code linked each participant to their app utilization data. Access to the app was provided from the start of the in-person treatment until the six-month follow-up assessment. Upon activating SmartQuit (2Morrow), the participant was prompted to create a personalized quit plan. In line with the ACT process of values clarification, the participant was encouraged to record why quitting smoking is deeply important (e.g., setting a positive example for the children) and to upload a photo to symbolize this value (e.g., picture of the children). Following this, (s)he was directed to complete eight core ACT exercises and track each urge that passed without smoking. Completing these activities unlocked 43 exercises, stories and tips in the app's *anytime coaching* section. These features nurtured psychological flexibility and promoted smoking cessation by enhancing acceptance of cravings to smoke (e.g., finger trap metaphor, carry cards exercise), encouraging defusion (e.g., leaves on a stream exercise, having the thought exercise) and cultivating present-moment awareness (e.g., five senses exercise, stop and

breathe exercise). The features were presented in audio or video format and accompanied by a text transcript.

The behavioral support program was delivered in six weekly 90 min group sessions according to an evidence-based treatment protocol (Health Service Executive, 2013). Each behavioral support session was delivered by both a doctoral-level and a bachelor's-level staff member who had undergone training in smoking cessation from the National Centre for Smoking Cessation and Training (NCSCT). The program was delivered using core skills of motivational interviewing (Miller & Rollnick, 2013). The first session aimed to increase participants' understanding of their smoking patterns and promote one positive change in their personal behavior. Session two focused on addressing ambivalence and motivation to quit as well as planning for a successful quit attempt. Increasing awareness of nicotine withdrawal symptoms and how to cope with them, promoting positive behavior choices and supporting a healthy quit attempt through good nutrition and physical activity were the focus of sessions three, four and five. The final session of the program aimed to help participants identify personal relapse prevention strategies.

Measures

Sociodemographic data including gender, age, years of education, employment status and marital status were recorded at baseline. Participants also self-reported smoking-related variables, including number of years smoking, living with a person who smokes, and number of four closest friends who smoke. Nicotine dependence was measured with the Fagerström Test for Nicotine Dependence (Heatherton, Kozlowski, Frecker, & Fagerström, 1991). The Commitment to Quitting Smoking Scale (Kahler et al., 2007) measured the state of being personally bound to persist in quitting despite potential difficulties, cravings and discomfort.

Primary outcome measure. Seven-day point-prevalence abstinence was selected as the primary outcome measure, as it is a standard outcome in trials of smoking cessation

(Hughes, Carpenter, & Naud, 2010). The outcome is defined as no smoking at all in the seven days preceding the assessment. Self-reported abstinence at post-treatment and six-month follow-up was biochemically verified with a piCO Smokerlyzer carbon monoxide breath test monitor (Bedfont Scientific Ltd., 2017). In accordance with the manufacturer's instructions and research on the expired-air carbon monoxide (CO) threshold for verifying smoking status (Brose, Tombor, Shahab, & West, 2013; Wee et al., 2015), a CO reading of >10 parts per million disconfirmed self-reported abstinence. The longest assessment period – six-month follow-up – was the primary endpoint (Lee et al., 2015; van den Brand et al., 2017).

Secondary outcome measures. Average number of cigarettes smoked per day by non-abstinent participants was selected as a secondary outcome measure, as smoking reduction has been shown to increase the probability of future cessation (Hughes & Carpenter, 2006). In addition, positive mental health was measured with the 14-item Mental Health Continuum Short Form (MHC- SF; Keyes, 2005). Participants rated the frequency with which they experienced facets of positive mental health over the past month on a 6-point scale from 0 (*never*) to 5 (*every day*); higher scores indicated greater levels of positive mental health. A sample item is "how often did you feel that you had something important to contribute to society?" A psychometric evaluation by Lamers, Westerhof, Bohlmeijer, ten Klooster, and Keyes (2011) supported the measure's convergent validity, discriminant validity and temporal stability. The MHC- SF displayed an excellent level of internal consistency in the present study (Cronbach's $\alpha = .91$).

Process measures. The Avoidance and Inflexibility Scale (AIS; Bricker et al., 2013; Farris, Zvolensky, DiBello, & Schmidt, 2015; Gifford et al., 2004) measured participants' willingness to experience internal states associated with smoking. The measure's 27 items were rated on a 5-point scale from 1 (*not at all*) to 5 (*very willing*); higher scores reflected greater acceptance of internal cues for smoking. A sample item is "how willing are you to

notice these feelings without smoking?" Previous research by Bricker et al. (2013) supported its concurrent validity. In the present study, the AIS demonstrated acceptable internal consistency (Cronbach's α = .78).

Present-moment awareness over the past week was measured with the Awareness subscale of the Philadelphia Mindfulness Scale (Cardaciotto, Herbert, Forman, Moitra, & Farrow, 2008). Participants rated its 10 items on a 5-point scale from 1 (*never*) to 5 (*very often*); higher scores indicated greater levels of present-moment awareness. A sample item is "I notice changes inside my body, like my heart beating faster or my muscles getting tense." A psychometric evaluation by Cardaciotto et al. (2008) revealed that the Awareness subscale can be administered independently and supported its convergent and discriminant validity. This subscale displayed good internal consistency in the present study (Cronbach's α = .80).

The Cognitive Fusion Questionnaire (CFQ; Gillanders et al., 2014) measured the excessive regulation of behavior by thoughts. The measure's 7 items were rated on a 7-point scale ranging from 1 (*never true*) to 7 (*always true*); higher scores reflected greater cognitive fusion. A sample item is "I get so caught up in my thoughts that I am unable to do the things that I most want to do." The CFQ demonstrated good construct validity in previous research (Gillanders et al., 2014) and excellent internal consistency in this study (Cronbach's α = .94).

Valued living over the past week was measured with the 10 item Valuing Questionnaire (VQ; Smout, Davies, Burns, & Christie, 2014). Items were rated on a 7-point scale ranging from 0 (*not at all true*) to 6 (*completely true*) and summed to produce two factors: progress in valued living, and obstruction to valued living. Higher scores on each factor reflected greater progress in valued living and obstruction to valued living, respectively. A sample item is "I made progress in the areas of my life I care most about." Previous research supported the measure's convergent and concurrent validity (Smout et al.,

2014). In the present study, reliability analyses revealed satisfactory internal consistencies for the progress (Cronbach's α = .83) and obstruction (Cronbach's α = .78) scales.

Treatment satisfaction. Participant satisfaction with treatment services was measured at post-treatment with a Brief Satisfaction Scale. The measure's 5 items were rated on a 7-point scale ranging from 1 (*strongly disagree*) to 7 (*strongly agree*); higher scores reflected greater satisfaction with treatment services. A sample item is "overall, I am satisfied with the program for quitting smoking."

App adherence. Smartphone app adherence data were delivered to a secured server. Engagement metrics included full adherence to the SmartQuit (2Morrow) program (i.e., earning a Certificate of Completion), and continued usage of the program after the in-person treatment (i.e., engagement with the smartphone app after the six-week group treatment). In line with Zeng, Heffner, Copeland, Mull, and Bricker (2016), a Certificate of Completion was awarded to users for completing four app components: (1) creating a personalized plan for quitting using the *my quit plan* feature, (2) using the *tracking* feature 10 times to record the passage of urges without smoking, (3) visiting the *anytime coaching* library for access to 43 on-demand tips and exercises (e.g., *magic wand*, duration = 1:01min; *thought tunes*, 1:49min; and *compassion*, 1:07min), and (4) completing eight ACT modules: *awareness* (2:09min), *don't think* (1:58min), *urge monster* (1:35min), *are you willing* (1:40min), *five senses* (1:21min), *leaves on a stream* (1:40min), *finger trap* (1:21min) and *having the thought* (1:04min). It was intended that participants would create a quit plan on the first day of app use. Following this, participants were intended to use the app at least twice per day and were prompted to do so through morning and evening reminders that appeared on the smartphone as push notifications. After completing the core SmartQuit (2Morrow) components and earning a Certificate of Completion, participants were encouraged to continue to use the app

twice per day for the remainder of the six-month program to practice ACT skills and track urges passed.

Therapist adherence. A random sample of 15% of audio-recorded ACT treatment sessions were assessed for treatment fidelity by two trained raters. The raters independently assessed the processes covered across each successive 10 min segment of the sessions. Cohen's Kappa coefficient provided a measure of the consistency of their ratings.

Data Analysis

The chi-square test for independence and Kruskal-Wallis test with post-hoc Mann-Whitney U tests analyzed nominal- and ordinal-level data, respectively. Cohen's *d* was computed to provide a standardized measure of effect size ($d = \frac{2t}{\sqrt{(df)}}$). The IBM SPSS mixed-effects program (MIXED) was used for repeated measures analysis of continuous and categorical outcomes. This program facilitates intention-to-treat (ITT) analysis by incorporating all available data from all participants as well as multilevel analysis in which time-points are nested within participants (Heck, Thomas, & Tabata, 2014; Heck, Thomas, & Tabata, 2012). The models were specified to include fixed effects for time (pre-, post-treatment, and six-month follow-up), treatment group (behavioral support, ACT, and combined), and their interaction (time*treatment). In accordance with best practice guidelines (West, Hajek, Stead, & Stapleton, 2005), a worst-case scenario was assumed in which all missing seven-day point-prevalence abstinence data at post-treatment and six-month follow-up were imputed as non-abstinent. Point-prevalence abstinence data were imputed for 17 participants at post-treatment (combined $n = 3$, ACT $n = 7$, behavioral support $n = 7$) and 18 participants at six-month follow-up (combined $n = 6$, ACT $n = 3$, behavioral support $n = 9$). This primary outcome was coded as a dichotomous variable (abstinent = 1; non-abstinent = 0), and the combined and ACT groups at baseline served as reference categories. To ensure optimal model fit and convergence, less complex models and covariance structures were

tested, and those with the smallest Akaike information criterion (AIC) were retained (Heck et al., 2014; Heck et al., 2012). The models were specified to determine the difference between the treatment groups at *each* occasion. Missing point-prevalence abstinence data were also replaced with multiple imputation and were analyzed with binary logistic regression.

Results

Participant Characteristics

Sociodemographic characteristics, process and smoking-related variables at baseline are shown in Table 1. Data were available for 133 participants at post-treatment (attrition rate 11.33%) and 132 participants at six-month follow-up (attrition rate 12.00%). Chi-square analyses revealed that the proportion of participants who provided data did not differ significantly between the groups at post-treatment, χ^2 (2, 150) = 2.12, p = .346, or six-month follow-up, χ^2 (2, 150) = 3.41, p = .182.

Participant Satisfaction and Utilization

In comparison to the behavioral support group, participants in both the combined and ACT groups reported significantly greater satisfaction with their treatment, greater agreement that it was helpful, suited to their needs, and of high quality, and were more likely to recommend it to a family member or friend. Participants in the combined group were also significantly more likely to recommend their treatment to a family member or friend than those in the ACT group (see Table 2). The number of sessions attended by participants in both the combined and ACT groups was also significantly greater than that of the behavioral support group. In terms of app utilization, 86% of participants in the combined group activated the SmartQuit (2Morrow) program. Twenty-eight percent of users earned a certificate of completion by (1) creating a personalized quit plan, (2) completing eight ACT modules, (3) using the app's *tracking* feature 10 times to record the passage of smoking urges, and (4) visiting the app's *anytime coaching* library for access to on-demand tips and

exercises. It took the fully adherent users a median of 24.79 days (IQR = 17.09–31.09) to complete the program. Overall, the combined group completed a mean of 56.48% (*SD* = 36.69) of the program. Fifty percent of participants continued to use the app after the in-person treatment.

Treatment Fidelity

The degree of agreement between the independent raters who classified the ACT processes from the random sample of audio-recorded treatment sessions was calculated based on 51 segments. The Kappa Measure of Agreement value was statistically significant, $\kappa = .766$, $p < .001$. According to Peat (2001), this value represents good agreement. Specifically, the independent raters consistently classified 27% of the segments as defusion, 20% as acceptance, 14% as psychoeducation, 12% as contact with the present moment, 4% as values and 2% as committed action.

Primary Outcome Measure

A fixed-effects model fit the data optimally to elucidate the impact of the treatments on seven-day point-prevalence abstinence. The primary comparison between the combined and ACT groups revealed biochemically verified quit-rates of 36% and 20%, respectively, at post-treatment, *OR* = 0.44, *p* = .079, 95% CI [0.18, 1.10]. Abstinence rates in the combined and behavioral support (24%) groups were not significantly different at post-treatment, *OR* = 0.56, *p* = .193, 95% CI [0.23, 1.34]. At the primary endpoint of six-month follow-up, the biochemically verified quit-rate was 24% in the combined group versus 24% in the ACT group, *OR* = 1.00, *p* = > .999, 95% CI [0.40, 2.51], and 20% in the behavioral support group, *OR* = 0.79, *p* = .630, 95% CI [0.31, 2.05]. Furthermore, abstinence rates in the ACT and behavioral support groups were not significantly different at post-treatment, *OR* = 1.26, *p* = .630, 95% CI [0.49, 3.27], or six-month follow-up, *OR* = 0.79, *p* = .630, 95% CI [0.31, 2.05].

Missing data were also replaced with logistic regression multiple imputation. Binary logistic regression analyses revealed that participants in the combined condition were not significantly more likely to be abstinent at post-treatment than those in the ACT, *OR* = 0.61, *p* = .262, 95% CI [0.26, 1.45], or behavioral support conditions, *OR* = 0.64, *p* = .332, 95% CI [0.27, 1.56]. Similarly, abstinence rates in the combined condition at six-month follow-up were not significantly different to those of the ACT, *OR* = 0.85, *p* = .732, 95% CI [0.35, 2.10], or behavioral support conditions, *OR* = 0.94, *p* = .903, 95% CI [0.34, 2.60]. Furthermore, abstinence rates in the ACT and behavioral support conditions were not significantly different at post-treatment, *OR* = 1.06, *p* = .905, 95% CI [0.40, 2.78], or six-month follow-up, *OR* = 1.10, *p* = .856, 95% CI [0.39, 3.12].

Secondary Outcome Measures

A multilevel model examined the effects of the treatments on non-abstinent participants' number of cigarettes smoked per day. The trajectories for the treatment groups are depicted in Supplementary Figure S2. As shown in Table 3, non-abstinent participants in the combined group reported a significant reduction in number of cigarettes smoked per day at post-treatment (*p* = < .001) and six-month follow-up (*p* = < .001) relative to baseline. Similarly, non-abstinent participants in the combined group reported significantly less cigarettes smoked per day at post-treatment relative to those in the behavioral support (*p* = .013) and ACT groups (*p* = .017). At six-month follow-up, the number of cigarettes smoked per day by non-abstinent participants in the combined group was not significantly different to that of the behavioral support (*p* = .759) or ACT groups (*p* = .930). The number of cigarettes smoked per day by non-abstinent participants in the ACT and behavioral support groups was not significantly different at post-treatment (*p* = .921) or six-month follow-up (*p* = .689).

To elucidate the treatments' impact on positive mental health, a multilevel model was specified. The combined group showed no significant difference relative to baseline positive

mental health at post-treatment (p = .156) or six-month follow-up (p = .198). Similarly, the behavioral support and ACT groups were not significantly different to the combined group at post-treatment (p = .594; p = .865) or six-month follow-up (p = .470; p = .990). The positive mental health reported by participants in the ACT group was not significantly different to that of the behavioral support group at post-treatment (p = .491) or six-month follow-up (p = .457).

Process Measures

Acceptance of cravings to smoke increased significantly in the combined group at post-treatment (p = < .001) and six-month follow-up (p = .009) relative to baseline. The combined group's acceptance of cravings to smoke was not significantly different to that of the ACT group at post-treatment (p = .465) but was greater than that of the behavioral support group (p = .039). At six-month follow-up, the combined group's acceptance of cravings to smoke was not significantly different to that of the ACT (p = .549) or behavioral support groups (p = .632). Acceptance of cravings to smoke in the ACT group was not significantly different to that of the behavioral group at post-treatment (p = .181) or six-month follow-up (p = .283). Present-moment awareness increased significantly in the combined group at post-treatment (p = .005), but not six-month follow-up (p = .255), relative to baseline. The combined group's present-moment awareness was not significantly different to that of the ACT group at post-treatment (p = .602) but was greater than that of the behavioral support group (p = .031). Present-moment awareness in the combined group at six-month follow-up was not significantly different to that of the ACT (p = .794) or behavioral support (p = .111) groups. In addition, the ACT group's present-moment awareness was not significantly different to that of the behavioral support group at post-treatment (p = .103) or six-month follow-up (p = .175).

Cognitive fusion decreases in the combined condition did not reach statistical significance at post-treatment (p = .154) or six-month follow-up (p = .140) relative to baseline. The combined group's cognitive fusion was not significantly different to that of the ACT or behavioral support groups at post-treatment (p = .702; p = .487). Similarly, the cognitive fusion reported by participants in the ACT group was not significantly different to that of the behavioral support group at post-treatment (p = .290). At six-month follow-up, the combined group showed no significant difference in cognitive fusion relative to the ACT group (p = .834), but the behavioral support group displayed a significant decrease relative to the combined (p = .023) and ACT groups (p = .036). Valued living in the combined group displayed no significant difference at post-treatment (Progress: p = .501; Obstruction: p = .165) or six-month follow-up (Progress: p = .981; Obstruction: p = .514) relative to baseline. Similarly, valued living in the behavioral support and ACT groups was not significantly different to that of the combined group at post-treatment (Progress: p = .850; p = .775; Obstruction: p = .537; p = .319) or six-month follow-up (Progress: p = .339; p = .921; Obstruction: p = .479; p = .806). The ACT group's valued living was not significantly different to that of the behavioral support group at post-treatment (Progress: p = .927; Obstruction: p = .719) or six-month follow-up (Progress: p = .384; Obstruction: p = .339).

Smartphone App Data

The biochemically verified quit rate at post-treatment was 57.14% among participants who were fully adherent to the smartphone app as compared with 27.77% among those who were not fully adherent, OR = 3.47, p = .060, 95% CI [0.95, 12.67]. At six-month follow-up, the odds of seven-day point-prevalence abstinence were over six times higher among fully adherent users (quit rate: 50.00%) as compared with those who were not fully adherent (quit rate: 13.88%), OR = 6.20, p = .012, 95% CI [1.49, 25.72]. There was no statistically significant difference in baseline commitment to quitting smoking between those who were

fully adherent to the smartphone app and those who were not, $t(48) = -1.00$, $p = .322$, 95% CI [-5.25, 1.76]. Moreover, a hierarchical logistic regression analysis revealed that app adherence significantly predicted smoking cessation at six-month follow-up over and above baseline commitment to quitting (see Supplementary Table S4). Sixty-one percent of participants who were abstinent at post-treatment continued to use SmartQuit (2Morrow) after the in-person treatment. Among participants who were abstinent at post-treatment, 63.64% of those who continued to use the smartphone app after the in-person treatment were abstinent at six-month follow-up versus 14.29% among those who discontinued use, $OR = 10.50$, $p = .060$, 95% CI [0.91, 121.39].

Discussion

This randomized controlled trial was the first to investigate the efficacy of a smartphone app in augmenting face-to-face ACT for smoking cessation. The primary comparison between the combined and ACT conditions revealed a non-significant difference in their abstinence rates of 36% and 20%, respectively, at post-treatment. Similarly, the abstinence rate in the behavioral support condition (24%) was not significantly different to that of the combined condition at post-treatment. At primary endpoint of six-month follow-up, no significant differences in abstinence rates were found between the combined (24%), ACT (24%) and behavioral support conditions (20%). The combined condition, however, was found to be significantly more efficacious than the behavioral support and ACT conditions in helping non-abstinent participants reduce their number of cigarettes smoked per day at post-treatment, but not at follow-up. With regard to ACT processes, participants in the combined condition demonstrated significantly greater present-moment awareness and willingness to experience internal states associated with smoking than those in the behavioral support condition at post-treatment, but not at follow-up. Contrary to hypotheses, the combined and ACT conditions did not yield significant improvements in positive mental health, cognitive

fusion or valued living relative to the behavioral support condition. In terms of acceptability, treatment satisfaction and utilization were significantly greater for participants in the combined and ACT conditions than for those in the behavioral support condition.

Overall, comparisons between the combined and ACT conditions in smoking outcomes at six-month follow-up did not support the efficacy of the smartphone app in augmenting face-to-face ACT for smoking cessation. Furthermore, although the smoking cessation outcomes in the combined and ACT conditions were comparable to the 14.8–27.9% ITT abstinence observed at six-month follow-up in previous controlled trials of face-to-face ACT for smoking cessation (Gifford et al., 2004, 2011; Hernandez-Lopez et al., 2009), they were not superior to those produced by the behavioral support group treatment. The high levels of treatment satisfaction reported by participants in the combined and ACT conditions were also consistent with previous controlled trials of face-to-face (Gifford et al., 2004, 2011; Hernandez-Lopez et al., 2009), telephone-delivered (Bricker, Bush et al., 2014), smartphone-delivered (Bricker, Mull et al., 2014) and web-based (Bricker et al., 2013) ACT interventions for smoking cessation. Given the natural tendency, cultural instruction (Hayes et al., 2012) and implicit attributional message in popular smoking cessation treatments (Gifford et al., 2004) to quit smoking by altering the form or frequency of aversive internal states (i.e., withdrawal symptoms), acceptance-based treatments offer a radically different approach which aims to alter the context and function of such experiences. As 93% of the participants randomized to the combined and ACT conditions reported making a previous quit attempt, their high level of treatment satisfaction may be accounted for by the unconventional and counterintuitive nature of ACT for smoking cessation.

On average, participants in the combined, ACT and behavioral support conditions attended 54%, 50% and 24% of sessions, respectively. In line with this finding, a systematic review of group-delivered behavioral interventions for smoking cessation by Stead, Carroll,

and Lancaster (2017) found that trials in which participants had agreed to attend group sessions prior to randomization often had low therapy session attendance. Conversely, participants in a trial of group-based ACT for smoking cessation by Hernandez-Lopez et al. (2009) were provided with financial incentives and attended 71% of treatment sessions. In accordance, recent research has shown contingency management to be a promising means of increasing therapy session attendance (Fitzsimons, Tuten, Borsuk, Lookatch, & Hanks, 2015; Kropp, Lewis, & Winhusen, 2017).

The significant increases in smoking-specific acceptance and present-moment awareness in the combined group at post-treatment were in line with the psychological flexibility model (Hayes et al., 2012) and indicate that this intervention affected its intended processes of change. These post-treatment findings contribute to a growing body of empirical support for the role of experiential acceptance in smoking cessation (Bricker et al., 2013; Bricker, Bush et al., 2014; Bricker, Mull et al., 2014; Gifford et al., 2004, 2011). The acceptance and present-moment awareness exhibited by the combined group at post-treatment were not significantly different to those of the ACT group. Moreover, no significant differences in acceptance or present-moment awareness were found between the combined, ACT and behavioral support groups at six-month follow-up. Also unexpected was the finding that valued living and cognitive defusion in the combined and ACT groups were not significantly greater than those of the behavioral support group. However, this finding may be due to the inclusion of instruments that assessed valued living and cognitive fusion in generalized contexts. The development of more context-specific measures of values-directed behavior and cognitive fusion could facilitate a more fine-grained investigation of these processes in the context of smoking cessation.

The non-significant effects of the treatments on positive mental health may be attributable to a ceiling effect, as 91% of the sample reported flourishing (42%) or moderate

(49%) mental health at baseline. This hypothesis could be tested in future research by evaluating the efficacy of a smartphone app (e.g., Vilardaga et al., 2018) in augmenting face-to-face ACT for smokers with mental health difficulties. Indeed, clinical populations have a higher smoking prevalence (Weinberger, Streck, Pacek, & Goodwin, 2018) and cessation is associated with reductions in mental health difficulties (Taylor et al., 2014).

Although smoking cessation rates in the combined condition were not significantly different to those in the ACT or behavioral support conditions at post-treatment, they were descriptively higher. The smoking cessation rate in the combined condition at post-treatment (36%), however, was not maintained at six-month follow-up (24%). The smartphone app utilization data suggest that increasing app engagement could be a possible means of maintaining the therapeutic gains observed at post-treatment in the combined condition. Indeed, participants in the combined condition who were fully adherent to the smartphone app had over six times the odds of abstinence at six-month follow-up of those who were not fully adherent, while participants who continued to use the app after the in-person treatment had over 10 times the odds of abstinence at six-month follow-up of those who discontinued use. The app utilization data, however, showed that engagement is predictive of abstinence but did not provide evidence of causation.

The limitations of this randomized controlled trial should be taken into account when making inferences from its findings. Firstly, the primary outcome of seven-day point-prevalence abstinence was verified by an expired CO breath sample. As CO testing only detects recent smoking (half-life = 2–3 hours), analysis of cotinine concentration (plasma, saliva or urine) would have provided a more sensitive and specific means of biochemical verification (West et al., 2005). A second limitation of this trial is that it did not feature a smartphone app-only treatment condition. As stand-alone interventions, smoking cessation apps have an enormous reach with the potential for population-level impact at a relatively

low cost (Bricker, Mull et al., 2014). In addition, smoking cessation smartphone apps hold promise for existing stepped care approaches (Sanford, 2018). Future research, therefore, should compare the efficacy of smartphone-delivered behavioral interventions with group-delivered interventions for smoking cessation. A third limitation of this trial is that the longest assessment period was limited to six-month follow-up. Given that abstinence at twelve-month follow-up has been found to be a strong predictor of long-term smoking cessation (Nohlert, Öhrvik, Tegelberg, Tillgren, & Helgason, 2013), future research should evaluate the smoking cessation outcomes of similar blended interventions at twelve-month follow-up.

Future studies should aim to identify the factors that promote user engagement with ACT-based smartphone apps. Potential avenues for future research to investigate include the provision of monetary or prize incentives (Marsch, 2015), gaming elements, and tailoring ACT skills training to the user's challenges and needs in a given moment (Bricker et al., 2017). Another important avenue for future research is to investigate the sequential use of a smartphone app as an aftercare program that directly follows a face-to-face ACT treatment. As the present study was designed to compare a blended intervention with a nonblended face-to-face intervention, it did not elucidate the specific contribution of the SmartQuit (2Morrow) program. Future work could explicate this by evaluating the effects of SmartQuit (2Morrow) relative to a comparison app as an adjunct to in-person treatment.

In conclusion, the combined treatment was found to be acceptable and efficacious in promoting smoking reduction, acceptance and present-moment awareness at post-treatment. However, smoking cessation outcomes were comparable across the combined, ACT and behavioral support conditions. Future studies of this novel approach to treatment delivery have the potential to provide innovation in the pursuit of efficacious behavioral and cognitive therapies for smoking cessation.

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Figure

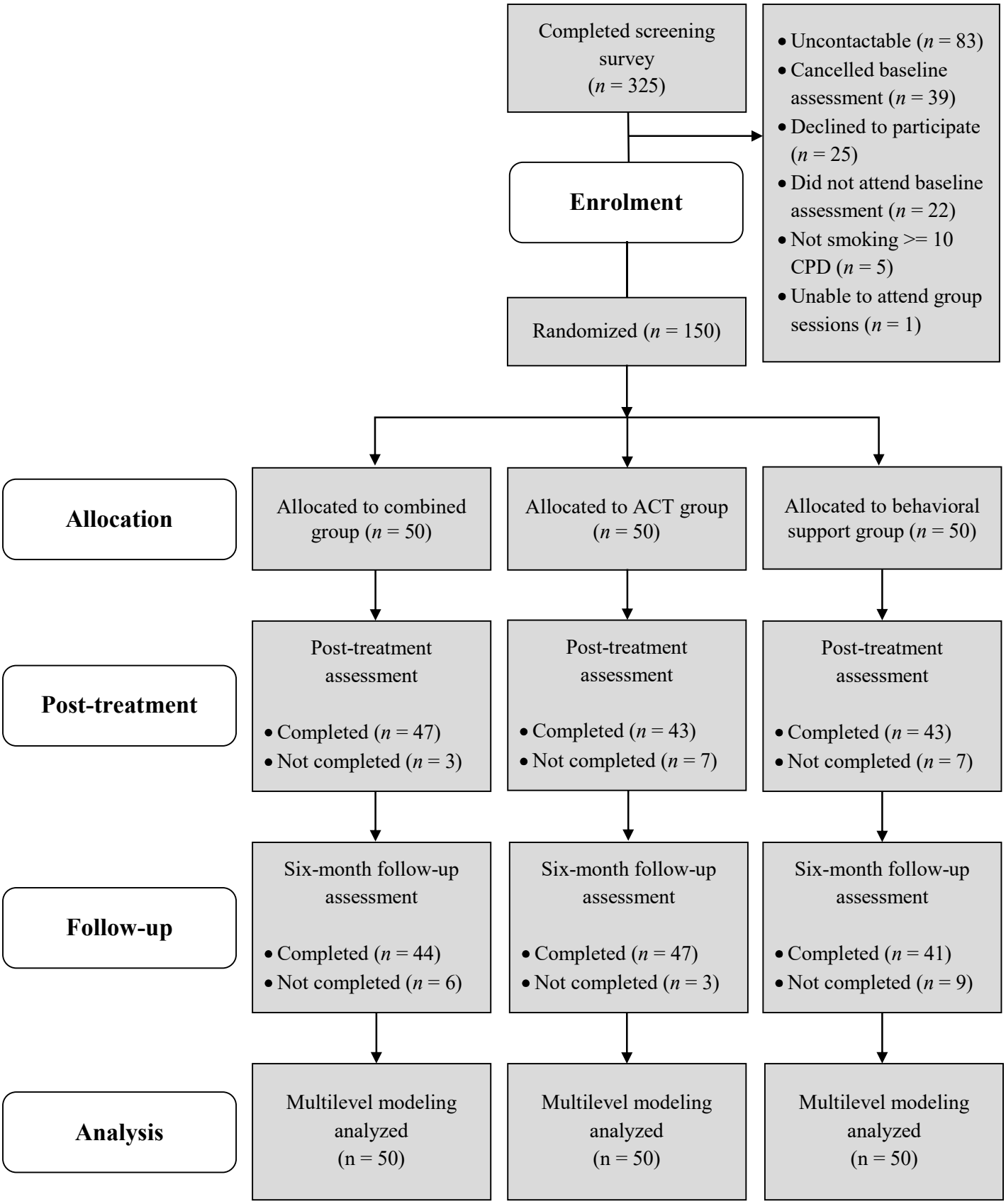

Figure 1. Participant flow diagram. ACT = acceptance and commitment therapy; CPD = cigarettes per day.

Table 1

Baseline Characteristics of Participants Randomized to Each Treatment Group

	Total	Combined	ACT	Behavioral Support
Sociodemographic				
Gender (female)	52.66% (79/150)	46.00% (23/50)	50.00% (25/50)	62.00% (31/50)
Age	35.99 (9.92)	34.08 (10.14)	35.08 (8.72)	38.80 (10.37)
Education (years)	16.66 (3.71)	17.19 (3.65)	16.74 (3.71)	16.04 (3.74)
Employed	74.66% (112/150)	72.00% (36/50)	74.00% (37/50)	78.00% (39/50)
Married	26.00% (39/150)	20.00% (10/50)	28.00% (14/50)	30.00% (15/50)
Smoking behavior				
Cigarettes per day	16.85 (7.77)	16.78 (6.51)	16.66 (6.00)	17.10 (10.26)
Nicotine dependence	4.74 (2.09)	4.64 (2.22)	4.88 (2.11)	4.70 (1.96)
Smoking (years)	18.07 (9.40)	16.60 (10.40)	17.08 (8.26)	20.52 (9.11)
Commitment to quitting	29.80 (5.71)	29.60 (5.54)	30.50 (5.83)	29.30 (5.80)
Close friends who smoke	2.19 (1.32)	2.32 (1.36)	2.20 (1.29)	2.04 (1.31)
Living with person who smokes	39.33% (59/150)	42.00% (21/50)	38.00% (19/50)	38.00% (19/50)
Positive mental health	40.30 (12.88)	39.62 (12.68)	40.36 (13.65)	40.92 (12.52)
Acceptance of cravings to smoke	2.98 (0.39)	3.02 (0.30)	2.98 (0.41)	2.95 (0.44)
Present-moment awareness	37.15 (5.77)	36.66 (6.45)	36.94 (5.38)	37.86 (5.46)
Cognitive fusion	27.83 (9.66)	28.50 (8.66)	26.96 (9.14)	28.02 (11.14)
Progress in valued living	18.62 (5.86)	18.28 (6.00)	19.18 (5.25)	18.40 (6.34)
Obstruction to valued living	13.56 (6.48)	14.34 (6.49)	12.70 (5.08)	13.64 (7.63)

Note. ACT = acceptance and commitment therapy.

Table 2

Participant Satisfaction and Utilization for Each Treatment Group

	Combined	ACT	Behavioral Support	Combined vs. Behavioral Support		ACT vs. Behavioral Support		Combined vs. ACT	
	M (SD)	*M (SD)*	*M (SD)*	*d*	*p*	*d*	*p*	*d*	*p*
Satisfaction									
The program was suited to my needs	5.83 (1.30)	5.62 (1.34)	4.51 (1.57)	0.96	< .001	0.79	.001	0.18	.370
The program was helpful	6.15 (1.17)	5.93 (1.29)	4.85 (1.66)	0.89	< .001	0.72	.002	0.21	.301
I would recommend the program	6.39 (1.20)	5.98 (1.33)	5.13 (1.69)	0.96	< .001	0.57	.010	0.43	.024
The program was of high quality	6.37 (1.16)	6.14 (1.22)	4.82 (1.54)	1.26	< .001	1.01	< .001	0.22	.240
I am satisfied with the program	6.35 (1.23)	5.95 (1.38)	4.85 (1.65)	1.10	< .001	0.75	.001	0.37	.056
Utilization									
Number of sessions attended	3.26 (2.16)	2.98 (2.19)	1.46 (1.76)	0.84	< .001	0.68	.001	0.14	.483

Note. ACT = acceptance and commitment therapy; *d* = Cohen's *d*; *M* = mean; *SD* = standard deviation.

Table 3

Fixed Effects Estimates and Effect Sizes for Secondary and Process Measures.

	Combined Within-participants			Combined vs. ACT			Combined vs. Behavioral Support			ACT vs. Behavioral Support		
	b	[95% CI]	*d*	*b*	[95% CI]	*d*	*b*	[95% CI]	*d*	*b*	[95% CI]	*d*
Cigarettes per day												
Post-treatment	-9.45	[-11.77, -7.12]***	-1.22	3.97	[0.73, 7.21] *	0.37	4.13	[0.89, 7.37]*	0.38	0.16	[-3.03, 3.35]	0.01
Follow-up	-4.80	[-7.04, -2.56]***	-0.65	0.14	[-2.95, 3.22]	0.01	-0.49	[-3.67, 2.68]	-0.05	-0.63	[-3.73, 2.47]	-0.06
Positive mental health												
Post-treatment	2.37	[-0.91, 5.65]	0.18	0.41	[-4.30, 5.11]	0.02	-1.30	[-6.08, 3.49]	-0.07	-1.70	[-6.56, 3.15]	-0.08
Follow-up	2.18	[-1.15, 5.51]	0.16	-0.03	[-4.68, 4.62]	0.00	1.77	[-3.05, 6.59]	0.09	1.80	[-2.96, 6.57]	0.09
Acceptance of cravings												
Post-treatment	0.44	[0.26, 0.62]***	0.60	-0.10	[-0.35, 0.16]	-0.09	-0.28	[-0.54, -0.01]*	-0.26	-0.18	[-0.45, 0.08]	-0.17
Follow-up	0.25	[0.06, 0.44]**	0.29	-0.08	[-0.34, 0.18]	-0.07	0.07	[-0.21, 0.34]	0.05	0.15	[-0.12, 0.42]	0.12
Present-moment awareness												
Post-treatment	1.94	[0.59, 3.29]**	0.38	-0.51	[-2.45, 1.42]	-0.07	-2.17	[-4.14, -0.20]*	-0.29	-1.65	[-3.65, 0.34]	-0.22
Follow-up	0.91	[-0.66, 2.48]	0.18	-0.29	[-2.48, 1.90]	-0.04	-1.84	[-4.11, 0.43]	-0.25	-1.55	[-3.79, 0.69]	-0.22
Cognitive fusion												
Post-treatment	-1.55	[-3.68, 0.58]	-0.18	0.59	[-2.47, 3.66]	0.05	-1.10	[-4.20, 2.00]	-0.09	-1.69	[-4.84, 1.45]	-0.13
Follow-up	-1.63	[-3.79, 0.54]	-0.18	-0.32	[-3.34, 2.70]	-0.03	-3.62	[-6.75, -0.50]*	-0.28	-3.30	[-6.39, -0.22] *	-0.26
Progress in valued living												
Post-treatment	0.57	[-1.09, 2.23]	0.08	-0.35	[-2.73, 2.04]	-0.03	-0.23	[-2.65, 2.19]	-0.02	0.11	[-2.34, 2.57]	0.01
Follow-up	-0.02	[-1.71, 1.66]	0.00	0.12	[-2.24, 2.47]	0.01	1.18	[-1.25, 3.61]	0.12	1.06	[-1.34, 3.46]	0.11
Obstruction to valued living												
Post-treatment	-1.33	[-3.22, 0.55]	-0.17	1.37	[-1.33, 4.08]	0.12	0.86	[-1.88, 3.61]	0.08	-0.51	[-3.29, 2.28]	-0.04
Follow-up	-0.63	[-2.55, 1.28]	-0.08	0.33	[-2.34, 3.01]	0.03	-0.99	[-3.74, 1.76]	-0.09	-1.32	[-4.05, 1.40]	-0.12

Note. ACT = acceptance and commitment therapy; *b* = estimated value of regression coefficient; CI = confidence interval; *d* = Cohen's d. $^{*}p < .05$. $^{**}p < .01$. $^{***}p < .001$.

Figure S2

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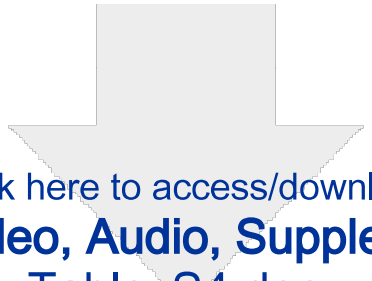
Table S4



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