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Feasibility of a Smartphone App with Mindfulness Training for Adolescent Smoking Cessation: Craving to Quit (C2Q)-Teen

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Abstract

Objectives—The use of mobile technology for smoking cessation holds promise for adolescents, who do not typically access traditional treatments, but most are not grounded in theory or mechanism. Operant conditioning theory suggests an addictive smoking loop is formed between nicotine use and affective states, leading to habitual cue-induced craving and automatic behavior; mindfulness training may bring automated smoking behavior into awareness, so smokers may work mindfully with cravings. Mindfulness training delivered via smartphone technology therefore has potential to help adolescent smokers break this addictive loop and quit smoking. This pair-matched cluster-randomized controlled school-based pilot study evaluated program feasibility and preliminary smoking outcomes in relation to intervention engagement.

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Authors' Contributions

LP and JB, multiple Principal Investigators on the funded trial, together were responsible for obtaining funding for the trial, the conception and design of the study, interpreting the data, and drafting and critically revising the manuscript for important intellectual content, and agree to be accountable for all aspect of the work. SC and CF analyzed all the data, prepared all tables and figures, and drafted the analyses and results sections of the paper. SD was responsible for overseeing all aspects of the research in the field. MT and SO made substantial contributions to the interpretation of data and critically revised the manuscript for important intellectual content from their areas of expertise. All authors read and approved the final manuscript.

Ethics Approval and Consent to Participate

The study protocol was approved by the University of Massachusetts Medical School Institutional Review Board. All participants completed the assent process.

Conflict of Interest

JB owns stock in Claritas MindSciences, the company that developed the Craving to Quit app. The other authors declare that they have no competing interest.

Methods—Six high schools were pair matched and randomly assigned to one of three interventions: (1) mindfulness training delivered via mobile smoking cessation application (Craving to Quit, C2Q), (2) NCI's QuitSTART smoking cessation application (NCI), and (3) written cessation materials (Materials). Adolescents (n = 146) smoking 5 or more cigarettes per day were recruited. Interventions were implemented over four weeks and study assessments were collected at baseline and 3- and 6- month follow-up, including self-reported 7-day point prevalence abstinence, program usage, smoking-related measures, and psychosocial factors.

Results—Overall cotinine-validated abstinence at 6 months was 15.8% and was similar between conditions. Odds of abstinence increased with each quartile increase in app/materials use with no significant differences between conditions (OR=1.60 (C2Q), 1.66 (Materials), and 2.69 (NCI)). Of participants still smoking at 6 months, for each quartile increase in engagement the number of cigarettes smoked in the previous 7 days showed a significantly greater decline in the C2Q condition (−5.71) compared to the Materials (−0.95) and NCI (+7.73) condition (p=0.02 for differences between conditions).

Conclusions—Cotinine-validated abstinence was similar between intervention conditions and tended to increase with greater engagement in each condition. Greater C2Q app engagement among continuing smokers was associated with a significantly greater decline in number of cigarettes smoked compared to the other conditions. The Craving to Quit (C2Q) mobile smoking cessation application with mindfulness training was feasible to use and has promise in assisting adolescents to quit or decrease cigarette smoking.

Clinical Trial Registration: Developing a Smartphone App with Mindfulness Training for Teen Smoking Cessation: [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02218281) Identifier: NCT02218281

Keywords

Adolescents; Smoking cessation; Mindfulness training; App delivery; Randomized controlled trial

Tobacco use continues to be the leading cause of preventable morbidity and mortality in the United States, with nearly all tobacco use beginning during youth and young adulthood. (U.S. Department of Health and Human Services, 2014) (U.S. Department of Health and Human Services, 2012) Eighty percent of adolescent smokers will continue to smoke into adulthood and, of those who do, one-half will die 13 years earlier than nonsmoking peers. (Doll, Peto, Boreham, & Sutherland, 2004; Fagerstrom, 2002) The SGR cited strong causal associations between youth smoking and nicotine addiction, reduced lung function, asthma, and early abdominal aortic atherosclerosis, concluding that smoking causes immediate damage to teens. (Fagerstrom, 2002) While rates of current cigarette smoking (smoking in the past 30 days) has declined in high school students from 15.8% in 2011 to 8.1% in 2018, in 2018 20.8% reported using electronic cigarettes in the past 30 days, an alarming increase from 1.5% in 2011. (Gentzke et al., 2019; Karen A. Cullen et al., 2018) As such, adolescent smoking continues to be a serious pediatric and public health issue. (Wang et al., 2018)

Most adolescent cigarette smokers want to quit and have attempted to quit in the past year. ("Cigarette use among high school students - United States, 1991-2009," 2010) Overall, 60.9% of high school students who ever smoked cigarettes daily reported trying to quit smoking, with quit attempts high among female students (67.3%) compared to male students

(55.5%).(Malarcher, Jones, Morris, & Kann, 2009) However, success is rare and relapse is high,("Cigarette use among high school students - United States, 1991-2009," 2010; Grimshaw et al., 2003; Mermelstein, 2003) with only 12.2% of high school students who smoke daily and attempt to quit being able to maintain abstinence, comparable to rates found among adult populations.(Babb, Malarcher, Schauer, Asman, & Jamal, 2017; Malarcher et al., 2009)

Previously tested interventions for adolescent smokers require intensive in-person treatment and have limited success, with 6-month abstinence rates averaging 11.8% in a meta-analysis of 64 adolescent studies.(Sussman & Sun, 2009) In-person treatment can be a challenge for adolescents and may contribute to modest effects of interventions. The use of mobile technology for smoking cessation holds promise for adolescents, who do not typically access traditional treatments ("Cigarette use among high school students - United States, 1991–2009," 2010; Grimshaw et al., 2003; Lenhart & Pew Research Center, April, 2015; Mermelstein, 2003; Sussman, 2002) and who favor mobile technology's ease of use and appreciate the degree of anonymity and confidentiality afforded by this venue.(Balch et al., 2004; Vuckovic, Polen, & Hollis, 2003) According to a 2015 Pew survey,(Lenhart, 2015) about 75% of adolescents own or have access to a smartphone, with less affluent teens vs. more affluent and girls vs. boys being equally likely to own smartphones. In addition, a nationally representative survey found about two-thirds of adolescents and young adults reported using a health-related mobile application.(Rideout, 2018) The increasing use of smartphones and health-related apps suggests the demand for and utility of smoking cessation smartphone apps will continue to grow and have the potential to reach an increasingly growing population of adolescents. However, a systematic review on tobacco cessation interventions for adolescents and young adults did not identify published literature on smartphone apps specifically tailored for adolescent smoking cessation, suggesting a need to fill this gap with smartphone apps tailored to adolescents.(Fanshawe et al., 2017)

While there are currently hundreds of smoking cessation apps (Abroms, Lee Westmaas, Bontemps-Jones, Ramani, & Mellerson, 2013; Bevins & Palmatier, 2004; Brewer et al., 2011; Hoepfner et al., 2016; Lenhart & Pew Research Center, April, 2015; Suhler & Churchland, 2009) these programs are not geared toward adolescents and are not necessarily grounded in theory or mechanism. Operant conditioning theory suggests the acquisition of tobacco dependence involves the formation of an addictive smoking loop between the use of nicotine and both positive (e.g., after a good meal) and negative (e.g. when stressed) affective states.(Bevins & Palmatier, 2004) Through repeated smoking, the addictive loop may become habitual, leading to cue-induced craving and automatic behavior that is challenging to overcome. Mindfulness training (MT) may bring automated smoking behavior into awareness and work mindfully with cravings. Delivered in person, MT has increased smoking cessation in adults.(Brewer et al., 2011; Davis, Fleming, Bonus, & Baker, 2007) In line with theory, the amount of practice moderated the decoupling of craving and smoking.(Elwafi, Witkiewitz, Mallik, Thornhill, & Brewer, 2013) Building on these results, with the growing interest in app-based delivery of treatment, smartphone-delivered MT has been developed and tested in adults.(Garrison et al., 2018; Garrison et al., 2015) Preliminary results demonstrated a behavioral decoupling of craving and smoking in line with that seen with in-person delivery.(Garrison et al., 2018) Further, a neuroimaging study showed

correlations between reduction in default-mode network cue-reactivity and cigarettes smoked and a dose effect that was specific to app-delivered MT, demonstrating a direct link between treatment, brain mechanism and smoking outcomes.(Janes, 2019)

While to our knowledge MT has not been studied to assist adolescents in quitting smoking, a number of school-based mindfulness meditation programs have shown promise in helping adolescents improve emotional and cognitive functioning, including decreased anxiety, improved concentration and academic performance, and importantly, improved self-regulation including their ability to calm themselves, relieve stress, cope with their emotions, and pay attention. (Beauchemin, Hutchins, & Patterson, 2008; Wisner, 2008) From a neurodevelopmental perspective, in adolescents, brain areas of executive function (the prefrontal cortex) where emotion regulation networks overlap with circuitry for attention control(Ochsner & Gross, 2005) (Lee, Heller, van Reekum, Nelson, & Davidson, 2012) require greater activation to regulate emotions compared to adults, and high-arousal situations impair decision-making abilities in adolescents to a greater extent than in adults. (Steinberg, 2005) This suggests that practices such as mindfulness, which have been shown to enhance executive functioning in youth, reduce cue-induced neural activity in brain regions associated with craving reactivity,(Janes, 2019) and reduce cue-induced craving in adult smokers,(Oberle, Schonert-Reichl, Lawlor, & Thomson, 2012; Westbrook et al., 2013) could help adolescents manage negative emotions like anxiety which interfere with working memory and attention(Shackman, Maxwell, McMenamin, Greischar, & Davidson, 2011; Shackman et al., 2006) as well as cravings from nicotine dependence which interfere with smoking cessation.

Based on the potential promise of MT and convenience of smartphone-delivered smoking cessation, we tested the feasibility of combining these approaches in assisting adolescent smokers. The present pilot study was designed to: 1) adapt and refine a theory-based mobile smoking cessation application, Craving to Quit, for use with youth, 2) test the feasibility of the app and study protocols, and 3) gather preliminary data to inform the design of larger trials by comparing it to a mobile application without mindfulness training (NCI's QuitSTART), and to written smoking cessation materials.

Methods

Participants

Adolescents in grades 9 through 12 were eligible to participate if they reported smoking at least 5 cigarettes on average per day for the past 7 days, were interested in quitting in the next three weeks, had a smartphone, provided assent, and were English-speaking. The cutoff of 5 or more cigarettes per day was selected to exclude teens without dependence and was based on our prior study which found a cutoff of 3.7+ cigarettes per day accurately distinguished adolescents with and without moderate/strong dependence as measured by the modified Fagerstrom Tolerance Questionnaire (mFTQ)(Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991). Parents of all 9-12 grade students were sent letters allowing them to opt out of their adolescent participating in the study. Students were recruited to a study about "smoking cessation" through recruitment packets containing an informational brochure and

eligibility criteria sent to all students, and through school nurse encounters. Interested adolescents completed the assent process.

For the feasibility randomized controlled trial, assessments were completed at baseline and 3 and 6 months later. Gift cards worth \$25 were provided for completion of each assessment. The University of Massachusetts Medical School Institutional Review Board (IRB) approved the study protocol.

Procedure

Study Design and Setting—Craving to Quit (C2Q) was adapted for use by adolescents, as described below. The two comparison interventions included the NCI QuitSTART app (NCI) and Materials only (Materials). A matched cluster-randomized controlled school-based feasibility trial was conducted with a convenience sample of 6 public high schools in Massachusetts. The total student enrollment at these schools ranged from 421 to 1127; the student populations were predominately white (72.6% to 92.7%). The percent of students considered low income ranged from 8.1% to 35.9%. Two sets of three schools were matched based on percentage low income, percentage African American, and number of students. Within each set of three, schools were randomly assigned to one of the three intervention conditions.

Study Conditions—The Craving to Quit app adapted for adolescents (smoking cessation assistance via app with MT) was compared to two other conditions, NCI's QuitSTART app designed for teen smokers (smoking cessation assistance via app without mindfulness training) and smoking cessation written materials only (smoking cessation assistance without an app and without mindfulness training). These study conditions were selected to provide smoking cessation assistance to all participants while allowing for comparison of app/no app and mindfulness training/no mindfulness training.

Craving to Quit App Adapted for Teens (C2Q): Our previous studies of the Craving to Quit (C2Q) app in adults demonstrated feasibility, behavioral decoupling of craving and smoking, and neural mechanisms (decreases in default-mode network cue-reactivity) in adults (Garrison et al., 2015); (Garrison et al., 2018); (Janes, 2019). Prior to conducting the randomized controlled trial, we adapted the adult version of the C2Q app for use by adolescents by gathering user feedback to determine: (1) what C2Q modules and features adolescent smokers found most useful, and (2) what features needed to be improved, added or removed to make the C2Q app appropriate for teens. Twenty-four adolescent smokers from two non-participating schools were recruited. They provided daily feedback on each C2Q module via 0-10 ratings of the content and exercises (helpful, clear, ease of understanding) and general feedback via email. Ten-minute semi-structured phone interviews were conducted at the end of each week (days 7, 14, and 21) to provide general feedback. A final exit interview was conducted one week after completion (day 28), which assessed which components overall were most helpful, how and when they used the app, and whether they would recommend the app to a friend. Data also were extracted from a third-party tracking software database that automatically tracked all components of app usage. On the semi-structured phone interviews at weeks 1, 2 and 3 as well as the final exit interview,

participants reported high levels of helpfulness for each of the app components and that they would recommend the app to a friend. No changes were made to the modules as they were deemed to be engaging and appropriate for adolescent smokers. The main recommendations had to do with enhancing app downloading and addressing concerns participants expressed regarding low likelihood of completing any app-based intervention without accountability and support. Based on the feedback, the following modifications were made to the intervention prior to implementing the randomized controlled pilot study: (1) the app was modified so that it could be downloaded without Wi-Fi, addressing the absence of Wi-Fi at the schools; (2) brief weekly meetings with the school nurse were incorporated into the protocol to provide support and accountability for completing the app sessions (and for all three conditions for consistency); and (3) the check-in feature was modified to allow adolescents greater control over the frequency with which they received reminders.

The C2Q program is based on the core elements of our manualized MT for smoking, shown to be efficacious in previous trials. (Brewer et al., 2011; Garrison et al., 2018; Garrison et al., 2015) Features included in the app help users self-monitor their smoking habits, recognize when and how often they smoke, identify triggers for smoking, and learn methods to become more aware of cravings and ride them out, and set a target quit date of 3 weeks from initiation of the app. (Brewer et al., 2011) C2Q has 22 unique modules (5-15 minutes/module) using educational videos, animations, and in vivo exercises. Each day, individuals have access to one new module (Table 1).

NCI QuitSTART App (NCI): QuitSTART is a free smartphone app, developed as a smoking cessation resource for teens created by the Tobacco Control Research Branch at the National Cancer Institute as part of the Smokefree Teen program. The app was designed in collaboration with tobacco control professionals and smoking cessation experts with input from teens who were ex-smokers. The app helps the user track their cravings and moods, monitor their progress toward achieving smoke-free milestones, identify their smoking triggers, and upload personalized “pick me ups” and reminders to use during challenging times to help them successfully become and stay smoke free. The NCI provides tips to use during cravings to help the user manage their mood and stay smoke free. To obtain additional tips and support, the user can follow, “like”, or share via social media.

Written Smoking Cessation Materials Only (Materials): The Materials control condition provided written smoking cessation materials by the school nurse. The written materials were pamphlets from Journeyworks, selected based on the appropriateness of their content and their clear and attractive layout designed for a low-literacy audience. The four pamphlets were: “A Teen's Guide to Quitting Smoking”, “Social Smoking”, “50 Things You Should Know about Quitting Smoking” and “Quitting Smoking: Common Problems, Good Solutions”.

School Nurse Role in the Three Interventions: During an initial visit, the school nurse introduced and instructed the adolescents in the use of the intervention to which their school was randomly assigned. The school nurse then met with each participant in all conditions weekly over 4 weeks to provide ongoing support in their effort to quit. For the Materials condition participants were provided one pamphlet a week to read. When done reading the

pamphlet, the school nurse asked if s/he had any questions. For the two app conditions, participants were asked how many days they used the app in the last week. If they had completed at least 2 days of the app since the last visit, they were asked about their experience with the app. If the student reported not completing at least 2 days of the app, the nurse and the participant problem-solved on how to increase app usage.

Measures

Study assessments were collected at baseline and at 3- and 6-month follow-up in the privacy of the school nurse's office.

Recruitment and Retention—The number of students screened and eligible to participate, number of eligible students who did and did not participate, and reasons for non-participation were documented. The number of study participants lost to follow-up at 3 and 6 months was documented along with reasons for attrition.

Program Usage/Engagement (i.e., treatment fidelity)—Participants reported the number of modules they completed for the C2Q app, the number of days they used the NCI app, and the number of minutes they spent reading the materials for the Materials group during visits with the school nurse. Quantitative data downloaded automatically by the C2Q app for each participant was used to calculate the number of completed C2Q modules. A criterion of at least 75% of participants in the C2Q group using the app per automatic download by the app was our a prior criterion for determining whether the C2Q app was acceptable and feasible.

Smoking Outcomes—Abstinence was defined as self-reported 7-day point prevalence abstinence confirmed by cotinine. Saliva samples were collected from participants that reported smoking 0 cigarettes in the previous 7 days prior to survey completion at each follow-up assessment. A cut-off of 11.4 ng/ml was used for cotinine validation.(Backinger et al., 2003; Caraballo, Giovino, & Pechacek, 2004) Cotinine-validated (true) abstinence was imputed for 3 participants for whom we did not have saliva samples using a logistic regression model predicting 'true' quitting. The model included study condition, time and the interaction of the two, as well as gender and baseline self-control score, which were found to be significantly associated with the outcome. For those participants who reported continuing to smoke, self-reported number of cigarettes smoked in the past 7 days was assessed.

Potential Mediators, Covariates and Effect Modifiers—At baseline, sociodemographic variables were assessed including age, gender, participation in reduced or free lunch program as a marker of socio-economic status, and grade in school. The participant's smoking history was assessed including the number of years they have been smoking, number of times they have tried to quit, and NRT and other medications used to quit; the latter variable also was assessed at the 3 and 6-month follow-up. Readiness to quit was assessed with the Prochaska's Stages of Change measure.(Prochaska & DiClemente, 1983) The participant's confidence in their ability to quit was assessed by the Self-efficacy Questionnaire (SEQ-12),(Etter, Bergman, Humair, & Perneger, 2000) and depressive

symptoms were assessed using a 6-item measure for adolescents (Kandel & Davies, 1982). Severity of nicotine dependence was assessed with the Modified Fagerstrom Tolerance Questionnaire (mFTQ) (Heatherton et al., 1991). The number of smokers who live with the participant was assessed, as well as the number of friends who smoke cigarettes.

Data Analyses

Baseline characteristics of participants were summarized and compared across the three intervention groups using analysis of variance and chi-square testing.

For analyses of primary outcomes, overall recruitment and rate of participation was calculated. Retention overall and by study condition was calculated, and reasons for non-participation were tallied. The distribution of self-report of program usage, collected in-person by the school nurse for each condition, as well as C2Q app-collected module usage, was estimated for each condition. For C2Q, self-report and app-collected usage were compared. Intervention arms were compared regarding total time spent with the school nurse across all five visits using nonparametric analysis of variance (Kruskal-Wallis test) and t-tests (Wilcoxon rank-sum test). Abstinence was compared longitudinally across arms using a random effects logistic regression model that included an interaction of study arm and time, adjusting for time spent with the nurse and baseline FTQ score as both predicted smoking outcomes, and a random effect for school to account for within-school correlation.

Secondary analyses estimated associations of app/material use with 6-month smoking. To facilitate comparisons of associations of intervention “dose” across conditions, app/material use was categorized according to condition-specific observed quartiles and treated as a continuous predictor. First, 7-day cotinine-validated abstinence at 6 months was modeled using random effects logistic regression stratified by intervention arm (Molenberghs & Verbeke, 2005) as a function of app/material use, with adjustment for baseline mFTQ score and time spent with the school nurse, and a random effect for school to handle within-school correlation. Parallel analyses were run for change in number of cigarettes smoked in the past 7 days among those still smoking, using random effects linear mixed modeling adjusting for baseline number of cigarettes smoked and time spent with the school nurse. To test condition-related differences in the association of app/material use and number of cigarettes smoked, an interaction term between condition and app/material use was added to a linear mixed model including data from all three conditions. The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Results

Recruitment and Retention

Study recruitment and retention are depicted in Figure 1, Consort Flow Diagram. One hundred eighty-four students were screened for eligibility and 146 were eligible and participated in the trial. The majority of the 38 not eligible for the study were ineligible due to not meeting the inclusion criterion of smoking at least 5 cigarettes on average per day over the past week. Retention was similarly high, ranging from 92% to 100%, at the 3 and 6-month across all conditions.

Baseline Participant Characteristics

Average age was 16.9 years and participants were predominantly White and non-Hispanic (Table 2). On average, smoking duration was just under 4 years, and number of cigarettes smoked in the past week was 34. Participants had tried to quit more than twice on average, and over half reported at least one quit attempt in the past year, with little use of cessation aids. Less than one-quarter had high nicotine dependence. In addition to cigarettes, one in 10 reported use of chewing tobacco, snuff or dip, almost three-quarters reported use of blunts, cigars, cigarillos, or little cigars, 22% used tobacco in a pipe (including water pipes), and 63% smoked e-cigarettes in the past month (data not shown). Average readiness to quit score was 6.6 out of a possible 10. There were few differences across study arms; exceptions included lower mean readiness to quit in the Materials group, more chewing tobacco use and greater percentage with elevated depressive symptoms in the C2Q arm, higher percentage reporting allowed to smoke at home in the NCI arm, and higher extremes for likeliness to quit in the NCI arm.

Program Usage/Engagement

Of the 48 participants in schools randomized to C2Q, 37 (77%) used the app. For these participants, the average number of modules completed was 13.4 out of a maximum of 22 (61% of the modules); 4 (11%) did not complete any modules, and 14 (38%) completed all 22 modules. The 36 participants with self-report data for NCI app usage reported using the app a total of 12.3 days on average (range 0-62) over the intervention period. The 47 participants in the Materials condition with self-reported use data reported reading the materials a total of 43.4 minutes on average (range 17-105) over the intervention period. The total time participants spent with the school nurse including the initiation visit and the 4 weekly visits was significantly lower ($p<0.0001$) for C2Q than the other conditions, at 23 minutes for C2Q, 36 minutes for NCI, and 43 minutes for Materials

Smoking Outcomes and Association with App/Materials Usage

Overall, 22 participants (15.8%) were abstinent (cotinine-validated) at 6 months and this did not differ significantly by condition (13.6% for the C2Q condition, 16.3% in the NCI condition, and 17.4% in the Materials condition ($p=0.88$)). In preliminary logistic regression analyses, adjustment for time spent with the school nurse reduced these between-arm differences further, with odds ratios for pairwise between-conditions comparisons ranging from 0.95 to 1.04 ($p\text{-value} > 0.94$); the odds ratio for abstinence was 2.47 (95% CI 1.10 – 5.50) for each additional 30 minutes spent with the school nurse.

The associations between app/materials use and smoking outcomes at 6 months are presented in Table 3. The odds of 7-day cotinine validated abstinence increased with each quartile increase in app/materials use in all conditions, with the NCI condition having the largest and only statistically significant increase (OR=2.69 (NCI) vs. 1.66 (Materials) vs. 1.60 (C2Q)). Of participants still smoking at 6 months, for each quartile increase in app/materials engagement, the number of cigarettes smoked in the previous 7 days declined by 5.71 (SE=2.88) in the C2Q condition compared to a decrease of 0.95 (SE=4.96) in the Materials condition and an increase of 7.73 (SE=4.17) in the NCI condition ($p=0.02$ for differences between conditions), although intervention-specific associations of engagement

with number of cigarettes smoked were not statistically significant due to the small per-group sample sizes.

Discussion

The Craving to Quit (C2Q) mobile smoking cessation application with mindfulness training was found to be feasible for adolescent smokers to use as determined by meeting the a priori criterion of at least 75% of C2Q participants using the app as assessed by automatic download by the app. Increased engagement in any of the three conditions – C2Q app with mindfulness training, NCI app without mindfulness training, and smoking cessation materials alone – resulted in increased cotinine-validated abstinence that did not differ significantly between conditions. However, among adolescents unable to quit and still smoking at 6 months, decreases in the number of cigarettes smoked associated with intervention engagement were significantly greater for those using the C2Q app.

Although cotinine-validated abstinence did not differ between conditions, for those adolescents who reported continuing to smoke, greater C2Q app use was associated with greater reduction in the number of cigarettes smoked. This was not the case in the other two conditions, where increased reading of the materials in the Materials condition was associated with a minimal decrease in number of cigarettes smoked and increased NCI app use was associated with an increase in the number of cigarettes smoked. One possible reason for the positive finding in the C2Q app condition and not in the other two conditions is that mindfulness training may have helped the adolescents increase their awareness of their cravings and of each cigarette smoked so that, while they were unable to quit smoking completely, they were able to ride out the cravings for some of the cigarettes they normally smoked. This hypothesis is consistent with prior work which found that mindfulness improves self-regulation (Beauchemin et al., 2008; Wisner, 2008) and executive functioning in youth and reduces cue-induced brain reactivity and craving in adult smokers (Janes, 2019; Oberle et al., 2012; Westbrook et al., 2013) both of which could account for the ability of the C2Q app users to ride out their cravings and reduce the number of cigarettes smoked. Whether this unique skill of improved awareness and ability to ride out cravings will ultimately lead to greater abstinence in the longer term or if additional training and support in the application of mindfulness is needed are empirical questions worthy of further exploration. Other possible contributors include a “sleeper effect” in which the effect of a treatment continues or builds as individuals continue to utilize the program beyond initial completion of the modules, as has been seen with cognitive behavioral therapy and metacognitive training. (Carroll et al., 2009; Moritz et al., 2014)

Most adolescents in the C2Q condition completed at least some of the modules on the app. While to the best of our knowledge this is the first paper reporting on the engagement of teens in a smoking cessation app, studies have demonstrated low rates of engagement with other adolescent mobile health-related apps. (Kenny, Dooley, & Fitzgerald, 2015; Lubans, Smith, Skinner, & Morgan, 2014; Muuraiskangas, Harjumaa, Kaipainen, & Ermes, 2016) The high rates of engagement may be due to the brief weekly meetings with the school nurse recommended by user feedback from the refinement phase of the study, or to the app

features that have been found to promote user engagement in adult smoking cessation smartphone apps.(Ubhi et al., 2016)

Statistically significant differences were found between the three study conditions in the total amount of time school nurses spent with the adolescent to complete the initiation visit and 4 weekly visits, with school nurses in the C2Q condition reporting spending about half the time as school nurses in the Materials condition. Our prior studies (Pbert et al., 2011; Pbert et al., 2006) found school nurse contact, whether they were delivering counseling or having the adolescents read and discuss smoking cessation materials with them (the latter consistent with the current Materials condition), was effective in helping teens quit smoking. As such, it is possible that the differences in the amount of time school nurses spent with the adolescents across the three conditions could have contributed to the non-significant differences in abstinence rates noted. This may also explain why the Materials only group showed an increase in number of cigarettes smoked at the 6-month follow-up, as this intervention and contact with the school nurse was no longer available to the adolescent.

The overall cotinine-validated abstinence rate at 6 months of 15.8% was comparable to if not somewhat higher than that found in a meta-analysis of 64 adolescent cessation trials (11.8%), which reported on interventions that require much more intensive in-person treatment.(Sussman & Sun, 2009) In the present study the adolescents and school nurses spent on average a total of one-half hour over 5 visits. This is an important finding and highly encouraging, as most adolescent smokers want to quit and make serious quit attempts("Cigarette use among high school students - United States, 1991-2009," 2010) but do not seek out or utilize smoking cessation assistance. ("Cigarette use among high school students - United States, 1991-2009," 2010; Grimshaw et al., 2003; Mermelstein, 2003) Having treatment approaches readily available within the school setting that require minimal in-person contact for both the adolescent and school nurse could potentially make any of these three treatment approaches attractive and accessible to adolescent smokers. Further investigation in a larger trial is warranted to determine if there is a statistically significant and meaningful difference between the three intervention approaches tested and if it is possible to determine which approach is most effective for which adolescent smokers.

Limitations and Future Research Directions

There are several strengths to the present pilot study including the cluster randomized design, high retention rates, and assessment of participant engagement with each intervention. Limitations of this pilot study include that participants were drawn from 6 schools in central Massachusetts, with a primarily White student population; therefore, results may not generalize to other populations. Future studies should include a more diverse and geographically representative population. The use of app-collected data for the C2Q intervention due to the ability to collect the objective data but use of self-reported data for the remaining interventions as there were no objective data available is a limitation. Furthermore, there may be differences in those who have and do not have smartphones. However, access may not be related to socioeconomic status, as teens living in households earning less than \$30,000/year are just as likely to own a smartphone as those living in the highest-earning households (> \$75,000).("Smartphone use among U.S. up sharply: Survey,"

2013) Small per-arm sample sizes reflect the pilot nature of this study, thus power for assessing outcomes other than feasibility is limited and therefore caution should be used when interpreting the intervention results. A fully powered, large scale trial will allow for the evaluation of abstinence outcomes and exploration of whether the C2Q app's ability to assist adolescents in reducing the number of cigarettes smoked will ultimately result in greater abstinence in the long term.

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Figure 1.
CONSORT diagram

Table 1.**C2Q App Modules**

Module Number	Contents	Practice focus	Playlist
Module 1	Intro, Quit Goals, Habit Loop	Smoking mindfully	Video – Introduction to Craving to Quit Animation - Habit Loop Animation Video – About Mindfulness Audio – Mindful Smoking Exercise Video – Sum it Up Input – Would you like to make mindful smoking your goal for today?
Module 2	Goals	Setting daily goals every morning, smoke mindfully	Video – Introduction to Goals Input – List three reasons why you want to quit smoking. Input – Would you like to make your goal today to mindfully smoke each cigarette you can?
Module 3	Body Scan	Body scan, smoke mindfully	Video – Introduction to Body Scan Audio – Body scan exercise Video – Sum it Up Input – Would you like to set the goal for today to practice the body scan at least once more and to smoke each cigarette mindfully?
Module 4	Urge Surfing with RAIN	Body scan, RAIN	Video – Introduction to Urge Surfing Animation – RAIN Video – More on Urge Surfing Audio – RAIN Exercise Video – Sum it Up Input – Would you like to practice RAIN at least twice more today?
Module 5	Tantrum Toddler	Body scan, RAIN	Video – Introduction to Craving as a Tantrum Animation – Tantrum Toddler Video – More on the Tantrum Toddler Metaphor Input – Would you like to try RAIN every time you feel a craving today?
Module 6	Triggers	Body scan, RAIN	Video – Introduction to Triggers Input – List some of your Triggers here. Video – Sum it Up Input – Would you like to continue to try RAIN every time you feel a craving today as your daily goal?
Module 7	Craving is a Fire	Body scan, RAIN,	Video – Introduction to Cravings Animation – Craving as a Fire Video – Sum it Up Input - Would you like to continue to try RAIN every time you feel a craving today as your daily goal?
Module 8	Noting practice	Noting practice	Video – Introduction to Noting Practice Input – Would you like to try noting practice for 1 minute at least twice today?
Module 9	Staying on Track/ Driving to California	Body scan, RAIN, noting practice	Video – Introduction to Staying on Track Input - Would you like to set today's goal of doing noting practice 4 times for 1 minute each time?
Module 10	(Un)resistance Training	Body scan, RAIN, Noting practice	Video – Introduction to (Un)resistance Training Input - Would you like to make it your goal today to use noting practice when you're resisting something?
Module 11	Get Curious	RAIN, Noting, curiosity	Video – Introduction to Getting Curious Video – Curiosity Exercise Video – Sum it Up Input – Would you like to practice curiosity once today?
Module 12	Hot Coal	RAIN, curiosity	Video – Introduction to Hot Coal Metaphor Input - Would you like to think about what you get from smoking after smoking mindfully today?
Module 13	Lovingkindness	RAIN, Noting, lovingkindness	Video – Introduction to Lovingkindness Audio – Lovingkindness Practice Video – Wild Geese by Mary Oliver Input - Would you like to set practicing loving kindness for 5-10 minutes today as a daily goal

Module Number	Contents	Practice focus	Playlist
Module 14	Costs & Benefits	Body scan/loving kindness, RAIN, curiosity	Video – Introduction to Costs & Benefits of Smoking Input – Might we suggest that today you keep practicing lovingkindness? How about seeing if you can do it for yourself for 1 minute twice today, and a third time as you go to sleep tonight.
Module 15	Misperceptions About Quitting	Body scan/loving kindness, Noting, RAIN, curiosity	Video – Introduction to Misperceptions About Quitting Input – Would you like to practice telling one of your smoking buddies that you're quitting as today's goal?
Module 16	Walking meditation	Noting	Video – Introduction to Walking Noting Practice Audio – Walking Noting Exercise Video – Sum it Up Input – Would you like to practice noting practice each time you walk somewhere today?
Module 17	Thoughts like a Radio	Thoughts as thoughts meditation, Noting	Video – Introduction to Thoughts Like a Radio Audio – Noting Exercise Video – Sum it Up Input – Would you like to practice just dropping into an open awareness whenever you notice thoughts chattering away today?
Module 18	Tripping on Thoughts	Noting	Video – Introduction to Tripping on Thoughts Animation- Tripping on thoughts Video – “Autobiography in Five Short Chapters” by Portia Nelson Video – Sum it Up Input – Would you like to practice noting practice whenever you are walking somewhere (no matter how far) today?
Module 19	Faith	All practices!	Video – Introduction to Faith Input – How about trying to see how many little moments today you can be mindful and curious by doing noting practice, with a particular eye out for doubt?
Module 20	Tips on Staying Motivated	Mantra	Video – Introduction to Tips Input - Write down a mantra that you might use. Video – More Tips Input – Would you like to be reminded of your mantra today so you can practice using it when cravings arise?
Module 21	Quit Day	Manta	Video – Introduction to Quit Day Video – Quit Day Ceremony Input – As your daily goal would you like to tell a friend or family member that today is your Quit Day?
Module 22	Sticking with it	All practices! Mantra	Video – Introduction to Sticking with It Input – Would you like to set as your daily goal to keep using your mantra whenever a craving comes up?
Bonus – available after module 17	Big mind meditation		Audio from Joseph Goldstein
Bonus – available after module 13	Tree Analogy	Reinforcing Noting etc.	Video – Tree Analogy
Bonus – available after module 1	Attitude is everything		Video – Attitude is Everything
Bonus – available after module 1	Mountain meditation		Audio from Joseph Goldstein
Bonus	Sitting Meditation		Audio

Table 2.

Baseline Characteristics of Study Population

	Intervention Condition				
	C2Q n=48	Materials n=48	NCI n=50	Total N=146	P-Value
	N (%)	N (%)	N (%)	N (%)	
Age – Mean (SD)	16.9 (1.1)	16.7 (1.1)	17.1 (1.2)	16.9 (1.1)	0.12
Female	29 (60.4%)	26 (54.2%)	27 (54%)	82 (56.2%)	0.77
Race					0.40
White	45 (93.8%)	43 (89.6%)	44 (88%)	132 (90.4%)	
Black/African American	0 (0%)	2 (4.2%)	2 (4%)	4 (2.7%)	
American Indian/Alaskan Native	0 (0%)	0 (0%)	1 (2%)	1 (0.7%)	
Other	2 (4.2%)	0 (0%)	0 (0%)	2 (1.4%)	
Multiple races chosen	1 (2.1%)	3 (6.3%)	3 (6%)	7 (4.8%)	
Hispanic Origin	5 (10.4%)	5 (10.4%)	4 (8%)	14 (9.6%)	0.88
Grade level					0.92
9th grade	4 (8.3%)	6 (12.5%)	7 (14%)	17 (11.6%)	
10th grade	11 (22.9%)	13 (27.1%)	9 (18%)	33 (22.6%)	
11th grade	17 (35.4%)	15 (31.3%)	17 (34%)	49 (33.6%)	
12th grade	16 (33.3%)	14 (29.2%)	17 (34%)	47 (32.2%)	
Participate in reduced or free lunch program	33 (68.8%)	33 (68.8%)	34 (68%)	100 (68.5%)	1.00
Number of years smoked cigarettes – Mean (SD)	3.7 (2.0)	3.6 (2.0)	4.3 (2.4)	3.9 (2.2)	0.21
Number of cigarettes smoked in previous 7 days – Mean (SD)	33.5 (21.8)	34.5 (29.5)	34 (19.5)	34 (23.8)	0.82
Number of times tried quitting smoking cigarettes – Mean (SD)	1.9 (0.88)	2.3 (1.3)	2.6 (1.9)	2.3 (1.4)	0.32
Readiness to Quit – Mean (SD) Range = 0 - 10	7.0 (2.7)	6.0 (2.5)	6.8 (2.7)	6.6 (2.7)	0.07
Number of other smokers who live with participant					0.36
0	8 (16.7%)	8 (16.7%)	12 (24%)	28 (19.2%)	
1	22 (45.8%)	13 (27.1%)	12 (24%)	47 (32.2%)	
2	10 (20.8%)	17 (35.4%)	12 (24%)	39 (26.7%)	
3	5 (10.4%)	5 (10.4%)	9 (18%)	19 (13%)	
4+	3 (6.3%)	5 (10.4%)	5 (10%)	13 (8.9%)	
Number of friends who smoke cigarettes					0.76
None	0 (0%)	1 (2.1%)	0 (0%)	1 (0.7%)	
A few	17 (35.4%)	12 (25%)	15 (30%)	44 (30.1%)	
Less than half	4 (8.3%)	3 (6.3%)	3 (6%)	10 (6.8%)	
About half	8 (16.7%)	15 (31.3%)	13 (26%)	36 (24.7%)	
Most or all	19 (39.6%)	17 (35.4%)	19 (38%)	55 (37.7%)	
Parents allow them to smoke cigarettes at home	9 (18.8%)	12 (25%)	21 (42%)	42 (28.8%)	0.03
During the past 12 months...					
Stopped smoking because trying to quit	29 (60.4%)	26 (54.2%)	28 (56%)	83 (56.8%)	0.82

	Intervention Condition				
	C2Q n=48	Materials n=48	NCI n=50	Total N=146	P-Value
	N (%)	N (%)	N (%)	N (%)	
Used nicotine replacement to help stop smoking	13 (27.1%)	6 (12.5%)	8 (16%)	27 (18.5%)	0.16
Used other medications to help stop smoking	1 (2.1%)	0 (0%)	1 (2%)	2 (1.4%)	1.00
Used none of the above to help stop smoking	34 (70.8%)	42 (87.5%)	41 (82%)	117 (80.1%)	0.11
High level of nicotine dependence (mFTQ)	9 (18.8%)	10 (20.8%)	14 (28%)	33 (22.6%)	0.52
Elevated depressive symptoms (cutoff score 29; possible range 16-34)	27 (56.3%)	18 (37.5%)	17 (34%)	62 (42.5%)	0.06
How helpful participant thinks smoking cessation program will be in helping to quit smoking					0.26
Not at all useful	1 (2.1%)	0 (0%)	5 (10.2%)	6 (4.1%)	
Somewhat useful	12 (25%)	17 (35.4%)	10 (20.4%)	39 (26.9%)	
Moderately useful	24 (50%)	19 (39.6%)	20 (40.8%)	63 (43.4%)	
Very useful	10 (20.8%)	9 (18.8%)	12 (24.5%)	31 (21.4%)	
Extremely useful	1 (2.1%)	3 (6.3%)	2 (4.1%)	6 (4.1%)	
By the end of the study, how likely participant expects they will be able to quit smoking (SEQ-12)					0.05
Not at all likely	2 (4.2%)	0 (0%)	6 (12.2%)	8 (5.5%)	
Somewhat likely	7 (14.6%)	16 (33.3%)	12 (24.5%)	35 (24.1%)	
Moderately likely	24 (50%)	21 (43.8%)	19 (38.8%)	64 (44.1%)	
Very likely	13 (27.1%)	10 (20.8%)	7 (14.3%)	30 (20.7%)	
Extremely likely	2 (4.2%)	1 (2.1%)	5 (10.2%)	8 (5.5%)	
mFTQ Score - Mean (SD) (Possible range: 0 - 9)	3.7 (1.6)	4.0 (1.6)	4.1 (1.7)	4.0 (1.6)	0.49

Table 3.

Association of Intervention Engagement with Smoking Outcomes at 6 months

Outcome	Adjusted Estimate (95% CI)
7 Day Cotinine-Validated Abstinence⁺ (OR)	6 Months
C2Q – Actual (n=43)	1.60 (0.36 to 7.21)
Materials (n=43)	1.66 (0.60 to 4.54)
NCI (n=31)	2.69 (1.42 to 5.11)
Number of cigarettes smoked in the past week^{*†} (Among those still smoking at 6 months)	
C2Q – Actual (n=32)	–5.71 (–11.63 to 0.20)
Materials (n=35)	–0.95 (–11.08 to 9.19)
NCI (n=25)	7.73 (–0.96 to 16.42)

⁺Model adjusted for baseline mFTQ Score and total time spent with the school nurse^{*}Model adjusted for baseline number of cigarettes smoked in previous week and total time spent with the school nurse[†]p = 0.02