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Mobile Applications for the Treatment of Tobacco Use and Dependence

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Abstract

Purpose of Review—Smoking remains a leading preventable cause of premature death in the world; thus, developing effective and scalable smoking cessation interventions is crucial. This review uses the Obesity-Related Behavioral Intervention Trials (ORBIT) model for early phase development of behavioral interventions to conceptually organize the state of research of mobile applications (apps) for smoking cessation, briefly highlight their technical and theory-based components, and describe available data on efficacy and effectiveness.

Recent Findings—Our review suggests that there is a need for more programmatic efforts in the development of mobile applications for smoking cessation, though it is promising that more studies are reporting early phase research such as user-centered design. We identified and described the app features used to implement smoking cessation interventions, and found that the majority of the apps studied used a limited number of mechanisms of intervention delivery, though more effort is needed to link specific app features with clinical outcomes. Similar to earlier reviews, we found that few apps have yet been tested in large well-controlled clinical trials, although progress is being made in reporting transparency with protocol papers and clinical trial registration.

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Compliance with Ethical Standards

Conflict of Interest

K.A.G. and E.C.-P. have nothing to disclose.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

Summary—ORBIT is an effective model to summarize and guide research on smartphone apps for smoking cessation. Continued improvements in early phase research and app design should accelerate the progress of research in mobile apps for smoking cessation.

Keywords

Tobacco use; Smoking cessation; Smartphone apps; Mobile health; Mobile technology; ORBIT model

Introduction

Tobacco use and dependence is a leading cause of preventable death worldwide [1], and costs the global economy $422 billion in healthcare expenditures annually due to smoking-attributable diseases [2]. Smoking remains the leading preventable cause of premature death in the USA, with additional negative consequences to society such as absenteeism from work and increased health care cost and utilization [2]. Despite that interest in quitting is high across all sectors of society, evidence-based tobacco treatments remain underutilized and are implemented far below recommended funding levels [3]. Promoting more accessible evidence-based interventions is critical, including to subpopulations (e.g., psychiatric disorders) with the highest smoking prevalence [3, 4].

Current research suggests that mobile health technology (mHealth) for smoking cessation, such as smartphone apps, may be key in delivering wider-reaching treatment more efficiently [5]. Smoking cessation apps have a number of advantages for evidence-based treatment. Apps can deliver interventions in the individual's natural context, potentially increasing real-world impact [6]. Further, by measuring behaviors in real time, apps increase ecological validity, reduce recall bias, and enable examination of behavioral patterns over time [7]. Apps also enable widespread distribution, improving dissemination [8–10] and overcoming barriers to treatment (e.g., transportation) [11, 12]. Apps can provide faster and more direct access to healthcare services and improve continuity of care. All these factors are key to cost-effectiveness [5, 9, 13]. Additionally, apps can be used to personalize or tailor treatments to the individual, such as tailored text messages and support based on user feedback [5, 9, 14], a major goal in precision science and medicine [15]. Finally, apps enable social networking, for example to share resources and experiences with other smokers who are trying to quit [16].

New smoking cessation apps are being released at a rapid rate: 400 apps were identified by review in 2013, and 546 apps were identified by review in 2017 [17, 18]. However, only a small portion of them has been empirically studied. Here, we present an empirical review of smoking cessation apps. We include reports on user-centered design research, pilot studies, and efficacy and effectiveness trials. mHealth is an interdisciplinary field that comprises not only behavior change technology but also the process of software design and engineering. User-centered design research ensures that app content can be received by the end user and have the intended effect. This is an important step prior to clinical trials to help ensure that the active ingredients of an intervention are implemented via the app. We also highlight available protocol papers, which report protocols for planned randomized controlled trials

(RCTs) prior to reporting any results; an important step in scientific rigor and research transparency.

Overview of Review Methods

Articles were included if they (1) reported research on a smoking cessation app, (2) were peer-reviewed, and (3) were indexed in PubMed or Google Scholar. “Research” was defined as any empirical effort to develop, refine, or test an app. Key search terms were “smoking cessation applications” and “smoking cessation apps.” This search resulted in 349 articles. One-hundred twenty did not contain empirical studies, 56 were duplicates, 53 did not refer to smoking, and 78 did not refer to smoking cessation apps. A few additional apps were identified through literature review and targeted Google Scholar searches. A total of 33 apps were identified for review. The review focused on (1) quality of the programmatic effort to develop or study the app; (2) description of app features, including theoretical foundation; and (3) data supporting the effect of the app on clinical outcomes following recommended outcome criteria for smoking cessation trials [19•].

Programmatic effort was described based on the ORBIT model, a model for development of behavioral treatments for chronic conditions [20••], developed by the U.S. National Institutes of Health and Obesity-Related Behavioral Intervention Trials (ORBIT) consortium. ORBIT is focused on early and pre-efficacy phases of behavioral treatment development, while retaining terminology from the drug development model. The model provides a framework for research milestones prior to conducting large and costly efficacy or effectiveness trials. ORBIT defines four phases to optimize behavioral interventions: phase I involves intervention design (phase Ia) and refinement (phase Ib) using cost-efficient methods (e.g., reviews, qualitative research, single-case trials, design research); phase II involves initial testing such as feasibility, proof-of-concept, or pilot clinical studies; phase III involves testing efficacy (explanatory); and phase IV involves testing effectiveness (pragmatic). ORBIT is a useful model to guide the optimization of smoking cessation apps since there is a substantial amount of design and software research needed prior to testing these interventions in full-scale clinical trials.

As part of the iterative review process, we identified all the app features described in the literature and organized these into the following categories: *psychoeducation* about tobacco dependence, consequences, treatment; *self-tracking* of units of behavior (e.g., cigarettes smoked); *personalized feedback* including content customized to user (e.g., gender) or user responses (e.g., app surveys); *social support* via social media or networking; *system of rewards* (e.g., badges) for behaviors of importance; *digital distractions* to distract from craving or smoking; *funnel-based* apps provided new content contingent on completion of earlier content; *geolocation* to track user location; *gamification* used gaming to incentivize behavioral skills or knowledge gain [21] (note that this could include rewards, but rewards alone did not satisfy criteria for gamification); *sensor-based just-in-time*, defined as any feature that relied on an app sensor to provide just-in-time feedback to the user; and *machine learning* to tailor or deliver app content.

Results

Thirty-three apps were identified from the 55 articles that met review criteria (Table 1). This discrepancy resulted from several apps being studied in multiple research phases (e.g., design and efficacy). Almost half of the apps (46%) were first reported between 2017 and 2018. Half of the apps targeted smoking in the general population (n = 16 apps; see Section 3.1), and half targeted specific populations (n = 17 apps; see Section 3.2). Finally, the theoretical basis for behavior change was identified in all of the apps. Here, we provide a brief description of the apps identified for this review, followed by a discussion of the state of research.

Apps Designed for the General Population

Clickotine

Clickotine delivers smoking cessation intervention components recommended by U.S. Clinical Practice Guidelines (USCPG) (e.g., the "5 A's") [55•] including breathing exercises; logging cravings, cigarettes, and feelings; receiving/responding to personalized messages; social support; and using quit smoking aids [41]. In an initial study (N = 416), self-reported 30-day smoking abstinence rates were 26% at 8 weeks [41].

Smartphone Smoking Cessation App (SSC App)

SSC App is described as a "decision aid with additional support" including information on pros/cons of quitting options, motivational messages, quitting diary, and quitting benefits tracker. *SSC App* was compared to an information-only app in an online, multi-country double-blind randomized controlled trial (RCT; N = 684). *SSC App* users reported greater continuous smoking abstinence rates (i.e., since quit date) at 6 months (10.2% vs 4.8%), and reported being more likely to have made an informed choice and feel confident about their quitting strategy [54].

Geo-Location Apps

Q Sense uses self-report data and geolocation to deliver tailored quit smoking messages. In a feasibility study in a convenience sample (N = 15), *Q Sense* was used for 3–6 weeks, and was found to be feasible and provide accurate and reliable identification of high-risk areas for smokers [34]. Smoking behavior, however, was underreported, and the authors suggested the use of app prompts to increase self-reporting compliance.

MapMySmoke uses 2 weeks of self-reported smoking and craving events with geolocation to inform a quit plan developed with the healthcare provider and then deliver support messages in a post-quit phase. Initial testing in the primary care setting (N = 8) demonstrated feasibility, in that users were able to log smoking events, and reported increased awareness of triggers and decreased craving and smoking [32].

StopApp was developed to increase motivation for uptake and attendance to smoking cessation services using evidence-based, personally tailored behavior change techniques with an online instant booking system. A user-centered design survey (N = 40) identified barriers to smoking cessation services such as lack of knowledge about services, beliefs that

booking would be difficult, beliefs that services were not needed or would not be helpful, social stigma, and fear of cessation failure [38]. The user-centered design of *StopApp* was described in a subsequent report [56].

SmokeBeat uses data from smartbands to identify the hand-to-mouth gestures that characterize smoking and notify users of smoking incidences in real time. A pilot trial (N = 40) compared *SmokeBeat* smoking monitoring and notification to waitlist control across 30 days and found that *SmokeBeat* correctly detected smoking incidences (> 80%) with few false alarms. Furthermore, cigarettes per day were significantly reduced for *SmokeBeat* compared with wait-list control [48•]. Other smartwatch-based smoking monitoring devices are being developed and tested to work with cessation apps (e.g., [57]).

TControl is a multifeatured app developed to track smokers' self-reported compulsion to smoke and provide tailored support via reinforcement and achievement messages, enable instant messaging with clinicians and other smokers, and provide information about nearest hospitals for tobacco treatment. A user-centered design study in a hospital setting (N = 31) suggested good usability standards, although 50% of patients reported needing some help to use the app [51].

E-Intervention Tabac Info Service (e-TIS) was developed by the French national smoking cessation service. The app uses personalized push notifications for questionnaires, advice, activities, and text messages, including content regarding tracking smoking and costs, decisional balance, quit date, nicotine replacement therapy, social support, craving, and other topics. Content was provided in four modules tailored to smokers' stage of readiness to quit. The study protocol has been published for a two-arm pragmatic RCT (N = 3000) to compare the effects of *e-TIS* with treatment as usual on self-reported 7-day point prevalence abstinence at 6 months [53].

SmokeFree delivers a toolbox of behavior change techniques for smokers to achieve 28-day abstinence and monitor progress toward that goal. *SmokeFree28* was tested in a pilot study [39] and in a RCT (N = 28,112) which compared a full and reduced version of the app. Self-reported continuous abstinence rates at 3 months were 19% versus 14% for the full and reduced app versions in those who completed follow-up (n = 2114) [58].

Cognitive-Behavioral Therapy (CBT)

Quit Genius (QG) is a gamified four-stage app using audio, exercises, and diary to deliver personalized CBT for self-reflection, changing thinking patterns, coping, problem solving, and mindfulness, for 8 weeks. A qualitative study (final N = explored users' perceptions of *QG* versus the *SmokeFree* app (non-CBT-based), and found that *QG* was associated with more positive user responses and increased motivation to quit and willingness to use the app [35]. Another study surveyed current *QG* users (N = 190 survey completers) and found that 36% reported quitting smoking after using the app [59].

Mindfulness

SmartQuit delivers acceptance and commitment therapy, including using mindfulness skills to cope with cravings, emotions, and thoughts, and making value-guided committed

behavior changes. In a pilot randomized controlled trial (*N*= 196), 13% of *SmartQuit* users reported 30-day point prevalence abstinence at two months versus 8% for the comparator, NCI *QuitGuide* [46]. A single-arm trial (*N* = 99) tested receptivity and smoking cessation with a second version of the app (*SmartQuit 2.0*), and found high satisfaction and usefulness ratings, as well as 21% of smokers reporting 7-day point prevalence abstinence at 2 months and 75% reporting smoking reductions [17].

CravingtoQuit teaches mindfulness training for smoking cessation including three standard mindfulness practices and an informal practice to recognize and work mindfully with cravings, and includes ecological momentary assessment (EMA) of smoking, craving, mood, and mindfulness [60•]. A full-scale two-arm RCT (*N* = 325) tested the efficacy of *CravingtoQuit* compared with an app delivering only EMA. Although 7-day point prevalence abstinence at 6 months did not differ between groups (18% self-reported, 11% biochemically verified overall), there was a significant reduction in the association between craving and smoking after treatment for *CravingtoQuit* versus control [52•].

Distraction-Based Apps

Crave-Out is multi-level pattern memory game designed to distract smokers during craving, with positive reinforcement and a link to a smoking cessation website. In a feasibility study (*N* = 30) with one 10-min laboratory session of game play, *Crave-Out* received positive user feedback (e.g., fun, challenging, distracted from cravings) and reduced cravings pre/post-game play [23].

Quittr is a mobile game app providing either distraction games or games that incentivize interaction with other app features including tracking quitting progress, support content, and educational material, to be used for 28 days. The app is currently undergoing late-stage development and beta-testing [36].

DistractMe provides smokers with access to distractions, tips to cope with cravings, and links to other smokers via comments. A qualitative 6-week user-centered design study (*N* = 14) tested how the app supported quitting. Results indicated that users engaged more with tips than distractions, although distractions facilitated content sharing. Although the initial idea of distraction through an app was appealing, smokers more commonly coped with cravings by paying attention to smoking and cravings rather than diverting their attention [27].

Contingency Management

Inspired is a contingency management app using game-based rewards to incentivize quitting and reduce the cost of contingency management for smoking cessation. A single-session feasibility study (*N* = 28) indicated that smokers found the app “fun” and reported being more likely to use *Inspired* than other smoking cessation aids, medications, or interventions [28].

Apps Designed for Targeted Populations

Women Smokers

See Me Smoke Free (SMSF) delivers guided imagery and behavior strategies to help women quit smoking, improve diet, and increase physical activity [61]. The app was refined iteratively based on prototype testing ($N = 6$) [25]. In a feasibility study ($N = 73$), use of the app was associated with improvements in all three targeted behaviors (smoking, diet, exercise), and self-reported 7-day abstinence at 3-months was 47% [62].

SmokeFree Baby delivers behavior change techniques for pregnant smokers targeting identity, health information, stress management, in-person support, and behavioral substitution [26]. The app underwent usability testing [26] and was then tested in a randomized full-factorial study ($N = 565$) designed to evaluate these five behavioral targets (modules). In that study, overall engagement with the app was low and no module had a significant impact on smoking abstinence during pregnancy [63].

It's about Two—Baby & You describes tobacco risks and cessation strategies through a story of a young pregnant smoker. A cross-sectional study in a clinical setting was conducted ($N = 210$) in which women used the app on an iPad and completed a survey, and a subset participated in focus groups ($n = 27$). Most users provided positive feedback including increased interest in quitting and ideas on how to quit smoking [29].

Nondaily Smokers

Smiling Instead of Smoking (SiS) was developed using the intervention mapping framework and is a behavioral coach for quitting for nondaily smokers based on USCPG and positive psychology principles [37]. App development was based on a literature review, content analysis of available smoking cessation apps, and interviews with nondaily smokers undergoing a quit attempt ($N = 38$). The resulting app delivered proactive, tailored behavioral coaching; interactive tools; daily positive psychology exercises; and smoking self-monitoring [37]. No direct testing of the app has yet been reported.

Adolescents

Most smokers smoke their first cigarette in early adolescence; therefore, smoking interventions for youth are needed. *SmokerFace* targets adolescents' interest in appearance by using "photoaging" to alter their "selfies" to depict future appearance if they smoke one pack daily. The app also portrays their appearance if they abstain from smoking. *SmokerFace* was initially tested in three schools ($N = 125$ students) by projecting the images in front of the whole class. The app was positively received (e.g., fun, motivating), but expensive to implement [64]. A study is underway testing a poster campaign for the app in 126 schools with long-term follow-up and biochemically verified abstinence [40•].

Young Adults

Young adults have high rates of smoking and mobile phone use and are consequently a promising target for smoking cessation apps [65, 66]. *Crush the Crave (CTC)* was developed based on USCPG and principles of persuasive technology for behavior change [22], and

includes a quit plan, benefits of quitting, identifying triggers, tracking smoking and craving, tailored quit smoking messages, social networking, quit smoking information, and access to cessation services [67]. A two-arm RCT (N = 1599 young adults) compared the effects of *CTC* with self-help material and found that self-reported continuous abstinence at 6 months was not significantly different at 7.8% for *CTC* versus 9.2% for control [68]. A qualitative study of young adults participating in the RCT (N = 31) identified components of the app reported to be productive, such as documenting cigarettes smoked and cravings, or unproductive, such as social support components of the app, and found that some preferences for app components differed by gender [69].

Real e Quit (REQ-Mobile) delivers text messages based on social cognitive theory and the transtheoretical model to increase self-efficacy across stages of quitting, with additional content related to quitting benefits and strategies, coping, and nicotine replacement therapy. A RCT (N = 102 young adults) was conducted comparing the app to text messaging only and found that text messaging led to greater self-reported 30-day point-prevalence abstinence at 3 months [45].

MyQuit USC (MQU) is a tailored just-in-time adaptive intervention prototype for Korean American emerging adult smokers. Qualitative data from a user-centered design study highlighted that smoking episodes among this population are highly context-driven and there is a need for personalized cessation strategies for different contexts [33].

Serious Mental Illness

Learn to Quit was developed for persons with serious mental illness. The app was based on acceptance and commitment therapy in combination with USCPG. The app uses behavior analytic principles to increase app engagement and retention and comprehension of app content. A series of user-centered design studies and case studies [31•, 70, 71•] informed the app design, including app layer structure, the use of storytelling, successive approximations to increase mastery of smoking cessation skills, and symbolic rewards [31•]. A feasibility trial is currently underway.

Kick.it was developed using intervention mapping framework and persuasive system design for smoking cessation among young adults with serious mental illness. EMA is used to record smoking, craving, mood, and triggers, and the app then provides tailored feedback based on stored information, in addition to digital diversions and random content to promote engagement and sustain interest [30]. Pilot testing is underway [72].

Post-Traumatic Stress Disorder (PTSD)

Stay Quit Coach (SQC) was designed by the U.S. National Center for PTSD and provides evidence-based techniques addressing PTSD symptoms and smoking urges. A preliminary trial (N = 11) evaluated the usability and feasibility of *SQC* combined with mobile contingency management, quit smoking counseling and medications (“QUIT4EVER”), versus the same intervention without *SQC*, and found positive user experience feedback for the *SQC* app including helpfulness [50]. Another pilot study (N = 20) incorporated *SQC* into an 8-week in-person integrated care protocol, resulting in 35.3% biochemically verified 30-day point-prevalence abstinence at 3 months [73].

Medical Populations

The opportunity for smoking cessation intervention arises during hospitalization [74], and several apps have been developed to address this need. *Computer-assisted Education System (CO-ED)* delivers psychoeducation on the dangers of smoking and was tested in a hospital setting ($N = 55$) where smokers used *CO-ED* for up to 45 min and then completed a survey and semi-structured interview. CO-ED increased smoking knowledge, self-efficacy, and readiness to quit [42].

SmokerFace-HIV—Individuals who are HIV positive are twice as likely to smoke; therefore, smoking cessation aids for this population are needed [75]. A kiosk version (i.e., tablet projecting to a wall-mounted monitor) of the face-aging *SmokerFace* was developed for the waiting room of an HIV outpatient clinic and tested during a 19-day period during which patients tried the app and then completed an anonymous questionnaire ($N = 187$). Most smokers reported that the app was fun and motivated them to quit; nonsmokers reported the app motivated them to never take up smoking [49].

Positively Smoke Free-Mobile (PSF-M) is a mobile website that aims to assist persons living with HIV in quitting smoking over 42 days by delivering motivational/educational quit smoking sessions based on social cognitive theory, interactive quit smoking messaging around the quit date, access to a quitline, and other functions. A pilot RCT ($N = 100$) compared *PSF-M* to standard care (all were offered 3 months of nicotine patch, used by ~ 70%) and found some support for feasibility (moderate acceptance, adherence, engagement, and satisfaction) despite no difference in biochemically verified 7-day point prevalence abstinence rates at 3 months [44].

Adherence to Smoking Cessation Medication

RxCoach was designed to improve adherence to quit smoking medications (i.e., varenicline) by collecting medication information via self-report and barcode reader; and providing tailored adherence feedback, medication tracking, motivational messages, and tips to deal with cravings, side effects, and lapses; reminders for refills and appointments; and a direct link to a physician/pharmacist. *RxCoach* was refined through a focus group ($N = 4$) and two usability tests ($N = 10$ per study), followed by feasibility testing, which had low participation ($N = 7$, $n = 5$ retained) but good medication adherence ($n = 4/5$ participants reported current use of varenicline at 1 month) [24].

Pfizer meds was also developed for varenicline users to provide educational information and quit smoking support, including motivational support and medication information. *Pfizer meds* was tested in a prospective observational study ($n = 131$ survey completers at 3 months) and was found to have moderate levels of usability and user satisfaction [43].

Socioeconomic Status (SES)

Lower SES has been associated with lower cessation rates [76]; therefore, individuals with lower SES may benefit from technology-based interventions, which have high reach and are cost-effective. *Smart-Treatment (Smart-T)* uses EMA to track triggers, craving, smoking, and other factors, and deliver tailored, just-in-time quit smoking messages. An feasibility

study in lower SES smokers ($N = 59$) tested use of *Smart-T* for 3 weeks with group counseling and pharmacotherapy and found high rates of app usage and EMA completion, and 20% biochemically verified 7-day point prevalence abstinence at 3 months [47]. A more recent study supported the approach of tailoring messages to specific triggers such as stress [77].

Discussion and Recommendations

Limited Range of App Features

This review extracted app key features from the literature (Fig. 1). Across apps, we identified categories of app features for delivering intervention content and found that most apps used a limited range of features. For example, the majority of apps used psychoeducation (76%) and self-tracking (70%). Personalized feedback (42%) was used in conjunction with self-tracking by customizing the intervention to the user. Social support (36%) and implementing a system of rewards (36%) were used by a smaller portion of apps. Less commonly used features included geolocation (9%), just-in-time sensors (6%), and machine learning (3%). We note that additional features were not categorized in this review due to being underutilized and/or delivered separately from the app itself, such as live counseling, a component of some app-based interventions (e.g., *Smart-T*, *QUIT4EVER/Stay Quit Coach*).

This breakdown indicates that the majority of apps deliver interventions using features that require little software engineering, while more complex features (e.g., machine learning) are not yet widely implemented. Overall, there was considerable overlap on use of a limited number of app features. The majority of apps (63%) implemented no more than three features, while some apps implemented up to six features (Fig. 1). It is possible that over time apps will implement a wider range of features to deliver smoking cessation interventions, and/or that more efficacious app features will be identified and become the focus of treatment delivery.

Decisions regarding which features to implement for treatment delivery should be empirically driven. Early-phase studies (phase Ia and Ib of the ORBIT model) offer an ideal set of methodologies to inform these decisions in a cost-effective manner. Qualitative studies, user-centered design methods, and small-*n* studies can provide a rich set of observations to guide and validate decisions for a given app and population. Likewise, large-*n* studies, including newer methods such as multiphase optimization strategy (MOST); sequential, multiple assignment randomized trials (SMART); and micro-randomized trials (MRTs) [78], albeit more costly, should also provide valuable data to inform mHealth interventions. With one exception (i.e., *SmokeFree Baby*), these approaches are currently absent from the literature.

App Features Could Be Described More Consistently

Our review indicated that app features were often not well specified or described. Understanding the active ingredients of an app-based intervention requires a detailed account of app features and content. Reports of phase II or III trials are typically limited to a

minimal description of app features, which is problematic when phase I research was not conducted or reported. Our review also identified inconsistencies in the vocabulary used to describe app features. For example, “gamification” was misused to describe games or digital diversions rather than the use of a game to enhance the acquisition of knowledge or skills [21]. Such inconsistencies can lead to confusion in the field about the design of app-based smoking cessation interventions. In particular, the field is lacking a complete understanding of which app features have been tested in which phase and how much evidence is available to support a given app feature, information that is critical to developing clinical practice guidelines in mHealth.

Further Programmatic Efforts Are Needed

This review used the ORBIT model to categorize available apps by their phase of development and testing (Table 1). Half of the papers identified in this review reported phase I studies, and among those, 23% progressed to a phase II study. The other half of papers first reported phase II studies such as proof-of-concept or two-arm pilot RCT without any previously reported design research. Finally, 31% of papers reported efficacy or effectiveness RCTs without reporting previous phase I or II research. This could be because earlier research phases were not conducted, or perhaps because they were conducted but not reported. While skipping research phases can be acceptable according to the ORBIT model, this can be problematic and cost-ineffective if the intervention needs to be re-designed to optimize its components. Not reporting user-centered design research can also be problematic because it limits the body of knowledge available to identify generalizable design features that could inform other interventions.

One approach gaining traction in clinical research more broadly, and also in mHealth, is the publication of protocol papers outlining the rationale, hypotheses, and methodology of a clinical trial prior to conducting the trial in order to reduce publication bias and improve reproducibility. Clinical trial pre-registration and evidence-based minimum reporting standards (e.g., Consolidated Standards of Reporting Trials [79]) also guide complete and transparent reporting and aid in interpreting clinical trials outcomes. Similarly, standards for evaluation of treatment feasibility (e.g., fidelity, adherence, acceptability) would improve the ability to interpret initial phase research of smoking cessation apps [80–82]. More generally, wider adoption of scientific transparency and data sharing should further improve the replicability and efficiency of mHealth research [83].

Overall, our review shows that there is a healthy amount of methodological diversity in smoking cessation app research [84], ensuring that the body of knowledge produced examines treatment development from multiple scientifically relevant perspectives (e.g., qualitative, efficacy, translational). However, we argue that greater programmatic efforts to organize the research endeavor so that design research is systematically conducted and precedes clinical research would improve the quality of these interventions. Lack of definition or optimization of an app design can lead to implementation failures. For example, an app might include theory-based components, but have a design with very low levels of usability. Conversely, some apps might have high usability, but incorporate content not supported by the scientific literature (e.g., astrology).

Few Studies Demonstrate Clinical Efficacy

Our review, similar to previous reviews [9, 11, 85], found only a few studies testing preliminary efficacy or efficacy of smoking cessation apps, despite apps being widely available and highly marketed. We found only four apps tested in Phase III or IV efficacy or effectiveness trials (Table 2). More specifically, only four well-powered studies have tested efficacy and effectiveness of mobile apps, two of them with positive findings and two reporting null results or a more efficacious control condition. Smoking abstinence rates ranged from 0.9% to 12% at trial endpoint [52•, 54, 58, 68]. Most of these trials used the app as stand-alone treatment, suggesting quit rates might be comparable to other non-app-based behavioral interventions for smoking cessation. Protocol papers and clinical trials registries indicate that there are additional clinical trials of smoking cessation apps underway.

An interesting question is whether a greater programmatic effort as suggested above would contribute to more positive clinical outcomes from smoking cessation apps. For example, the *SSC App* used a limited number of interventional features (Fig. 1), and was directly tested in a large multi-site phase IV effectiveness study, but showed positive results compared with control. *SmokeFree*, using three interventional features (Fig. 1), was tested in a phase II pilot study, and later in a large phase IV effectiveness trial, showing positive results compared with the control, but by a small margin. *SmokeFree Baby* underwent phase I research through a thematic analysis of think-aloud procedures with the final app and then was further evaluated in a large MOST design ($N = 565$; phase II) that systematically tested specific app features. This phase II study did not support the utility of specific app features, suggesting a need for more in-depth phase I work and/or refinements. Finally, *Craving to Quit* used a well-defined theoretical framework based on positive outcomes in an earlier in-person smoking cessation RCT, and was tested in a large phase IV effectiveness trial, but did not find significant differences in smoking cessation compared with control, although interesting mechanistic findings were reported.

To this question of whether a greater programmatic effort is needed, drug development research provides a useful parallel. In drug development, early phase research is conducted to evaluate the harm potential of novel drug compounds, as well as to understand key mechanisms of action, dosage, and unintended effects of the drug on other biological systems. This early phase research does not ensure effective translation from animal models to human trials. We argue that early phase research of smoking cessation apps is similarly key to understanding a range of factors including but not limited to cultural norms of the target population, impact of tone and style on the user, and whether the app promotes change consistent with theory-driven processes and clinically relevant outcomes (e.g., does the smoker take proximal steps in smoking cessation). These data are key to supporting whether an app is ready for a larger clinical study. However, phase I research may not directly indicate clinical impact of an app (e.g., *SmokeFree Baby*). In other words, phase I research may be a necessary but not sufficient step in smoking cessation apps research that establishes an empirical foundation for further app development and optimization if negative outcomes result from clinical trials.

Conclusions

Smoking cessation apps incorporate a diversity of mechanisms of delivery (i.e., features) to promote behavior change. Our review found that all app studies report some information on the theoretical basis of the intervention, an important sign of progress in the field [86]. However, it has been argued that existing behavior change theories may not be well suited to inform mHealth interventions as these become more interactive and adaptive [87]. Our review also found an increase in early-phase app development studies; however, there is still a lack of reporting of this stage of research. Finally, only a few studies have tested the efficacy and effectiveness of smoking cessation apps, and among those, only one app (*Crush the Crave*) conducted thorough early phase research. In an effort to increase access to smoking cessation treatment and curb the rates of disease caused by tobacco use and dependence, future studies should continue to standardize and optimize app development, testing, and reporting, to improve treatments and increase the transparency of this scientific process.

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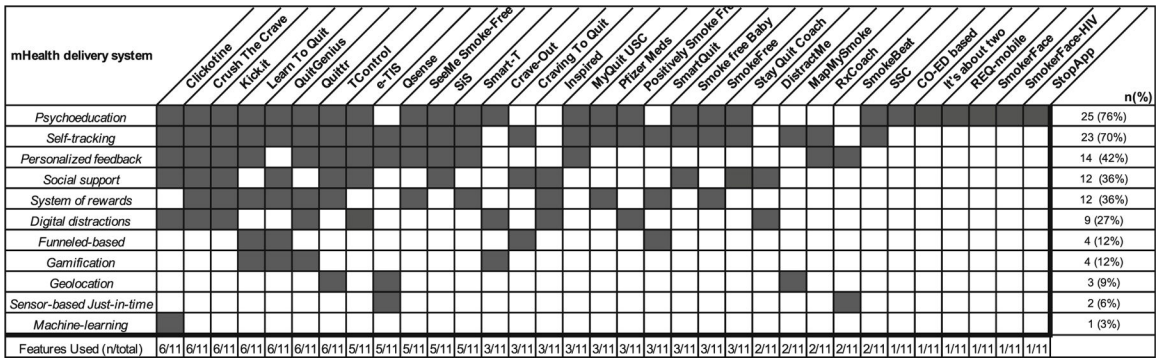

Fig. 1.
Interventional features

Table 1

Mobile applications for smoking cessation

App	Population	Theory-based components	ORBIT model
Crush the Crave [22]	Young adults	Principles of persuasive technology and US Clinical Practice Guidelines (USCPG)	Phase I, II, IV
Crave-Out [23]	General population	Principles of classical conditioning, counter-purpose and relapse prevention model	Phase I, II
RxCoach [24]	General population	USCPG	Phase I, II
See Me Smoke Free [25]	Women	Cognitive behavioral therapy-framed guided imagery	Phase I, II
SmokeFree Baby [26]	Pregnant women	COMB[a] model and PRIME[a] theory	Phase I, II
Distract Me [27]	General population	Relapse Prevention	Phase I
Inspired [28]	General population	Contingency management	Phase I
It's about Two [29]	Pregnant women	Psychoeducation	Phase I
Kick.it [30]	Serious mental illness	Intervention Mapping and Principles of Persuasive Technology	Phase I
Learn to Quit [31]	Serious mental illness	Acceptance and commitment therapy, USCPG and applied behavior analysis	Phase I
MapMySmoke [32]	General population	Geospatial smoking behavior topography and individualized healthcare planning	Phase I
MyQuit USC [33]	Korean American young adults	Just-in-Time Adaptive Intervention (JITAI) approach	Phase I
Q Sense [34]	General population	Just-in-Time Adaptive Intervention (JITAI) approach	Phase I
Quit Genius [35]	General population	Cognitive-behavioral therapy	Phase I[b]
Quittr [36]	General population	Motivational Affordances and Principles of Persuasive Technology	Phase I
SiS App [37]	Non-daily smokers	Positive Psychology and Intervention Mapping	Phase I
StopApp [38]	General population	Behavior Change Wheel (BCW) framework	Phase I
SmokeFree [39]	General population	PRIME theory	Phase II, IV
Smokerface [40]	Adolescent population	Theory of Planned Behavior	Phase II, IV (ongoing)
Clickotine [41]	General population	USCPG	Phase II
CO-ED based app [42]	Medical population	Principles of adult learning and instructional technology	Phase II
Pfizer meds [43]	General population	Varenicline adherence and educational information	Phase II
PSF-M [44]	HIV patients	Social Cognitive Theory	Phase II
REQ-Mobile [45]	Young adults	Cognitive-behavioral therapy, social cognitive theory, and modified version of transtheoretical model	Phase II
SmartQuit [46]	General population	Acceptance and commitment therapy	Phase II
Smart-T [47]	Low/middle income	Just-in-Time Adaptive Intervention (JITAI) approach	Phase II
SmokeBeat [48]	General population	Self-awareness via automated and real-time monitoring of smoking episodes	Phase II
SmokerFace-HIV [49]	HIV patients	Theory of Planned Behavior	Phase II

App	Population	Theory-based components	ORBIT model
Stay Quit Coach [50]	PTSD patients	Relapse Prevention	Phase II
TControl [51]	General population	Healthcare coordination, social support, and positive reinforcement	Phase II
Craving to Quit [52]	General population	Mindfulness	Phase III
e-TIS [53]	General population	Social Cognitive Theory and Motivational Interviewing	Phase III (ongoing).
SSC App [54]	General population	Ottawa decision support framework	Phase IV

Apps are sorted by ORBIT model phase and alphabetically

[a] COMB model: 'capability', 'opportunity', 'motivation' and 'behavior' model; PRIME: 'plans', 'responses', 'impulses', 'motives', 'evaluations' theory of motivation

[b] This study had elements of phase II of the ORBIT model; however, given the emphasis on user experience and usability, it was categorized as phase I

Table 2

Summary of phase III and phase IV studies of mobile apps in tobacco treatment

Studies	Population	*N*	Comparison group	Main outcomes	End-point (months)	Final *N*	Abstinence verification	Quit rates (%) (experimental vs. control)	Relative risk (95% CI) Odds ratio (95% CI)
SSC App (BinDhim et al. 2018) [54]	General population	684	Static information app	Self-reported continuous abstinence	6	583	No	7.3% vs. 3.2%	RR: 2.27 (1.09 to 4.86)
SmokeFree (Crane et al.2018) [58]	General population	28,112	Reduced app version	Self-reported continuous abstinence	3	2114	No	1.6% vs. 0.9%	OR: 1.86 (1.49 to 2.31)
Craving to Quit (Garrison et al. 2018) [52]	General Population	505	Experience sampling app	Biochemically verified 7-day point prevalence abstinence	6	325	Yes	9.8% vs. 12.1%	OR: 1.27 (0.62 to 2.57)
Crush the Crave (Baskerville et al. 2018) [22, 68]	Young adults	1599	Evidence-informed self-help booklet	Self-reported continuous abstinence	6	725	No	7.8% vs. 9.2%	OR: 0.83 (0.59 to 1.18)