Evaluating the Impact of a Game (Inner Dragon) on User Engagement Within a Leading Smartphone App for Smoking Cessation: A Randomized Controlled Trial

Justin S. White, Séverine Toussaert, Bethany R. Raiff, Marie K. Salem, Amy Yunyu Chiang, David Crane, Edward Warrender, Courtney R. Lyles, Lorien C. Abroms, J. Lee Westmaas, Johannes Thrul

Submitted to: Journal of Medical Internet Research
on: February 28, 2024

Table of Contents

Evaluating the Impact of a Game (Inner Dragon) on User Engagement Within a Leading Smartphone App for Smoking Cessation: A Randomized Controlled Trial

Justin S. White[1, 2, 3] PhD, MA, MSPH; Séverine Toussaert[4] PhD; Bethany R. Raiff[5] PhD; Marie K. Salem[2, 6] MPH; Amy Yunyu Chiang[2] PhD; David Crane[7] PhD; Edward Warrender[7]; Courtney R. Lyles[8] PhD; Lorien C. Abroms[9] SCD; J. Lee Westmaas[10*] PhD; Johannes Thrul[11, 12, 13*] PhD

[1]Department of Health Law, Policy and Management Boston University School of Public Health Boston US
[2]Philip R. Lee Institute for Health Policy Studies University of California, San Francisco San Francisco US
[3]Department of Epidemiology and Biostatistics University of California, San Francisco San Francisco US
[4]Department of Economics University of Oxford Oxford GB
[5]Department of Psychology Rowan University Glassboro US
[6]Department of Health Policy and Management Fielding School of Public Health University of California, Los Angeles Los Angeles US
[7]23 Limited London GB
[8]Department of Public Health Sciences University of California, Davis Davis US
[9]Department of Prevention and Community Health Milken Institute School of Public Health The George Washington University Washington US
[10]Population Science American Cancer Society Atlanta US
[11]Department of Mental Health Johns Hopkins Bloomberg School of Public Health Baltimore US
[12]Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Baltimore US
[13]Centre for Alcohol Policy Research La Trobe University Melbourne AU
[*]these authors contributed equally

Corresponding Author:
Justin S. White PhD, MA, MSPH
Department of Health Law, Policy and Management
Boston University School of Public Health
Talbot Building - 249W
715 Albany Street
Boston
US

Abstract

Background: Smartphone applications are a convenient, low-cost approach to delivering smoking cessation support to large numbers of individuals. Yet, the apps are susceptible to low rates of user engagement and retention.

Objective: This study tested the efficacy of a new game module (called “Inner Dragon”) integrated into Smoke Free, a leading smoking cessation app with established efficacy. The primary outcomes measured user engagement with the app.

Methods: A two-arm, parallel-group, randomized controlled trial was conducted in the US with 8-week follow-up. Adult individuals who smoked 1 or more cigarettes daily and planned to quit smoking within 7 days were recruited and randomized (N=500), with equal allocation. Both groups received free access to the original Smoke Free app with “core” features of its smoking cessation program (e.g., a diary and cravings log), and the treated group received additional access to the internal Inner Dragon game that incorporated several game mechanics designed to increase user engagement. User engagement outcomes were number of unique app sessions, average minutes per session, and days with a session. Measures of program adherence, self-reported and verified smoking abstinence, and app satisfaction were also assessed. The main analysis estimated the intent-to-treat effect of access to Inner Dragon on each outcome. Further analyses assessed effect modification by participant characteristics and the association of intensity of game use with program adherence and abstinence.

Results: Overall, user engagement was greater for treated vs. control participants: with 5.3 more sessions of Smoke Free (mean 29.6, SD 36.5 vs. mean 24.3, SD 37.9; P=.06), 0.8 more minutes per session (mean 6.9, SD 5.4 vs. mean 6.1, SD 5.2, P=.047), and 3.4 more days with a session (mean 14.3, SD 15.3 vs. mean 11.9, SD=14.3, P=.03). Program adherence, based on number of times core features of the original Smoke Free app were used, was higher for treated vs. control participants (mean 29.4, SD 41.3

vs. mean 22.6, SD 35.6; P=.03). Self-reported 7-day and 30-day and verified 7-day point-prevalence abstinence at 8 weeks did not significantly differ by study group. Mean repeated 1-day prevalence of quitting was higher among the treated group vs. the control group (17.3%, SD 25.6 vs. 12.4%, SD 21.3; P=.01). App satisfaction and motivation to (stay) quit did not differ by study group. Higher intensity of game use was associated with increased program adherence and self-reported abstinence.

Conclusions: Findings suggest that the Inner Dragon game increased user engagement and program adherence. Additional refinements to the game design may clarify whether the game increases abstinence rates. Overall, it is feasible to deploy games and gamification to enhance user engagement in existing smoking cessation interventions. Clinical Trial: The trial was registered at ClinicalTrials.gov (NCT05227027).

(JMIR Preprints 28/02/2024:57839)
DOI: https://doi.org/10.2196/preprints.57839

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**
Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.
Only make the preprint title and abstract visible.
No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**
Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain v
Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="http

Original Manuscript

Evaluating the Impact of a Game (Inner Dragon) on User Engagement Within a Leading Smartphone App for Smoking Cessation: A Randomized Controlled Trial

Justin S. White, PhD [1,2,3]
Séverine Toussaert, PhD [4]
Bethany R. Raiff, PhD [5]
Marie K. Salem, MPH [2,6]
Amy Yunyu Chiang, PhD [2]
David Crane, PhD [7]
Edward Warrender, BA [7]
Courtney R. Lyles, PhD [8]
Lorien C. Abroms, ScD [9]
J. Lee Westmaas, PhD [10[]
Johannes Thrul, PhD [11,12,13[]

[1] Department of Health Law, Policy and Management, Boston University School of Public Health, Boston, MA, United States
[2] Philip R. Lee Institute for Health Policy Studies, University of California, San Francisco, CA, United States
[3] Department of Epidemiology and Biostatistics, University of California, San Francisco, CA, United States
[4] Department of Economics, University of Oxford, Oxford, United Kingdom
[5] Department of Psychology, Rowan University, Glassboro, NJ, United States
[6] Department of Health Policy and Management, Fielding School of Public Health, University of California, Los Angeles, CA, United States
[7] 23 Limited, London, United Kingdom
[8] Department of Public Health Sciences, University of California, Davis, CA, United States
[9] Department of Prevention and Community Health, George Washington University, DC, United States
[10] Population Science, American Cancer Society, Atlanta, GA, United States
[11] Department of Mental Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, United States
[12] Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD, United States
[13] Centre for Alcohol Policy Research, La Trobe University, Melbourne, Australia

[These authors contributed equally to this work.

Corresponding author: Justin S. White, PhD, Department of Health Law, Policy and Management, 715 Albany Street, Boston, MA 02118. Telephone: 617-358-1916; Email: juswhite@bu.edu.

ABSTRACT

Background. Smartphone applications are a convenient, low-cost approach to delivering smoking cessation support to large numbers of individuals. Yet, the apps are susceptible to low rates of user engagement and retention.

Objective: This study tested the efficacy of a new game module (called “Inner Dragon”) integrated into Smoke Free, a leading smoking cessation app with established efficacy. The primary outcomes measured user engagement with the app.

Methods. A two-arm, parallel-group, randomized controlled trial was conducted in the US with 8-week follow-up. Adult individuals who smoked 1 or more cigarettes daily and planned to quit smoking within 7 days were recruited and randomized (N=500), with equal allocation. Both groups received free access to the original Smoke Free app with “core” features of its smoking cessation program (e.g., a diary and cravings log), and the treated group received additional access to the internal Inner Dragon game that incorporated several game mechanics designed to increase user engagement. User engagement outcomes were number of unique app sessions, average minutes per session, and days with a session. Measures of program adherence, self-reported and verified smoking abstinence, and app satisfaction were also assessed. The main analysis estimated the intent-to-treat effect of access to Inner Dragon on each outcome. Further analyses assessed effect modification by participant characteristics and the association of intensity of game use with program adherence and abstinence.

Results. Overall, user engagement was greater for treated vs. control participants: with 5.3 more sessions of Smoke Free (mean 29.6, SD 36.5 vs. mean 24.3, SD 37.9; *P*=.06), 0.8 more minutes per session (mean 6.9, SD 5.4 vs. mean 6.1, SD 5.2, *P*=.047), and 3.4 more days with a session (mean 14.3, SD 15.3 vs. mean 11.9, SD=14.3, *P*=.03). Program adherence, based on number of times core features of the original Smoke Free app were used, was higher for treated vs. control participants (mean 29.4, SD 41.3 vs. mean 22.6, SD 35.6; *P*=.03). Self-reported 7-day and 30-day and verified 7-day point-prevalence abstinence at 8 weeks did not significantly differ by study group. Mean repeated 1-day prevalence of quitting was higher among the treated group vs. the control group (17.3%, SD 25.6 vs. 12.4%, SD 21.3; P=.01). App satisfaction and motivation to (stay) quit did not differ by study group. Higher intensity of game use was associated with increased program adherence and self-reported abstinence.

Conclusions. Findings suggest that the Inner Dragon game increased user engagement and program adherence. Additional refinements to the game design may clarify whether the game increases abstinence rates. Overall, it is feasible to deploy games and gamification to enhance user engagement in existing smoking cessation interventions.

Trial registration. The trial was registered at ClinicalTrials.gov (NCT05227027).

Keywords. smoking cessation, mobile app, games for health, gamification, engagement, randomized controlled trial, mobile phone

INTRODUCTION

Cigarette smoking remains a leading cause of preventable death and illness in the US [1]. Although various clinic- and phone-based smoking cessation treatments are effective, the most effective cessation treatment, which combines counseling with medication, is used by fewer than 5% of individuals attempting to quit smoking [1-3]. Most individuals attempting to quit smoking do so without any assistance, resulting in success rates of less than 5% [4].

The advent of smartphone-delivered smoking cessation support offers a compelling alternative to traditional clinical treatments, given its potential reach and convenience. Smoking cessation apps, in particular, have gained popularity due to their low cost and just-in-time support.
Research shows that English-language smoking cessation apps had been downloaded 33 million times as of 2020 [5]. The widespread ownership of smartphones has contributed to the extensive reach of cessation apps. As of 2020, 85% of US adults, including 84% of Black and Hispanic adults, three-quarters of adults in low-income households (<$30,000 per year), and 83% of adults age 50-64, owned a smartphone [6]. Consequently, smartphone-based interventions hold promise in reducing the substantial burden and disparities associated with tobacco-related cancer risk and mortality.

While smoking cessation apps offer the advantage of providing timely assistance, only a small proportion of the numerous apps available in app stores have undergone rigorous testing. A systematic review conducted up until 2019 indicated that 11 smoking cessation apps had been subjected to randomized controlled trials (RCTs), although only three were beyond the pilot or feasibility stage [7]. Early-stage evaluations have indicated that smartphone cessation apps tend to yield abstinence rates from 21% to 29% over a period of one to two months [8-15]. However, the translation of these early-efficacy rates into real-world effectiveness remains uncertain, particularly in terms of app features that enhance user engagement and contribute to sustained abstinence [16].

To address this gap, researchers have explored the use of serious games and gamification techniques as potential strategies to enhance user engagement and motivation [17-20]. Serious games have a primary purpose other than entertainment, such as health promotion. Gamification is a related motivational tool that uses nonmonetary rewards to make nongame activities fun or challenging. By increasing user engagement, games and gamification may increase exposure and adherence to a smoking cessation program and, in turn, quit success [21]. Games may have particular appeal to individuals who smoke, three-quarters of whom play video games, according to one survey [22]. Many smokers also express belief in the motivating potential of game-based approaches for smoking cessation [22, 23].

Several standalone smartphone-based games for smoking cessation, such as Cigbreak, Crush the Crave, Inspired, QuitIT, Quittr, and Tobbstop, have been developed [13, 24-32]. A few of these games have also been tested in randomized trials. While users generally reported satisfaction with the gamified apps, most studies have not observed significant increases in smoking abstinence [13, 26, 30, 32]. The variability in user engagement and retention across these apps further complicates the assessment of their overall effectiveness, with each study adopting different measurement approaches.

We conducted an RCT to test the efficacy of a novel game intervention called Inner Dragon. Whereas prior games have been standalone products, Inner Dragon was integrated into the Smoke Free app, providing a unique opportunity to estimate the incremental benefit of embedding a game in a high-

quality smoking cessation app. Smoke Free has been found to increase continuous abstinence at 6 months (12.7% intervention vs 7% comparator) on a per-protocol basis in a pragmatic RCT of 3,000 participants [33]. Smoke Free is also one of the most downloaded smoking cessation apps in the Apple and Android stores, with more than 800,000 downloads per year and 7 million downloads to date [34, 35]. Inner Dragon is a multifaceted game iteratively developed by our team that uses virtual pet retention mechanics with some social features and customization options to promote user engagement and retention [36]. In a single-arm feasibility trial, Inner Dragon was found to have high user satisfaction and generally high user engagement [36]. The present study aimed to assess whether the Inner Dragon game integration increased user engagement among users of a leading smartphone app for smoking cessation.

METHODS

Trial Design

We conducted a parallel-group RCT with equal allocation to two groups. The treated group received free access to the Smoke Free app with the integrated Inner Dragon game. The control group received free access to the Smoke Free app without the game embedded in the app. The study protocol is provided in the supporting online information with a CONSORT guideline checklist [37]. The protocol was approved by the University of California, San Francisco Institutional Review Board (IRB # 19-29335) and was preregistered at ClinicalTrials.gov (NCT05227027). No changes to the pre-specified trial design and methods were made after trial commencement. The supplementary appendix provides details of the study protocol.

Recruitment and Participants

Individuals were recruited from among the population of general users of the Smoke Free smartphone app in the US. Users were invited to participate in the trial during the initial onboarding screens within the Smoke Free app via an on-screen recruitment message, “Interested in a research study to test the latest version of Smoke Free?” If a user clicked “Yes, learn more,” they were taken to a screening questionnaire to assess eligibility and a consent form in Qualtrics.

Inclusion criteria were: individuals age ≥18 years old living in the US who currently smoked at least 1 cigarette per day, had downloaded the Smoke Free app, planned to quit smoking within 7 days, and were able to speak, read, and write in English. A quota of at least 100 individuals age ≥50 years old was programmed into Qualtrics, to ensure the study was representative with respect to age. There were no exclusion criteria.

Randomization and Masking

Eligible, consenting participants were randomized within strata with equal allocation to one of two groups: a control group that received free access to the core features of the original Smoke Free app or a treated group that received free access to the Smoke Free app with the integrated Inner Dragon game. Allocation, concealed from investigators, was performed through the Qualtrics randomizer and

transmitted to the Smoke Free database using the Qualtrics API. Participants were then automatically given access to the assigned intervention within the Smoke Free app. Randomization was stratified by age (<50 and ≥50 years old) and smoking intensity (<5 and ≥5 cigarettes per day, on average), to facilitate assessment of effect modification.

The assessor of the salivary cotinine test was blinded to participants' group assignment; other aspects of the trial were not blinded.

Procedures

As part of the screening questionnaire, participants selected an initial quit date within the next 7 days. Eligible participants were asked via email to complete a baseline questionnaire in Qualtrics after consenting to participate in the study. The baseline questionnaire included additional questions about the person's demographic and smoking history. A follow-up questionnaire in Qualtrics was performed 8 study weeks (56 days) after the person's initial quit date (56 to 63 days after screening and consent depending on each participant's selected quit date). Those reporting having abstained for 7 days in the follow-up questionnaire were mailed a salivary cotinine test kit via two-day mail. They were asked to upload photos of the cotinine test results using a Qualtrics survey link provided by text message. Participants received three reminders via text message and two via email to complete the follow-up questionnaire, and they received three reminders to complete the saliva testing.

Participants in both groups received $20 for completing the baseline questionnaire, $40 for completing the follow-up questionnaire, and $40 for completing the saliva test, if requested. All payments were provided, via email link, as a choice of a Visa® prepaid card or one of hundreds of gift cards through the Tango digital payment platform.

Control Group Intervention

Participants in the control group received free access to an educational intervention consisting of the original Smoke Free app, which has previous per-protocol trial evidence of continuous abstinence at 6 months [33]. The app leverages behavior change techniques that are effective in face-to-face behavioral support programs [38]. "Core" features of the original Smoke Free app include: (1) a calculator that tracks the total amount of money saved by not smoking; (2) a calendar that tracks the time elapsed since the user quit smoking; (3) a scoreboard that awards badges to users for not smoking; (4) progress indicators that inform users about health improvements that the user can expect because they started their quit attempt; (5) daily missions that assign evidence-based tasks to help users avoid and resist urges to smoke (e.g., noting situations when the person smokes and plans for handling those situations without smoking); (6) a diary and cravings log that track the frequency, strength, and location of cravings to smoke; and (7) a text-based chatbot that delivers quitting guidance in a friendly, conversational tone. In previous randomized trials, a full version of the app with chatbot was shown to increase user engagement compared with a reduced version of the app [39], and the daily missions were shown to increase user retention and self-reported smoking abstinence at 3 months [34]. The current core version of the Smoke Free app does not contain any additional gamification features.

Treated Group Intervention

Participants in the treated group received free access to core features of the original Smoke Free app as well as the integrated Inner Dragon game module. Inner Dragon uses traditional virtual pet retention with some social features and many options for customization and personalization. Virtual pets have been popular with consumers because they can foster bonding and companionship [40].

More specifically, Inner Dragon includes several game mechanics designed to increase user engagement and retention. First, the user maintains a pet dragon that hatches on the user's quit day and evolves every 7 days to unlock new attributes and powers. The dragon acts as a virtual avatar that represents the user's progress. Second, the user earns experience points by engaging in selected activities, including those in the game (e.g., playing a minigame or feeding the dragon) and those in the original Smoke Free app (e.g., completing a mission or logging a diary entry). Rewards for engaging with core app features in the original app were designed to improve adherence to the smoking cessation program. The experience points unlock gifts and cosmetics for the dragon, directly rewarding frequent and consistent use of the app. The user can customize their dragon (e.g., wing shape or clothing accessories) over the course of the quit experience by steadily unlocking features. Third, the Inner Dragon home screen has "care meters" that users must work to keep from falling very low: calmness, nutrition, hygiene, and energy. Engaging with the dragon in various ways increases the meters. For example, petting the dragon increases calmness, and feeding the dragon increases nutrition. Caring for and interacting with a virtual pet through the care meters can foster a bond with the pet and motivate users to return to the game regularly [40]. Fourth, the game provides tools for the user to better cope with the challenges of withdrawal: a dragon-led breathing exercise to provide calmness and a memory minigame as a distraction. Fifth, a user can asynchronously interact with other users' dragons in a "dragon park" by (1) viewing others' profile and progress and (2) sending and receiving motivational messages and emojis from a preset menu. We hypothesize that these game mechanics increase users' engagement with the app and, subsequently, their chance of quitting successfully.

Inner Dragon's game design was informed by principles from the fields of psychology and behavioral economics [36]. The avatar provided salient, visual feedback with endogenous value (tied closely to the user's motivation to quit) that may sustain and enhance motivation to quit. Self-determination theory predicts that this type of feedback is highly intrinsically motivating [41]. Furthermore, the user may identify with the digital pet as an avatar, and this may cultivate a digital therapeutic alliance with the game and app, for example, by creating a bond with the dragon and increasing the user's confidence to succeed [42, 43]. The use of frequent, salient, in-game rewards was designed to counter the behavioral economic constructs of present bias and inattention to app use [44, 45]. The design further included evidence-based practices from contingency management, such as the use of escalating in-game rewards for abstinence, with a reset point for lapses and sustained abstinence (by harnessing regret and loss aversion) [46]. The use of surprise gifts provided a variable reward structure designed to boost engagement and novelty [47-49]. The asynchronous interactions with other users in the dragon park provided opportunities for limited social support and social comparisons that may motivate the user to exert more effort in the quit attempt [50, 51].

The various game mechanics and elements were designed to appeal to users with different motivations. For example, Yee [52] identified 3 main components of player motivation: achievement (advancement and competition), social (socializing and relationship), and immersion (discovery, customization, and escapism). The experience point system may appeal to achievers; the interaction with other players and a sense of connection with the dragon may appeal to socializers, and the rich opportunities for dragon customization and distraction game may appeal to players seeking immersion.

A more thorough description of the design and development of Inner Dragon are described elsewhere [36].

Measures

Outcome Measures

The study focused on outcomes within the domains of user engagement, abstinence from smoking, and user satisfaction and motivation.

User engagement measures included the two *primary outcome measures* of (1) the total number of unique app sessions from enrollment through 8 weeks after the user's initial quit date, measured as the number of times the app was opened, and (2) the mean duration of app sessions, in minutes, through 8 weeks after the quit date; the *secondary outcome measures* of (3) the number of unique days with ≥1 app session, and (4) the proportion entering Inner Dragon; and the *tertiary outcome measures* of (5) program adherence, measured as the total number of times selected "core" features of the original Smoke Free app were used (reported a craving, recorded a diary entry, completed a mission, read a tip, and used the chatbot), and (6) the number of times using selected game features (opening gifts, breathing exercise, cleaning the dragon, feeding the dragon, memory minigame, using the customization menu to change appearance, and reading the dragon instruction guide). All engagement outcomes were passively collected by the app. A new session was defined as opening the app after at least 30 minutes of inactivity.

Smoking abstinence measures included the *secondary outcome measures* of (1) the proportion of participants who reported abstaining during the past 7 days at the 2-month follow-up assessment (self-reported 7-day point-prevalence abstinence), (2) the proportion of participants who reported abstaining during the past 30 days at the 2-month follow-up assessment (self-reported 30-day point-prevalence abstinence), and the *tertiary outcome measures* of (3) biochemically verified 7-day point-prevalence abstinence at the 2-month follow-up assessment, obtained from uploaded results from a self-administered salivary cotinine test (Alere iScreen Oral Fluid Device), and (4) repeated 1-day point-prevalence smoking abstinence, measured as the mean proportion of days each participant self-reported having abstained in the last 24 hours, collected via a pop-up box that appeared the first time each day a participant opened the app throughout the 8-week, post-quit date period. Self-reported 7-day point-prevalence abstinence followed the Russell Standard, allowing for fewer than 5 slips [53]. Those who reported using nicotine replacement therapy (NRT) or electronic nicotine delivery systems (ENDS) within the prior 7 days were coded as abstinent for the verified measures, as long as no cigarettes were used [53, 54].

User satisfaction and motivation measures included the *secondary outcome measures* of (1) satisfaction with Smoke Free ("I liked using the Smoke Free app"), reported on a 5-point Likert scale ranging from "Not at all" (score=1) to "Extremely" (score=5), (2) satisfaction with Inner Dragon ("I liked the dragon game"), reported on the same 5-point Likert scale, and the *tertiary outcome measures* of (3) rating of whether the person would recommend the assigned app to a friend on a 5-point Likert scale, (4) motivation to (stay) quit at the 8-week follow-up, reported on a 10-point scale from 0 (not at all motivated) to 10 (very motivated), and (5) digital therapeutic alliance, measured from the bonding and confidence subscales of the Mobile Agnew Relationship Measure, reported as a 16-point ordinal measure [42, 43].

Covariates

The screening questionnaire collected demographic information on age, gender (female, male, non-binary/other), race and ethnicity (recoded to non-Hispanic White, non-Hispanic Black, Hispanic, or other), household income category ($0-$19,999, $20,000-$39,999, $40,000-$59,999, $60,000-$79,999, $80,000-$99,999, $100,000 and more), and educational attainment (high school diploma and less, some college or technical school, bachelor's or associate degree, graduate degree). Smoking characteristics at screening included mean cigarettes per day, Fagerström Test for Nicotine Dependence (score of 0 to 10, where 10 is highly nicotine-dependent) [55], number of past quit attempts, years since initiated, use of ENDS in last 30 days (yes or no), use of NRT in last 30 days (yes or no). Baseline information also included frequency of video game usage (not at all, less than once a month, at least monthly but not weekly, at least weekly but not every day, every day).

Sample Size

Power calculations were based on an anticipated sample size of 500, with assumed 70% retention (as observed in other app-based smoking cessation trials) [13, 26]. We further anticipated a mean number of app sessions of 30.0 per participant and a standard deviation of 45.0 in the control group, based on data from past Smoke Free users provided to the study team by Smoke Free. A sample size of 500 participants with 70% retention was estimated to detect a between-group difference in app sessions, one of the primary outcomes, of 13.5 at 80% power (α=0.05).

Data Analysis

Main Analysis

The main analyses were conducted on an intent-to-treat basis using all randomized participants. For those outcomes measured continuously, including the two primary outcomes, we calculated the crude (unadjusted) difference in outcomes between each study group, using t-tests of the difference in means to assess statistical significance at the 5% level. For those outcomes measured categorically, we calculated the mean difference in proportions corresponding to the risk difference and used a similar approach to assess statistical significance. For the abstinence outcomes, the intent-to-treat approach implies that those lost to follow-up are assumed to have resumed smoking ("missing=smoking").

Outcome Trends

Next, we assessed visual changes over time in the number of users with a Smoke Free session, a key engagement outcome, and self-reported 1-day point-prevalence abstinence on an intent-to-treat basis (missing=smoking) and using complete cases. For each outcome, we plotted the mean for each study group by study day.

Intensity of Game Use

We assessed whether the intensity of game use was associated with more distal outcomes: total user engagement (total number of sessions), program adherence, and self-reported abstinence (at follow-up and repeated). This analysis, conducted among participants in the treated group only, entailed plotting estimates from local linear regressions of the number of sessions with game use on each of these outcomes, following the nonparametric approach proposed by Calonico and colleagues [56].

Sensitivity and Exploratory Analyses

We examined subgroup differences across study groups for the primary engagement outcomes, in which we evaluated heterogeneity by estimating a stratified model for each covariate.

We conducted covariate-adjusted regression analyses to assess the robustness of our findings. We estimated the difference in each outcome by study group using linear regressions for continuous outcomes and logistic regressions for binary outcomes. The models adjusted for a range of pre-specified potential confounders (described in the Covariates section above), including characteristics of participants' socio-demographic background, smoking history, and frequency of video game usage. Coefficients from the logistic regressions were expressed as risk differences, with an interpretation as a change in percentage points.

We repeated our abstinence analysis using complete case analysis that included only those participants who were successfully followed up. Whereas missing=smoking can lead to downward bias if loss to follow-up occurs for reasons other than relapse to smoking, complete case analysis may lead to upward bias if participants refuse to engage with follow-up because they have resumed smoking. As a further sensitivity analysis of the abstinence outcome, we estimated the treatment effect for self-reported 7-day point-prevalence abstinence from a pattern-mixture model that varied the informative missingness odds ratio between the outcome and an indicator for missingness, adjusting for covariates [57, 58].

Adverse Events

We tabulated the number of serious adverse events by type for each study group, as reported in an open-ended text field in the follow-up questionnaire.

Analyses were conducted in Stata, v18.0 (Stata Corporation, College Station, TX).

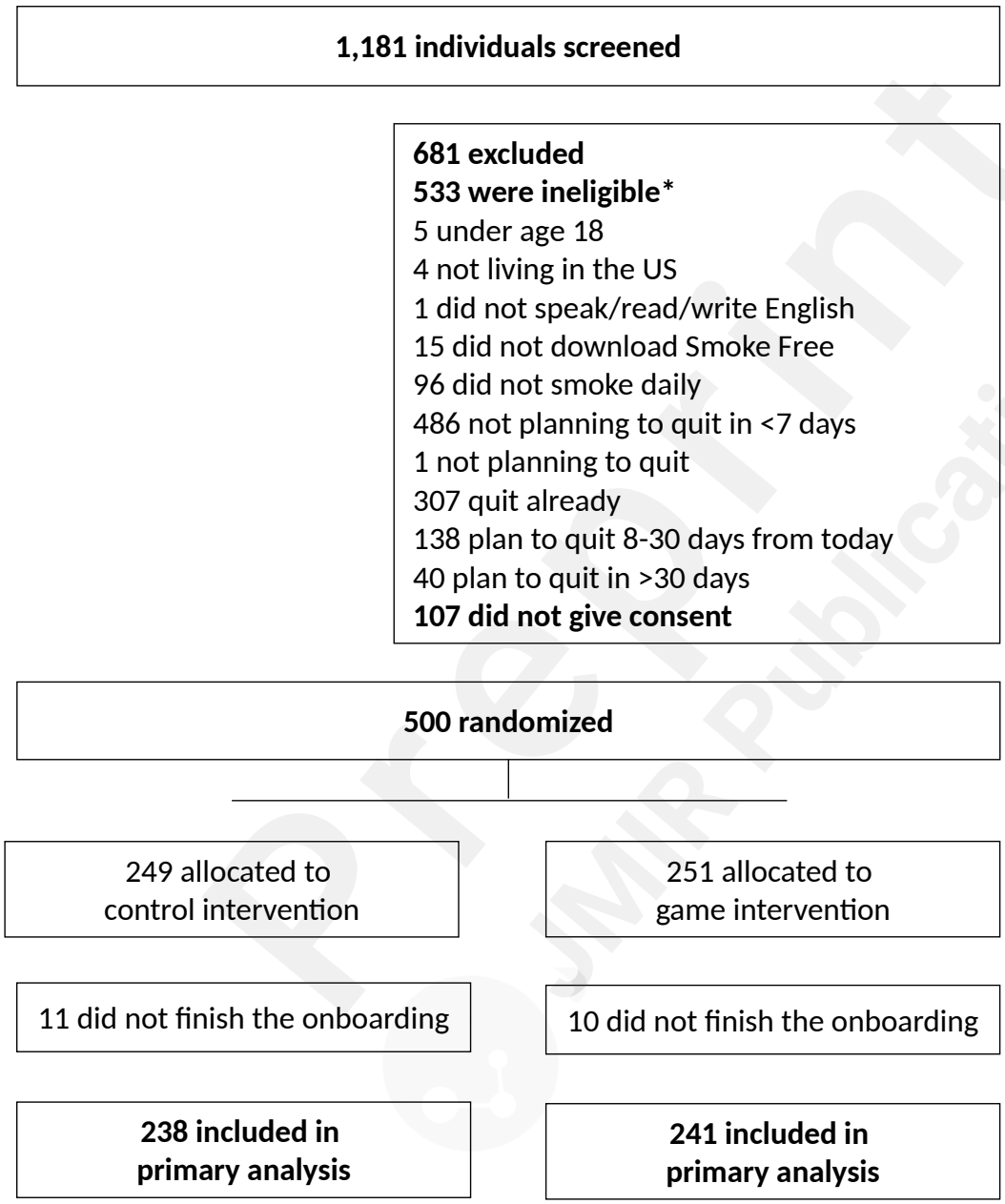
RESULTS

Sample Characteristics

Figure 1 shows the study flow diagram. We screened 1,181 new Smoke Free users from February 9, 2022 through March 16, 2022 to reach our goal of enrolling 500 eligible, consenting individuals for the RCT. Of the 500 randomized participants, 479 (96%, 238 treated, 241 control) opened Smoke

Free after completing the screening questionnaire, thereby completing the onboarding process within Smoke Free. This is the denominator used for the primary analyses.

Figure 1. Study flowchart



Note: *Individuals may be ineligible because of more than one factor. Individuals who did not finish the onboarding did not return to the app after the screening survey and did not learn their allocation group.

There was a 61% (292/479) response rate for the 8-week follow-up questionnaire (64% treated, 58% control), and a 71% (137/193) response rate for the saliva test (among those completing the follow-

up questionnaire and reported having quit within the prior 7 days), including 74% (73/99) of invited control participants and 68% (64/94) of invited treated participants. Non-response for the follow-up questionnaire and saliva test was unrelated to study group assignment, according to *t*-tests of the difference in means. However, response rates for the questionnaire and saliva test increased with number of app sessions, and the response rate for the saliva test was higher for non-Hispanic Black participants (48%) and lower for non-Hispanic White participants.

Demographic and smoking characteristics were balanced across study groups (Table 1, Table S1). Participants were drawn from 48 states across the US (26% Midwest, 19% Northeast, 33% South, 22% West). The median participant was 36 years old (IQR 29-47), with 20% (95/479) participants aged 50 or older due to the recruitment quota. Three-quarters of participants (358/479) identified as female. Most (368/479, 77%) were non-Hispanic White, with 10% (48/479) non-Hispanic Black or African American and 6% (28/479) Hispanic. Nearly 63% (300/479) had household income below $60,000, and 41% (198/479) had household income below 150% of the federal poverty level at the time. Most (277/479, 58%) did not hold a college degree. For smoking and gaming characteristics, participants were mostly moderate-to-heavy smokers (median of 15.0 cigarettes per day, IQR 10-20), had previously attempted to quit (median of 4 past attempts, IQR 2-9), and varied in terms of video game use during the prior 30 days (24% not at all, 34% every day).

Table 1. Characteristics of participants by study group

	Control (n = 238)	Treated (n = 241)	Total (N = 479)
Panel A. Demographics			
Age, median (IQR)	35 (28-47)	38 (29-47)	36 (29-47)
Gender, n (%)			
Female	181 (76%)	177 (73%)	358 (75%)
Male	55 (23%)	59 (24%)	114 (24%)
Non-binary/other	2 (1%)	5 (2%)	7 (1%)
Race and ethnicity, n (%)			
Non-Hispanic White	182 (76%)	186 (77%)	368 (77%)
Non-Hispanic Black	26 (11%)	22 (9%)	48 (10%)
Hispanic	9 (4%)	19 (8%)	28 (6%)
Other	21 (9%)	14 (6%)	35 (7%)
Household income, n (%)			
Less than $20,000	35 (15%)	35 (15%)	70 (15%)
$20,000 to $39,999	65 (27%)	63 (26%)	128 (27%)
$40,000 to $59,999	51 (21%)	51 (21%)	102 (21%)
$60,000 to $79,999	24 (10%)	32 (13%)	56 (12%)
$80,000 to $99,999	18 (8%)	21 (9%)	39 (8%)
$100,000 or more	45 (19%)	39 (16%)	84 (18%)
Education, n (%)			
High school diploma or less	55 (23%)	45 (19%)	100 (21%)
Some college or technical school	84 (35%)	93 (39%)	177 (37%)
Bachelor's or associate degree	68 (29%)	83 (34%)	151 (32%)
Graduate degree	31 (13%)	20 (8%)	51 (11%)
Panel B. Smoking characteristics			
Cigarettes per day, median (IQR)	15 (10-20)	15 (10-20)	15 (10-20)

	Control (n = 238)	Treated (n = 241)	Total (N = 479)
Fagerström Test, median (IQR)	5 (3-7)	5 (4-7)	5 (4-7)
Past quit attempts, median (IQR)	4 (2-8)	4 (2-9)	4 (2-9)
Years since initiated, median (IQR)	16 (10-28)	19 (11-29)	18 (10-29)
Used ENDS[a] in last 30 days, n (%)	61 (26%)	57 (24%)	118 (25%)
Used NRT[b] in last 30 days, n (%)	43 (18%)	56 (23%)	99 (21%)
Panel C. Other			
Frequency played video games, n (%)			
Not at all	59 (25%)	57 (24%)	116 (24%)
Less than once a month	25 (11%)	36 (15%)	61 (13%)
At least monthly but not weekly	25 (11%)	26 (11%)	51 (11%)
At least weekly but not every day	40 (17%)	49 (20%)	89 (19%)
Every day	89 (37%)	73 (30%)	162 (34%)

[a] ENDS: electronic nicotine delivery system.
[b] NRT: nicotine replacement therapy.

Main Intervention Effects

User Engagement

Compared with control participants, treated participants had 5.3 more sessions of Smoke Free app use during the 8 study weeks, although this difference in primary outcome was not statistically significant (mean 29.6, SD 36.5 vs. mean 24.3, SD 37.9; *P*=.06; Table 2). Treated participants used the app for more minutes per session than control participants (mean 6.9, SD 5.4 vs. 6.2, SD 5.2; *P*=.047, primary outcome) and had more days with an app session (mean 14.3, SD 15.3 vs. 13.3, SD 11.9; *P*=.03, secondary outcome). Overall, treated participants used the Inner Dragon game for an average of 7.1 days (SD 14.9), with some use of all game features (Table S2).

Program adherence, as measured by the number of times using certain core features in the original Smoke Free app, was greater for treated participants than control participants (mean 29.4, SD 41.3 vs. mean 22.6, SD 35.6; *P*=.03, tertiary outcome). The largest increase in core features for the treated group occurred for the number of diary entries completed (mean 12.1, SD 15.9 vs. mean 9.2, SD 13.2; *P*=.01, tertiary outcome), although use of all core features increased (Table 2).

Table 2. Differences in engagement, abstinence, and satisfaction by study group

	Control	Treated	Difference In means	p-value	No. obs.
Panel A. User engagement					
No. app sessions[a], mean (SD)	24.3 (37.9)	29.6 (36.5)	5.3	0.06	479
Minutes per session[a], mean (SD)	6.1 (5.2)	6.9 (5.4)	0.9	0.047	479
No. days with session, mean (SD)	11.9 (13.3)	14.3 (15.3)	2.5	0.03	479

No. game sessions, mean (SD)	–	7.1 (14.9)	–	–	241
Index of core feature use, mean (SD)	22.6 (35.6)	29.4 (41.3)	6.8	0.03	479
Use of core features, mean (SD)					
No. cravings reported	1.9 (4.1)	2.7 (5.0)	0.8	0.02	479
No. diary entries	9.2 (13.2)	12.1 (15.9)	3.0	0.01	479
No. missions completed	3.8 (8.8)	4.9 (10.2)	1.0	0.12	479
No. chatbot sessions	4.0 (9.9)	5.4 (11.5)	1.4	0.08	479
Index of game feature use, mean (SD)	–	112.9 (258.6)	–	–	241
Panel B. Point-prevalence abstinence					
7-day abstinence at 2 months, n (%)					
Self-reported, missing = smoking	101 (42.4%)	94 (39.0%)	-3.4	0.45	479
Self-reported, complete cases	101 (73.2%)	94 (61.0%)	-12.1	0.03	292
Verified[b], missing = smoking	54 (22.7%)	47 (19.5%)	-3.2	0.39	479
Verified[b], complete cases	54 (74.0%)	47 (73.4%)	-0.5	0.94	137
30-day abstinence at 2 months, n (%)					
Self-reported, missing = smoking	50 (21.0%)	54 (22.4%)	1.4	0.71	479
Self-reported, complete cases	50 (36.2%)	54 (35.1%)	-1.2	0.84	292
Mean repeated 1-day abstinence, mean (SD)					
Self-reported, missing = smoking	12.4% (21.3)	17.3% (25.6)	4.9	0.01	479
Self-reported, complete cases	55.0% (42.8)	65.0% (39.0)	10.0	0.01	401
Panel C. Satisfaction and motivation					
Satisfaction with app[c], mean (SD)	3.7 (1.1)	3.7 (1.0)	-0.0	0.91	271
Satisfaction with game[d], mean (SD)	–	3.3 (1.4)	–	–	84
Recommend app to friends[e], mean (SD)	4.0 (1.1)	3.8 (1.1)	-0.2	0.20	271
Motivation to (stay) quit, mean (SD)	9.4 (1.5)	9.3 (1.3)	-0.0	0.87	144
Digital therapeutic alliance, mean (SD)	12.9 (2.4)	12.7 (2.2)	-0.2	0.75	268

Note: The p-value is derived from a t-test of the crude (unadjusted) difference in means between the treated and control group. The number of observations (rightmost column) varies by outcome based on whether it was collected passively or in the follow-up survey, as well as whether it applies to all participants or treated participants only.

[a] Denotes a primary outcome measure.

[b] Codes those who self-reported abstinence but reported use of nicotine replacement therapy or vaping products within last 7 days as abstinent.

[c] "I liked using the Smoke Free app" on Likert scale from “not at all” (1) to “extremely” (5).

[d] "I liked Inner Dragon" on Likert scale from “not at all” (1) to “extremely” (5).

[e] "I would recommend the Smoke Free App to a friend who wants to quit” on Likert scale from “not at all” (1) to “extremely” (5).

Smoking Abstinence

Self-reported 7-day point-prevalence abstinence on an intent-to-treat basis (assuming missing=smoking) was 39.0% (94/241) for the treated group and 42.4% (101/238) for the control group (difference -3.4 percentage points [pp]; *P*=.45, secondary outcome). The difference widened when considering complete cases only, such that 61.0% (94/154) abstained in the treated group and 73.2% (101/138) in the control group (difference -12.1 pp; *P*=.03).

Verified 7-day point-prevalence abstinence at 2-months similarly showed no advantage for the treated group, such that the intent-to-treat estimates were 19.5% (47/241) in the treated group and 22.7% (54/238) in the control group (difference -3.2 pp; *P*=.39). This included 20 in the treated

group and 19 in the control group who were coded abstinent because they reported having used NRT or ENDS within the prior 7 days at the 2-month follow-up. Self-reported 30-day point-prevalence abstinence at 2 months was similar among the treated group (22.4%, 54/241) and the control group (21.0%, 50/238) on an intent-to-treat basis (difference 1.4 pp; *P*=.71, secondary outcome).

Self-reported mean repeated 1-day abstinence was higher for the treated group (17.3%, SD 25.6) than for the control group (12.4%, SD 21.3) on an intent-to-treat basis (difference 4.9 pp; *P*=.01) and among complete cases (difference 10.0 pp; *P*=.01, tertiary outcome).

Satisfaction and Motivation

Satisfaction with the Smoke Free app on a 5-point Likert scale (1=not at all, 5=extremely) did not differ by study group among those who completed the follow-up questionnaire (mean 3.7, SD 1.1 treated group vs. mean 3.7, SD 1.0 control group; *P*=.91, secondary outcome). Additional questions regarding satisfaction with the app were also similar between study groups (Figure S2). Satisfaction with the Inner Dragon game (mean 3.3, SD 1.4) was a bit lower in the treated group than for the app overall.

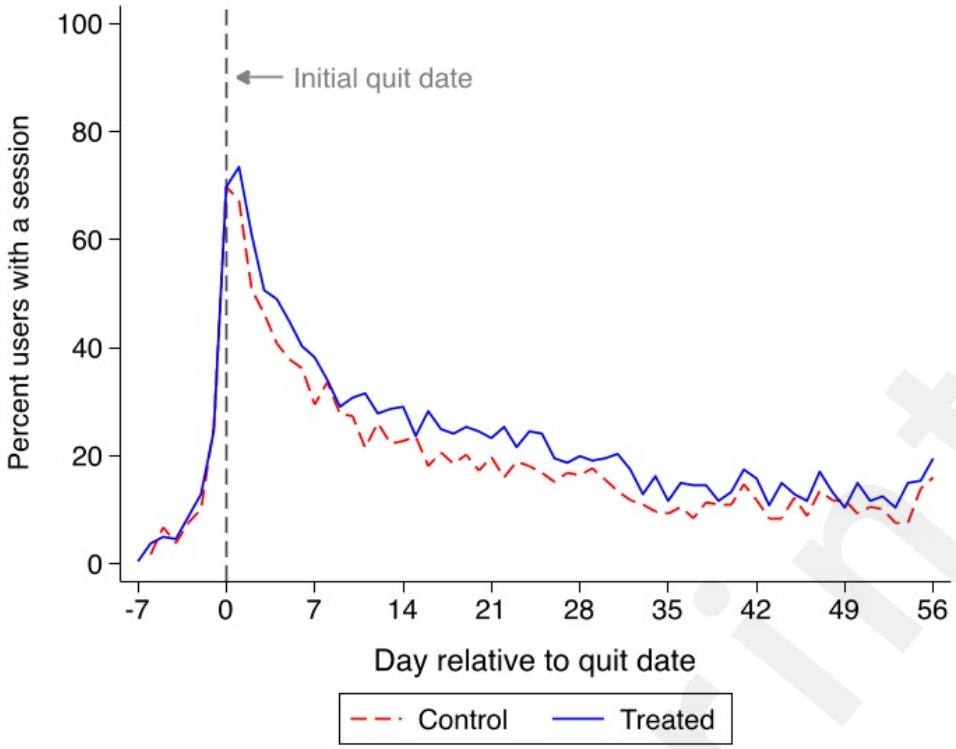
Motivation to (stay) quit at follow-up, measured on a 10-point scale (0=not at all motivated, 10= very motivated), did not differ significantly (mean 9.3, SD 1.3 treated group vs. mean 9.3, SD 1.3 control group; *P*=.87, tertiary outcome); however, a Qualtrics programming error led to missing data for 139 respondents who reported having continued to smoke. Digital therapeutic alliance also did not differ by study group at follow-up (mean 12.7, SD 2.2 treated group vs. mean 12.9, SD 2.4 control group; *P*=.75).

Outcome Trends

Days with any app sessions decreased for both study groups over time, from roughly 80% on the person's quit day to roughly 20% on Day 56 (Figure 2). The treated group retained slightly increased usage throughout this period.

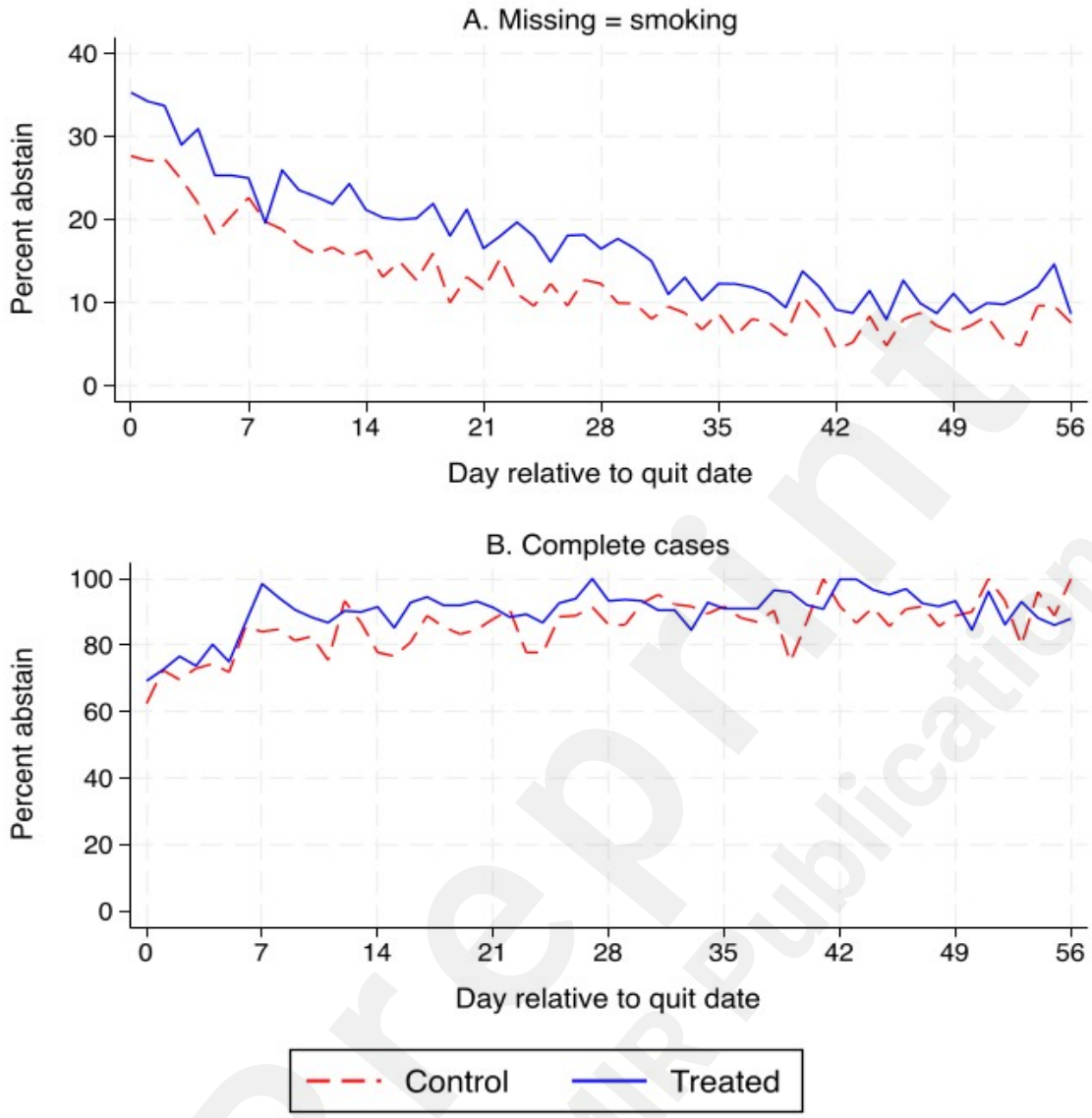
While the share of participants reporting having abstained the prior day decreased for both study groups, the treated group retained its advantage over the control group throughout the study period when analyzing the data on an intent-to-treat basis (Figure 3A). When analyzing complete cases only, we observe that the percentage reporting having abstained remained high throughout the study period and the magnitude of the difference between study groups was not as great as when assuming missing=smoking (Figure 3B).

Figure 2. Percent participants with any sessions by day



Note: This figure shows the percentage of participants with any Smoke Free session by study day (N = 479).

Figure 3. Self-reported repeated 1-day point-prevalence abstinence by day and study group

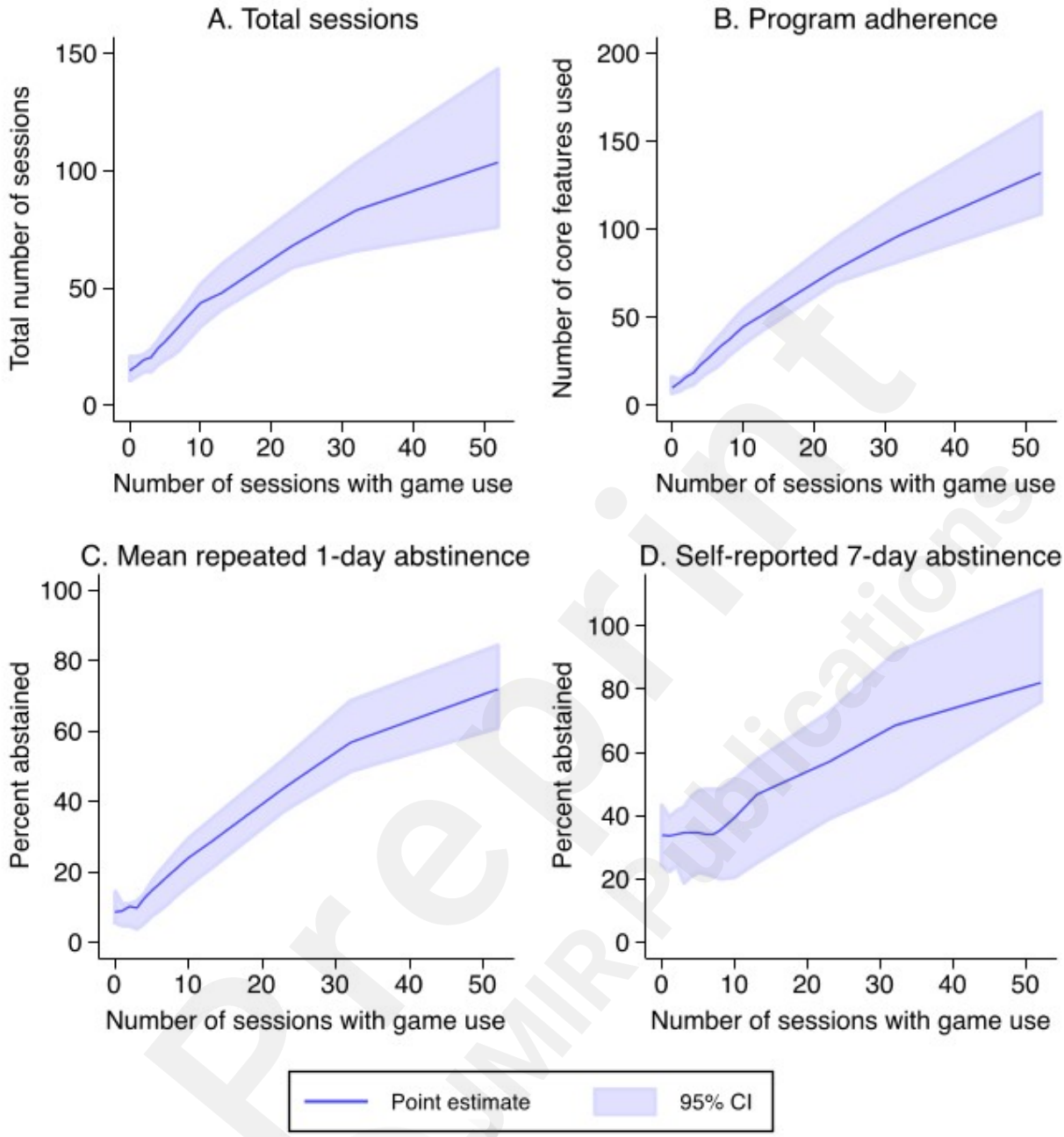


Note: This figure shows the percentage of participants who abstained from smoking according to self-reports from the daily pop-up message. Panel A assumes that missing reports are current smokers, and Panel B uses complete cases only.

Intensity of Game Use

Treated participants who had more sessions of game use had more app sessions overall, a mechanical relationship. More game use was also associated with increased program adherence, increased mean repeated 1-day abstinence, and 7-day abstinence at follow-up (Figure 4). A one standard deviation in sessions of game use (from 0 to 15 game sessions) was associated with a 4-fold increase in program adherence and an increase in self-reported 7-day point-prevalence abstinence at follow-up of 12.9 percentage points (from 33.8% to 46.7%).

Figure 4. Association of intensity of game use with selected outcomes



Note: The plot shows the relationship between intensity of game use, as measured by number of sessions with game use, and several outcome variables: A) total number of sessions, B) program adherence, as measured by total number of core features used, C) mean self-reported repeated 1-day abstinence (i.e., during the prior day), assuming missing=smoking, and D) self-reported 7-day point-prevalence abstinence, assuming missing=smoking. Estimates are derived from local linear regression with mean squared error-optimal bandwidth and 30 evaluation points. The shaded area denotes the 95% CI, calculated from a heteroskedasticity-robust nearest neighbor variance estimator with 3 neighbors.

Sensitivity Analyses

Subgroup Analyses

The effects of Inner Dragon on user engagement did not significantly vary with participant characteristics, according to subgroup analyses, although certain patterns emerged (Figure S5). In unadjusted analyses, the treatment effect on total number of app sessions was larger for younger participants (age <50) and non-Hispanic White participants compared with non-Hispanic Black or Hispanic participants, and decreased with household income. Further, the effects were greater for those with low nicotine dependence, fewer (<4) past quit attempts, and use of e-cigarettes in the last 30 days. Intervention effects did not vary by video gaming history.

Covariate-Adjusted Analyses

Adjusting for participant characteristics (listed in Table 1) as covariates, the differences in user engagement outcomes by study group were similar to, but slightly smaller in magnitude than, the crude differences for number of app sessions (4.6, 95% CI -2.2 to 11.3; *P*=.18), average minutes per session (0.8, 95% CI -0.2 to 1.9; *P*=.11), days with a session (2.2, 95% CI -0.4 to 4.7; *P*=.10), and program adherence (6.6, 95% CI -0.4 to 13.6; *P*=0.06; Table S3). The effect sizes for self-reported and verified 7-day and self-reported 30-day point-prevalence abstinence remained similar to the crude differences in magnitude. Estimates, on an intent-to-treat basis, were -2.4 pp (95% CI -11.1 to 6.4; *P*=.60) for self-reported 7-day abstinence, -2.7 pp (95% CI -10.0 to 4.6; *P*=.47) for verified 7-day abstinence, and 1.4 pp (95% CI -6.0 to 8.9; *P*=.70) for self-reported 30-day abstinence. Mean repeated 1-day abstinence remained higher for the treated group than the control group (4.5 pp, 95% CI 0.2 to 8.7; *P*=.04) on an intent-to-treat basis (Table S3).

Sensitivity of Abstinence Estimates

Results from the pattern-mixture model indicated that the treatment effect estimates for abstinence were highly sensitive to assumptions about the nature of the missing outcomes (Figure S1). Assuming missingness is random (equivalent to missing=smoking), there would be no difference in abstinence between groups, whereas assuming informative missingness, there would be reduced abstinence in the treated group compared with the control group.

Adverse Events

There were no serious adverse events reported during the trial. In total, 1.2% (3/241) reported adverse events in the treated group and 2.9% (7/239) in the control group. Adverse events were: feelings of withdrawal, craving, or irritability (1 report in treated group, 4 in control group), being anxious or depressed (1 in treated group, 3 in control group), and constipation (1 in treated group, 0 in control group).

DISCUSSION

Principal Findings

Our RCT assessed the efficacy of the novel Inner Dragon game module integrated into the Smoke Free app for promoting user engagement. The study of 479 participants revealed that treated individuals exhibited some increased user engagement metrics, including a (non-significant) 21.8%

increase in the number of app sessions and a significant 20.2% increase in days of app use. Engaging with Inner Dragon led treated users to use core features of the original Smoke Free app significantly (30.1%) more often, and this increase in smoking cessation program adherence implies that game use complemented ("crowded in") rather than replaced ("crowded out") use of the non-game content. User engagement is a fundamental concern for mHealth apps [59-61], and our findings support the role of gamification as a key driver of user engagement.

Smoking abstinence outcomes showed a nuanced picture, with self-reported 7-day point-prevalence abstinence favoring the control group and repeated 1-day abstinence favoring the treated group. In exploratory analyses, we found that this difference was driven in part by treated participants with missing abstinence data having much higher mean repeated abstinence than control participants with missing data (54.5% vs. 35.4%, difference 19.1 pp; *P*=.01). Nevertheless, improving user engagement and program adherence metrics did not definitively produce higher smoking abstinence rates in this trial. One possibility is that gamifying the quit process may have undermined participants' focus on the higher purpose of quitting smoking. Further research into features of the game, user characteristics, and the original app may be warranted to understand the relationship between user engagement and smoking abstinence.

Finally, the study found a positive association between the intensity of game use and both program adherence and smoking abstinence, suggesting that game-driven engagement may support downstream outcomes.

Comparison with Previous Studies

In the context of the existing literature on smartphone apps for smoking cessation, our findings align with studies emphasizing the importance of user engagement in digital interventions [59-61]. Notably, the increased engagement observed in our study was associated with positive outcomes such as greater program adherence in the form of higher core feature use. To our knowledge, the link between user engagement and program adherence has not been explored with regards to games for smoking cessation, in part because previously evaluated games have been standalone products [62].

We found some evidence of effect modification, such that user engagement was greater for younger and lower-income users. Our results echo the call for personalized interventions, consistent with research suggesting the impact of individual characteristics on engagement and outcomes in digital health interventions [63]. Further, our exploration of gamification elements in the Inner Dragon game aligns with literature highlighting the potential of gaming features to enhance engagement and promote behavior change in smoking cessation apps [62]. Prior studies of smartphone-based games for smoking cessation have found mixed evidence regarding smoking abstinence [26, 30, 32, 64], although study quality in the broader literature has generally been deemed fair or poor with important methodological limitations [64].

Our study supports the integration of personalized strategies such as games in digital interventions, tailored to individual characteristics and broadly appealing to users with different motivations (e.g., achievement, socializing, immersion), to optimize user engagement and intervention effectiveness. Emerging capabilities of artificial intelligence may facilitate this process [65].

Strengths and Limitations

The study has important strengths. First, this study is one of the largest randomized trials of a smartphone-based intervention involving games or gamification for smoking cessation. Second, it is, to our knowledge, the first to assess a game that is integrated into an existing smoking cessation app. By integrating Inner Dragon into one of the most downloaded smoking cessation apps that also has established effectiveness, we were able to evaluate the added benefit of the game module for user engagement. The game intervention can be readily scaled to the 800,000 users who download Smoke Free each year; Inner Dragon is planned to become available to general users of Smoke Free starting in 2024. Third, passive collection of usage data ensured that our primary outcome data were complete, accurate, and able to be tracked longitudinally. Fourth, the availability of high-frequency, longitudinal abstinence data was unique for studies of smoking cessation games and uncommon for studies of smoking cessation interventions more generally [66].

The study has several limitations. First, the short-term follow-up limits our ability to assess sustained abstinence outcomes. Second, the generalizability of our findings may be constrained by the demographic composition of the app-recruited study population. It is noteworthy that our study drew from a general population of users of the Smoke Free app, a diverse user base in a real-world context. Yet, the use of the Smoke Free app may not be representative of all smoking cessation apps, and the rapidly evolving landscape of digital interventions may influence the generalizability of our findings over time. Third, our game intervention includes a bundle of interlocking features, and we cannot disentangle their individual effects. Fourth, while our study was adequately powered for our primary outcomes, we may have been underpowered for some secondary outcomes such as smoking abstinence, as well as for subgroup analyses.

Conclusions

In conclusion, our study contributes valuable insights to the growing body of literature on digital smoking cessation interventions involving serious games, emphasizing the role of user engagement. The positive associations between game use with program adherence and smoking cessation outcomes underscore the potential of gamification interventions in promoting behavior change. Future research should extend follow-up durations, refine personalized interventions, evaluate effectiveness in a real-world setting, and address methodological challenges such as missing data to guide the development of evidence-based digital health interventions for smoking cessation.

ACKNOWLEDGEMENTS

The authors would like to thank Keith McCullough and his team at Workinman Interactive, LLC, which contributed to the game design and provided artwork for Inner Dragon. Adam MacLean, Elena McGahey, Giselle Edwards, Pallavi Chaudhary, and Janardan Devkota provided valuable research assistance. This study was supported by funding from the National Cancer Institute (R21 CA238301); National Institute of Aging (P30 AG012839); Center on the Economics and Demography of Aging at the University of California, Berkeley; and Hellman Fellows Fund. The content is solely the responsibility of the authors and does not necessarily represent the official views

of the National Institutes of Health or the US government.

CONFLICTS OF INTEREST

BR is founder of Re-Connect Health, Inc., a company that develops mobile apps for health behavior change. CL was a Visiting Researcher at Google during the preparation of this manuscript. DC is the founder and CEO of the Smoke Free app, EW is the CTO, both derive income from it. LA receives royalties for the sale of Text2Quit, a quit smoking program. JT reports membership on the scientific advisory board of MindCotine, Inc, which offers a smoking cessation program. This arrangement has been reviewed and approved by the Johns Hopkins University in accordance with its conflicts of interest policies. All other authors declare no other conflicts of interest.

REFERENCES

1. US Department of Health and Human Services. The health consequences of smoking—50 years of progress: A report of the Surgeon General. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.
2. Babb S. Quitting smoking among adults—United States, 2000–2015. MMWR Morbidity and Mortality Weekly Report. 2017;65.
3. Organization. USNCIaWH. The Economics of Tobacco and Tobacco Control. In: 16-CA-8029A NCITCMNPN, editor. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; and Geneva, CH: World Health Organization; 2016.
4. Rafful C, García-Rodríguez O, Wang S, Secades-Villa R, Martínez-Ortega JM, Blanco C. Predictors of quit attempts and successful quit attempts in a nationally representative sample of smokers. Addict Behav. 2013;38(4):1920-3.
5. Abroms LC, Lee Westmaas J, Bontemps-Jones J, Ramani R, Mellerson J. A content analysis of popular smartphone apps for smoking cessation. Am J Prev Med. 2013 12;45(6):732--6. doi: http://dx.doi.org/10.1016/j.amepre.2013.07.008.
6. Pew Research Center. Mobile Fact Sheet2021 May 2, 2022. Available from: https://www.pewresearch.org/internet/fact-sheet/mobile/.
7. Chu KH, Matheny SJ, Escobar-Viera CG, Wessel C, Notier AE, Davis EM. Smartphone health apps for tobacco cessation: A systematic review. Addict Behav. 2021 Jan;112:106616. PMID: 32932102. doi: 10.1016/j.addbeh.2020.106616.
8. Bricker JB, Mull KE, Kientz JA, Vilardaga R, Mercer LD, Akioka KJ, Heffner JL. Randomized, controlled pilot trial of a smartphone app for smoking cessation using acceptance and commitment therapy. Drug Alcohol Depend. 2014;143(0):87 - 94. doi: http://dx.doi.org/10.1016/j.drugalcdep.2014.07.006.
9. Ubhi HK, Michie S, Kotz D, Wong WC, West R. A mobile app to aid smoking cessation: preliminary evaluation of SmokeFree28. J Med Internet Res. 2015;17(1).
10. Bricker JB, Copeland W, Mull KE, Zeng EY, Watson NL, Akioka KJ, Heffner JL. Single-arm trial of the second version of an acceptance & commitment therapy smartphone application for smoking cessation. Drug Alcohol Depend. 2017;170:37-42.

11. Iacoviello BM, Steinerman JR, Klein DB, Silver TL, Berger AG, Luo SX, Schork NJ. Clickotine, a personalized smartphone app for smoking cessation: initial evaluation. JMIR mHealth uHealth. 2017;5(4).
12. BinDhim NF, McGeechan K, Trevena L. Smartphone Smoking Cessation Application (SSC App) trial: a multicountry double-blind automated randomised controlled trial of a smoking cessation decision-aid 'app'. BMJ open. 2018;8(1):e017105.
13. Krebs P, Burkhalter J, Fiske J, Snow H, Schofield E, Iocolano M, et al. The QuitIT Coping Skills Game for Promoting Tobacco Cessation Among Smokers Diagnosed With Cancer: Pilot Randomized Controlled Trial. JMIR mHealth uHealth. 2019;7(1):e10071. PMID: 30632971. doi: 10.2196/10071.
14. Marler JD, Fujii CA, Utley DS, Tesfamariam LJ, Galanko JA, Patrick H. Initial Assessment of a Comprehensive Digital Smoking Cessation Program That Incorporates a Mobile App, Breath Sensor, and Coaching: Cohort Study. JMIR mHealth uHealth. 2019;7(2):e12609. PMID: 30670372. doi: 10.2196/12609.
15. van den Brand FA, Nagelhout GE, Winkens B, Chavannes NH, van Schayck OC. Effect of a workplace-based group training programme combined with financial incentives on smoking cessation: A cluster-randomised controlled trial. The Lancet Public Health. 2018. doi: http://dx.doi.org/10.1016/S2468-2667(18)30185-3.
16. Paige SR, Alber JM, Stellefson ML, Krieger JL. Missing the mark for patient engagement: mHealth literacy strategies and behavior change processes in smoking cessation apps. Patient Educ Couns. 2018 2018/05/01/;101(5):951-5. doi: https://doi.org/10.1016/j.pec.2017.11.006.
17. Cafazzo AJ, Casselman M, Hamming N, Katzman KD, Palmert RM. Design of an mHealth app for the self-management of adolescent type 1 diabetes: A pilot study. J Med Internet Res. 2012 May;14(3):e70. doi: 10.2196/jmir.2058.
18. Primack BA, Carroll MV, McNamara M, Klem ML, King B, Rich M, et al. Role of video games in improving health-related outcomes. Am J Prev Med. 2012;42(6):630--8.
19. King D, Greaves F, Exeter C, Darzi A. `Gamification': Influencing health behaviours with games. J R Soc Med. 2013;106(3):76-8. doi: 10.1177/0141076813480996.
20. Looyestyn J, Kernot J, Boshoff K, Ryan J, Edney S, Maher C. Does gamification increase engagement with online programs? A systematic review. PLoS One. 2017;12(3):e0173403. doi: 10.1371/journal.pone.0173403.
21. Richardson A, Graham LA, Cobb N, Xiao H, Mushro A, Abrams D, Vallone D. Engagement Promotes Abstinence in a Web-based Cessation Intervention: Cohort Study. J Med Internet Res. 2013;15(1):e14. doi: 10.2196/jmir.2277.
22. Raiff BR, Jarvis BP, Rapoza D. Prevalence of video game use, cigarette smoking, and acceptability of a video game–based smoking cessation intervention among online adults. Nicotine Tob Res. 2012;14(12):1453-7.
23. Oliver JA, Hallyburton MB, Pacek LR, Mitchell JT, Vilardaga R, Fuemmeler BF, Joseph McClernon F. What do smokers want in a smartphone-based cessation application? Nicotine Tob Res. 2018.
24. Edwards EA, Caton H, Lumsden J, Rivas C, Steed L, Pirunsarn Y, et al. Creating a Theoretically Grounded, Gamified Health App: Lessons From Developing the Cigbreak Smoking Cessation Mobile Phone Game. JMIR serious games. 2018;6(4).
25. Baskerville NB, Struik LL, Dash D. Crush the Crave: Development and Formative Evaluation of a Smartphone App for Smoking Cessation. JMIR mHealth uHealth. 2018;6(3):e52. PMID: 29500157. doi: 10.2196/mhealth.9011.
26. Baskerville NB, Struik LL, Guindon GE, Norman CD, Whittaker R, Burns C, et al. Effect of a Mobile Phone Intervention on Quitting Smoking in a Young Adult Population of Smokers:

Randomized Controlled Trial. JMIR mHealth uHealth. 2018;6(10):e10893-e.
27. Raiff BR, Fortugno N, Scherlis DR, Rapoza D. A Mobile Game to Support Smoking Cessation: Prototype Assessment. JMIR Serious Games. 2018;6(2):e11. doi: 10.2196/games.9599.
28. Krebs P, Burkhalter JE, Snow B, Fiske J, Ostroff JS. Development and alpha testing of QuitIT: an interactive video game to enhance skills for coping with smoking urges. JMIR research protocols. 2013;2(2).
29. Bindoff I, de Salas K, Peterson G, Ling T, Lewis I, Wells L, et al. Quittr: The Design of a Video Game to Support Smoking Cessation. JMIR Serious Games. 2016;4(2).
30. Bindoff I, Ling TR, Gee P, Geelan B, Ferguson SG, Peterson GM. Effects of a Mobile App Called Quittr, Which Utilizes Premium Currency and Games Features, on Improving Engagement With Smoking Cessation Intervention: Pilot Randomized Controlled Trial. JMIR Serious Games. 2020;8(4):e23734. PMID: 33315016. doi: 10.2196/23734.
31. Marin-Gomez FX, Garcia-Moreno Marchán R, Mayos-Fernandez A, Flores-Mateo G, Granado-Font E, Barrera Uriarte ML, et al. Exploring Efficacy of a Serious Game (Tobbstop) for Smoking Cessation During Pregnancy: Randomized Controlled Trial. JMIR Serious Games. 2019;7(1):e12835. PMID: 30916655. doi: 10.2196/12835.
32. Pallejà-Millán M, Rey-Reñones C, Barrera Uriarte ML, Granado-Font E, Basora J, Flores-Mateo G, Duch J. Evaluation of the Tobbstop Mobile App for Smoking Cessation: Cluster Randomized Controlled Clinical Trial. JMIR mHealth uHealth. 2020;8(6):e15951. PMID: 32589153. doi: 10.2196/15951.
33. Jackson SE, Kale D, Beard E, Perski O, West R, Brown J. Effectiveness of the offer of the Smoke Free smartphone application compared with no intervention for smoking cessation: A pragmatic randomised controlled trial. medRxiv2023. p. 2023.01.12.23284463.
34. Crane D, Ubhi HK, Brown J, West R. Relative effectiveness of a full versus reduced version of the `Smoke Free' mobile application for smoking cessation: an exploratory randomised controlled trial [version 2; peer review: 2 approved]. F1000Research. 2019;7(1524). doi: 10.12688/f1000research.16148.2.
35. Jackson SE, Perski O, Crane D, Michie S, West R, Brown J. Effectiveness of an offer of the Smoke Free smartphone application for smoking cessation: protocol for a randomized controlled trial. Addiction. 2019 Nov;114(11):2078-86. PMID: 31083767. doi: 10.1111/add.14652.
36. White JS, Salem MK, Toussaert S, Westmaas JL, Raiff BR, Crane D, et al. Developing a Game (Inner Dragon) Within a Leading Smartphone App for Smoking Cessation: Design and Feasibility Evaluation Study. JMIR Serious Games. 2023;11:e46602. PMID: 37566442. doi: 10.2196/46602.
37. Eldridge S, Chan C, Campbell M, Bond C, Hopewell S, Thabane L, Lancaster G. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239-i.
38. Ubhi HK, Michie S, Kotz D, van Schayck OCP, Selladurai A, West R. Characterising smoking cessation smartphone applications in terms of behaviour change techniques, engagement and ease-of-use features. Transl Behav Med. 2015;6(3):410-7. doi: 10.1007/s13142-015-0352-x.
39. Perski O, Crane D, Beard E, Brown J. Does the addition of a supportive chatbot promote user engagement with a smoking cessation app? An experimental study. Digital Health. 2019;5:2055207619880676. PMID: 31620306. doi: 10.1177/2055207619880676.
40. Bylieva D, Almazova N, Lobatyuk V, Rubtsova A, editors. Virtual Pet: Trends of Development. 2020; Cham: Springer International Publishing.
41. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. Am Psychol. 2000;55(1):68.
42. D'Alfonso S, Lederman R, Bucci S, Berry K. The Digital Therapeutic Alliance and Human-Computer Interaction. JMIR Mental Health. 2020;7(12):e21895.

43. Berry K, Salter A, Morris R, James S, Bucci S. Assessing Therapeutic Alliance in the Context of mHealth Interventions for Mental Health Problems: Development of the Mobile Agnew Relationship Measure (mARM) Questionnaire. J Med Internet Res. 2018;20(4):e90. PMID: 29674307. doi: 10.2196/jmir.8252.
44. Chaloupka FJIV, Levy MR, White JS. Estimating Biases in Smoking Cessation: Evidence from a Field Experiment. National Bureau of Economic Research Working Paper Series. 2019;No. 26522. doi: 10.3386/w26522.
45. Goldin J, Homonoff T. Smoke Gets in Your Eyes: Cigarette Tax Salience and Regressivity. American Economic Journal: Economic Policy. 2013;5(1):302-36. doi: 10.1257/pol.5.1.302.
46. Roll JM, Higgins ST. A within-subject comparison of three different schedules of reinforcement of drug abstinence using cigarette smoking as an exemplar. Drug Alcohol Depend. 2000 2000/02/01/;58(1):103-9. doi: https://doi.org/10.1016/S0376-8716(99)00073-3.
47. Shen L, Fishbach A, Hsee CK. The Motivating-Uncertainty Effect: Uncertainty Increases Resource Investment in the Process of Reward Pursuit. Journal of Consumer Research. 2014;41(5):1301-15. doi: 10.1086/679418.
48. Golman R, Loewenstein G, Molnar A, Saccardo S. The Demand for, and Avoidance of, Information. Management Science. 2022;68(9):6454-76. doi: 10.1287/mnsc.2021.4244.
49. Buechel EC, Li R. Mysterious Consumption: Preference for Horizontal (vs. Vertical) Uncertainty and the Role of Surprise. Journal of Consumer Research. 2022;49(6):987-1013. doi: 10.1093/jcr/ucac039.
50. Meeker D, Linder JA, Fox CR, al e. Effect of behavioral interventions on inappropriate antibiotic prescribing among primary care practices: A randomized clinical trial. JAMA. 2016;315(6):562-70. doi: 10.1001/jama.2016.0275.
51. Allcott H, Rogers T. The Short-Run and Long-Run Effects of Behavioral Interventions: Experimental Evidence from Energy Conservation. Am Econ Rev. 2014;104(10):3003-37. doi: 10.1257/aer.104.10.3003.
52. Yee N. Motivations for Play in Online Games. CyberPsychology & Behavior. 2006;9(6):772-5. PMID: 17201605. doi: 10.1089/cpb.2006.9.772.
53. West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. Addiction. 2005;100(3):299-303.
54. Benowitz NL, Bernert JT, Foulds J, Hecht SS, Jacob P, Jarvis MJ, et al. Biochemical Verification of Tobacco Use and Abstinence: 2019 Update. Nicotine Tob Res. 2020 Jun 12;22(7):1086-97. PMID: 31570931. doi: 10.1093/ntr/ntz132.
55. Heatherton TF, Kozlowski LT, Frecker RC, Fagerström K-O. The Fagerström test for nicotine dependence: a revision of the Fagerstrom Tolerance Questionnaire. Br J Addict. 1991;86(9):1119-27.
56. Calonico S, Cattaneo MD, Farrell MH. On the Effect of Bias Estimation on Coverage Accuracy in Nonparametric Inference. J Am Stat Assoc. 2018 2018/04/03;113(522):767-79. doi: 10.1080/01621459.2017.1285776.
57. White IR, Horton NJ, Carpenter J, statistics rim, social, Pocock SJ. Strategy for intention to treat analysis in randomised trials with missing outcome data. BMJ. 2011;342:d40. doi: 10.1136/bmj.d40.
58. White IR, Carpenter J, Horton NJ. A mean score method for sensitivity analysis to departures from the missing at random assumption in randomised trials. Stat Sin. 2018 Oct;28(4):1985-2003. PMID: 30283213. doi: 10.5705/ss.202016.0308.
59. Amagai S, Pila S, Kaat AJ, Nowinski CJ, Gershon RC. Challenges in Participant Engagement and Retention Using Mobile Health Apps: Literature Review. J Med Internet Res. 2022;24(4):e35120. PMID: 35471414. doi: 10.2196/35120.

60. Meyerowitz-Katz G, Ravi S, Arnolda L, Feng X, Maberly G, Astell-Burt T. Rates of Attrition and Dropout in App-Based Interventions for Chronic Disease: Systematic Review and Meta-Analysis. J Med Internet Res. 2020;22(9):e20283. PMID: 32990635. doi: 10.2196/20283.
61. Baumel A, Muench F, Edan S, Kane JM. Objective User Engagement With Mental Health Apps: Systematic Search and Panel-Based Usage Analysis. J Med Internet Res. 2019;21(9):e14567. PMID: 31573916. doi: 10.2196/14567.
62. Derksen ME, van Strijp S, Kunst AE, Daams JG, Jaspers MWM, Fransen MP. Serious games for smoking prevention and cessation: A systematic review of game elements and game effects. J Am Med Inform Assoc. 2020;27(5):818-33. doi: 10.1093/jamia/ocaa013.
63. Perski O, Blandford A, West R, Michie S. Conceptualising engagement with digital behaviour change interventions: a systematic review using principles from critical interpretive synthesis. Transl Behav Med. 2016;7(2):254-67. doi: 10.1007/s13142-016-0453-1.
64. Rajani NB, Bustamante L, Weth D, Romo L, Mastellos N, Filippidis FT. Engagement With Gamification Elements in a Smoking Cessation App and Short-term Smoking Abstinence: Quantitative Assessment. JMIR Serious Games. 2023;11:e39975. PMID: 36724003. doi: 10.2196/39975.
65. Hassoon A, Baig Y, Naiman DQ, Celentano DD, Lansey D, Stearns V, et al. Randomized trial of two artificial intelligence coaching interventions to increase physical activity in cancer survivors. npj Digital Medicine. 2021 2021/12/09;4(1):168. doi: 10.1038/s41746-021-00539-9.
66. Businelle MS, Ma P, Kendzor DE, Frank SG, Wetter DW, Vidrine DJ. Using Intensive Longitudinal Data Collected via Mobile Phone to Detect Imminent Lapse in Smokers Undergoing a Scheduled Quit Attempt. J Med Internet Res. 2016;18(10):e275. PMID: 27751985. doi: 10.2196/jmir.6307.

Supplementary Files

Multimedia Appendixes

Supplementary Appendix.
URL: http://asset.jmir.pub/assets/eeda0cc2f3c91991d9587050b599031d.docx

Study protocol.
URL: http://asset.jmir.pub/assets/93398e965fd03e0334fd61a708a7a030.pdf

CONSORT (or other) checklists

CONSORT checklist.
URL: http://asset.jmir.pub/assets/f1651009a550bb69caff7b1a5eab8ec9.pdf