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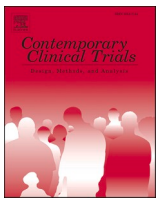

Using augmented reality to deliver cue exposure treatment for smoking cessation: App usability findings and protocol for a randomized controlled trial

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ABSTRACT

Background: Augmented Reality (AR) is a rapidly developing technology with potential utility for treating addictive behaviors, including tobacco smoking. AR inserts digital images into a natural real-time scene as viewed on a smartphone or other video devices. With respect to smoking cessation, AR can place virtual smoking cues (i.e., smoking "triggers") within an individual's natural smoking environment. Repeated exposure to these cues could enhance smoking cessation through Pavlovian extinction processes.
Method: In a usability study ($N = 10$), we evaluated the acceptability of a smoking cessation AR app to inform modifications to the app prior to an upcoming randomized controlled trial (RCT). For the subsequent RCT, individuals who enroll in a state tobacco quitline will be referred to the study and, if eligible and consented, randomized to use the app with AR features or without AR features (control) for 5 weeks. The efficacy of the AR features to enhance smoking cessation in the context of concurrent quitline treatment will be evaluated with the primary outcome of self-reported 7-day point-prevalence cigarette abstinence at 6 months post-enrollment. Implementation will be evaluated via incremental cost-effectiveness analyses and interviews with participants, quitline staff, and app coaches.
Conclusions: Interventions utilizing emerging mobile technologies such as AR have the potential, compared to traditional therapies, to improve both reach and efficacy by administering therapeutic elements in users' natural environments. Our AR app will target tobacco smoking, but the approach could be used to deliver exposure therapies for other addictive behaviors, as well as anxiety disorders.
Clinical Trial Registration: NCT06088498

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1. Introduction

Smoking is a significant public health concern with an estimated 8 million deaths annually worldwide and an economic burden of more than $1 trillion [1]. Whereas over 77 % of smokers are reportedly interested in quitting, only 7.4 % successfully quit each year [2], with the low rate attributed partly to a lack of accessibility and engagement in effective interventions. One strategy for increasing the reach of smoking cessation interventions is to deliver treatment components via mobile technologies such as smartphones. These mobile health (mHealth) interventions are usually less costly and more accessible to the user than those delivered through more traditional means, such as direct patient-provider contact. As mobile technology advances, emerging smartphone capabilities may allow for novel treatment options. One such technological advancement is augmented reality (AR), which inserts digital images into real-world scenes in real-time as viewed via a smartphone or other device screens. AR is increasingly used in social media (e.g., Snapchat filters), gaming (e.g., Pokémon Go), commerce (e.g., viewing potential furniture purchases in home settings), education (e.g., physician training), and the arts (e.g., interactive museum displays) [3–5].

Another potential use of AR in the therapeutic domain is to deliver motivationally salient stimuli to individuals while they are in their natural environments in the context of behavioral therapies based on Pavlovian conditioning and extinction; that is, cue exposure therapies (CETs) [6–8]. With respect to tobacco smoking, it is well-established that smoking-related cues (e.g., cigarettes, lighters, ashtrays) can trigger urges or cravings to smoke, even long after individuals have quit smoking. This cue-reactivity is also thought to contribute to smoking relapse [9,10]. CET involves the repeated presentation of these triggering cues to gradually extinguish the resultant cravings to smoke. That is, CET should weaken the associations between the cues (conditioned stimuli) and smoking (unconditioned stimulus), thereby reducing cravings (conditioned response), which is hypothesized to aid smoking cessation and reduce relapse risk [9]. However, traditional CET delivered in a clinic has limited reach and tends not to generalize to patients' natural smoking environments [7,11,12]. Through AR, it is possible to deliver CET using digital smoking cues at the times and places that are most associated with each individual's unique smoking history, which should mitigate the generalizability barrier of traditional CET [13,14].

Our team previously developed a smartphone AR app for presenting smoking cues called App for Reducing Craving (ARC) [6,8,14]. Controlled laboratory studies showed that the AR images delivered by the ARC app elicited cravings to smoking that approximated those elicited by physical smoking stimuli (e.g., AR cigarette vs real cigarette) when compared to neutral cues [6]. A single cue-exposure session (i.e., involving repeated presentation of the cues in the lab) using this app also produced evidence of extinction—reduced cravings to smoke [8]. We then asked 23 daily smokers who were not seeking smoking cessation treatment to test the initial ARC app outside the lab. They reported high usability and acceptability of the app. Further, even though these individuals were not seeking cessation treatment, 56.5 % of users reported reduced smoking, with an average reduction of 26 % in the number of cigarettes smoked per day (CPD) at follow-up after 7-days of AR app use [14]. These studies indicated potential utility of the ARC app for enhancing smoking cessation. Importantly, we do not conceptualize CET via AR to be a sufficient, stand-alone smoking cessation approach. Rather, we envision the app as an adjuvant to other cessation strategies that address the spectrum of biopsychosocial influences on smoking and smoking cessation.

This paper presents two studies. Study 1 was a small usability study of an enhanced version of the ARC app used in the proof-of-concept research described above [8]. Study 2 is an upcoming two-arm randomized controlled trial (RCT) to test the efficacy of the ARC app to improve smoking cessation outcomes among individuals enrolled in a

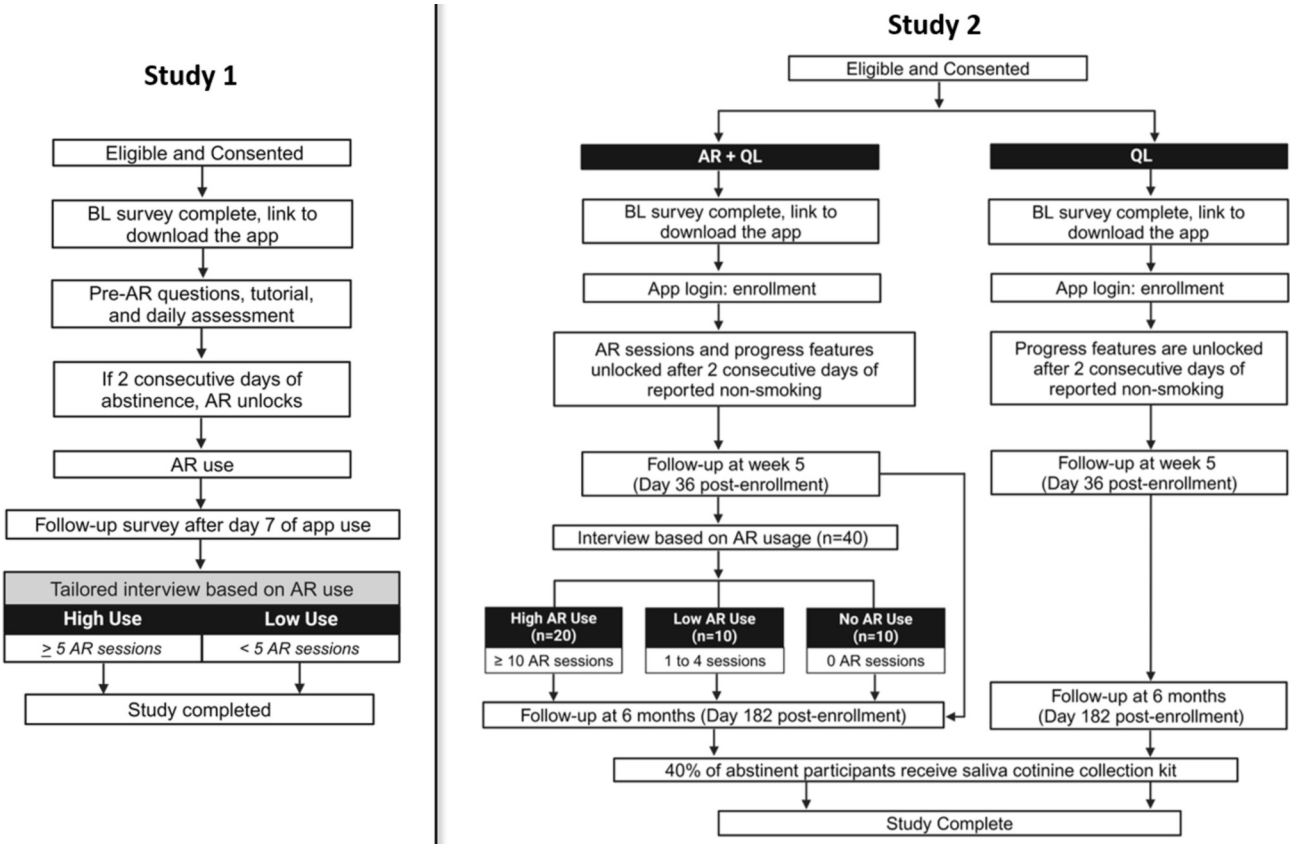

Fig. 1. Study Flow for Study 1 and Study 2. Note. BL = Baseline; AR = augmented reality; QL = Quitline.

state tobacco quitline. Fig. 1 displays an overview of each study. Protocols for both these studies were approved by Moffitt Cancer Center's Institutional Review Board, Advarra (Protocol # 21980).

2. Study 1 – Usability of the ARC app

2.1. Method

The enhanced app tested in Study 1 is improved upon the original app [8] by including additional AR smoking-related images, in-app videos to introduce participants to the rationale for AR-delivered CET and instructions for use, and engagement features such as rewards for achieving usage milestones. Usability testing of the enhanced app was conducted via a single arm, remote, non-randomized study (Fig. 1) to identify any modifications that might be needed prior to the Study 2 RCT.

We developed 20 smoking-related AR images with single cues (e.g., lighter, ashtray), including motion (e.g., smoke rising; see Figs. 2 and S1) or combined cues (e.g., cigarette pack with lighter; see Fig. S1). To encourage user engagement in the app, we created 8 additional non-smoking reward AR images (e.g., flowerpot, star; see Fig. S2) that are unlocked after a certain number of AR sessions are completed. Table 1 presents the components included within the app based on: (1) current recommendations for mHealth interventions, guided by both self-determination theory (SDT) and the behavioral intervention technologies (BIT) model [15,16], (2) recommendations for smoking cessation apps [17–19], and (3) our experience developing the original version of the app [14].

2.2. Participants

For short-term usability testing and feedback on the enhanced ARC app, we enrolled individuals ($N = 10$) who recently quit smoking. Current smokers were not recruited because we were not offering full smoking cessation treatment in Study 1, and AR sessions are designed to occur following smoking cessation to facilitate extinction-based processes. Inclusion criteria were: 1) ≥18 years of age; 2) former daily smokers who self-reported quitting smoking within the past 3 months; 3) owning a smartphone capable of supporting AR; and 4) able to read, write, and speak English. Exclusion criteria included having a member of the household previously or currently enrolled.

Participants were recruited through online advertisements statewide in Florida and contacted by phone to assess eligibility. Eligible participants who provided verbal informed consent and returned the baseline survey were enrolled in the study and texted a link to download the ARC app onto their personal smartphones. Participants were removed from the study if they did not download the app within one week.

2.2.1. Procedures

2.2.1.1. ARC app use. Participants were instructed to use the ARC app for 7 days. Each day, participants were prompted by the app to complete a daily assessment that captured cigarette and nicotine replacement therapy (NRT) usage from the previous day and to rate their current urge to smoke (10-point Likert scale) [20]. As ongoing smoking during CET is counter-productive to extinguishing urges, participants had to self-report two consecutive days of abstinence before the AR sessions were unlocked and became available for use. After their first smoke-free day, participants were asked a series of in-app questions regarding the situations and settings in which they typically smoked based on five parameters: location, with/after any food or drink, activity, mood, and presence of others. Participants were also asked to select their preferred number (i.e., 0–2) of daily reminder notifications to complete an AR session.

Once AR was unlocked after the second consecutive smoke-free day, participants viewed 3 brief instructional videos. The first explained the purpose of AR-based CET and how AR sessions could extinguish cravings (see Supplemental Methods for detailed in-app video script); the second included best practices (e.g., lighting conditions) during AR sessions; and the third provided detailed instructions of when and how to conduct AR sessions (e.g., complete 2–5 sessions/day at times and places where one typically smoked or experienced urges to smoke, refrain from smoking during AR sessions). After viewing the videos, they were given the opportunity to practice a tutorial AR session using a neutral cue (a rubber ducky).

At the beginning of each AR session, participants indicated their current situation/setting and urge to smoke (See Fig. S3), followed by viewing the AR cues. Participants used the ARC app to superimpose cues on a flat surface in their natural environment (Fig. 2). Each AR session presented 3–8 randomly selected cues for 20 to 40 s each (cue-exposure lasted approximately 3 min/session). That is, the selection of cues was generated by the app, not chosen by participants. Variability in the cue

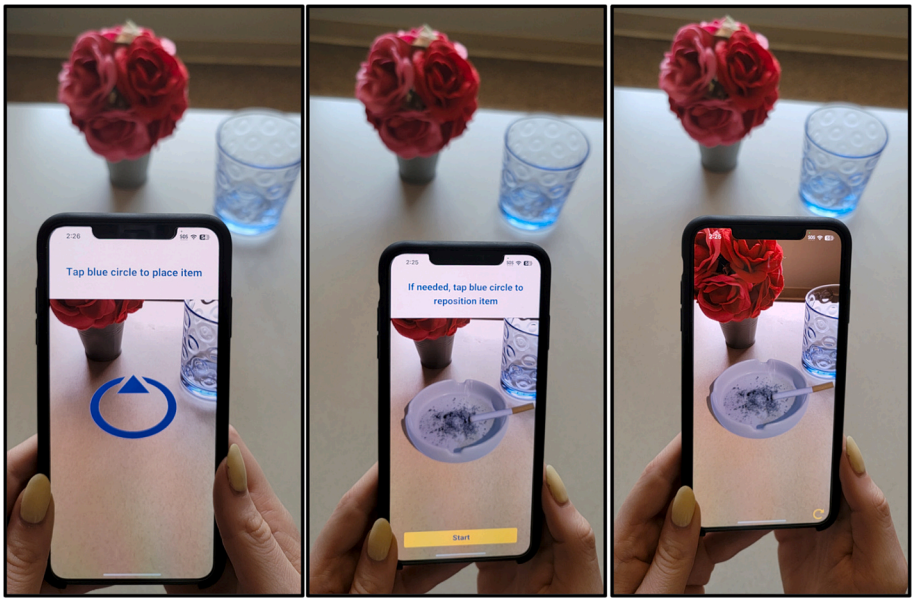

Fig. 2. Screenshots of digitally created placement indicator and an example of smoking cues superimposed on a table in real-time.

Table 1
App Components.

Feature	Description	Delivery/ presentation modality
Daily Assessment	Participants will complete a daily assessment of cigarette and NRT use from the previous day and rate their current urge to smoke.	Push notification In-app assessment
Situation Menu	Participants will choose which situations and settings are most appropriate for their AR sessions based on where and when they smoke.	In-app icon menu
Tutorials	Tutorial on how to use AR in the app (e.g., placing AR stimuli), with unlimited interactive practice sessions.	In-app video
Rationale for Cue Exposure	Rationale for cue-exposure to help quit smoking/support participant goals.	In-app video
AR Sessions	Participants will be encouraged to complete 2–5 AR sessions per day. Each session will present 3–8 cues randomly, and each cue will be presented for 20–40 s (average amount of extinction per day will be approximately 10 min). Participants will be encouraged to conduct the AR sessions when high cravings are expected. Participants will rate their urge to smoke prior to the first cue and again following the first and last cue within each session.	Push notification In-app AR trials
Best Practices for AR Sessions	Specific guidelines for using the app (e.g., no smoking during sessions; how to use NRT in conjunction with AR)	In-app video
AR Non-engagement Notifications	If AR is unlocked but participants do not do an AR session, a series of notifications will be sent over several days to remind them to do an AR session.	Push notification
Progress Tracker	Participants will be able to view 1) their progress through the program overall, 2) changes in urge ratings over time, 3) daily cigarette use, 4) use of NRT, 5) money and time saved by not smoking, and 6) number of AR sessions completed (for those in QL + AR).	In-app graphs and other visualizations
Troubleshooting	Available any time within the app to support use of the app.	In-app button
Rewards	AR visual rewards become available as participants complete more AR sessions.	In-app AR cues
App Coach	Available in the app to either call or email an App coach.	In-app button

Note. AR = augmented reality; NRT = Nicotine Replacement Therapy.

presentations was designed to decrease predictability and maintain general interest in the sessions. During each AR session, participants again rated their urge to smoke following the first and the last cue.

Once AR sessions were unlocked, all other app features became available on demand, including AR resources (e.g., the video tutorials), AR troubleshooting, telephone and email links to an App Coach, a progress page, and rewards for reaching milestones related to the number of AR sessions completed (i.e., non-smoking related AR images such as a flowerpot or star). The progress pages (Fig. S3) provided feedback and encouragement on cessation and app use progress, including days of app use, weekly "streaks" in completing daily assessments, number of AR sessions completed, days without smoking, graphs of NRT use and smoking urges over time, and money and time saved by not smoking. If a participant contacted an App Coach for help, the conversation would focus on reinforcing study rationale for CET (see Supplemental Methods for details); problem-solving technical issues with app download or usage; issues related to smoking or using NRT while using the app; and/or guidance on how to be fully engaged in AR sessions to maximize its potential benefit (see Supplemental Methods for details). If a participant relapsed (defined as 3 consecutive days of smoking) after the AR sessions were unlocked, AR access was removed until they re-achieved two consecutive days of abstinence.

2.2.1.2. Self-report measures and app data. A REDCap survey collected data at baseline and at the end of the 7-day app use period. Baseline measures assessed demographics, prior AR experience, current smoking, and smoking history. At the end of their 7 days of app use, participants completed the System Usability Scale (SUS) to measure perceptions of usability and learnability of the app [21,22], 3 Likert scale questions to assess reality/co-existence of the AR images, and additional Likert scale items to assess appeal, ease of use, days until comfortable with app use, and satisfaction with the app experience.

During the AR sessions, participants also rated their urge to smoke on a single 10-point Likert scale prior to the first cue and again following the first cue and the last cue. The circumstances surrounding AR session use (e.g., at home, with alcohol) were assessed via checklists. We also collected real-time app use metadata, including the proportion of sessions started that were completed, time spent in the app, days of use, and engagement with app features (e.g., rewards after milestones).

A phone interview was conducted at the end of the one week of app use and included open-ended questions regarding participants' perceptions of the ARC app (see Supplemental Methods for examples of questions included). Interviews were tailored to participants' app use to understand challenges and barriers experienced among those with lower AR use (i.e., completed <5 sessions) versus higher use (completed ≥5 sessions).

2.3. Results

2.3.1. Participant characteristics

Fig. 3 displays the CONSORT diagram for Study 1. Online ads yielded 121 responses. Research staff screened 50 individuals and consented 15, with 10 individuals downloading the ARC app and completing the study through follow-up and the post-treatment interview. Participant demographics and average number of CPD are shown in Table 2.

2.3.2. Daily assessment, app usage, and metadata

Out of 10 participants, 6 completed all 7 daily assessments; 3 completed 4–6 assessments; and 1 completed 2 assessments. Mean daily urge to smoke on a scale of 1–10 was only 3.4 (SD = 2.9), most likely reflecting that participants in this usability study had been abstinent for at least 3 months. One individual reported smoking one cigarette, and one reported using NRT.

App usage metadata can be found in Table S1. On average, participants used the app and completed daily assessments on most days. Over the 7-day period, 6 participants completed ≥5 AR sessions (higher AR use) and 4 completed <5 AR sessions (lower AR use). Over the 7 days, higher AR users spent an average of about an hour total in the app whereas lower AR users spent about 20 min. Two out of 10 participants contacted App coaches for help; one discussed the continuation of app use after smoking, and another requested technical assistance with the app.

2.3.3. Follow-up survey and interview

Table 3 summarizes the results of the follow-up survey. Briefly, the mean SUS score was considered acceptable, and participants perceived the AR images as realistic and useful. The app was also perceived as easy to use, with participants noting only a short period of time needed to become comfortable using the app. Ninety percent of participants

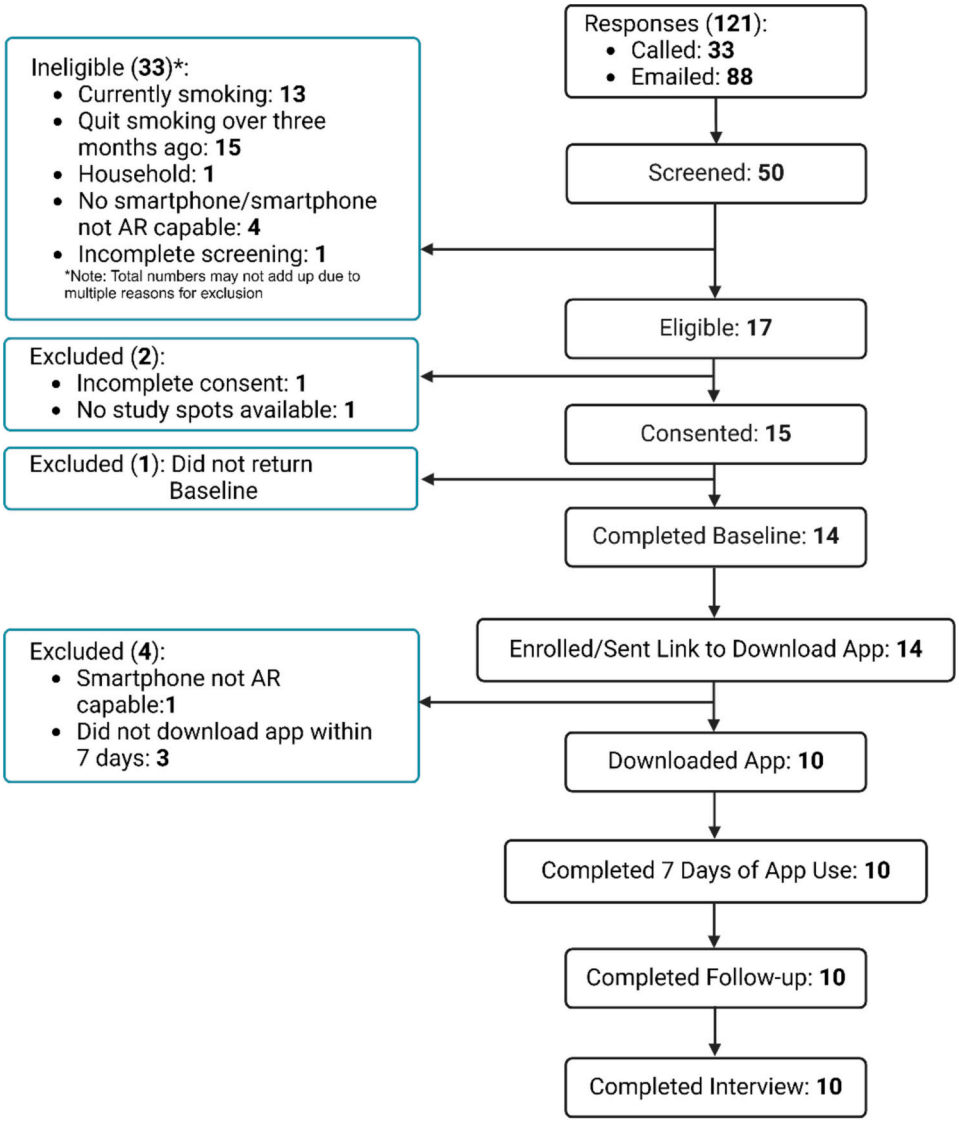

Fig. 3. Study 1 CONSORT Diagram. *Note.* AR = augmented reality.

reported being mostly or very satisfied with the app and would recommend it to a friend.

Table S2 provides a detailed summary of the interview results. Overall, participants reported the app as easy to use and helpful for reducing smoking urges. Barriers/challenges related to app use included wanting a clearer rationale, improved help using AR technology, and more reminder notifications. Based on participant feedback in Study 1, the app in Study 2 was modified to include additional emphasis on CET rationale, additional instruction on AR image placement, added reminder notifications, and an additional popup page reinforcing smoke-free days.

3. Study 2 – RCT on the efficacy of the ARC app

3.1. Method

Study 2 is designed to evaluate the efficacy of the ARC app as an adjuvant to a standard state tobacco quitline service. The Tobacco Free Florida Quitline (TFFQ) provides an evidence-based tobacco cessation treatment delivered via phone, web, and text that includes 5 key elements: setting a quit date, coping with triggers, effectively using medications, removing tobacco paraphernalia, and social support. The TFFQ also offers four weeks of NRT. Participants will be referred from TFFQ and randomized to one of the two treatment arms: (1) Quitline plus the ARC AR app (QL + AR) or (2) Quitline alone (QL). Participants in the QL arm will receive the same app without the AR features (Fig. 1).

The primary aim of Study 2 is to evaluate the efficacy of QL + AR compared to QL (Aim 1a). We hypothesize that participants randomized to QL + AR will demonstrate higher tobacco abstinence rates 6 months post-enrollment when compared to QL participants. We will also examine prospective moderators of treatment success: sex, baseline nicotine dependence, and trait cue-reactivity (Aim 1b). Furthermore, we will explore prospective predictors of abstinence within the QL + AR arm: initial cue-reactivity, extinction magnitude and latency, treatment engagement, smoking status during treatment, TFFQ use, NRT use, and App Coach use. For participants in QL + AR, extinction will be operationally defined as reporting, using the 10-point post-AR rating scale, on at least 4 out of the last 5 days either (a) a mean rating of 1 or 2 or (b) at or below 50 % of the mean rating from the first day of AR trials.

The second aim will evaluate treatment implementation to guide future adoption of the ARC app by a quitline, including cost-assessment and incremental cost-effectiveness analyses comparing QL + AR with QL (Aim 2a). We will also examine treatment engagement and acceptability among those in QL + AR (Aim 2b) and identify facilitators and barriers

Table 2
Study 1 Participant Characteristics (N = 10).

Variable	M (SD) or N (%)
Age (years)	37.9 (14.2)
Gender	
Male	6 (60 %)
Female	4 (40 %)
Non-Hispanic/Latino	10 (100 %)
Race	
Black/African American	4 (40 %)
White	6 (60 %)
Income	
$30,000 - $59,999	6 (60 %)
$60,000 - $89,999	1 (10 %)
≥ $90,000	3 (30 %)
Education	
High school or less	1 (10 %)
Some college	2 (20 %)
Technical school/ Associates degree	1 (10 %)
4-year college degree	2 (20 %)
More than 4-year degree	4 (40 %)
Marital Status	
Married	5 (50 %)
Single	3 (30 %)
Divorced/Separated	2 (20 %)
Cigarettes per day (CPD)	12.3 (6.5)

Note. M = Mean; SD = Standard Deviation, CPD is a measure of historical smoking.

Table 3
Study 1 Follow-up Survey Results.

Variables	Mean (SD)	Scale
SUS	70.3 (20.1)	0–100
Reality/co-existence of AR images	7.9 (2.0)	1–10
Usefulness	3.3 (0.6)	1–4
Ease of use (Beginning)	3.6 (1.5)	1–5
Ease of use (End)	4.1 (0.8)	1–5
Days until comfortable to use	2.9 (2.0)	1–7
Recommend to a friend	3.3 (0.6)	1–4
Satisfaction	3.4 (0.6)	1–4

Note. M = Mean; SD = Standard Deviation; SUS = System.

to incorporating AR treatment into quitline services via qualitative interviews with quitline staff, App Coaches, and a subset of participants (Aim 2c).

3.1.1. Participants

Study 2 inclusion criteria include: 1) ≥18 years of age; 2) currently smoking ≥3 CPD for the past year; 3) owns an AR-capable smartphone; 4) willing to download the ARC app; and 5) able to read, write, and speak in English. The exclusion criterion is same as Study 1. The target sample size is 2072. Based on observed abstinence rates from quitline/telephone counseling [23–25], we estimated a 7-day point prevalence abstinence rate of 10 % at 6 months for the QL among those who achieved 48-h of abstinence. With 1036 randomized to each arm, we expect 725 participants to achieve 48-h of abstinence in each arm (to activate the ARC app) [26,27]. Power is ≥0.80 to detect an abstinence rate of at least 15 % (OR ≥ = 1.59) in QL + AR using alpha =0.05, a 2-sided test, and 5 % of variance in abstinence rates to be accounted for by other variables. A parallel analysis will be conducted using all 2072 randomized participants, regardless of whether they achieved 48 h of abstinence. Estimating 7 % abstinence for QL in the entire sample, power is ≥0.80 will detect an abstinence rate of at least 10.6 % for QL + AR (OR ≥ 1.57).

3.1.2. Procedures

3.1.2.1. Recruitment and randomization. Recruitment will take place via TFFQ. Upon enrolling in the standard adult quitline service program, individuals who are English speaking and report daily smoking of 3 or more CPD will be presented with a brief study description and enrollment offer. The offer will be made verbally by a TFFQ coach for those who phone the quitline or online for those who enroll in TFFQ via online processes. Eligible and interested callers will be asked for their consent for TFFQ to send their contact information to the research team. Research staff will call individuals to complete eligibility screening, informed consent, and to randomize consented participants to one of the two study arms. Participants will be enrolled in the study after they login to the study app. Participants will receive compensation for completing surveys at baseline, 5 weeks, and 6 months ($20 each), as well as for completing daily assessments via the app (up to $50 total), the post-treatment interview ($20), and cotinine kit return ($25).

3.1.2.2. Treatment arms. Participants randomized to QL + AR will receive usual care via TFFQ and use the ARC app that was updated following Study 1. Participants randomized to QL will receive usual care via TFFQ and have access to the app with basic features (e.g., daily assessments, progress trackers), but without any of the AR-related features (i.e., AR sessions, AR tutorials, AR rewards, Help screen).

3.1.3. Measures

3.1.3.1. Self-report measures. Participants will be sent REDCap links to complete survey measures at baseline and at two follow-up points: 5 weeks and 6 months post-enrollment. Variables assessed at baseline will include demographics (e.g., gender, age, race, marital status, income, education) and smoking-related factors (e.g., smoking history and other tobacco product use). Additional self-report measures at all time points will include: 1) Heaviness of Smoking Index (HSI) to assess nicotine dependence [28]; 2) Brief Wisconsin Inventory of Smoking Dependence Motives (WISDM-37 and 68) subscales of Automaticity, Affective Enhancement, and Cue Exposure/Associative Processes [29,30]; 3) Self-efficacy Scale to assess situational confidence for not smoking [31]; and 4) Positive and Negative Affect Schedule Short-Form (PANAS-SF) to assess affect [32]. At baseline and 6 months, the Tobacco Quality of Life Impact Tool (TQoLIT) will be administered to assess smoking-specific symptoms and quality of life [33], along with the EQ-5D-5L (EuroQol 5 Dimension 5 Level) to assess health status [34].

At the 5-week assessment, avoidance strategies used during the AR sessions (e.g., watching TV to avoid being fully immersed with the AR cues) will be assessed via a checklist and will be considered in our analysis of treatment engagement. We will assess treatment satisfaction using a modified Client Satisfaction Questionnaire (CSQ) [35], the SUS [21,36], and unique items to assess features of the app and AR experience (e.g., "How would you rate the quality of the ARC app?", "Did the ARC app provide the help you wanted in managing your urges to smoke?"), including the App Coaches.

3.1.3.2. App use. Participants in both study arms will complete the same in-app daily assessments described in Study 1 for 5 weeks. As in Study 1, we will collect metadata on app use as indicators of treatment engagement. We will derive treatment engagement variables consistent with our theoretical model of Pavlovian extinction that are hypothesized to be associated with increased abstinence, such as number of AR sessions completed and completion of AR sessions across multiple locations and settings (to increase generalizability of extinction). Indices of extinction magnitude (i.e., craving reduction over time) and latency (i.e., time to meeting extinction criteria) will also be derived.

3.1.3.3. Quitline and app coach usage. The TFFQ will provide participant data including quitline call completion dates, target quit date, and NRT that was shipped. Use of the App Coaches will be quantified by calculating the frequency, content, and duration of calls and email

correspondence, with findings used to refine the ARC app and inform future implementation with respect to staffing requirements. App Coach calls will also be recorded and a random sample of 10 % will be rated for coaching fidelity by the investigators using a measure developed for this study.

3.1.3.4. Tobacco abstinence (primary outcome). The primary outcome will be self-reported 7-day point prevalence smoking abstinence [37] collected via the 6-month assessment. A random sample of approximately 40 % of abstinent-reporting participants will be mailed a saliva collection kit to biochemically verify smoking status. Based on recommendations of an expert panel in biochemical verification convened by the Society for Research on Nicotine and Tobacco's Treatment Research Network [38] combined with budget considerations, a random sample of approximately 40 % of abstinent-reporting participants will be mailed a saliva collection kit to biochemically verify smoking status.

A saliva cotinine cutoff of <10 ng/ml [38] will be used to confirm self-reported abstinence. Deviations from self-report will be used to qualify abstinence rates reported from this study.

3.1.3.5. Intervention cost assessment. Resource utilization associated with both arms of the intervention itself (i.e., not including research-related expenses) will be assessed, allowing us to determine relative costs and cost-effectiveness. Our cost-assessment methodology will affix a standardized "price" to intervention resources (e.g., staff time, digital platform use). This approach, long recommended as the most appropriate means of calculating true resource costs [39,40], results in "costs" that are comparable between the arms in this study and across alternative interventions.

3.1.3.6. Post-treatment interviews. To identify multi-level barriers and facilitators of incorporating the ARC app into a quitline, the following groups will be interviewed: a subset of study participants randomized to QL + AR ($n = 40$), a subset of TFFQ staff (n = ~10), and all App Coaches. For study participants, interviews will be tailored to app use: no app use (no AR sessions completed; $n = 10$), low app use (completed 1 to 4 AR sessions; n = 10), and high app use (completed ≥10 AR sessions; $n = 20$). Semi-structured interview guides will be developed for each unique group based on the Consolidated Framework for Implementation Research [41] and will assess intervention characteristics (e.g., technical challenges with the ARC app), organizational characteristics (e.g., app compatibility with quitline workflow), individual characteristics (e.g., beliefs about the ARC app, self-efficacy for app use), process (e.g., sufficiency of training and engagement strategy), and external context (e.g., how well the app fits with quitline external incentives and policies). Interviews will be approximately 30 min in length and conducted by individuals trained in qualitative research; interviews will be recorded and transcribed verbatim. We anticipate that data saturation (i.e., the point at which no new themes are generated from the data) will be achieved with the planned sample sizes but will modify the protocol to increase recruitment if data saturation is not achieved.

3.2. Planned analyses

All analyses described below will be performed for those who achieved 48 h of self-reported abstinence via the app, as well as the full sample of those enrolled. The primary statistical analysis for Aim 1a, the primary test of the efficacy of QL + AR over QL, will use logistic regression on self-reported smoking abstinence at 6 months following the application of multiple imputation to handle missing data. A second test of efficacy will use generalized estimating equations (GEE) with both 5-week and 6-month abstinence as the outcomes. This approach permits evaluating a change in abstinence over time, differences in change over time, and cumulative effects of the intervention. For Aim 1b, prospective moderators of the QL + AR intervention will be explored separately by extending the analyses described above through the inclusion of the moderator and the moderator x intervention as predictors of abstinence. Variables will include sex, baseline nicotine dependence, and trait cue-reactivity. Prospective predictors of the ARC app will be evaluated using only participants from the QL + AR arm. AR-related variables will be added to a logistic regression model of abstinence that includes demographics and baseline smoking-related variables found to be predictors of abstinence among QL + AR participants. The following variables will be explored: initial cue-reactivity, extinction magnitude and latency, indices of treatment engagement, smoking status during treatment, TTFQ use, NRT use, and App Coach use.

Aim 2a includes a cost-effectiveness assessment with a primary trial endpoint of smoking abstinence at 6 months as the main outcome. We will calculate the incremental cost-effectiveness of QL + AR compared to QL in increasing smoking abstinence (e.g., cost per quitter). For Aims 2b and 2c, descriptive statistics will be used to evaluate treatment engagement (i.e., greater completion of the AR sessions, conducting the AR sessions in several different locations, and less use of avoidance strategies during the AR sessions), acceptability (i.e., CSQ, SUS, and items that assess app features and the AR experience, including contact with the App Coach). Variables derived from engagement with the app will be explored as predictors in multivariable models that already include baseline predictors. Qualitative methods such as thematic analysis (see Supplemental Methods for details) will be used to identify facilitators and barriers to app usage.

4. Discussion

This line of research leverages the growing AR capabilities of smartphones to deliver behavioral smoking cessation strategies (i.e., Pavlovian extinction trials) in individuals' natural smoking environments. Study 1 enhanced the existing ARC app and then tested its usability to inform any necessary modifications prior to an RCT. Study 2 will test the efficacy of the updated ARC app to be used in conjunction with standard tobacco quitline services.

Participants in Study 1 reported high usability and acceptability of the ARC app. Participants used the app most days, completed most daily assessments, and completed an average of 7 AR extinction sessions. Participants reported that the AR cues were realistic and well-integrated in their natural environments. Interviews revealed minor barriers that were addressed through modifications to the app.

Study 2's primary outcome will be 7-day point-prevalence smoking abstinence at 6 months post-enrollment. Findings will examine the potential added benefit of the ARC app as an adjuvant to a standard state tobacco quitline. To our knowledge, this trial will be the first large-scale study to test AR-delivered CET in the field of addiction – smoking cessation, in this case. Compared to traditional face-to-face CET, we expect the ARC app to improve both patient accessibility of treatment (because of the app modality) and extinction generalizability (because of extinction trials occurring within natural smoking environments). Although one might be concerned that presenting smoking-related cues via the app may increase risk of relapse, it is important to remember that the digital images presented by the app (i.e., cigarettes and smoking paraphernalia) represent stimuli that participants would likely encounter in their natural environment. However, the AR images are a safer exposure modality than actual physical smoking products in that they cannot be used in a relapse episode. Moreover, they are presented in a planned and controlled manner with the goal of reducing cravings to smoke.

Such a large-scale trial allows for the examination of predictor and moderator variables that may facilitate tailoring AR as a personalized smoking cessation intervention. Moreover, the implementation and economic measures should be useful for informing implementation and scaling decisions by tobacco quitlines and other cessation-delivery organizations. If found to be efficacious, AR could be included as an adjuvant therapy to improve smoking cessation outcomes obtained from

quitlines, pharmacotherapies, clinics, and other treatment approaches, and it could be adapted and tested for use to treat other addictive behaviors and perhaps other behavioral disorders (e.g., anxiety disorders) for which extinction-based treatment strategies are warranted.

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AR = augmented reality.

CRediT authorship contribution statement

Ranjita Poudel: Writing – review & editing, Writing – original draft, Visualization, Formal analysis. **Skye O. Dougan:** Writing – review & editing, Visualization, Project administration, Data curation. **Helen Yates:** Writing – review & editing, Visualization, Project administration, Data curation. **Leslie Sawyer:** Writing – review & editing, Methodology. **Ursula Martinez:** Writing – review & editing, Project administration, Methodology, Data curation. **Karen O. Brandon:** Writing – review & editing, Project administration, Methodology, Formal analysis, Data curation. **Steven K. Sutton:** Writing – review & editing, Methodology, Investigation, Formal analysis. **Damon J. Vidrine:** Writing – review & editing, Methodology, Investigation. **Lee M. Ritterband:** Writing – review & editing, Methodology, Investigation. **Kara P. Wiseman:** Writing – review & editing, Methodology, Investigation. **Katrina A. Vickerman:** Writing – review & editing, Resources, Methodology, Investigation. **Kea Turner:** Writing – review & editing, Methodology, Investigation. **Margaret M. Byrne:** Writing – review & editing, Methodology, Investigation. **Min-Jeong Yang:** Writing – review & editing, Methodology. **Marilyn Horta:** Writing – review & editing, Visualization, Project administration. **Thomas H. Brandon:** Writing – review & editing, Visualization, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization. **Christine Vinci:** Writing – review & editing, Visualization, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2025.107827.

Data availability

Data will be made available on request.

References

[1] M.B. Reitsma, et al., Spatial, temporal, and demographic patterns in prevalence of smoking tobacco use and attributable disease burden in 204 countries and territories, 1990–2019: a systematic analysis from the global burden of disease study 2019, Lancet 397 (10292) (2021) 2337–2360, https://doi.org/10.1016/S0140-6736(21)01169-7.

[2] A.M. Leventhal, H. Dai, S.T. Higgins, Smoking cessation prevalence and inequalities in the United States: 2014-2019, J. Natl. Cancer Inst. 114 (3) (2022) 381–390, https://doi.org/10.1093/jnci/djab208.

[3] S. Stumpp, T. Knopf, D. Michelis, User experience design with augmented reality (AR), in: Proceedings of the ECIE 2019 14th European Conference on Innovation and Entrepreneurship, 2019.

[4] B.W. Munzer, et al., Augmented reality in emergency medicine: a scoping review, J. Med. Internet Res. 21 (4) (2019) e12368, https://doi.org/10.2196/12368.

[5] E.Z. Barsom, M. Graafland, M.P. Schijven, Systematic review on the effectiveness of augmented reality applications in medical training, Surg. Endosc. 30 (2016) 4174–4183, https://doi.org/10.1007/s00464-016-4800-6.

[6] K.O. Brandon, et al., Testing augmented reality for eliciting cue-provoked urges to smoke: toward moving cue-exposure into the real world, Nicotine Tob. Res. 23 (5) (2021) 861–865, https://doi.org/10.1093/ntr/ntaa259.

[7] C. Vinci, et al., The clinical potential of augmented reality, Clin. Psychol. **27** (3) (2020), https://doi.org/10.1111/cpsp.12357.

[8] M.J. Yang, et al., Augmented reality for extinction of cue-provoked urges to smoke: proof of concept, Psychol. Addict. Behav. 36 (8) (2022) 990–998, https://doi.org/10.1037/adb0000868.

[9] R. Thewissen, et al., Renewal of cue-elicited urge to smoke: implications for cue exposure treatment, Behav. Res. Ther. 44 (10) (2006) 1441–1449, https://doi.org/10.1016/j.brat.2005.10.010.

[10] C. Vinci, L. Sawyer, M.J. Yang, Minding the gap: leveraging mindfulness to inform Cue exposure treatment for substance use disorders, Front. Psychol. 12 (2021) 649409, https://doi.org/10.3389/fpsyg.2021.649409.

[11] C.A. Conklin, Environments as cues to smoke: implications for human extinction-based research and treatment, Exp. Clin. Psychopharmacol. 14 (1) (2006) 12, https://doi.org/10.1037/1064-1297.14.1.12.

[12] C.A. Conklin, et al., Proximal versus distal cues to smoke: the effects of environments on smokers' cue-reactivity, Exp. Clin. Psychopharmacol. 16 (3) (2008) 207, https://doi.org/10.1037/1064-1297.16.3.207.

[13] C. Vinci, et al., Augmented reality for smoking cessation: development and usability study, JMIR Mhealth Uhealth 8 (12) (2020) e21643, https://doi.org/10.2196/21643.

[14] M.-J. Yang, et al., Augmented reality as a novel approach for addiction treatment: development of a smoking cessation app, Ann. Med. 54 (1) (2022) 3095–3105, https://doi.org/10.1080/07853890.2022.2140451.

[15] M. Floryan, et al., The model of gamification principles for digital health interventions: evaluation of validity and potential utility, J. Med. Internet Res. 22 (6) (2020) e16506, https://doi.org/10.2196/16506.

[16] D.C. Mohr, et al., The behavioral intervention technology model: an integrated conceptual and technological framework for eHealth and mHealth interventions, J. Med. Internet Res. 16 (6) (2014) e146, https://doi.org/10.2196/jmir.3077.

[17] A.L. Hartzler, et al., Prioritizing the mHealth design space: a mixed-methods analysis of Smokers' perspectives, JMIR Mhealth Uhealth 4 (3) (2016) e95, https://doi.org/10.2196/mhealth.5742.

[18] J.L. Heffner, et al., Feature-level analysis of a novel smartphone application for smoking cessation, Am. J. Drug Alcohol Abuse 41 (1) (2015) 68–73, https://doi.org/10.3109/00952990.2014.977486.

[19] A. Ortis, et al., A report on smoking detection and quitting technologies, Int. J. Environ. Res. Public Health 17 (7) (2020), https://doi.org/10.3390/ijerph17072614.

[20] L.T. Kozlowski, et al., Asking questions about urges or cravings for cigarettes, Psychol. Addict. Behav. 10 (4) (1996) 248, https://doi.org/10.1037/0893-164X.10.4.248.

[21] J. Brooke, SUS-A quick and dirty usability scale, Usabil. Eval. Indus. 189 (194) (1996) 4–7.

[22] J.R. Lewis, J. Sauro, The factor structure of the system usability scale, in: Human Centered Design: First International Conference, HCD 2009, Held as Part of HCI International 2009, San Diego, CA, USA, July 19–24, 2009 Proceedings 1, Springer, 2009.

[23] B. Piñeiro, et al., Implementation of ask-advise-connect in a safety net healthcare system: quitline treatment engagement and smoking cessation outcomes, Transl. Behav. Med. 10 (1) (2020) 163–167, https://doi.org/10.1093/tbm/iby108.

[24] M. Fiore, Treating Tobacco Use and Dependence: 2008 Update: Clinical Practice Guideline, Diane Publishing, 2009.

[25] J. Hartmann-Boyce, Telephone counselling for smoking cessation, Cochrane Database Syst. Rev. 5 (2019), https://doi.org/10.1002/14651858.CD002850.pub4.

[26] S. Shiffman, et al., First lapses to smoking: within-subjects analysis of real-time reports, J. Consult. Clin. Psychol. 64 (2) (1996) 366–379, https://doi.org/10.1037//0022-006x.64.2.366.

[27] S. Shiffman, et al., Prediction of lapse from associations between smoking and situational antecedents assessed by ecological momentary assessment, Drug Alcohol Depend. 91 (2–3) (2007) 159–168, https://doi.org/10.1016/j.drugalcdep.2007.05.017.

[28] T.F. Heatherton, et al., Measuring the heaviness of smoking: using self-reported time to the first cigarette of the day and number of cigarettes smoked per day, Br. J. Addict. 84 (7) (1989) 791–799, https://doi.org/10.1111/j.1360-0443.1989.tb03059.x.

[29] S.S. Smith, et al., Development of the brief Wisconsin inventory of smoking dependence motives, Nicotine Tob. Res. 12 (5) (2010) 489–499, https://doi.org/10.1093/ntr/ntq032.

[30] M.E. Piper, et al., A multiple motives approach to tobacco dependence: the Wisconsin inventory of smoking dependence motives (WISDM-68), J. Consult. Clin. Psychol. 72 (2) (2004) 139, https://doi.org/10.1037/0022-006X.72.2.139.

[31] W.F. Velicer, et al., Relapse situations and self-efficacy: an integrative model, Addict. Behav. 15 (3) (1990) 271–283, https://doi.org/10.1016/0306-4603(90)90070-e.
[32] E.R. Thompson, Development and validation of an internationally reliable short-form of the positive and negative affect schedule (Panas), J. Cross-Cult. Psychol. 38 (2) (2007) 227–242, https://doi.org/10.1177/0022022106297301.
[33] J.E. Ware, et al., Evaluation of smoking-specific and generic quality of life measures in current and former smokers in Germany and the United States, Health Qual. Life Outcomes 13 (2015) 1–10, https://doi.org/10.1186/s12955-015-0316-3.
[34] M. Herdman, et al., Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L), Qual. Life Res. 20 (2011) 1727–1736, https://doi.org/10.1007/s11136-011-9903-x.
[35] C.C. Attkisson, T.K. Greenfield, Client Satisfaction Questionnaire-8 and Service Satisfaction Scale-30, 1994.
[36] P.W. Jordan, Usability Evaluation in Industry, London; Bristol, PA, Taylor & Francis. xvii, 1996, p. 252.
[37] M.E. Piper, et al., Defining and measuring abstinence in clinical trials of smoking cessation interventions: an updated review, Nicotine Tob. Res. 22 (7) (2020) 1098–1106, https://doi.org/10.1093/ntr/ntz110.
[38] N.L. Benowitz, et al., Biochemical verification of tobacco use and abstinence: 2019 update, Nicotine Tob. Res. 22 (7) (2020) 1086–1097, https://doi.org/10.1093/ntr/ntz132.
[39] G.D. Sanders, et al., Recommendations for conduct, methodological practices, and reporting of cost-effectiveness analyses: second panel on cost-effectiveness in health and medicine, JAMA 316 (10) (2016) 1093–1103, https://doi.org/10.1001/jama.2016.12195.
[40] M.C. Weinstein, et al., Recommendations of the panel on cost-effectiveness in health and medicine, JAMA 276 (15) (1996) 1253–1258.
[41] L.J. Damschroder, et al., Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science, Implement. Sci. 4 (2009) 1–15, https://doi.org/10.1186/1748-5908-4-50.