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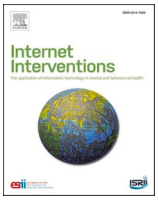

Evaluation of effectiveness and acceptability of a psychological treatment for smoking cessation combined with a smartphone App: A pilot study

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ABSTRACT

Despite the increasing number of mobile-based interventions to quit smoking over the last years, few studies have investigated the efficacy of smoking cessation interventions blended with smartphone Apps. The present pilot study aims to examine the preliminary effectiveness and acceptability of a cognitive-behavioral treatment combined with a smartphone App, compared to the same psychological treatment without the App. The sample comprised 206 treatment-seeking smokers, who were assigned to: 1) an experimental group receiving a cognitive-behavioral intervention combined with the "Non Fumo" App (n = 102), and 2) a control group receiving only the cognitive-behavioral intervention to quit smoking (n = 104). Results concerning the primary outcomes showed no significant differences between conditions in point-prevalence abstinence rates at 12-month follow-up (35.30 % in the experimental group vs. 31.70 % in the control group) and in treatment acceptability. Regarding the secondary outcomes, both groups obtained similar point-prevalence abstinence rates at the end of treatment (61.80 % vs. 65.40 %), at 3-month (42.20 % vs. 45.20 %, respectively) and 6-month follow-ups (37.30 % vs. 37.50 %). No significant differences were found between conditions in prolonged abstinence rates at 6-month (35.3 % vs. 35.6 %) and 12-month follow-ups (30.4 % vs. 26.9 %). Overall, good abstinence rates and treatment acceptability were obtained, although there were no significant differences between conditions. More research is needed to establish clear conclusions about the efficacy of psychological smoking cessation treatments blended with smartphone Apps.

1. Introduction

Worldwide, approximately 7 million people die yearly from direct tobacco use (World Health Organization, 2022). Tobacco consumption contributes to numerous physical diseases (U.S. Department of Health and Human Services, 2014) and mental health problems (U.S. Department of Health and Human Services, 2012). In fact, smoking cessation is associated with numerous benefits in physical and psychological health (Jha et al., 2013; Taylor et al., 2021; U.S. Department of Health and Human Services, 2020).

Behavioral treatments have consistently been shown to be effective for smoking cessation (Lancaster and Stead, 2017; Siu, 2015; U.S. Preventive Services Task Force, 2021). Different ways of delivering psychological treatments have been tested recently, including Information and Communication Technologies (ICTs). Research has shown that technology-based behavioral treatments (e.g., mobile phone, web-based) increase abstinence rates after six months (15–88 %) compared with control conditions such as usual care (Patnode et al., 2021). Furthermore, ICT-based smoking cessation interventions have advantages: they are cost-effective (Iribarren et al., 2017), they reduce barriers associated with traditional treatments such as time and transportation (USDHHS, 2020), are easy to use and accessible anywhere and anytime, can personalize the content to the user's characteristics and responses, can provide social support, and they can reach large populations (Whittaker et al., 2016, 2019). Additionally, ICTs provide an opportunity to support abstinence maintenance, as they can include relapse prevention components or tools reinforcing the skills acquired during the intervention (Keoleian et al., 2015).

Mobile Apps are the most frequently used ICT tools to quit smoking (Regmi et al., 2018). Smoking cessation Apps can be used as a self-help

Abbreviations: CBT-App, cognitive-behavioral smoking cessation treatment plus a smartphone App; *CBT*, cognitive-behavioral smoking cessation treatment.

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intervention or an adjunct to face-to-face smoking cessation treatment (Barroso-Hurtado et al., 2021). Most studies have focused on self-help Apps, and scarce research has investigated the efficacy of using Apps as an adjunct to face-to-face interventions to quit smoking (Vilardaga et al., 2019).

Regarding self-help Apps to quit smoking, the existing literature reveals significant heterogeneity in study design and mixed outcomes in terms of their effectiveness (Barroso-Hurtado et al., 2021; Chu et al., 2021). In this line, a recent systematic review and meta-analyses examining the effectiveness of smartphone app–based interventions to quit smoking found no significant differences between the smartphone app group and the comparators (i.e., standard care, SMS text messaging intervention, web-based intervention) (Guo et al., 2023). In contrast, Fang et al. (2023) report that mobile Apps may have a significant short-term effect on abstinence (3-months follow-up) but not in the long-term (6-months follow-up).

The few studies that use Apps combined with smoking cessation treatments analyze different aspects such as their efficacy, mainly through abstinence rates or satisfaction with the mobile Apps and with smoking cessation treatments. For instance, Masaki et al. (2020), in a study comparing a pharmacotherapy and counseling intervention combined with an App (CASC App) with a control group that received the same treatment with an App that had only the basic functions of the CASC App found that the experimental group had higher continuous abstinence rates than the control group from week 9 to 24 (63.9 % vs. 50.5 %, respectively) and from week 9 to 52 (52.3 % vs. 41.5 %). O'Connor et al. (2020) compared three treatment conditions, a behavioral support treatment, an acceptance and commitment therapy treatment (ACT), and the same ACT treatment combined with a mobile App. They found more significant smoking reductions in the number of cigarettes at post-treatment favoring the combined condition, but comparable abstinence rates between study conditions at the end of the treatment (combined condition 36 %, behavioral support condition 24 %, ACT condition 20 %) and at the 6-month follow-up (24 % in the combined and ACT conditions vs. 20 % in the behavioral support condition). In addition, the authors also analyzed treatment satisfaction, finding that participants in the ACT and combined conditions reported significantly greater treatment satisfaction than those in the behavioral support group. Other studies have found no significant differences in smoking outcomes between conditions, despite showing high rates of satisfaction with the study Apps, as in Krishnan et al. (2019) who compared a brief advice plus mobile App condition and only brief advice (3 % vs. 2 % abstinence rates at the 1-month follow-up, respectively). In the same line, Asayut et al. (2022) found no significant differences between usual smoking cessation treatment (pharmacotherapy and counseling) and the same treatment plus a mobile App at the end of the intervention (15.4 % vs. 14.1 %, respectively), the 1-month (26.9 % vs. 25.6 %), 2-month (32.1 % vs. 28.2 %), 4-month (32.1 % vs. 32.1 %), and 6-month (34.6 % vs. 321 %) follow-ups.

Therefore, regardless of whether the Apps are self-help or combined with other treatments, the available systematic reviews of the literature highlight the existence of low certainty regarding the efficacy of smoking cessation Apps. The authors highlight the need for further research to determine the usefulness of smoking cessation Apps (Chu et al., 2021; Guo et al., 2023; Whittaker et al., 2019).

Based on the reviewed literature, more research is needed to establish the efficacy of psychological treatments combined with smoking cessation Apps (Barroso-Hurtado et al., 2021; Bricker et al., 2014; Chu et al., 2021). Thus, the main aim of this pilot study is to assess the preliminary effectiveness and acceptability of a cognitive-behavioral psychological treatment for smoking cessation combined with the "Non Fumo" App, compared to the same psychological treatment without the mobile App, focusing on the differences in abstinence rates between both conditions.

2. Material and methods

2.1. Participants

The initial sample comprised 452 smokers seeking treatment at the Smoking Cessation and Addictive Disorders Unit of the University of Santiago de Compostela (Spain). To participate in the study, smokers met the following inclusion and exclusion criteria. The inclusion criteria were: (1) being at least 18 years old, (2) wishing to participate in the smoking cessation treatment, (3) having a smartphone, (4) completing the pre-treatment assessment, (5) smoking at least six cigarettes per day, and (6) providing written informed consent. The exclusion criteria were: (1) other substance use dependence (e.g., cannabis or cocaine dependence), (2) smoking tobacco products other than cigarettes (e.g., e-cigarettes), (3) a diagnosis of severe mental disorder (e.g., schizophrenia), and (4) presence of a high-risk physical pathology that required immediate intervention (e.g., cancer). After meeting the above criteria, the final sample consisted of 206 smokers who received a cognitive-behavioral treatment for smoking cessation (Fig. 1).

2.2. Measures

2.2.1. Smoking Habit Questionnaire (Becoña, 1994)

This questionnaire is made up of 59 items about sociodemographic variables (age, sex, educational level, and marital status), history of physical illnesses (current and past), and tobacco related-variables (e.g., number of cigarettes smoked per day, tobacco brand, stages of change, previous quit attempts).

2.2.2. Fagerström Test for Cigarette Dependence (FTCD, Fagerstrom, 2012; Heatherton et al., 1991)

This is a self-report questionnaire composed of 6 items. The total score ranges from 0 to 10 points. Higher scores indicate greater cigarette dependence. The Spanish adaptation of the scale was used, which has a Cronbach's alpha of 0.66 (Becoña and Vázquez, 1998). The Cronbach alpha in our sample was 0.59.

2.2.3. Client Satisfaction Questionnaire (CSQ-8, Larsen et al., 1979; Roberts et al., 1984)

This questionnaire assesses general satisfaction with treatment services. It consists of 8 items, with a total score ranging from 8 to 32. Higher scores indicate greater satisfaction with the treatment received. We used the Spanish adaptation of the questionnaire, with a Cronbach's alpha of 0.80 (Vázquez et al., 2019). The Cronbach alpha in our sample was 0.88.

2.2.4. Satisfaction with "Non Fumo" App questionnaire

This ad hoc questionnaire gathers data on the usability and satisfaction with the App. These data were collected at the end of the treatment and in the follow-ups (3-, 6-, and 12-month).

2.2.5. Abstinence

Participants were considered abstinent if they reported abstinence, not smoking even a puff, for 24 h at the end of treatment, for 7 days at the 3-month follow-up and for 30 days at the 6- and 12-month follow-ups, and if they also presented an expired carbon monoxide (CO) measure $\leq$5 parts per million (ppm) (Benowitz et al., 2020). For the CO measurements, we used the Micro+Smokerlyzer (Bedfont ScientificLtd., Maidstone, Kent, UK).

In addition, following the Russell standard criteria (West et al., 2005), participants were considered to have achieved prolonged abstinence if they self-reported not smoking >5 cigarettes from the end of the treatment to the 6- and 12-months follow-ups (Piper et al., 2020).

However, as a large part of the sample received smoking cessation treatment during the COVID-19 pandemic, abstinence for 76.21 % (n = 157) of the sample could only be self-reported at the end of the

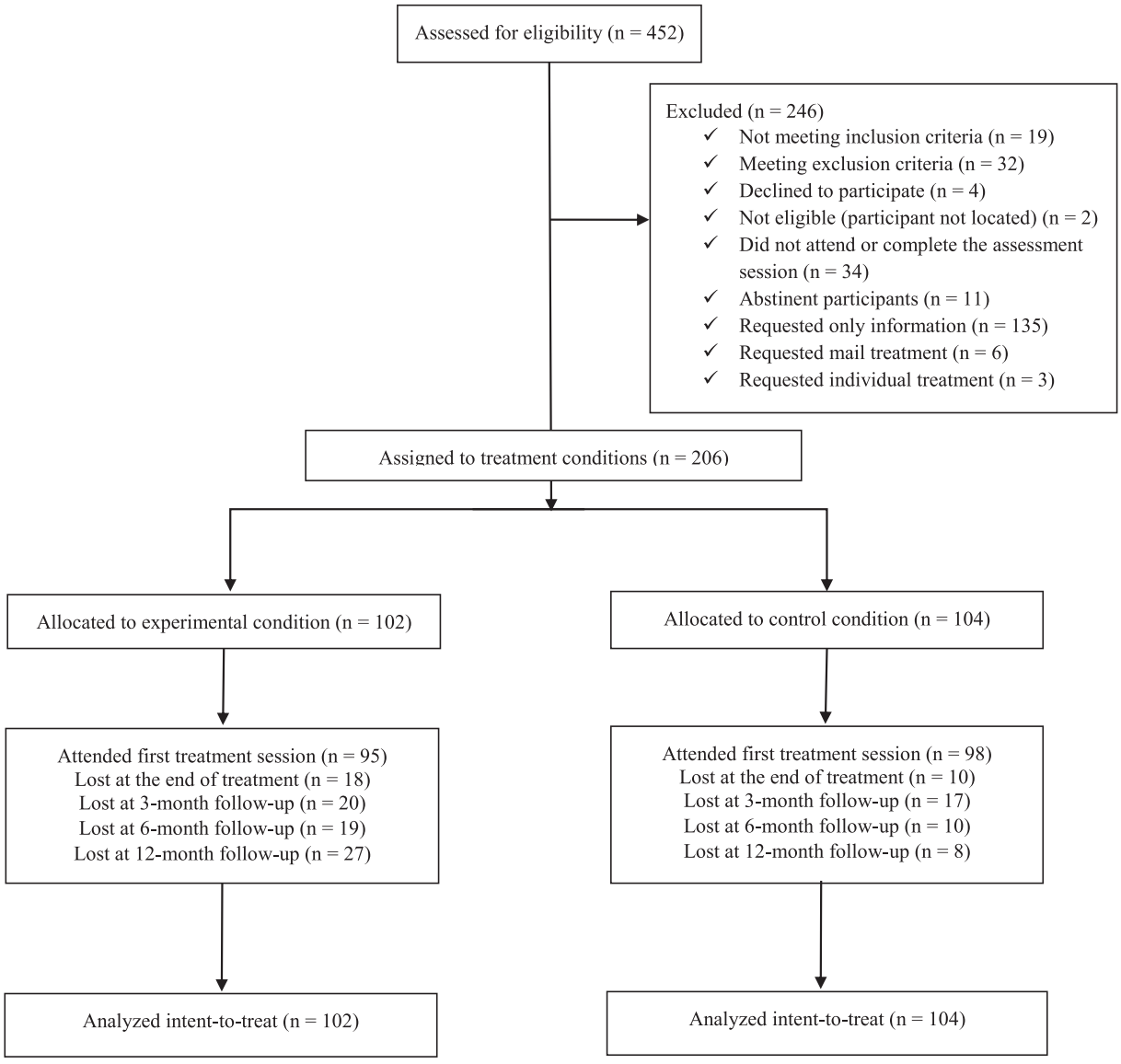

Fig. 1. Consort flow chart. Diagram for participants' allocation.

treatment, 87.4 % ($n = 180$) at 3-months follow-up, and exclusively self-reported at 6-, and 12-months follow-up. We compared abstinence rates between the participants with CO measurement and those with only self-reported information to check the possible bias this could entail. The results showed no significant differences in abstinence rates at the end of treatment ($\chi^2 = 0.013$, $p = .911$) and at the 3-month ($\chi^2 = 0.017$, $p = .896$). Furthermore, no significant differences in abstinence rates were found for participants with self-reported abstinence or self-reported abstinence and biochemical verification at the end of the intervention ($\chi^2 = 0.055$, $p = .815$; $\chi^2 = 2.523$, $p = .112$, respectively) and at 3-month follow-ups ($\chi^2 = 0.050$, $p = .823$; $\chi^2 = 0.394$, $p = .530$) according to treatment condition.

Participants who did not attend the end-of-treatment assessment or follow-up (3-, 6-, and 12-month) were considered smokers in the intention-to-treat analysis.

2.3. Procedure

Participants were recruited between 2019 and 2021 using the following methods: posters in healthcare centers and various places in Santiago de Compostela (Spain), mass media (e.g., radio or television), publications on Instagram and Facebook of the Smoking Cessation and Addictive Disorders Unit, through referrals by health professionals (e.g., primary care physicians, dentists), and through other participants who had previously received the same psychological treatment in the Unit.

People interested in participating in the smoking cessation treatment contacted the Smoking Cessation Unit by phone or email to request information. After confirming their decision to participate, they were assigned an appointment for the pre-treatment assessment, which was carried out with each participant individually. A clinical assessment session was conducted to collect information about the participants' and assess their eligibility for the study. In addition, the above-described instruments were administered. Informed consent was also obtained, signed by each participant before the intervention.

After the pre-treatment assessment session and meeting the above inclusion and exclusion criteria, participants were assigned to the following treatment conditions: 1) The experimental group received a cognitive-behavioral treatment to quit smoking combined with the "Non Fumo" smartphone App ($n = 102$) (CBT-App), 2) The control group only received the cognitive-behavioral treatment to quit smoking ($n = 104$) (CBT). Both interventions were administered by therapists with a Master's degree in clinical or counseling psychology, who had received

previous training to deliver the cognitive-behavioral intervention "Programa para Dejar de Fumar" (Becoña, 2007). Initially, participants were allocated to a group according to their availability (e.g., work schedules, childcare). Subsequently, these groups were assigned to the treatment conditions (CBT or CBT-App) according to a computer-generated allocation sequence (ratio: 1.1).

Both treatment conditions received the psychological smoking cessation treatment called "Programa para Dejar de Fumar" ([Program to Quit Smoking], Becoña, 2007). This multicomponent cognitive-behavioral intervention consists of eight weekly one-hour group sessions. The intervention includes information about tobacco (e.g., components, consequences of smoking, and benefits of smoking cessation), nicotine fading (decreasing the intake of nicotine and tar gradually), smoking self-report and graphic representation of tobacco use per day, behavioral activation, stimulus control, relapse-prevention strategies (e.g., management of anger and anxiety, physical exercise) and activities for coping with withdrawal syndrome.

Given the sanitary measures applied during the COVID-19 pandemic, two different delivery formats were used in the two treatment conditions: 1) in-person format in the Smoking Cessation Unit located in the Faculty of Psychology of the University of Santiago de Compostela. This format was applied to patients who received treatment from September 2019 to February 2020; and 2) through video calls using the Microsoft Teams platform. This format was applied to patients who received treatment from March 2020 to July 2021. Specifically, 26.2 % of the sample ($n = 54$) received the treatment in person, and 73.8 % ($n = 152$) received the treatment sessions through video calls. This psychological treatment delivery format has proven to be as effective as traditional in-person treatments (Berryhill et al., 2019; Greenwood et al., 2022).

Furthermore, various follow-ups were carried out from the end of the treatment, specifically 3, 6, and 12 months after the last treatment session.

Participants in the study did not receive any economic compensation, and no pharmacological smoking cessation treatment was used with them. This study was approved by the Bioethics Committee of the University of Santiago de Compostela with reference number USC-26/2020.

2.3.1. "Non Fumo" App

The experimental group, in addition to receiving the cognitive-behavioral treatment for smoking cessation, had access to the "Non Fumo" App. A team of experienced clinicians and researchers in Psychology designed the App, which aims to support the cognitive-behavioral smoking cessation treatment "Programa para Dejar de Fumar" (Becoña, 2007)". This App includes components such as cigarette smoking tracking (including number, hour, smoking pleasure from 0 to 10, and smoking situations), educational information about tobacco-related health consequences, achievements when quitting (e.g., health, money), social support, providing cognitive and behavioral strategies for the maintenance of abstinence and coping with craving and tobacco withdrawal syndrome (e.g., distraction and relaxation techniques videos). The App consists of 2 phases (Table 1): Phase 1, during treatment sessions, which comprised 2 components; Phase 2, during the follow-up period, which consisted of 6 components.

Table 1
"Non Fumo" App components.

Phase 1: treatment	Phase 2: follow-ups
"Non Fumo" App tool	"Non Fumo" App tool
1.Smoking self-monitoring component: allows recording the number of cigarettes consumed daily by the participants.	1.SOS component: distraction contents for coping with craving, such as gifs, games, videos, and an emergency contact list (close people to call if participants need support).
2.Treatment-related materials: access to the written materials in PDF format provided during the treatment sessions to the participants.	2.Gain and Achievements: components aimed at reinforcing abstinence maintenance. The Gain component includes: 1) the day they quit smoking; 2) the number of days without smoking; 3) money saved; and 4) time gained since quitting smoking. The Achievements component focuses on the physical improvements experienced since quitting smoking. It consists of a list of benefits that is completed based on the number of days that the person has been abstinent. 3.Tips: cognitive-behavioral recommendations to reinforce abstinence maintenance and cope with craving. 4.My videos: self-recorded videos and videos of close people (e.g., friends, family members) to motivate them to maintain abstinence. 5.Smoking self-monitoring component: allows recording the number of cigarettes consumed daily by the participants. 6.Treatment-related materials: access to the written materials in PDF format provided during the treatment sessions to the participants.

2.4. Outcomes

2.4.1. Primary outcomes

The primary outcomes were point-prevalence abstinence rates at 12-month follow-up and treatment acceptability. Point-prevalence abstinence at 12-month follow-up was defined following the Russell Standard criteria (Benowitz et al., 2020; West et al., 2005). The criterion for point-prevalence rate is previously specified in the abstinence section. Treatment acceptability was assessed with the two questionnaires about satisfaction described previously, the Client Satisfaction Questionnaire (CSQ-8, Larsen et al., 1979; Roberts et al., 1984) and the satisfaction with "Non Fumo" App questionnaire.

2.4.2. Secondary outcomes

The secondary outcomes were point-prevalence abstinence rates at the end of the treatment and 3- and 6-month follow-ups, prolonged abstinence rates and reduction in the number of cigarettes per day. Point-prevalence abstinence rates and prolonged abstinence at 6- and 12-month follow-ups were defined according to Russell Standard criteria (Benowitz et al., 2020; West et al., 2005), with the criteria described in the abstinence section. Reduction in the number of cigarettes per day (at least 50 % of cigarettes) was analyzed in those participants who continued smoking at the 12-month follow-up according to treatment conditions. Finally, acceptability was assessed with the two questionnaires about satisfaction described previously, the Client Satisfaction Questionnaire (CSQ-8, Larsen et al., 1979; Roberts et al., 1984) and the satisfaction with "Non Fumo" App questionnaire.

2.5. Statistical analysis

Statistical analyses were performed using the SPSS version 27 for Windows. Descriptive statistics (sociodemographic, psychological, tobacco-related variables, and satisfaction of the participants of the experimental group with the "Non Fumo" App) were calculated for the

Table 2
Baseline sociodemographic and tobacco-related variables according to treatment condition.

	CBT-App (n = 102)	CBT (n = 104)
	Mean/n (SD/%)	Mean/n (SD/%)
Age (years)	44.9 (9.9)	45.2 (11.8)
Sex		
Female	59 (57.8)	65 (62.5)
Education		
< High school diploma	17 (16.7)	15 (14.4)
High school or general education diploma	28 (27.4)	35 (33.7)
University or technical school	57 (55.9)	54 (51.9)
Current work situation		
Working (yes)	63 (61.8)	64 (61.5)
Marital status		
Single	36 (35.3)	36 (34.6)
Married	51 (50.0)	48 (46.2)
Other marital status (e.g., widowed divorced/separated)	15 (14.7)	20 (19.2)
CPD	18.6 (9.6)	17.3 (6.7)
Nicotine content (mg)	0.77 (0.20)	0.8 (0.1)
Years smoking	24.5 (12.4)	26.7 (11.9)
Age of onset of regular daily smoking	18.2 (5.2)	17.4 (2.8)
FTCD	5.0 (2.0)	4.89 (2.2)

Note. CPD: Cigarettes smoked per day; FTCD: Fagerström Test for Cigarette Dependence; CBT-App: cognitive-behavioral smoking cessation treatment plus a smartphone App; CBT: cognitive-behavioral smoking cessation treatment.

present study. Analyses were performed using two approaches: a) intention-to-treat principle, which includes all study participants assigned to treatment conditions, considering missing participants as smokers and b) complete-case analyses, including only those participants who responded the end of the treatment or follow-up assessments and self-reported their smoking status.

Contingency tables applying the Chi-square statistic and Mann-Whitney U test (in cases where the assumption of normality was not met) were used to calculate the differences between the treatment conditions in the pre-treatment variables (sociodemographic, psychological, and tobacco-related variables).

Chi-square statistics were applied to examine the differences between conditions in abstinence rates at the end of treatment and in the 3-, 6-, and 12-month follow-ups, as well as the possible differences in the scores of the items of the satisfaction questionnaire between the conditions. Furthermore, the Mann-Whitney U test was performed to examine significant differences in the total treatment acceptability score between the two groups. The value used to establish the statistical significance level was $p \leq .05$.

App use was examined in the experimental group. Firstly, the Mann-Whitney U test was used to assess App use according to smoking status at 12-months follow-up (abstinent vs. smoker). Secondly, a binary logistic regression analysis was conducted to examine whether the App use was associated with abstinence at 12-month follow-up.

3. Results

3.1. Descriptive analysis

At baseline, in the total sample, the mean age was 45.12 years (SD = 10.94), and 60.20 % (n = 124) of the participants were females. The mean FTCD score was 4.97 (SD = 2.11) points. Participants smoked a mean of 18 (SD = 8.29) cigarettes/day and a mean of 0.79 (SD = 0.18) milligrams (mg) of nicotine.

Table 3
Abstinence rates at the end of treatment and at the 3-, 6-, and 12-month follow-ups according to treatment condition.

	CBT-App (n = 102)	CBT (n = 104)		
Outcome variable (ITT)	***n* (%)**	***n* (%)**	χ^2	***p***
End of treatment	63 (61.8)	68 (65.4)	0.29	0.58
3-month follow-up	43 (42.2)	47 (45.2)	0.19	0.66
6-month follow-up	38 (37.3)	39 (37.5)	0.00	0.97
12-month follow-up	36 (35.3)	33 (31.7)	0.29	0.58
Outcome variable (Complete case)	***n* (%)**	***n* (%)**	χ^2	***p***
End of treatment[a]	63 (75)	68 (72.3)	0.16	0.68
3-month follow-up[b]	43 (52.4)	45 (51.7)	0.00	0.92
6-month follow-up[c]	36 (43.4)	39 (41.5)	0.06	0.80
12-month follow-up[d]	36 (48)	33 (34.4)	3.24	0.07

Note. CBT-App: cognitive-behavioral smoking cessation treatment plus a smartphone App; CBT: cognitive-behavioral smoking cessation treatment; ITT: Intention-to-Treat.
[a] CBT-App (n = 84); CBT (n = 94).
[b] CBT-App (n = 82); CBT (n = 87).
[c] CBT-App (n = 83); CBT (n = 94).
[d] CBT-App (n = 75); CBT (n = 96).

No significant differences were found between conditions in any of the baseline sociodemographic variables (Table 2), such as age (U = 5251.50, p = .90), sex (χ^2 = 0.46, p = .49), education (χ^2 = 0.96, p = .61), current work situation (χ^2 = 0.00, p = .97) or marital status (χ^2 = 0.78, p = .67). In addition, no differences were found in the tobacco-related variables of the study participants according to treatment condition, such as CPD (U = 5231.50, p = .86), nicotine content (U = 4890.00, p = .28), years smoking (U = 4831.50, p = .26), age of onset of regular daily smoking (U = 5241.00, p = .88), and FTCD (U = 5424.50, p = .58).

3.2. Primary outcomes

3.2.1. Point-prevalence abstinence rates at 12-month follow-up

The abstinence rates of the total sample at 12-month follow-up were 33.5 %. Following the ITT approach, no significant differences were found between conditions in abstinence rates at 12-month follow-up (Table 3). Results were similar when the complete case data were analyzed and no significant differences between both conditions at that assessment point were found.

We also examined abstinence at 12-month follow-up according to App use in the experimental group. The average number of accesses to the App was 295.85 (SD = 215.42). Abstinent participants at 12-month follow-up accessed to the "Non Fumo" App an average of 334.42 (SD =192.51) times and smokers 274.82 (SD = 225.56) times. No significant differences were found in App accesses according to smoking status (abstinent vs. smoker) (U = 977.00, p = .13).

The binary logistic regression analysis showed that App accesses were not associated with 12-month abstinence (OR = 1.00; p = .191; 95 % CI, 0.99; 1.00).

3.2.2. Treatment acceptability

The average score in satisfaction with the treatment (total score scale ranging from 8 to 32) measured at the end of the treatment was 30.65 (SD = 2.37) in the total sample (N = 170), 31.04 (SD = 1.79) in the CBT-App group (n = 80), and 30.30 (SD = 2.75) in the CBT group (n = 90).

Satisfaction with the treatment, was high in both treatment

Table 4
Satisfaction with the "Non Fumo" App at the end of the treatment.

	Satisfaction with the App at the end of the treatment (n = 80)			
	Strongly disagree/ not at all satisfied	Somewhat agree/ somewhat satisfied	Agree/ satisfied	Strongly agree/very satisfied
	n (%)	n (%)	n (%)	n (%)
1. Recording cigarettes through the App has been comfortable and easy for me	0 (0)	3 (3.75)	19 (23.75)	58 (72.5)
2. Having the session materials in the App has been useful to me	0 (0)	5 (6.25)	34 (42.5)	41 (51.25)
3. The App has been easy to use	0 (0)	1 (1.25)	13 (16.25)	66 (82.5)
4. In general, I consider that the App has helped me to quit smoking	1 (1.25)	9 (11.25)	43 (53.75)	27 (33.75)
5. Overall, I would recommend the use of the App to other people	0 (0)	2 (2.5)	24 (30)	54 (67.5)
6. Overall, my level of satisfaction with the App is...[a]	0 (0)	2 (2.5)	27 (33.75)	51 (63.75)

[a] This item is answered with the second answer option (Not at all satisfied/ Somewhat satisfied/Satisfied/Very satisfied).

conditions, and no significant differences were found between the CBT-App group and the CBT group when the total score of the CSQ-8 scale was considered.

The responses of the participants in the experimental group regarding satisfaction with the "Non Fumo" App at the end of the treatment are shown in Table 4. Most participants considered that the App was easy to use (98.75 %), would very satisfied or satisfied recommending the use of the App to other people (97.5 %), and overall, were very satisfied or satisfied with the App (97.5 %).

Participant satisfaction with the "Non Fumo" App was also analyzed during the 3-, 6-, and 12-month follow-ups (Table A.1). Participants showed high satisfaction with the "Non Fumo" App in all the assessment points, and most of them were very satisfied or satisfied overall with the App at the 3- (90.7 %), 6- (80 %), and 12-month follow-ups (84.5 %).

3.3. Secondary outcomes

3.3.1. Point-prevalence abstinence rates at the end of the treatment and 3- and 6- months follow-ups

Abstinence rates of the total sample were 63.6 % at the end of treatment, 43.7 % at the 3-month follow-up, and 37.4 % at the 6-month follow-up. Following the ITT approach, no significant differences were found between treatment conditions in abstinence rates at the end of treatment and the 3- and 6-month follow-ups (Table 3). When the complete case data were analyzed, no significant differences were found in abstinence rates between conditions at the end of treatment and the 3- and 6-month follow-ups.

3.3.2. Prolonged abstinence rates

For the total sample, prolonged abstinence rates were 35.4 % at 6-month and 28.6 % at 12-month follow-ups. No significant differences were found in prolonged abstinence rates according to treatment conditions at 6- and 12-month follow-ups. Specifically, 35.3 % of the participants in CBT-App group and 35.6 % of those in the CBT group were continuously abstinent at the 6-month follow-up ($\chi^2 = 0.00$, $p = .96$) and 30.4 % in the CBT-App condition and 26.9 % in the CBT condition at the 12-month follow-up ($\chi^2 = 0.30$, $p = .58$).

3.3.3. Reduction in the number of cigarettes per day

Of the total subsample of smokers at 12-month follow-up ($n = 137$), 16.6 % ($n = 23$) reduced their cigarette consumption by at least half (≥50 %) from pre-treatment to this follow-up. No significant differences were found in CPD reduction between the study conditions ($\chi^2 = 1.986$, $p = .159$).

4. Discussion

The main aim of this study was to assess the preliminary effectiveness and acceptability of the cognitive-behavioral treatment to quit smoking with the "Non Fumo" App, compared to the same psychological treatment alone. Experimental and control groups showed similar abstinence rates at the end of treatment (61.80 vs. 65.40 %, respectively) and at the 3-month (42.20 vs. 45.20 %), 6-month (37.30 vs. 37.50 %), and 12-month follow-ups (35.30 vs. 31.70 %). No significant group differences were found at these evaluation points in abstinence rates and smoking reduction. These results align with previous studies that analyze the efficacy of using Apps combined with smoking cessation treatments compared to the same smoking cessation treatment alone (Asayut et al., 2022; Krishnan et al., 2019; O'Connor et al., 2020). A plausible reason that could explain the absence of differences between both groups is that the cognitive-behavioral treatment "Programa para Dejar de Fumar" (Becoña, 2007) is an intervention that has demonstrated high levels of abstinence rates in previous studies (Martínez-Vispo et al., 2019; Rodríguez-Cano et al., 2016). Furthermore, the "Non Fumo" App was composed of the same components as the treatment received in the CBT group, although in a digital format. Therefore, future studies are needed to examine whether incorporating additional components or personalized content could improve abstinence outcomes.

Another possible variable that could be influencing the results is the frequency of App usage. Previous studies have shown that App use is a significant predictor of long-term abstinence (Bricker et al., 2022; Hoepper et al., 2022). However, our results showed that App use was not associated with abstinence at 12-month follow-up. Further research analyzing other variables (e.g. sociodemographic or tobacco-related variables) that could be related to App use and abstinence is warranted.

Focusing specifically on the abstinence results obtained in the experimental group, our results are slightly better than those presented by other studies that analyze the use of mobile Apps combined with other smoking cessation treatments (e.g., Asayut et al., 2022; Krishnan et al., 2019; O'Connor et al., 2020). However, given the variety of treatments to quit smoking used in these studies, it is impossible to establish comparisons between them. On the one hand, this is due to the kind of smoking cessation treatment applied, as some studies use brief interventions (e.g., Asayut et al., 2022; Krishnan et al., 2019) and others 6-session treatments (O'Connor et al., 2020). On the other hand, the mobile Apps used are also different and include different components. For example, some Apps are based on acceptance and commitment therapy exercises (O'Connor et al., 2020), and others use carbon monoxide measures with message support (Krishnan et al., 2019).

Regarding the participants' treatment satisfaction, we found high

percentages of satisfaction in both groups, with no significant differences between them. These results are in the same line as those obtained by O'Connor et al. (2020), who reported high satisfaction with the treatment in the ACT-only group and the combined condition (ACT treatment plus an App). Furthermore, the present satisfaction-related outcomes are consistent with those obtained in previous studies conducted in the same Smoking Cessation Unit (Martínez-Vispo et al., 2019). This suggests that the use of the App combined with psychological treatment could be a satisfactory option for people receiving smoking cessation treatment.

Finally, the participants' satisfaction with the "Non Fumo" App was analyzed, showing high percentages of satisfaction with the App during treatment and subsequent follow-ups. Thus, despite not having obtained significant smoking cessation outcomes, the App is perceived to be useful; participants would recommend it to others; and generally, they are very satisfied with it. Previous studies show similar results; that is, they do not obtain significant differences between the treatment conditions in abstinence rates, but the participants showed high satisfaction with the Apps used (Asayut et al., 2022; Krishnan et al., 2019; O'Connor et al., 2020). Our data also show high satisfaction levels with the treatment and with the "Non Fumo" App, suggesting that the intervention and the inclusion of the App were both acceptable for participants.

Even though no significant differences were found in the abstinence and treatment acceptability outcomes between the two conditions, using the App might have numerous advantages related to smoking cessation treatment. For example, the App facilitates tasks such as cigarette self-reports and increases access to the session materials anywhere and anytime. Furthermore, using the App has some advantages for the professionals applying the intervention. For example, the App's web allows the professional to check the participant's progress (e.g., the number of cigarettes smoked each day during the week) prior to the session, which could help to reduce the duration of treatment sessions. Therefore, the high satisfaction of the experimental group with the "Non Fumo" App and the numerous advantages associated with its use for both participants and professionals could be a positive indicator for further research on the use of different delivery formats, such as mobile Apps, for smoking cessation treatments.

The present study has some limitations. First, due to the sanitary measures applied during the COVID-19 pandemic, only 23.79 % of the participants carried out a biochemical verification of their abstinence. Nevertheless, authors like Benowitz et al. (2020) and West et al. (2005) suggest that abstinence outcomes are also reliable in those studies in which biochemical verification is not feasible, such as those in which the data are collected by phone or through the internet or when personal contact is limited. Furthermore, Chu et al. (2021) highlight that most studies that used smoking cessation Apps use self-reported abstinence measures. Second, using self-reported questionnaires could lead to bias, such as social desirability. Third, given the nature of the study, interventionists and participants could not be blinded to the study conditions. However, participants were unaware of the specific smoking cessation treatment components and the study research questions. Fourth, a formal sample size calculation was not performed before conducting the study. However, the sample size of the present study falls within the range recommended for pilot studies (Lancaster et al., 2004; Teresi et al., 2022). Fifth, no prior registration of the study was carried out due to the exploratory nature of the study. However, it is important to note that pre-registration of scientific studies contributes to improving rigour, reproducibility, and transparency in research and should be conducted as a regular practice. Sixth, participants of the present study were allocated to the treatment conditions based on their availability (e.g., work schedules, family responsibilities) which could introduce potential selection bias. In order to gain confidence in our results, we examined whether differences existed between the control and experimental conditions according to the schedule availability (morning and afternoon schedules), not founding significant differences. Finally, the results cannot be generalized to the general population of smokers because the sample of the present study was composed by treatment-seeking smokers.

This research has some strengths. First, the data provided are based on a pilot trial that provides an evidence-based treatment to the participants (Becoña, 2007). Previous literature highlights that more research is necessary to determine the efficacy of smoking cessation Apps (Bricker et al., 2014; USDHHS, 2020). Second, this research contributes to the scarce literature assessing abstinence outcomes of mixed interventions to quit smoking (cognitive-behavioral intervention plus an App) (Barroso-Hurtado et al., 2021; Vilardaga et al., 2019). Finally, the present research was conducted with a large clinical sample, which contributes to expanding the previous literature that sometimes uses smaller sample sizes (Dan et al., 2016; Hertzberg et al., 2013; Raiff et al., 2017).

Future studies are warranted to continue examining the efficacy of mobile Apps combined with smoking cessation treatments. Thus, future research should focus on analyzing moderator variables that may influence the efficacy of these mixed smoking cessation treatments. For example, examining the role of variables such as age or educational level would be interesting. Furthermore, an important issue that could improve the results of future studies is the personalization of the App components based on the participants' characteristics (e.g., age). In fact, previous studies investigating the preferences of participants who use smoking cessation Apps show that one of their main demands is that the App be personalized (Bendotti et al., 2022; Hartzler et al., 2016).

5. Conclusions

In summary, the results of the present pilot study show adequate treatment acceptability and abstinence outcomes when combining the psychological treatment to quit smoking with the use of the "Non Fumo" App, with no significant differences in satisfaction rates compared with traditional treatment. However, more studies are needed to establish clear conclusions on whether mixed treatments of smoking cessation interventions with mobile Apps are effective. Furthermore, using novel delivery formats, such as mobile Apps, for smoking cessation interventions could increase the attractiveness of conventional treatments for smokers who have not actively considered quitting smoking. Additionally, these novel formats can simplify and facilitate some tasks associated with the effectiveness of these interventions.

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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

Table A.1
Satisfaction with the "Non Fumo" app during 12 month follow-up period.

	3 month follow-up ($n = 75$)				6 month follow-up ($n = 75$)				12 month follow-up ($n = 71$)			
	Strongly disagree/not at all satisfied	Somewhat agree/somewhat satisfied	Agree/ satisfied	Strongly agree/very satisfied	Strongly disagree/not at all satisfied	Somewhat agree/somewhat satisfied	Agree/ satisfied	Strongly agree/very satisfied	Strongly disagree/not at all satisfied	Somewhat agree/somewhat satisfied	Agree/ Satisfied	Strongly agree/very satisfied
	n (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)
1. Being able to consult/have the sessions materials in the App has been useful to me	2 (2.7)	10 (13.3)	39 (52)	24 (32)	4 (5.3)	16 (21.3)	35 (46.7)	20 (26.7)	2 (2.8)	11 (15.5)	44 (62)	14 (19.7)
2. The gain and achievements tools (money saved, time gained, health improvements) has been useful to me	5 (6.7)	13 (17.3)	29 (38.7)	28 (37.3)	4 (5.3)	12 (16)	31 (41.3)	28 (37.3)	9 (12.7)	5 (7)	36 (50.7)	21 (29.6)
3. The tips tool of the App has been useful to me	7 (9.3)	22 (29.3)	29 (38.7)	17 (22.7)	5 (6.7)	22 (29.3)	26 (34.7)	22 (29.3)	4 (5.6)	19 (26.8)	37 (52.1)	11 (15.5)
4. The tips seemed enough to me	4 (5.3)	18 (24)	40 (53.3)	13 (17.3)	5 (6.7)	21 (28)	25 (33.3)	24 (32)	4 (5.6)	13 (18.3)	43 (60.6)	11 (15.5)
5. The SOS content (gifs, videos, emergency contact list) of the App has been useful to me	13 (17.3)	24 (32)	22 (29.3)	16 (21.3)	12 (16)	27 (36)	14 (18.7)	22 (29.3)	10 (14.1)	26 (36.6)	26 (36.6)	9 (12.7)
6. In general, I consider that the App has helped me to maintain abstinent	5 (6.7)	23 (30.7)	31 (41.3)	16 (21.3)	6 (8)	25 (33.3)	24 (32)	20 (26.7)	3 (4.2)	24 (33.8)	30 (42.3)	14 (19.7)
7. I consider that the content of the App has helped me manage the urge to smoke	2 (2.7)	21 (28)	37 (49.3)	15 (20)	5 (6.7)	25 (33.3)	25 (33.3)	20 (26.7)	4 (5.6)	21 (29.6)	38 (53.5)	8 (11.3)
8. Overall, I would recommend the use of the App to other people	2 (2.7)	5 (6.7)	34 (45.3)	34 (45.3)	1 (1.3)	7 (9.3)	30 (40)	37 (49.3)	1 (1.4)	5 (7)	32 (45.1)	33 (46.5)
9. Overall, my level of satisfaction with the App is...[a]	1 (1.3)	6 (8)	41 (54.7)	27 (36)	1 (1.3)	14 (18.7)	29 (38.7)	31 (41.3)	1 (1.4)	10 (14.1)	38 (53.5)	22 (31)

[a] This item is answered with the second answer option (Not at all satisfied/Somewhat satisfied/Satisfied/Very satisfied).

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