Substance Abuse Treatment, Prevention, and Policy

RESEARCH

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Effect and acceptability of an mHealth smoking cessation intervention 'Stopcoach' combined with smoking cessation counseling for people from multiple levels of socioeconomic position: a multi-methods study

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Abstract

Introduction Smoking cessation interventions tend to be less effective for people of lower socioeconomic position (SEP) compared to those of higher SEP. Mobile phone-based interventions have been shown to increase abstinence from smoking. Stopcoach is an mHealth smoking cessation intervention that specifically targets people with a lower SEP. A pilot study showed the potential and feasibility of Stopcoach but as yet no research exists that assesses the effectiveness of Stopcoach.

Objective This study aims to evaluate whether using Stopcoach in combination with group-based smoking cessation counselling (SCC; intervention group) increases short- and long-term abstinence compared to SCC alone (control groups). Secondarily, this study aims to assess acceptability of Stopcoach as perceived by people who smoke and SCC group coaches.

Methods This multi-methods study was originally designed comparing an intervention group ($n=242$; 2020–2022) to a historical control group ($n=3362$; 2018–2020) that did not use Stopcoach. However, the COVID-19 pandemic hampered realistic comparison due to declining abstinence rates. Therefore, a COVID-era control group was added ($n=312$; 2020–2021). All participants enrolled in professionally led SCC groups. The primary outcome was abstinence at four weeks and one year after quit date. In the intervention group, usability, acceptability and usefulness were also measured. In a qualitative assessment, eight SCC trainers were interviewed to explore acceptance by trainers and integration of Stopcoach into SCC.

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Results Due to the COVID-19 related overall decline in abstinence rates, the intervention group had lower abstinence rates compared to the pre-COVID control group (73.6% vs. 78.2% $p < 0.001$). However, the COVID-era control group revealed that Stopcoach, as addition to accredited SCC, was associated with higher abstinence rates after four weeks than SCC alone (73.6% vs. 57.1%, $p < 0.001$). This difference was sustained in the lower SEP subgroup (65.6% vs. 49.6%, $p = 0.043$). No overall significant differences in 1-year abstinence rates were found between the intervention group and both control groups. Participants rated usability, acceptability and usefulness highly positive, irrespective of SEP. Qualitative measures showed most trainers welcomed adding Stopcoach to their SCC.

Conclusion Addition of the Stopcoach app to SCC appears effective and feasible. Importantly, this also holds for the lower SEP subgroup. This makes Stopcoach one of the few smoking cessation mHealth interventions that also meets the needs of people with lower SEP who smoke.

Keywords Smoking cessation, mHealth, Socioeconomic position, Smoking cessation counselling, Stopcoach

Introduction

Despite the known deleterious effects of tobacco on health and wellbeing, almost 1 in 5 adults worldwide smoke [1]. Smoking is a bigger problem among lower socioeconomic position (SEP) groups [2]. This bigger problem is also observed in the Netherlands, where 23.6% of adults from lower SEP smoked in 2021 compared to 14.2% of higher SEP [3, 4]. In addition, in lower SEP groups in the Netherlands, heavy smoking is more prevalent whereas successful quitting is less common [5]. More than half of people who smoke die from their addiction [1, 3] Partly for this reason, smoking explains about one third of the differences in life expectancy between lower and higher socioeconomic status groups [6]. Smoking cessation can reduce relative morbidity and mortality of people who smoke., Smoking cessation interventions tend to be more effective for those with higher versus lower SEP, even though adequate smoking cessation support can definitely help people with lower SEP to quit smoking [7, 8, 9] In order to reduce this gap in effectiveness, more smoking cessation services that adequately target the lower SEP groups are required.

Multiple methods and services to quit smoking exist, but professional guidance in combination with supportive medication has proven the most effective [3]. In the last decade, eHealth and mHealth (mobile Health) interventions such as quit-smoking apps have become very popular. Due to low costs, 24/7 availability and options for automated feedback, mHealth applications have a great potential to augment the effectiveness of smoking cessation counselling. mHealth interventions can result in higher quit rates, especially if interventions are tailored, interactive and include messages [10, 11] Mobile phone-based cessation interventions have been shown to increase abstinence up to 26 weeks [10, 11] Furthermore, eHealth interventions added to other smoking cessation guidance was more effective than the smoking cessation guidance alone [12, 13] However, eHealth interventions often suffer from low adherence (high drop-out) rates, and are used less often by lower-SEP than higher-SEP individuals [14]. Previous studies stress that cessation support services have to target people with lower SEP to increase their quit chances and overcome social inequalities [7, 16] In general, usability and acceptability are important factors influencing mHealth adherence and sustained use [15].

To specifically support people with lower SEP in smoking cessation, a consortium consisting of practitioners and scientists developed the Dutch Stopcoach app. Stopcoach is a mobile application intervention inspired by StopAdvisor, an English interactive theory-based website intervention. StopAdvisor is one of the few eHealth smoking cessation interventions that specifically targets people with lower SEP, through the use of simple language and behavior change techniques aimed at supporting the target group in cessation [17]. A study with 4613 participants who smoked daily demonstrated that StopAdvisor resulted in higher abstinence rates among people with lower SEP compared to an information-only website [18]. Inspired by the StopAdvisor, the Stopcoach app uses understandable language, includes behavior change techniques especially aimed at supporting lower SEP individuals such as emotional support and feedback on progress made, and incorporates a virtual coach that sends motivational messages. Although Stopcoach has different content, structure, and delivery-mode than StopAdvisor, key behavior change techniques in StopAdvisor were also included in Stopcoach. To optimize adherence in people with lower SEP backgrounds who smoke, they were included in the development and testing process of Stopcoach. As a result, the information shared, the way information is shared and the look and feel of Stopcoach are primarily aimed at people with lower SEP. A previous implementation pilot study in five Dutch municipalities with a relatively large lower-SEP population showed that end-users, project leaders and healthcare professionals think positively of the Stopcoach app. Also, all three groups believed that Stopcoach would work best in combination with smoking cessation counselling (SCC), as this could improve adherence to the app [19]. The pilot

study showed post hoc associations between Stopcoach adherence or app activity and quit attempts but the design was not suited to clearly demonstrate the added value of Stopcoach on abstinence rates. More generally, even though studies exists combining mHealth and face-to-face interventions, to our knowledge, no other studies assess the effect of mHealth smoking cessation interventions as an addition to or in combination with professional SCC in a general population [13, 20] Therefore, in the current study, we aim to evaluate whether using the Stopcoach app in combination with participating in accredited group-based SCC increases short term abstinence compared to participating in accredited group-based SCC alone. Secondarily, we want to assess usability, acceptability, and perceived usefulness of Stopcoach as perceived by SCC providers. Tertiarily, our goal is to assess both effectiveness and feasibility in a subgroup of people from lower SEP. Quantitative and qualitative data will be used to answer both primary and secondary research questions.

Methods

Design

This multi-methods study aimed to assess the effect of adding Stopcoach to accredited group-based SCC provided by SineFuma (https://rookvrijookjij.nl/), an SCC company, on smoking abstinence at 4 weeks after quit date. We compared an intervention group (Stopcoach and SCC) to a historical control group (SCC only), as well as an additional COVID-era control group (SCC only; see below). The historical control group was chosen to limit the required number of participants (vs. an RCT) and prevent contamination between conditions. The SCC at SineFuma consists of seven live group sessions across a period of eight weeks. Groups start at approximately 12 participants. In the fourth week, all participants quit smoking. In the eighth week, four weeks after the quit date, abstinence was assessed according to the Russell Standard using self-report. One year after the quit date, self-reported abstinence was assessed according to the Russell standard via a phone call. During SCC, SineFuma encouraged participants to use pharmacotherapy. Data for the intervention group were collected in the Netherlands from December 2020 until June 2022.

Changes to protocol because of the COVID pandemic

The study initially included an intervention group of SCC participants who took part in SCC in two regions in the Netherlands (i.e., Zuid-Holland and Noord-Brabant) combined with Stopcoach, to be compared with a historical control group of SCC participants who did not use Stopcoach, with data collected prior to the intervention period between January 2018 and December 2020. The COVID-pandemic led to two changes to the original design. Firstly, as due to the pandemic fewer people participated in SCC, the recruitment region for the intervention group was expanded to all of the Netherlands as of December 2021. Secondly, during the initial analyses, we learned that the overall abstinence rates of SSC provided by SineFuma had been declining since the emergence of the coronavirus, such that 4-week abstinence rates were 78.2%, 76.5%, 73.1% and 65.5% respectively in the years 2019, 2020, 2021 and 2022. This was likely due to changes in SCC delivery and in smoking cessation processes more generally. The original historical control group would give slanted results due to this decline, as the overall abstinence rates were 13% lower in three years. A potential effect of an intervention could therefore be nullified by being compared to a historical control group with higher overall abstinence rates. A post hoc analysis was performed to deal with this, using an additional second control group from the same year as the intervention group. To minimize chronology bias, we included all SCC participants from December 2020 to December 2021 from all regions except Zuid-Holland and Noord-Brabant, i.e., all regions in the Netherlands where Stopcoach was not offered to SCC participants. In sum, three groups were compared in this study: (a) the *intervention group* who used Stopcoach in addition to SCC, and who were recruited in Zuid-Holland and Noord-Brabant from December 2020– December 2021, and in all of the Netherlands from December 2021 - June 2022); (b) the *historical control group* who participated in SCC (without Stopcoach) between January 2018 - December 2020, i.e. before the COVID pandemic; (c) the *COVID-era control group* who participated in SCC (without Stopcoach) between December 2020– December 2021 and were recruited in all of the Netherlands except for Zuid-Holland and Noord-Brabant, where Stopcoach was implemented in that period.

For inclusion, SineFuma sent everyone who registered for their SCC groups an email with a digital invitation for our study. In addition, all 16 SineFuma trainers in the participating regions were instructed to mention Stopcoach in their first SCC group sessions. The researchers provided all SineFuma trainers with a full version of Stopcoach with all stages unlocked to familiarize themselves with the app (for app users, the app would have a step-by-step process for unlocking next phases). They were also able to download the Stopcoach App with the regular step-by-step process. For their help in participant recruitment, trainers were reimbursed once with a €40 gift voucher. When SCC participants were interested, they could click a link to receive an information letter and the electronic informed consent papers. Informed consent included retrieval of data from SineFuma, obtaining data through questionnaires, and use of data in scientific research. After providing informed consent, participants

were actively involved in the study for 12 weeks. Participants followed group-based SSC from SineFuma as normal and, in addition, used Stopcoach and filled out three questionnaires. Participants who filled out all three questionnaires received a €20 gift voucher. A visual overview of the design is provided in Fig. 1.

Participants

All participants were adults who smoked and started SCC at SineFuma in the Netherlands. Further eligibility criteria included having a smartphone and basic understanding of the Dutch language. The intervention group consisted of 242 participants. For the historical control group, the pseudonymized data of 3,362 adults who smoked who enrolled into SineFuma and started SCC between January 2018 and December 2020 in any Dutch region was used. The COVID-era control group consisted of all 312 adults who smoked who started SSC during the intervention period, i.e. between December 2020 and December 2021, but taking part in all Dutch regions where Stopcoach was not offered in that period, that is, all regions apart from Zuid-Holland and Brabant.

In this study, SEP plays a large role. The concept of SEP is difficult to define but income, level of education and occupation play a role [21]. In order to classify participants based on SEP we used educational level. Educational level is often used to assess SEP in smoking research. Previous studies showed that educational level is a more reliable indicator of smoking risk compared to income and occupational class [22, 23] We used four education levels: Primary education (in Dutch: basisschool), lower secondary education (in Dutch: lbo, mavo, vmbo, mbo-1, havo-onderbouw), higher secondary education (in Dutch: havo, vwo, mbo 2–4) and tertiary education (in Dutch: hbo, wo). We further categorized these levels into lower SEP (the lower two levels) and higher SEP (the higher two levels).

Sample size calculation was performed using sealedenvelope.com. When performing studies into real-world effectiveness, sample size considerations should be based on detecting the smallest effect size of interest [24]. Studies involving mobile phone applications report average abstinence rates of 7.9–9.2% [25, 26]. To detect a similar difference in abstinence of 10%, with a significance level (α) of 0.05 and a power (1-β) of 80%, and a starting abstinence rate at 4 weeks of 80%, we needed 200 participants per group (study and historical control). To allow for an expected 20% attrition during the initial sessions of the SCC, we aimed to include a total of 240 participants.

Intervention

The intervention consisted of using the Stopcoach smoking cessation app in addition to group-based SCC. An earlier paper describes the Stopcoach app in more detail [19]. In short, Stopcoach provides users with step-by-step evidence-based information and tips about quitting smoking before and during their quit attempt. Features include motivational messages sent by a virtual coach, descriptive statistics showing participants' money saved and cigarettes not smoked, stars that participants earn for completing steps, audio and video material showing of people who had successfully quit smoking, and an easy link to the national telephone quitting helpline. At the start, participants were prompted to select a quit date at

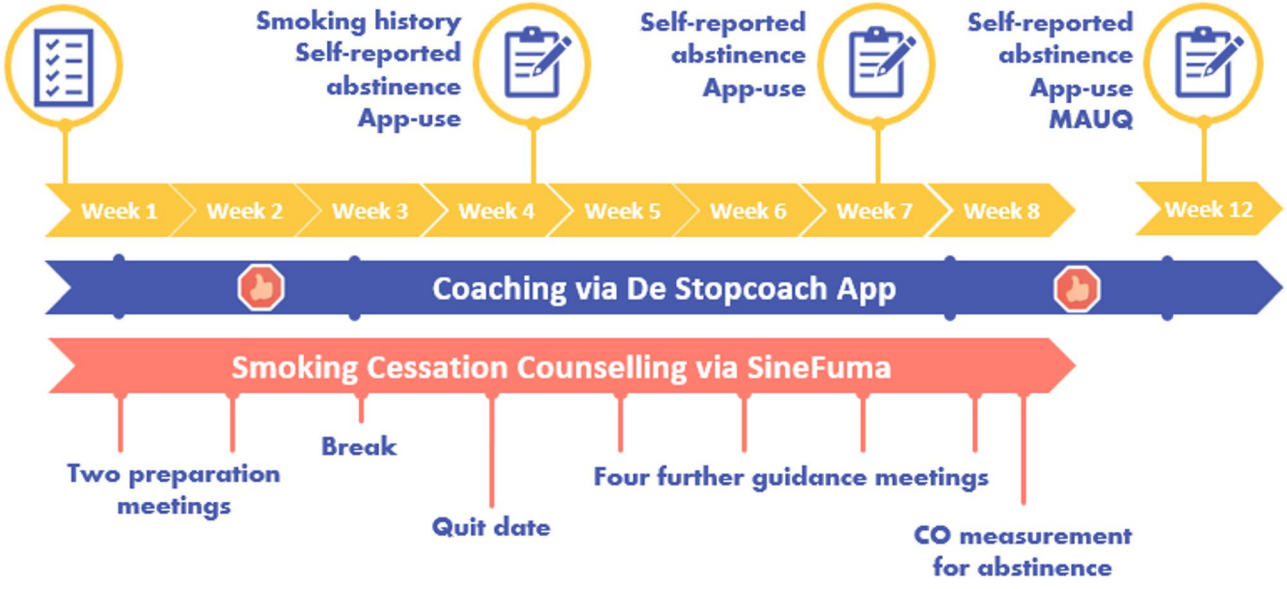

Fig. 1 Overview of Stopcoach effect study. Blue shows the coaching via Stopcoach. Pink shows the smoking cessation counselling by SineFuma. At the top of the overview, informed consent and questionnaires are noted

least two days in the future to allow for adequate preparation of the quit attempt. The subsequent program was structured into several phases, including a preparation phase, sessions for the day immediately before quitting, and the actual quit day, daily sessions during the first week following the quit date, two sessions in the second week after quitting, and six weekly sessions from weeks 3 through 12. Each step of the program delivered relevant tips and information in a clear and concise manner. Visual and auditory materials, such as videos, voice clips, and images, were prioritized to minimize the amount of textual content within the application. Starting from the quit date, users were regularly asked about their smoking status (yes/no) and overall well-being, with response options (good/OK/mediocre/bad) represented by four smiley faces. The virtual coach also sent motivational messages, tailored to users' responses to the aforementioned questions, in addition to providing tips, information, personal anecdotes, and videos through push notifications. The frequency of these push notifications decreased gradually over the weeks, transitioning from daily notifications to every other day, and eventually to once a week. Participants had continuous access to previous program steps, and the app featured a dedicated "tips & exercises" section that could be accessed at any time. Based on findings of the pilot study in 2019–2020, showing that the app's limited duration was considered its major downside, the duration of Stopcoach was extended from eight to twelve weeks [19]. Before the start of the study, a SineFuma trainer reviewed the unlocked version of Stopcoach for fit and alignment for integration with SineFuma SCC. A meeting was then scheduled with a representative of the research team. No changes to Stopcoach were deemed necessary. Participants could use Stopcoach for as long as they wanted, preferably at least until 12 weeks after the start of the study.

Procedure and data collection

Quantitative measurements

SineFuma provided data on abstinence at four weeks and one year after quit date, gender, number of pack years (number of daily cigarettes divided by 20 and multiplied by the number of years smoked), educational attainment (primary, lower secondary, higher secondary and tertiary), number of sessions attended, pharmacotherapy used and self-reported medical history. Participants provided data on age, self-reported abstinence, app usage, usability, acceptability, and usefulness by filling out three questionnaires at 4, 7, and 12 weeks during the study. The questionnaires were delivered using the Castor platform, a system to capture and integrate research data easily and securely. To measure acceptability and usability, participants filled out the mHealth App Usability Questionnaire (MAUQ) at the last timepoint, at 12 weeks [27]. The MAUQ is an 18-item validated questionnaire consisting of three subscales; usefulness, acceptability and usability. To fit the current study, we made minimal modifications to the MAUQ; items 14 "The app improved my access to healthcare services" (usefulness subscale) and 17 "I could use the app even when the Internet connection was poor or not available." (usefulness subscale) were omitted as in our study, the mHealth does not aim to improve access to healthcare services and internet connectivity was not a focus point of this study. Furthermore, we added an item "the App motivates me to quit smoking" (usefulness subscale) as this was the principal aim of the Stopcoach App. All MAUQ questions contained a 5-point Likert scale (completely agree– agree– neutral– disagree– completely disagree). The questionnaire also contained a question about app use. This self-reported app use was used as an indication of app engagement. At the end of the questionnaire, participants filled out two open-ended questions on potential improvements and reasons for not using the app.

SineFuma provided all data for the historical control group and the COVID-era control group from their records: abstinence, gender, number of pack years and level of education (primary, lower secondary, higher secondary and tertiary). To prevent traceability of data and ensure participants' privacy, we retrieved a more succinct set of data points of the control groups compared to the intervention group. SineFuma categorized and pseudonymized data before retrieval. SineFuma's database is sufficiently large to ensure that participants cannot be identified through the combination of variables obtained.

Qualitative measurements

During the intervention period, an impartial researcher not involved in the development of Stopcoach conducted semi-structured telephone interviews with SineFuma SCC trainers from the selected regions (see Appendix for the interview protocol). In the instruction materials trainers received about Stopcoach, they were informed of the opportunity to participate in such an interview, to share their experiences with Stopcoach. All interviews took place after the trainers used Stopcoach in their SCC training sessions, except for one trainer who was interviewed after giving the third session in her first SineFuma SCC training. Therefore, this trainer had not yet fully used Stopcoach during the SCC (Trainer 5). Participation was voluntary, but trainers received a €35 gift voucher after the interview (on top of the aforementioned €40 for their role in inclusion).

The interviewer followed a semi-structured interview guide to discuss multiple topics, using open questions and dialogue to discuss all topics. They discussed their experiences with Stopcoach in combination with regular SCC (i.e., preparation, offering Stopcoach to participants

during the SCC program, trainers' experiences, feedback from participants, suitability for lower-SEP participants, adding Stopcoach to SCC training). The interviews were conducted by telephone and were recorded. Oral informed consent was recorded in a separate audio file prior to the interview.

Analysis

Quantitative measures

For the primary outcome, two chi-square tests (i.e., for each control group separately) were used to evaluate whether the addition of Stopcoach to SCC is associated with improved 4-week smoking abstinence compared to SCC alone in the pre-COVID and COVID-era control groups. Subsequently, the impact of various independent factors on the 4-week abstinence was assessed separately for each control group. This assessment was conducted through logistic regression analysis, with educational level, gender, number of pack years, and the intervention type (Stopcoach vs. control) serving as independent variables. The referent groups were the intervention group, being male, the highest number of pack years and the highest educational level. In addition, two chi-square tests were used to compare long term abstinence at one year between the intervention group and, separately, each control group. To separately assess the potential effects of Stopcoach in people with lower SEP, we also performed subgroup analyses based on educational level. We combined the two lower levels of education: primary and lower secondary into low SEP, and the two higher levels of education: higher secondary and tertiary into high SEP.

As secondary outcome, overall MAUQ usability was calculated by taking the average of all MAUQ items [27]. To further specify, the items relating to usability, acceptability, and usefulness were averaged separately. In line with previous studies, usability scores were interpreted as follows: 1 = poor, 2 = fair, 3 = good, 4 = very good, 5 = excellent [28, 29]. To be able to separately assess the potential effects of Stopcoach in people with a lower SEP, we also performed subgroup analyses based on educational level. We combined the two lower levels of education: primary and lower secondary into low-SEP, and the two higher levels of education: higher secondary and tertiary into high-SEP.

Qualitative measures

AZ transcribed the interviews verbatim, after which audio recordings of the interviews were deleted. After familiarization with the transcripts, AZ analyzed and inductively coded the important passages of the transcript to capture experiences with Stopcoach in combination with regular SCC. AZ set up coding trees whilst coding the interviews. Codes were mainly structured according to pre-defined subjects used in the interview protocol, but interviews were recoded as the code tree expanded. Within the expanded topics, codes were divided into subcategories (e.g., positive and negative experiences with a particular topic). To improve reliability of the analysis, two interviews were coded separately by two researchers, after which the coded transcripts, labels, and code trees were discussed, and discrepancies were resolved. After coding the last transcript and finalizing the analytical framework, AZ and DF selected and translated relevant quotes per code. The quotes have been shortened for the sake of brevity and clarity.

Ethics

The Medical Ethical Committee of the Leiden University Medical Center in the Netherlands approved the protocol of the study (decision reference number N20.137). The team adhered to the requirements for privacy and confidentiality as listed in the Privacy Statement of the Leiden University Medical Center as well as the GDPR. All intervention group participants provided electronic informed consent for the questionnaires and retrieval of data from SineFuma, using Castor. Trainers participating in the interviews also provided their Informed consent. For both control groups, SineFuma provided data in such a way that it was not traceable to the individual participants. Every individual attending SCC group training with SineFuma had agreed to their data being used for research purposes as long as the data cannot be traced back to the individual. In Castor, data was pseudonymized and could only be accessed by authorized research personnel working on this study. All data was saved securely on the Research Memory of the Cardiology Department of the Leiden University Medical Center and will be saved for 15 years as legally required.

Results

Quantitative results

A total of 439 potential participants notified us of their interest in the study and 242 (55.6%) provided informed consent. Of these 242, 186 (76.2%) fully completed questionnaire 1 at four weeks, 163 (66.8%) fully completed questionnaire 2 at 7 weeks and 122 (50.0%) completed questionnaire 3 at 12 weeks. A total of 141 (57.8%) participants completely filled out the MAUQ at the last timepoint. From the intervention group, 106 (86.2%) participants reported to have used or actively use the Stopcoach app.

Compared to both control groups, the intervention group contained significantly more female participants (65.7% vs. 52.3%, $p < 0.001$ in the pre-COVID group and 65.7% vs. 51.9%. $p = 0.001$ in the COVID-era group) and had significantly fewer participants with over 50 pack years (12.0% vs. 17.4%, $p < 0.001$ in the pre-COVID group and 12.0% vs. 20.2% $p < 0.001$ in the COVID-era group).

Table 1 Participant characteristics

	Intervention group	Pre-COVID control group	COVID-era control group
Gender	159/242 (65.7%) female	1760/3362 (52.3%) female	162/312 (51.9%) female
Level of education			
Primary education	2 (0.8%)	130 (3.9%)	14 (4.5%)
Lower secondary	59 (24.4%)	1120 (33.3%)	99 (31.7%)
Upper secondary	81 (33.5%)	858 (25.5%)	84 (26.9%)
Tertiary or higher	78 (32.3%)	855 (25.4%)	92 (29.5%)
Unknown	22 (9.1%)	399 (11.9%)	23 (7.4%)
Packyears at start of SCC			
Fewer or equal to 10	44 (18.2%)	329 (9.8%)	42 (13.5%)
1–20	43 (17.8%)	661 (19.7%)	53 (17.0%)
21–30	48 (19.8%)	715 (21.3%)	61 (19.6%)
31–40	40 (16.5%)	618 (18.4%)	58 (18.6%)
41–50	25 (10.3%)	454 (13.5%)	35 (11.2%)
Over 50	29 (12.0%)	585 (17.4%)	63 (20.2%)

Table 2 Extra characteristics of the intervention group

M(SD)	frequency (%)
Age	52.5 (+- 12.4)
Medical history	
- Ischemic heart disease	15 (6.2%)
- Stroke	18 (7.4%)
- Hypertension	17 (7.0%)
- COPD	17 (7.0%)
Pharmacotherapy used	
None	65 (26.9%)
Patch	86 (35.5%)
Bupropion	34 (14.0%)
Patch + lozenges	24 (9.9%)
Other	33 (13.6%)
N of sessions attended	
1	2 (0.8%)
2	2 (0.8%)
3	1 (0.4%)
4	2 (0.8%)
5	6 (2.5%)
6	4 (1.7%)
7	219 (90.5%)
Self-reported current smoking at 4 wk	93/197 (47.4%)
Self-reported current smoking at 7 wk	13/166 (7.8%)
Self-reported current smoking at 12 wk	18/123 (14.6%)
App use at 12 weeks	
- Never	17 (13.8%)
- Have used	50 (40.7%)
- Use now	56 (45.5.%)

For educational level, results showed no significant deviations from expected counts in the control groups (all $ps > 0.05$). However, in the intervention group, participants with primary education and lower secondary education were underrepresented and participants with upper secondary education were overrepresented (all $ps < 0.05$, Table 1).

Participants in the intervention group had a mean age of 52.5 years. A total of 73.1% of participants in the intervention group used pharmacotherapy during their quit attempt. Nicotine patches were the most frequently used (45.4%). Almost all participants (90.5%) attended all seven sessions of the SCC program (Table 2).

Table 3 Abstinence at four weeks and one year after quit date

	Intervention group	Pre-COVID control group	Significance [a]	COVID-Era control group	Significance [b]
Abstinence at four weeks after quit date					
Entire sample	73.6%	78.2%	$P < 0.0001$	57.1%	$P < 0.001$
Lower SEP subgroups	65.6%	78.9%	$P = 0.013$	49.6%	$P = 0.043$
Higher SEP subgroups	80.5%	79.9%	$P = 0.732$	61.9%	$P < 0.001$
Abstinence at one year after quit date					
Entire sample	34.7%	38.9%	$P = 0.20$	27.9%	$P = 0.08$
Lower SEP subgroups	32.3%			30.3%	$P = 0.23$
Higher SEP subgroups	38.8%			29.5%	$P = 0.09$

Notes. (a) intervention vs. pre-COVID control group; (b) intervention vs. COVID-era control group

Effect of adding Stopcoach to SCC

When comparing the intervention group to the historical control group, the intervention group had a lower abstinence rate at four weeks after the quit date than the historical control group (73.6% vs. 78.2%, $X^2 = 29.935$, $df = 2$, $p < 0.0001$) (Table 3). A logistic regression was performed to ascertain associations between gender, the number of pack years, the level of education and Stopcoach use and the probability of being biochemically abstinent at four weeks after quit date. The logistic regression revealed that being male decreased the odds of being biochemically abstinent at four weeks after quit date by 29.7% (Exp(B) = 0.703, 95% CI [0.590–0.837], B=-0.353, $SE = 0.089$, Wald = 15.574, $p < 0.0001$). No significant difference in four-week abstinence was found for Stopcoach use (Exp(B) 1.187, 95% CI [0.855–1.647], $p = 0.306$), education level (Exp(B) 0.941, 95% CI [0.787–1.125], $p = 0.506$) or the number of pack years ($p = 0.137$).

Post hoc subgroup analysis to evaluate abstinence rates in the two lower educational levels (primary education and lower secondary education) and the two higher educational levels (higher secondary education and tertiary education) was performed using a chi-square test. In the higher SEP subgroup, no significant difference was found between the control group and the intervention group (79.9% vs. 80.5%, $X^2 = 0.038$, $df = 1$, $p = 0.846$). In the lower SEP subgroup, the abstinence in the control group was

significantly higher than in the intervention group (78.9% vs. 65.6%, $X^2 = 6.141$, $df = 1$, $p = 0.013$).

When comparing the intervention group to the COVID-era control group, the intervention group showed higher abstinence rates compared to the COVID-era control group (73.6% vs. 57.1%, $X^2 = 17.353$, $df = 1$, $p < 0.001$; Table 3). Logistic regression was used to analyze the relationship between Stopcoach use, gender, the amount of pack years and level of education and the probability of being biochemically abstinent at four weeks after quit date. It was found that the addition of Stopcoach SCC increased the odds of abstinence at four weeks by 137.7% (Exp(B) = 2.377, 95% CI [1.587–3.561], $B = 0.866$, $SE = 0.206$, Wald = 17.622, $p < 0.0001$). It was also found that higher education level increased the odds of being biochemically abstinent at four weeks after quit date by 67.8% (Exp(B) = 1.678, 95% CI [1.121–2.511], $B = 0.517$, $SE = 0.206$, Wald = 6.325, $p = 0.012$). No significant difference in four-week abstinence was found for gender (decrease of 31%, Exp(B) 0.692, 95% CI [0.466–1.027], $p = 0.068$) or the number of pack years ($p = 0.356$).

Post hoc subgroup analysis to evaluate abstinence rates in the two lower educational levels (primary education and lower secondary education) and the two higher educational levels (higher secondary education and tertiary education) was performed using a chi-square test. In both subgroups the intervention group showed consistently higher abstinence rates compared to the COVID-era control group (higher SEP: 80.5% vs. 61.9%, $X^2 = 13.921$, $df = 1$, $p < 0.001$ and lower SEP: 65.6% vs. 49.6%, $X^2 = 4.109$, $df = 1$, $p = 0.043$).

No significant differences in abstinence rates at one year after the intervention were found between the intervention group (34.7%) and the pre-COVID control group (38.9%), X^2 (1) = 1.68, $p = 0.20$, Cramer's $V = 0.02$. However, a marginally significant difference was found between the intervention group and the COVID control group, such that abstinence rates at one year after the intervention were higher in the intervention group (34.7%) compared to the COVID control group (27.9%), $X^2(1) = 2.98$, $p = 0.08$, Cramer's $V = 0.07$.

Subgroup analysis to evaluate abstinence rates in the two lower educational levels (primary education and lower secondary education) and the two higher educational levels (higher secondary education and tertiary education) was performed using a chi-square test. In the lower SEP subgroup, no significant difference was found in abstinence between the intervention group and the COVID-control group (32.3% vs. 30.3%, X^2 (1) = 1.43, $p = 0.23$). In the higher SEP subgroup, a marginally significant difference was found between the intervention group and the COVID-control group (38.8% vs. 29.5%, X^2 (1) = 2.93, $p = 0.087$).

Usability of Stopcoach

A total of 142 participants filled out the MAUQ questionnaire. The mean MAUQ score was *very good* (M = 4.05, SD = 0.62). All three components of the MAUQ, usability, acceptability and usefulness were rated around *very good*. The ease of use received the best mean rating (M = 4.19, SD = 0.59). Furthermore, acceptability (M = 3.94, SD = 0.74) and usefulness (M = 3.93, SD = 0.74) received similar marks. Figure 2 shows the mean MAUQ scores of the intervention group when split into two groups. The lower SEP group contains the two lower educational levels (primary and lower secondary) and the higher SEP group contains the two higher educational levels (higher secondary and tertiary or higher). The differences between the two educational groups were not statistically significant.

Potential improvements

Participants were asked for suggestions regarding Stopcoach and comments were offered in 281/732 questionnaires (38.4%). A majority said no improvements were needed (163/281, 58.0%). In 32 comments participants spontaneously reported the app was helpful, for example *"The App is an extra support on top of the sessions with SineFuma."*. Participants also mentioned potential improvements to the app, including wanting more information on health ($n = 26$), information about smoking in general ($n = 18$), motivational messages ($n = 14$), interactions with the app ($n = 13$) or tips ($n = 4$). For example, one participant suggested *"Perhaps a better overview of the progress in health after quitting smoking. Lung function for example."* Other options for improvement suggested by participants were a more extensive preparation (4), a longer duration of the App (3), entering a more specific money savings amount (3), gamification (2), and adding other forms of smoking such as cigars or pipe (2). "The app could use a longer timeline than 12 weeks." And "The price of cigarettes is incorrect (22 cigarettes according to the app is €8.- but is in fact €8.70)."

Negative responses focused mainly on the inflexibility of the quit date (21) and technical issues (11). Participants were only able to choose a quit date 2 to 14 days in the future, which did not always match the SCC program and resulted in a suboptimal alignment between Stopcoach and the SineFuma SCC program. After making the quit date in the app adjustable (February 2022), no more remarks on this topic were received. Participants also mentioned the time-consuming login procedure (5), the difficulty of adjusting mistakes (4), the fact that automatically generated post when sharing your attempt on social media is not esthetically pleasing (4), the oversimplicity of the app (4), the content of messages they received (3), and the overuse of smileys (2). For example, participants stated "Don't have me enter my pin code every time I log

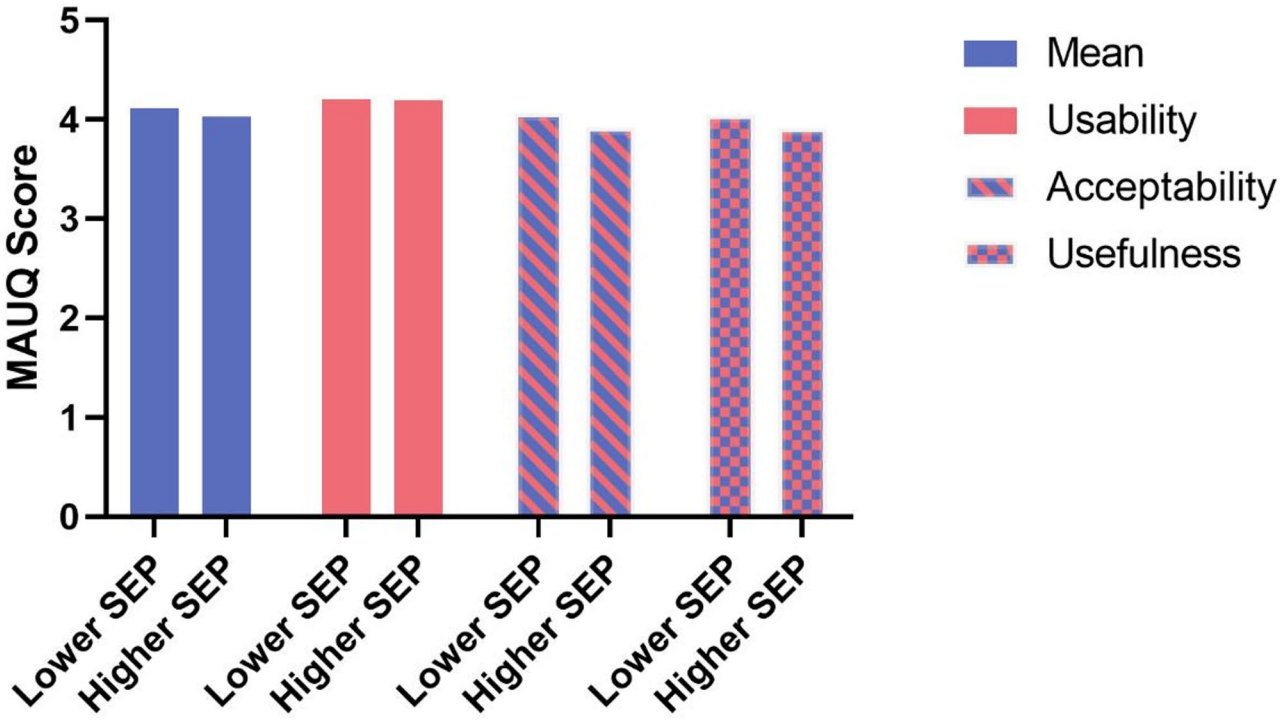

Fig. 2 Mean MAUQ scores of the intervention group split between the two lower levels of education and the two higher levels of education

in or save some work." Or "The personal messages are artificial and unmotivating."

Qualitative findings

Data saturation for the main topics in the interview guide was reached after eight participants, such that no new interview participants were recruited. Trainers worked for SineFuma from 3 to 6 years. Trainers were between 33 and 66 years old, none of them currently smoked and two had successfully quit smoking. Duration of the interviews was 22 min on average (ranging from 17 to 32 min).

Evaluation of stopcoach

Trainers' experiences with Stopcoach were mostly positive. Trainers saw Stopcoach as a good incentive and support for participants of SCC (T1,2,7,8). One trainer mentioned that Stopcoach functioned almost as a buddy for participants (T2). Trainers also appreciated that participants received additional information about quitting smoking from a different source than the SCC sessions (T6,7).

T7: *'Because in a training session, you take out a few pieces of what they find most difficult at that moment. That does not mean that there are no other things they can really think about at that moment.'*

Another positive aspect was the application's good distribution of intensity. Because Stopcoach provides more intensive support at the beginning than later in the process and lasts longer than the SCC, this was seen as a good addition to the training program (T7).

Two trainers said that Stopcoach was offered at the wrong time in the training sessions, such that the stop date in the app did not match the SineFuma stop date. Another good addition would be a contemplation phase, which would also allow stopping later (T1,7).

T1 said: *'It is an added value, I think, if you treat the process before they are going to quit as well then people feel much more in control of the process and that gives them much more confidence.'*

A contradictory finding is that trainers T4 and T6 thought that more in-depth information and clearer tips could be given, while trainer T7 thought that already too much information was provided because SCC itself is an intensive period with a lot of information.

T4 said: *'On putting in the nicotine lozenge… here (in Stopcoach) I think the information is a little brief… I always make a short step-by-step plan with the people before they put in those nicotine lozenges so that depends very much on the person.'*

Trainers' perception of SCC participants' use of stopcoach

SineFuma trainers were not specifically instructed to ask participants about their experiences with Stopcoach. However, they received both positive and negative feedback from participants. The vast majority of trainers reported that participants were extra motivated to quit by Stopcoach. Especially the overview screen showing the

number of days not smoked, the number of cigarettes not smoked and the amount of money saved were reported to be very motivating (T1,3,6,7,8). In addition, it was mentioned that the daily question of whether the participant had smoked was experienced as motivating (T7). Support from Stopcoach in case of a temporary relapse during the quit attempt was also regarded positively (T8). Negative experiences heard by trainers were mainly that participants had no need for apps during SCC (T2) and that the app did not send push notifications (T4).

Suitability for participants from lower-SEP groups

Trainers had different views on the suitability of Stopcoach for participants from lower-SEP groups. Most trainers considered the app to be suitable due to the psychosocial tools it provides and the appropriate language it uses (T2,3,4,6,7). It was also seen as an advantage that participants could download the app for free (T4).

On the other hand, some trainers perceived the language as too difficult and would like to see more visual information (T1,6,7). It seemed that trainers' different perspectives on the appropriateness of language used related to variation in literacy levels among participants from low-SEP groups. According to trainers, Stopcoach was not suitable for participants with mild cognitive impairment or low literacy.

Several trainers noted that participants from lower-SEP groups did not always see the benefit of using an app during SCC (T3,4,6,8). As such, in addition to literacy in general, digital literacy also played a role. They also mentioned that some participants from lower-SEP groups lack access to a smartphone, or have a mobile phone with fewer features. In this way, the use of Stopcoach can increase the SEP inequalities in smoking cessation.

T6 said: *'I even have a group now and those people don't have the letters right in their heads, imagine then installing an app. So that might be a slightly less convenient target group then.'*

Integration of Stopcoach within SCC program

All trainers downloaded the Stopcoach app, familiarizing themselves with it to varying degrees. They shared information about the app with participants via email and discussed it during the initial training session. The extent to which they discussed the app was at their discretion, with four trainers discussing it in multiple sessions, two in every session, and two not beyond the first session. Five trainers expressed interest in integrating Stopcoach into the SineFuma SCC program beyond the study. Specifically, three found it to be a good match, while two favored apps in general. T4 mentioned that the app complements regular counseling. Suggestions for improving Stopcoach included translation into different languages (English, Polish, Moroccan, Turkish), aligning it more closely with SCC topics, and enhancing interactivity by personalizing content based on users' motivations.

Discussion

This multi-method study aimed to better understand whether adding a smartphone application Stopcoach to SCC improves smoking cessation rates. Even though studies exist combining mHealth and face-to-face interventions on other health issues, to our knowledge, no other studies evaluate mHealth smoking cessation interventions as addition to professional SCC in a general population [13, 20] The current study provided novel insights into the effectiveness and acceptability of Stopcoach from the perspectives of both participants and trainers. There are three key findings of this study. First, analyses with an COVID-era control group in a similar period as the intervention group showed that people participating in SCC who use Stopcoach have higher abstinence rates at four weeks after quit date than people participating in SCC without Stopcoach, also after controlling for gender, number of pack years, and educational level. When comparing the COVID intervention group to the COVID control group at one year after the quit date, a marginally significant difference was found such that the intervention group showed higher abstinence rates. Second, people who used Stopcoach alongside SCC find the app usable, acceptable, and useful, regardless of their SEP. Many users were positive and wanted a longer duration of Stopcoach. Third, most SCC trainers interviewed would like to add Stopcoach to their SCC program.

The primary analysis with the historical, pre-COVID control group revealed lower abstinence rates in the intervention group compared to the historical control group (73.6% vs. 78.2% $p<0.001$). This was very likely caused by a COVID-19 related overall decline in abstinence rates of SineFuma SSC from 78.2% in 2019 to 65.5% in 2022. Repetition of the analysis with the COVID-era control group showed higher abstinence rates for SCC participants that used Stopcoach during their quit attempt (73.6% vs. 57.1%, $p<0.001$). This difference was still present after correcting for gender, the number of pack years and educational level. Notably, this difference was larger than the anticipated 10%. A potential explanation is that Stopcoach compensated for reduced effectiveness of the SCC program. The results are a continuation of a pilot study in municipalities, showing a positive association between Stopcoach intervention adherence and quit attempts [19]. This is in line with earlier studies demonstrating the potential of mHealth smoking interventions to increase abstinence [13]..

Unfortunately, the positive association between Stopcoach use and higher abstinence rates disappeared after one year. This could be due to the fact that Stopcoach was intended for use for up to 12 weeks. The application

can be used longer to display number of cigarettes not smoked and amount of money saved but does not provide novel information or functionalities.

Notably, in the intervention group, four-week cessation rates remain different between the SEP groups (80.5% vs. 65.6%). High-SEP group members are still more successful in smoking cessation, even when using interventions specifically developed for lower-SEP group members. As we know from literature and practice, people with lower SEP have lower quitting rates due to a variety of causes [30, 31] While better smoking cessation services can address some of these, broader initiatives to increase social, human, and material capital are needed to address others. Perhaps because of these disparities, and because of experiencing less economic and social stress induced by the pandemic, high-SEP group members seem to be less affected by COVID-19 [32]. However, adding the app to SCC was associated with significantly higher cessation rates in lower-SEP groups, which suggests the app has the desired effect at four weeks. The integration of new technology into existing healthcare infrastructure is an important factor in the success or failure of the new technology [33]. An excessive workload for the professionals or an inadequate fit into the organization are barriers to successful implementation, while the acceptance of the healthcare professionals working with the new technology is a clear facilitator [33, 34] In this study, Stopcoach was very well accepted by SCC trainers. The majority viewed Stopcoach as a good motivator and a solid support during a quit attempt. In their view, participants of SCC found Stopcoach useful, especially the overview with the number of days not smoked and the amount of money saved. A point of concern regarding the integration was the mismatch between the quit date in the app and the quit date at SCC, resulting from suboptimal alignment before study start despite efforts to optimize the integration. We changed stop date configurations as soon as this was noticed, which was the only change made to Stopcoach during the study. No more complaints about this topic were received after the issue was fixed. In addition, trainers thought that Stopcoach matched the training well (after fixing the quit date issue) and that Stopcoach was a valuable addition to SCC training. However, not all trainers fully integrated Stopcoach into their training sessions. A future challenge might be to better integrate Stopcoach into the SCC program from SineFuma and to integrate Stopcoach into SCCs other than SineFuma.

Another good indicator of success for new eHealth technology is its usability and acceptance as perceived by end users [33, 35] This study reveals the app was found usable, acceptable and useful by participants of an SCC program. All areas were rated around 'very good' (4 out of 5) on the questionnaires. Stopcoach users did offer a few points of improvement for Stopcoach when asked. More information on smoking in general and health effects of (quitting) smoking was one of the most reported improvements. Previous studies also indicated that end users would like to see health benefits come up in mobile phone support for smoking cessation [16]. More (motivational) messages or interaction possibilities in the app were also mentioned, although in Stopcoach, messages/pop-ups could be switched on in functionalities. The fact that users asked for more messages implies that this functionality is too difficult to find. We will fix this as messages are an effective part of an mHealth intervention. Message-based apps in addition to other interventions that showed increased abstinence compared to the other interventions alone [12]. However, despite the points of improvement, the most received feedback were compliments. In addition, users requested a duration of Stopcoach longer than the current 12 weeks. All things considered, SCC participants using Stopcoach think there are some ways to improve Stopcoach but overall were very positive about its usability, acceptability and usefulness.

Multiple smoking cessation mHealth interventions exist but Stopcoach is one of the few that targets people with lower SEP specifically. To investigate the effect of Stopcoach on people with lower SEP attending SCC, we repeated the primary and secondary analysis on a subgroup of the two lower educational levels (primary education and lower secondary education). Also in this subgroup, the intervention group which used Stopcoach showed significantly higher abstinence rates at four weeks after quit date than the COVID-era control group, however this did not last up to one year after the quit date. This could indicate that people with lower SEP can benefit from Stopcoach in addition to SCC in. The same subgroup analyses performed on the historical control group and the intervention group revealed no difference in abstinence between the intervention group and the original control group in higher SEP participants but showed a higher abstinence in the control group compared to the intervention group (78.9% vs. 65.6%, $p = 0.013$). Our study design is not adequate to determine the mechanism behind this difference, but a potential explanation is that the COVID pandemic had more impact on the abstinence rates of SCC participants with lower SEP than on those with higher SEP. Furthermore, when evaluating the MAUQ scores in the lower-SEP and higher-SEP subgroups, we saw no significant differences in appreciation of Stopcoach between the two groups. Even though the study was not powered for this research question, it could indicate good receptance on usability, acceptability and usefulness by the lower SEP SCC participants. At the same time, people with higher SEP do not seem bothered by the accessible language used. Lastly, most trainers

of SineFuma think Stopcoach could be a useful app for lower SEP SCC participants. Main reasons were the psychosocial support the app provides and the appropriate language level in the app. However, some trainers mention that Stopcoach is too difficult for people with low literacy or mild cognitive disability. All in all, Stopcoach seems to support the four-week and one-year abstinence of lower SEP SCC participants, and most SCC trainers and lower SEP users of Stopcoach find the app useful for people with lower SEP who attempt to quit.

This study has limitations. The main limitation concerns the interference of COVID, which necessitated the COVID-era control group. COVID-19 caused many SCC training sessions to be cancelled, and social distancing restrictions limited SCC sessions to an online format which may have conflicted with participants' preferences. In addition to SCC delivery, COVID-19 could also have influenced smoking behavior in many ways. One could argue that COVID-19 would be a good reason to quit smoking, given the higher risks for people who smoke, but research suggests that COVID-19 did not encourage people to quit smoking [36]. A Dutch study on smoking during the pandemic suggests that the relationship between covid and smoking cessation was mediated by stress. People who experienced more stress during the pandemic (potentially people with a lower SEP background) were more likely to change their smoking behavior, whether it was an increase or a decrease [37]. Finally, there is even evidence that the lockdown and home isolation led to increased smoking prevalence and increased quantities of smoking [36]. Furthermore, COVID-19 likely contributed to the declining rates of abstinence for SineFuma's SCC program. This led to slanted results in our primary analysis. The subsequent post hoc analysis is a risk for confirmation bias as we performed the analyses after our primary analyses. In addition, we cannot rule out the role of potential regional differences, as participants in the intervention and COVID-era control groups were recruited from different regions. However, the addition of the COVID-era control group is still the best option to evaluate Stopcoach's effectiveness in this situation. The COVID-era control group enabled a comparison between similar groups at similar timepoints, thus reducing the chronology bias from the historical control group. Importantly, this study was conducted amidst the backdrop of the COVID-19 pandemic, which had varying effects on smoking behaviors. Some individuals were motivated to quit smoking, while others increased their smoking, and some reported no change in their smoking habits [37, 38] Therefore, it is essential to acknowledge that the study's findings may not be entirely applicable to contexts outside the influence of a pandemic. Interviews with participants were not feasible within the study's timeframe but would have shed more light on this. Although the primary focus of the current study was not to investigate the pandemic's role in supporting quit attempts, it did demonstrate that Stopcoach remains a valuable tool, even in the challenging context of a pandemic.

In addition to the role of the pandemic, the modifications made to the MAUQ may have reduced the reliability and replicability of the questionnaire results. In our opinion, the results of the MAUQ are still adequate to gauge the usability of Stopcoach in the eyes of the users. Furthermore, to protect the privacy of control group participants, limited data was available for these groups. Ideally, SEP would have been measured more comprehensively (e.g. including income and/or neighborhood deprivation), and factors such as use of pharmacotherapy would have been included as covariates. Lastly, the issue with the inflexible quit date in Stopcoach, which was missed when ensuring alignment between Stopcoach and the SCC program, was a limitation to the study. It may have lowered the validity of our results as it may have led to lower app adherence by participants. A positive note here is that we have a real-life study with a relatively large sample size.

Future research could focus on identifying reasons for the finding that Stopcoach appears to work at four weeks but does not seem to support abstinence at one year. Also, information on the association between app adherence and abstinence could be of use. Further iterations of Stopcoach could focus on longer and more interactive support, better integration with SCC programs, and providing more information on health and smoking without losing accessibility.

The main result of this study is that mHealth intervention Stopcoach, as addition to an accredited SCC, shows higher abstinence rates than accredited SCC alone both at short and long term. Noteworthy, this difference remains when evaluating a subgroup of lower SEP participants at short-term. This could indicate Stopcoach as a low cost, 24/7 available, and likely effective addition to SCC. Stopcoach is also received well by SCC participants and trainers. This indicates that Stopcoach could be a very useful tool in helping people to quit smoking.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13011-025-00651-z.

Supplementary Material 1

Acknowledgements

The authors would like to express their gratitude to SineFuma and especially Marcel Clarijs for the warm, proactive and constructive collaboration during this study. Also, the authors would like to thank Saïda Moaddine and Amber Zeeman for their contribution regarding the inclusion of participants. Stopcoach is inspired by StopAdvisor, which was originally developed and evaluated in a research collaboration led by a team at

UCL. Resulting academic outputs are available in scientific literature. We acknowledge the authors of these outputs and those contributors listed in the acknowledgments of those papers.

Author contributions
DF and EM thought up and prepared this study. DF collected data, ran the analyses, and interpreted the short-term outcomes. AZ analyzed the qualitative data and ran the analyses and interpreted the long-term outcomes. DF wrote the first version of the manuscript and AZ wrote the first version of the qualitative sections. EM supervised both DF and AZ during the study. BP, ST and SH formed a steering committee during the study. EM did substantial revisory work. BP, ST, SH, VJ, DA and NC did revisory work. All authors read and approved the final manuscript.

Funding
Noaber Foundation, the Netherlands Expertise Centre for Tobacco Control, part of Trimbos-institute, Pharos (Dutch Centre of Expertise on Health Disparities) and Leiden University Medical Center co-funded the development and evaluation of Stopcoach.

Data availability
Data is provided within the manuscript. Any further request can be made to the authors.

Declarations

Ethics approval and consent to participate
The Medical Ethical Committee of the Leiden University Medical Center in the Netherlands approved the protocol of the study (decision reference number N20.137). The team adhered to the requirements for privacy and confidentiality as listed in the Privacy Statement of the Leiden University Medical Center as well as the GDPR. All intervention group participants provided electronic informed consent for the questionnaires and retrieval of data from SineFuma, using Castor. Trainers participating in the interviews also provided their Informed consent. For both control groups, SineFuma provided data in such a way, that it was not traceable to the individual participants. Everyone attending SCC group training with SineFuma had agreed to their data being used for research purposes as long as the data cannot be traced back to the individual. In Castor, data was pseudonymized and could only be accessed by authorized research personnel working on this study. All data was saved securely on the Research Memory of the Cardiology Department of the Leiden University Medical Center and will be saved for 15 years as legally required.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 15 November 2024 / Accepted: 11 May 2025
Published online: 28 May 2025

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