Randomised factorial experiment of components of the SmokeFree Baby smartphone application to aid smoking cessation in pregnancy

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Declarations

The authors have full control of all primary data and allow the journal to review it if requested. This manuscript is not being simultaneously submitted elsewhere and the data/views have not been previously published.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethical approval for this study was received from the UCL Psychology and Language Sciences Departmental Ethics Committee (Project ID: CEHP/2013/508).

Informed consent was obtained from all individual participants included in the study.

This article does not contain any studies with animals performed by any of the authors.

Abstract

Background: Smartphone applications (apps) might be able to reach pregnant smokers who do not engage with face-to-face support. However, we do not know how far pregnant smokers will engage with smoking cessation apps or what components are likely to be effective.

Purpose: This study aimed to assess pregnant smokers' engagement with the SmokeFree Baby app (v1) and to assess the short-term efficacy of selected components ('modules') for smoking abstinence. Positive outcomes would provide a basis for further development and evaluation.

Methods: SmokeFree Baby was developed drawing on behaviour change theories and relevant evidence. Pregnant smokers (18+) who were interested in quitting and set a quit date were recruited. Following multiphase optimisation development principles, participants (N=565) were randomly allocated to one of 32 (2x2x2x2x2) experimental groups in a full factorial design to evaluate five modules (each in minimal and full version: identity, health information, stress management, face-to-face support, behavioural substitution). Measures of engagement included duration and frequency of engagement with the app. Smoking abstinence was measured by self-reported number of smoke-free days up to four weeks from the quit date.

Results: Participants engaged with the app for a mean of 4.5 days (SD=8.5) and logged in a mean of 2.9 times (SD=3.1). Main effects of the modules on the number of smoke-free days were not statistically significant (identity: p=0.782, health information: p=0.905, stress management: p=0.103, face-to-face support: p=0.397, behavioural substitution: p=0.945).

Conclusions: Despite systematic development and usability testing, engagement with SmokeFree Baby (v1) was low and the app did not appear to increase smoking abstinence during pregnancy.

Key words: smartphone app, intervention optimisation, factorial experiment, engagement, smoking cessation, pregnant smokers

Introduction

Digital behaviour change interventions (DBCIs), such as smartphone apps aimed at helping people to stop smoking, are being developed at a rapid rate [1, 2] with hundreds of such apps available on app stores (e.g. Apple app store or Google play). Only a few apps have any evidence behind them [3] and high-quality randomised controlled trials (RCTs) have yet to provide clear evidence for their effectiveness to aid cessation [4-6]. Pregnant smokers might benefit from support from such apps but to date we do not have any evidence-based apps for this population. This paper reports on a study aimed at identifying potentially effective components to put into such an app, named SmokeFree Baby.

DBCIs could be attractive to pregnant smokers who do not engage with face-to-face support [7, 8] and who face numerous barriers, such as lack of access to specialised services [9]. There is some evidence that text messages can increase cessation rates during pregnancy [10] and when provided alongside routine care [11], but to date smoking cessation apps have not been evaluated among pregnant smokers [12].

This study followed the Multiphase Optimisation Strategy (MOST) approach to intervention development [13]. MOST involves an optimisation phase in which intervention components are evaluated in one or more factorial screening experiments to identify which components show promising effects prior to evaluating the intervention as a treatment package in an RCT. The primary aim of factorial screening experiments is to generate hypotheses for further evaluation [14]. Understanding the effectiveness of specific intervention components and

using factorial designs to guide intervention development have been recognized as important but relatively neglected areas of smoking cessation research [15]. Only a few studies have reported using this approach to inform the development of DBCIs in other areas, e.g. to prevent substance use [16] and to reduce alcohol consumption [17].

Assessing participants' engagement with DBCIs is key to understand intervention effectiveness [18]. However, the nature and level of engagement can vary extensively across DBCIs, behaviours and populations [19, 20]. Moreover, an integrative definition of engagement with DBCIs proposes that it comprises more than one component: one's subjective experience (e.g. interest in using the DBCI) and behaviour (e.g. frequency of use) [21]. Therefore, although previous studies suggest that text messages can engage pregnant smokers with smoking cessation support [10, 11], the evidence is scarce regarding engagement with apps in this context, and this needs further research.

Prior to the optimisation phase, intervention development should involve arriving at an intervention that is likely feasible and acceptable enough to generate sufficient engagement [22]. This phase of the pregnancy-specific smoking cessation app, SmokeFree Baby involved focus groups with health care providers who work with pregnant smokers [23], usability testing of the prototype app [24], and a think-aloud study with pregnant smokers to explore their views on the design, content and usability of the app [25]. Results from this formative work suggested that there would be good engagement with the app.

The current study assessed the potential efficacy of five app components: 1) fostering a positive non-smoker identity, 2) providing health information about the consequences of smoking and benefits of cessation, 3) promoting use of face-to-face support, 4) improving

stress management, and 5) promoting behavioural substitution. A detailed description of the modules and the rationale for their inclusion has been reported previously [24]. For example, findings from our formative work suggested that pregnant smokers wanted further cessation support (preferably face-to-face) in addition to an app. The 'face-to-face' module was designed with these findings in mind to provide participants with easy access to local stop smoking services and stop smoking websites [26].

The following research questions were addressed:

1. What is the extent to which pregnant smokers engage with the app in terms of (i) duration and frequency of app use and (ii) use of app features ('active engagement')?
2. What are the main effects of, and two-way interactions between full and minimal version of five components (identity, health information, face-to-face support, stress management, behavioural substitution) on self-recorded smoking abstinence during the four weeks after the quit date?

Methods

Ethics

Ethical approval for this study was received from the UCL Psychology and Language Sciences Departmental Ethics Committee (Project ID: CEHP/2013/508).

Study design

Participants were randomly allocated to one of 32 experimental groups in a 2x2x2x2x2 full factorial design. Intervention components that were experimentally varied were termed 'modules'. Each of five modules (identity, health information, face-to-face support, stress

management, behavioural substitution) had a ‘minimal’ version (brief quit advice) and a ‘full’ version (interactive content). The CONSORT guideline for reporting RCTs was followed, and the completed checklist is reported in the supplementary file.

Participants

Data were collected between October 2014 and October 2016. The SmokeFree Baby app (v1) was developed in England, but it was available to anyone through worldwide app stores, including the Apple app store (itunes.apple.com/us/app/smokefree-baby/id925671396) and Google play (play.google.com/store/apps/details?id=com.silverbackis.smokefreebaby). The app was in English.

Participants were recruited through a number of methods, as follows. Stop smoking advisors who interact with pregnant smokers recommended the app to their patients. Printed information leaflets (https://osf.io/6usyp/ and https://osf.io/qj4gc/) were distributed in England. The leaflets could be ordered through Public Health England’s Start4Life campaign resources website (https://campaignresources.phe.gov.uk/resources/campaigns/2-start-4-life/resources/129). A dedicated website (www.smokefreebaby.co.uk) was developed and an online advertisement was placed on a pregnancy-related charity’s website (www.tommys.org/pregnancy-information/i’m-pregnant/smoking-and-pregnancy/get-help-stop-smoking). The app could also be found through independent worldwide searches on the app stores. Participants did not receive financial compensation for taking part in the study.

Participants were included if they opened the app with the study code (‘9123’), provided consent to participate, were pregnant, aged 18+, smoked cigarettes at least once a week, were interested in stopping smoking and set a quit date in the app.

The sample size was determined based on an *a priori* power calculation. To detect an assumed small to medium effect size of d=0.3 for main effects on the number of smoke-free days with 80% power and a two-tailed α=0.05, a minimum of 352 participants (11 participants in each of 32 groups with an equal allocation ratio) had to be recruited.

Measures

At baseline, a unique device identifier (device ID) was automatically registered in the study database when the app was opened at the first time. If duplicated device IDs were registered, they were excluded and the first case of downloads was retained for further analysis. Uptake of the app (number of eligible participants who completed the registration) was automatically registered. Data on the operating system (iOS or Android) and participants' country of registration were also automatically registered.

Participants completed a questionnaire that asked them about their age, highest completed educational qualification, employment status, week of pregnancy and the number of children they had (Table 1). Nicotine dependence was assessed by the Heaviness of Smoking Index (a composite measure of number of cigarettes smoked per day and time to first cigarette) [27]. They were asked 'When did your most recent quit attempt start?' (not yet attempting; in the last week; more than a week and up to a month; more than one month and up to two months; more than two months and up to three months; more than three months and up to six months; more than six months and up to a year) and 'What types of support are you using in addition to the SmokeFree Baby app to help you quit smoking?' (see response options in Table 1). Motivation to stop smoking was assessed by asking participants how much they wanted to stop smoking during this pregnancy (not very; quite; very; extremely). Participants selected a

behaviour change goal and a date within 14 days from the date of registration to either stop smoking completely or cut down to fewer than three cigarettes per day. The cutting down option was offered to those who did not feel confident to quit abruptly, to assess whether or how far this would prove attractive and ultimately lead to cessation [28, 29]. Complete cessation was the primary target behaviour and all participants were encouraged to stop smoking completely.

Measures of engagement included duration of engagement (number of days between participants' first and last log-in), frequency of engagement (number of log-ins) and active engagement (interacting with or rating the usefulness of an app component). Smoking abstinence was measured by the number of self-reported smoke-free days up to four weeks from participants' target quit date. This measure was selected because it was an optimisation study and we sought what we thought would be the most sensitive measure that would predict longer-term cessation. Smoking abstinence was assessed once a day, when participants first logged in to the app, by asking them 'Did you smoke any cigarettes at all yesterday?'.

Intervention

The full content specification of SmokeFree Baby is available through Open Science Framework (https://osf.io/nv8t2/). The intervention development process, including a detailed description of the theoretical underpinning and the selection of intervention components, is published elsewhere [24]. Forty-two distinct behaviour change techniques (BCTs) were included in the app; these are defined as the smallest intervention components that on their own have the potential to change behaviour [30, 31], from the BCT Taxonomy v1 [32]. The BCT specification of the app has also been published [24]. Intervention components that were available to all participants were termed 'general app features' (e.g. 'Withdrawal symptom'

features included tips to cope with withdrawal). The app was available for iOS (version 6.0 and later) and Android (version 4.1 and later) devices, and it was provided free of charge.

Procedure

Once SmokeFree Baby was downloaded to a digital device, a code had to be entered to open the app. The study code ('9123') was offered as default on the main screen and a separate code ('5555') was provided for those who wanted to opt out of the study; they could still access a minimal version of the app. In order to minimise contamination, a code ('1234') was advertised for health professionals and researchers who were interested in the app.

Randomisation was implemented using an algorithm embedded in the SmokeFree Baby program. The randomisation matrix is reported in the electronic supplementary materials (Supplementary Table 1). Participants had to be online at the time of randomisation. In order to maximise recruitment, eligible participants were randomised immediately after opening the app for the first time. The background questionnaire could be completed and a quit date set at a later point, online or offline. A random number of 1-32 was generated when a new user entered the code for the experiment until one participant was added to each group. Then randomisation started again with the next block of 32 groups. Participants were blinded to group allocation. The research team, who assessed the outcomes, were able to see the group allocation to check if the procedure was implemented correctly.

In the next step, information about the study was provided and consent was obtained from each participant. A brief questionnaire was included to collect background information and to assess participants' eligibility to participate in the study. Because eligibility was checked after randomisation, recruitment and random allocation of participants commenced until each

cell contained the minimum number of eligible participants. Follow-up was implemented automatically by using an in-app feature that prompted participants at the first login each day to record if they had smoked any cigarettes at all in the past 24 hours. The research team had no contact with study participants at any point during the RCT, apart from directing them to the app developers for technical support.

Analysis

Data analysis was conducted using SPSS 20.0. Descriptive statistics were used to report uptake of the app, device characteristics and participants' baseline characteristics, and engagement with the app. Differences in baseline characteristics between minimal and full versions of each module were explored using Pearson's chi-squared test (for categorical variables) and one-way ANOVA (for continuous variables). Between-subject factorial ANOVA was used to evaluate main effects of, and two-way interactions between (all interactions were included in the analysis, but not reported), the five modules on engagement and smoking abstinence. 'Effect coding' was used, so that main effects and interactions could be interpreted according to their classical definition, where the 'minimal' level of each module was coded as -1 and the 'full' level was coded as +1. Participants who were lost to follow-up were retained in the intention-to-treat (ITT) analysis and assumed to achieve zero smoke-free days. In case of a non-significant main effect, Bayes factors were calculated with half-normal distribution using mean difference parameter estimates to represent the alternative hypothesis. This was done using an online tool (http://www.lifesci.sussex.ac.uk/home/Zoltan_Dienes/inference/Bayes.htm). Bayes factors are indicators of the relative strength of evidence for one's theory over the null-hypothesis given the data [33], and they allow determination of whether the results can be interpreted as evidence to support a null-hypothesis or the data are inconclusive as to whether or not the

differences were present [34]. Conventional cut-offs [33, 35] were used to interpret Bayes factors (<1/3: evidence for null hypothesis; >3: evidence for alternative hypothesis; 1/3< and <3: the data were inconclusive). Sensitivity analyses were conducted among those who logged in at least once after their quit date, and Bayes factors were calculated for large effects.

Results

Uptake and user characteristics

Participant flow is reported in Figure 1. Of 1702 downloads, 565 people (33.2%) met the eligibility criteria. The uptake of the app by eligible participants was a mean of 22.6 people per month (SD=12.8). Of eligible participants, those who set a quit date more than a month prior to 31st October 2016 and engaged with the app up to 28 days from the quit date were included in the primary analysis (N=494; 87.4%). The minimum requirement for engagement was the completion of registration. Of these, 318 (64.4%) did not respond to any follow-up questions regarding their smoking status (308 participants used the app only on the day of registration and 10 did not log in after the quit date).

Baseline characteristics are reported in Table 1. Sixty-three per cent used an iOS device, 51% were from the UK, 30.4% had non-manual occupation, 57.5% were in the first trimester of pregnancy, 38.8% used only SmokeFree Baby to aid cessation and 72% wanted to stop smoking completely. There were no statistically significant differences between the minimal and full versions of the modules in terms of participants' baseline characteristics.

Participants' engagement with the app

Participants engaged with the app for a mean period of 4.5 days (SD=8.5) (from registration until last login) and logged in a mean of 2.9 times (SD=3.1) with 62.3% (N=308) logged in once or twice and 29.0% (N=143) logged in three to five times. Main effects of, and interactions between, modules on duration and frequency of engagement, respectively are reported in Supplementary Tables 2 and 3. The full health information module had a statistically significant main effect on duration of engagement (F=5.018; p=0.026). The interaction between face-to-face support × behavioural substitution (F=4.170; p=0.042) was also statistically significant; the full version of both modules yielded longer engagement than other conditions. There were no statistically significant main effects on frequency of engagement, but the interaction between identity × behavioural substitution was statistically significant (F=4.882; p=0.028); those who received the full version of the modules logged in more frequently.

Participants' active engagement with general app components is reported in Table 2. Five general app features ('How addicted are you?', 'Reasons to quit' – 1 and 2, 'Getting ready', 'Withdrawal symptoms') were available after registration. Thirty-six per cent (N=178) of all participants engaged with at least one of these (Mean=0.6; SD=1.1). A further four general app features ('Medicine'; 'Phone support'; 'Video memos'; 'Social') were available after the quit date, and 55.1% (N=272) engaged with at least one of these (Mean=0.7; SD=0.8).

Participants' active engagement with the full version of the modules is reported in Table 3. Of those who received the full version, 25.8% (N=65) actively engaged with at least one of four interactive content features in the identity module, no participant engaged with the 'Tip of the day' in the health information module, 19.3% (N=47) engaged with at least one of three interactive content features in the face-to-face module, 7.9% (N=21) engaged with at

least one of two interactive content features in the stress management module and 2.9% (N=7) engaged with at least one of two interactive content features in the behavioural substitution module.

Effects of modules on smoking abstinence

Main effects of, and two-way interactions between, modules are reported in Table 4. Since main effects of the modules on smoking abstinence were not statistically significant, Bayes factors were calculated. Bayes factors suggested that the findings were either inconclusive (as to whether or not the differences were present) or supported the null hypothesis. The interaction between identity × behavioural substitution was statistically significant (F=6.368; p=0.012); those who received the full version of the modules attained more smoke-free days. In the sensitivity analysis (Supplementary Table 4), when only those were included who logged in at least once after the quit date (N=176), the pattern of results remained the same.

Discussion

Only a small proportion of pregnant smokers used the app following registration, responded to in-app follow-up questions, and engaged actively with the intervention content. The factorial screening experiment found that from the identity, health information, face-to-face support, stress management and behavioural substitution modules none had a statistically significant main effect on smoking abstinence.

Low engagement is one of the main challenges of DBCIs [19] even when they are developed according to best practice [22, 30]. SmokeFree Baby was developed by systematically selecting BCTs using a rigorous methodology, including drawing on theory and evidence from the scientific literature [24]. Experts also rated the app as high quality based on its

engagement, functionality, aesthetics, information, subjective qualities and adherence to smoking cessation treatment guidelines [36]. Although participants were asked to complete a background questionnaire after downloading the app, only a minority (4.9%) of participants, who would have otherwise been eligible, disengaged prior to setting a quit date. Therefore, the process of registration prior to accessing the intervention itself does not appear to drive substantial disengagement.

Nevertheless, pregnant smokers, who met all inclusion criteria, engaged with SmokeFree Baby to a lesser extent than previously found in generic smoking cessation apps [37] and pregnancy-orientated smoking cessation text-messages [38]. Compared with a pre-/post-natal health-related app that did not specifically target smoking or pregnant smokers [39], engagement with SmokeFree Baby appears to be low. In high income countries, the vast majority (85-94%) of adults (including women of childbearing age) own a smartphone with internet access [40, 41], and health-related apps are widely used among pregnant women [42, 43]. However, evidence regarding the use of smartphones and engagement with health-related apps specifically among pregnant smokers is scarce; it is therefore difficult to draw conclusions about the relative app usage and engagement in this sample. In terms of active engagement with SmokeFree Baby, it was also low overall, although some of the app features that provided practical tips to cope with social situations and withdrawal appeared to be more engaging than other features.

We did not have *a priori* hypotheses for interactions between modules and thus inferences from these effects should be regarded as tentative. The combined use of the full version of identity (aimed at prompting positive self-labels, self-images and self-thoughts as a non-smoker) and behavioural substitution modules (aimed at providing distraction from urges to

smoke) yielded a small but statistically significant effect on smoking abstinence. This is in line with integrative behaviour change theories proposing that reflective and automatic motivation interact in driving behaviour [44-46]. For example, PRIME theory [44] suggests that identity (e.g. reflective motivation to become a non-smoker mum) as well as impulses (e.g. automatic motivation to have a cigarette in response to smoking cues) are important sources of wants and needs, the strongest of which will drive behaviour at any relevant moment. Acting in line with self-conscious intentions in the face of conflicting impulses requires self-regulation. Identity can strengthen self-regulation, but because resisting conflicting impulses is likely to be mentally effortful, distraction strategies such as behavioural substitution may help by saving the person's mental resources. Although the interactive effect between identity and behavioural substitution warrants further research, another DBCI with better participant engagement should be used for testing this association further.

In terms of practical implications, our formative work involving qualitative studies (e.g. using think-aloud methodology) provided useful insights as to what potential users want and how they may interact with the app. However, these studies had small samples, were conducted in laboratory settings with potentially more motivated participants who also received incentives (e.g. vouchers) for taking part in the study. Therefore, engagement also needs to be tested in real-world settings from the early phases of intervention development. A potentially useful way of doing this is to draw on principles from agile methodology [47], where intervention modules are delivered and tested iteratively (e.g. with concurrent or sequential A-B testing) over short periods of time (usually within weeks). This approach might have been adopted in this study and the app revised until engagement was sufficient.

However, it may be that apps are not suitable for reaching and engaging pregnant smokers with smoking cessation, even if procedures for conducting formative work are improved. This may be because engaging with apps may be more effortful (e.g. they require users to log in and follow through a programme) which requires higher motivation, as opposed to, for example, text-messages that are more difficult to ignore when received and thus easier to engage with. There may be issues around app literacy in that if apps are too complex or have too many components, it may be difficult for pregnant smokers to understand and engage with the content. It is also possible that pregnancy-specific smoking cessation apps might need to be integrated with face-to-face support in order to engage this population with digital support.

Engagement with the app plummeted within days of registration despite various strategies in place to boost engagement. This included sending push notifications on three consecutive days after registration and then once a week for three consecutive weeks. Participants were also prompted (both by push notifications and in-app notifications) to view the new content that was released every day, and the content was presented in various modalities (e.g. videos, quizzes, simple text). However, push notifications could have been turned off, and the in-app notifications could have remained unnoticed if participants did not log in. The low levels of active engagement with various app contents suggest that participants were not particularly interested in and did not particularly enjoy the content. Potential strategies to boost engagement with apps in the future may include multiple sources of health messaging and tailored provision of specific app components so that participants are only exposed to content that are most relevant and helpful for them.

One of the limitations of the study was that participants were screened against eligibility criteria after randomisation, and there was a slight imbalance in sample size, reducing power to detect differences between modules. Bayes factors were calculated that supported the null hypothesis, except for the stress management module where it suggested that the data were inconclusive to detect an effect. Another limitation was high attrition and consequently low response rate to daily follow-ups on the primary outcome. Although there was no biochemical validation of smoking abstinence, data on self-reported smoking status were collected automatically with no contact from the researchers and no material rewards were given for participants for being abstinent; therefore, it is unlikely that smoking status would have been misreported. Although understanding the experiential and behavioural facets of engagement with DBCIs is important [21], we were not able to investigate this with the data collected in this study. Further research is needed to be able to disentangle factors related to engagement and effectiveness, and to test strategies to improve engagement with the app. The latter can lead to a better evaluation of the effects of intervention components.

Findings from this study do not support the effectiveness of individual modules in the SmokeFree Baby app to increase smoking abstinence during pregnancy. Pregnant smokers do not appear to engage with the intervention which is a key issue to be addressed in the future because, until satisfactory engagement with the intervention is achieved, it is not possible to test the effects of modules.

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Table 1: Baseline characteristics

Reference group:	Total sample										
Factor:		Identity		Health information		Face-to-face support		Stress management		Behavioural substitution	
Level:		Minimal	Full	Minimal	Full	Minimal	Full	Minimal	Full	Minimal	Full
N:	565	277	288	288	277	292	273	266	299	283	282
Operating system:											
iOS: % (N)	63.0 (356)	62.8 (174)	63.2 (182)	60.1 (173)	66.1 (183)	62.7 (183)	63.4 (173)	59.4 (158)	66.2 (198)	60.4 (171)	65.6 (185)
Android: % (N)	37.0 (209)	37.2 (103)	36.8 (106)	39.9 (115)	33.9 (94)	37.3 (109)	36.6 (100)	40.6 (108)	33.8 (101)	39.6 (112)	34.4 (97)
Country of registration:											
UK: % (N)	51.0 (288)	48.0 (133)	53.8 (155)	50.3 (145)	51.6 (143)	48.6 (142)	53.5 (146)	48.1 (128)	53.3 (160)	51.2 (145)	50.7 (143)
USA: % (N)	26.0 (147)	28.9 (80)	23.3 (67)	25.0 (72)	27.1 (75)	27.4 (80)	24.5 (67)	28.2 (75)	24.1 (72)	28.3 (80)	23.8 (67)
Other: % (N)	23.0 (130)	23.1 (64)	22.9 (66)	12.6 (71)	10.4 (59)	24.0 (70)	22.0 (60)	23.7 (63)	22.4 (67)	20.5 (58)	25.5 (72)
Age: Mean (SD)	27.3 (5.5)	27.3 (5.5)	27.3 (5.5)	27.5 (5.5)	27.0 (5.5)	27.2 (5.3)	27.4 (5.7)	27.2 (5.7)	27.4 (5.3)	27.5 (5.7)	27.1 (5.3)
Highest level of formal education achieved:											
No qualification: % (N)	14.7 (83)	14.4 (40)	14.9 (43)	12.5 (36)	17.0 (47)	14.7 (43)	14.7 (40)	13.2 (35)	16.1 (48)	15.9 (45)	13.5 (38)
Secondary school: % (N)	45.1 (255)	41.5 (115)	48.6 (140)	43.8 (126)	46.6 (129)	47.3 (138)	42.9 (117)	45.9 (122)	44.5 (133)	45.6 (129)	44.7 (126)
Undergraduate degree: % (N)	26.9 (152)	28.5 (79)	25.3 (73)	31.6 (91)	22.0 (61)	24.3 (71)	29.7 (81)	27.1 (72)	26.8 (80)	26.5 (75)	27.3 (77)
Postgraduate degree: % (N)	13.3 (75)	15.5 (43)	11.1 (32)	12.2 (35)	14.4 (40)	13.7 (40)	12.8 (35)	13.9 (37)	12.7 (38)	12.0 (34)	14.5 (41)
Employment status:											
Unemployed/on state benefit: % (N)	27.8 (157)	27.4 (76)	28.1 (81)	26.0 (75)	29.6 (82)	29.1 (85)	26.4 (72)	30.8 (82)	25.1 (75)	28.6 (81)	27.0 (76)
Manual occupation: % (N)	41.8 (236)	42.2 (117)	41.3 (119)	41.7 (120)	41.9 (116)	42.5 (124)	41.0 (112)	38.0 (101)	45.2 (135)	41.0 (116)	42.6 (120)
Non-manual occupation: % (N)	30.4 (172)	30.3 (84)	30.6 (88)	32.3 (93)	28.5 (79)	28.4 (83)	32.6 (89)	31.2 (83)	29.8 (89)	30.4 (86)	30.5 (86)
Pregnancy gestation:											
1-12 weeks: % (N)	57.5 (325)	55.2 (153)	59.7 (172)	58.0 (167)	57.0 (158)	58.9 (172)	56.0 (153)	59.4 (158)	55.9 (167)	57.6 (163)	57.4 (162)
13-28 weeks: % (N)	36.5 (206)	37.9 (105)	35.1 (101)	36.1 (104)	36.8 (102)	36.6 (107)	36.3 (99)	32.7 (87)	39.8 (119)	37.1 (105)	35.8 (101)
29+ weeks: % (N)	6.0 (34)	6.9 (19)	5.2 (15)	5.9 (17)	6.1 (17)	4.5 (13)	7.7 (21)	7.9 (21)	4.3 (13)	5.3 (15)	6.7 (19)
Pregnancy parity:											
Pregnant with the first child: % (N)	57.7 (326)	58.8 (163)	56.6 (163)	55.9 (161)	59.6 (165)	57.5 (168)	57.9 (158)	57.9 (154)	57.5 (172)	56.2 (159)	59.2 (167)

Heaviness of Smoking Index: Mean (SD)	2.5 (1.4)	2.6 (1.4)	2.5 (1.4)	2.5 (1.4)	2.5 (1.4)	2.5 (1.4)	2.5 (1.4)	2.5 (1.4)	2.5 (1.4)	2.5 (1.4)	2.5 (1.4)
Past quit attempts:											
Quit attempt in past year: % (N)	33.6 (190)	33.9 (94)	33.3 (96)	35.8 (103)	31.4 (87)	33.2 (97)	34.1 (93)	35.7 (95)	31.8 (95)	34.6 (98)	32.6 (92)
Use of cessation aids [a]:											
Only SmokeFree Baby app [b]: % (N)	38.8 (219)	37.2 (103)	40.3 (116)	36.8 (106)	40.8 (113)	38.0 (111)	39.6 (108)	35.7 (95)	41.5 (124)	41.3 (117)	36.2 (102)
Non-nicotine medication [c]: % (N)	0.7 (4)	0.7 (2)	0.7 (2)	1.0 (3)	0.4 (1)	1.0 (3)	0.4 (1)	0.4 (1)	1.0 (3)	1.1 (3)	0.4 (1)
Nicotine-replacement therapy [d]: % (N)	21.4 (121)	22.4 (62)	20.5 (59)	21.2 (61)	21.7 (60)	21.6 (63)	21.2 (58)	20.7 (55)	22.1 (66)	21.2 (60)	21.6 (61)
E-cigarettes: % (N)	16.8 (95)	18.4 (51)	15.3 (44)	14.9 (43)	18.8 (52)	16.4 (48)	17.2 (47)	15.8 (42)	17.7 (53)	16.3 (46)	17.4 (49)
Books or leaflets: % (N)	8.7 (49)	9.0 (25)	8.3 (24)	9.0 (26)	8.3 (23)	8.9 (26)	8.4 (23)	11.3 (30)	6.4 (19)	8.8 (25)	8.5 (24)
Websites: % (N)	11.7 (66)	11.2 (31)	12.2 (35)	12.2 (35)	11.2 (31)	12.3 (36)	11.0 (30)	13.5 (36)	10.0 (30)	11.3 (32)	12.1 (34)
Other smoking cessation app: % (N)	12.4 (70)	11.6 (32)	13.2 (38)	14.9 (43)	9.7 (27)	13.7 (40)	11.0 (30)	11.3 (30)	13.4 (40)	12.4 (35)	12.4 (35)
Support from a stop smoking advisor: % (N)	10.8 (61)	9.4 (26)	12.2 (35)	9.7 (28)	11.9 (33)	12.3 (36)	9.2 (25)	11.3 (30)	10.4 (31)	9.9 (28)	11.7 (33)
Other: % (N)	5.1 (29)	5.4 (15)	4.9 (14)	6.6 (19)	3.6 (10)	6.2 (18)	4.0 (11)	6.0 (16)	4.3 (13)	5.7 (16)	4.6 (13)
Motivation to stop smoking: Mean (SD)	3.8 (0.6)	3.7 (0.6)	3.8 (0.5)	3.8 (0.6)	3.7 (0.5)	3.8 (0.6)	3.7 (0.6)	3.7 (0.6)	3.8 (0.5)	3.8 (0.5)	3.8 (0.6)
Goal setting:											
Stopping smoking completely: % (N)	72.0 (407)	72.9 (202)	71.5 (205)	71.2 (205)	72.9 (202)	69.9 (204)	74.4 (203)	70.3 (187)	73.6 (220)	73.9 (209)	70.2 (198)
Cutting down: % (N)	28.0 (75)	27.1 (158)	28.8 (83)	28.8 (83)	27.1 (75)	30.1 (88)	25.6 (70)	29.7 (79)	26.4 (79)	26.1 (74)	29.8 (84)
Quit date:											
Quit date set for the day of enrolment; % (N)	41.8 (236)	41.5 (115)	42.0 (121)	40.3 (116)	43.3 (120)	40.8 (119)	42.9 (117)	41.4 (110)	42.1 (126)	40.3 (114)	43.3 (122)

[a] Multiple cessation aids could be selected; [b] Participants selected SmokeFree Baby and did not select any other cessation aids; [c] Champix (varenicline) or Zyban (bupropion); [d] Nicotine patch, gum, nasal spray, inhalator or lozenge; Bonferroni-corrected statistically significant difference: p=0.002

Table 2: Active engagement with general app features that were aimed at all participants

General app feature:	Active engagement type:	N:	Engaged with the feature at least once: % (N)
'How addicted are you?' [a]	Completing a two-item quiz as per the Heaviness of Smoking Index	494	16.6 (82)
'Reasons to quit' – 1 [a]	Listing why the person wants to quit smoking	494	7.5 (37)
'Reasons to quit' – 2 [a]	Indicating personal relevance of pre-defined reasons to quit	494	4.9 (24)
'Getting ready' [a]	Indicating if pre-defined activities to prepare for the quit attempt have been completed	494	10.1 (50)
'Withdrawal symptoms' [a]	Rating usefulness of tips to cope with withdrawal symptoms	494	25.1 (124)
'Medicine' [b]	Indicating interest in trying out a nicotine replacement product [c]	494	7.7 (38)
'Phone support' [b]	Adding contact details of people to get instant support	494	1.2 (6)
'Video memos' [b]	Recording supportive video messages from friends and family and/or recording personal commitment to quitting smoking	494	30.6 (151)
'Social' [b]	Rating usefulness of tips to cope with social situations and advice on using social support	494	31.2 (154)

[a] Available from registration; [b] Available after quit date; [c] Including nicotine gum, patch, lozenge, nasal spray, mouth spray, inhaler and microtab

Table 3: Active engagement with interactive content in the full version of the modules

Module:	**Interactive content:**	**Active engagement type:**	**N:**	**Engaged with the feature at least once: % (N)**
Identity	'I am…'	Endorsing statements about a new non-smoker identity	252	16.7 (42)
Identity	'Video diary'	Recording progress with cessation and pregnancy	252	2.0 (5)
Identity	'Ex-smokers'	Rating usefulness of videos of ex-smokers talking about their experiences with quitting	252	4.0 (10)
Identity	'Tip of the day'	Rating usefulness of tips to establish a positive non-smoker identity	252	15.1 (38)
Health information	'Tip of the day'	Rating usefulness of advice about the effects of smoking and cessation	242	0
Face-to-face support	'Tip of the day'	Rating usefulness of tips to engage with face-to-face support	244	16.0 (39)
Face-to-face support	'Pro advice'	Rating usefulness of videos of stop smoking advisors talking about what face-to-face support involves	244	3.3 (8)
Face-to-face support	'Local services'	Clicking on phone numbers/links to websites of local stop smoking services	244	6.6 (16)
Stress	'Stress management tips'	Rating usefulness of tips to cope with stress	265	6.0 (16)
Stress	'Stress plan'	Selecting strategies to plan how to cope with stress	265	6.0 (16)
Behavioural substitution	'Behavioural substitution tips'	Rating usefulness of tips to distract oneself from smoking	244	2.5 (6)
Behavioural substitution	'Distraction plan'	Selecting strategies to plan how to distract oneself from smoking	244	2.9 (7)

Table 4: Main effects and interactions between modules on the number of smoke-free days up to four weeks from quit date (N=494)

Factor:	**Level:**	**Smoke-free days: Mean (SD):**	**F-ratio:**	**Df:**	**P-value:**	**Partial eta^2:**	**Bayes factor:**	
							0.6 day	**1.6 days**
Identity	Minimal Full	0.40 (1.9) 0.45 (1.9)	0.077	1	0.782	<0.000	0.36	0.14
Health information	Minimal Full	0.43 (2.0) 0.41 (1.9)	0.014	1	0.905	<0.000	0.25	0.10
Face-to-face support	Minimal Full	0.50 (1.9) 0.35 (1.9)	0.719	1	0.397	0.002	0.17	0.07
Stress management	Minimal Full	0.28 (1.9) 0.56 (1.9)	2.668	1	0.103	0.006	1.81	0.77
Behavioural substitution	Minimal Full	0.43 (1.9) 0.42 (2.0)	0.005	1	0.945	<0.000	0.22	0.08
Identity × Health information			1.019	1	0.313	0.002		
Identity × Face-to-face support			0.008	1	0.930	<0.000		
Identity × Stress management			1.089	1	0.297	0.002		
Identity × Behavioural substitution			**6.368**	**1**	**0.012**	**0.014**		
Health information × Face-to-face support			0.000	1	0.987	<0.000		
Health information × Stress management			1.310	1	0.253	0.003		
Health information × Behavioural substitution			0.627	1	0.429	0.001		
Face-to-face support × Stress management			1.349	1	0.246	0.003		
Face-to-face support × Behavioural substitution			0.012	1	0.911	<0.000		
Stress management × Behavioural substitution			0.045	1	0.832	<0.000		

Figure 1: Participant flow