

A smoking cessation smartphone app that delivers real-time 'context aware' behavioural support: the Quit Sense feasibility RCT

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This report contains transcripts of interviews conducted in the course of the research, or similar, and contains language which may offend some readers.

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Scientific summary

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Scientific summary

Background

Three million UK smokers attempt to stop smoking each year, but over 80% relapse. A lapse (any smoking) early on in a quit attempt is strongly associated with subsequent relapse back to smoking. Approximately half of all lapses are due to environmental smoking cues which can elicit cravings to smoke, such as the presence of cigarettes or being in a location which a smoker associates with smoking. Few interventions are effective at targeting cue-induced cravings. Smokers are more likely to prevent lapses if they better understand their smoking cues and use lapse prevention strategies, such as controlled deep breathing or avoiding other smokers, to combat these. This would likely help them avoid or cope with cue-induced cravings, but smokers typically lack skills in applying these effectively. If smokers trying to quit used effective lapse prevention strategies, this would very likely increase their chances of success.

With patient and public involvement, we developed, refined and piloted a theory-guided Just-In-Time Adaptive Intervention smartphone app called Quit Sense that provides support to help smokers manage environmental cues to smoke as they arise. Pilot studies have shown that Quit Sense can provide 'in the moment' support to smokers, including lapse prevention strategies, and that users will engage with the app and find it acceptable. As Quit Sense is such a novel intervention, before a 'definitive' randomised controlled trial (RCT) can be conducted to test effectiveness, it is important to first undertake a RCT to establish whether such a study might be feasible.

Objectives

The main objective was to conduct a feasibility RCT of Quit Sense to inform a definitive effectiveness trial, by estimating:

1. completion rates for the anticipated primary outcome for a full trial (6-month self-reported abstinence with biochemical validation, based on the Russell standard);
2. usual care arm cessation rate;
3. cost of recruitment using online advertising;
4. rates of app installation, use and acceptability;
5. completion of smoking cessation-related resource use and quality-of-life data;
6. intervention effect on anticipated primary outcome;
7. intervention effect on hypothesised mechanisms of action of app at 6 weeks post enrolment;
8. participant views of the app, as part of a qualitative process evaluation.

Design

A parallel, two-arm RCT with an embedded qualitative interview process evaluation was undertaken. The evaluation included a preliminary cost-effectiveness analysis and a nested randomised study [Study Within A Trial (SWAT)] assessing the effects of different financial incentives on 6-month follow-up rates.

Setting

The study setting was online and trial procedures were primarily automated.

Participants

Participants were recruited via online adverts on Google search, Facebook and Instagram, screened for eligibility on the study website and enrolled if they were regular smokers, aged 16 years and above, were willing to make a quit attempt and owned an Android smartphone.

Interventions

After completing the baseline questionnaire participants were then randomly allocated to a 'usual care' arm (text message referral to NHS SmokeFree website) or a 'usual care' plus Quit Sense arm, via a text message invitation to install the Quit Sense app. The Quit Sense app required users to set a quit date and then, leading up to their quit date, alongside other support features, invited them to report their smoking in real time and indicate the presence of key environmental smoking cues using a smoking behaviour logging tool. Once their quit date arrived, the app used location sensing and what it had learnt about the individual's smoking behaviour to tailor the timing and content of support messages when they spent time in self-identified high-risk locations. The support and advice aimed to help smokers learn about their smoking behaviour, prepare for their quit attempt and promoted the use of effective lapse prevention strategies during their quit attempt.

Main outcomes measures

All participants were contacted at 6-week and 6-month follow-up. This was done initially by text message with an embedded link to the follow-up questionnaires or, if no response, manually by telephone. As part of a SWAT, participants underwent secondary randomisation to receive either a £10 or £20 incentive for completion of the 6-month questionnaire.

Four progression criteria and corresponding thresholds for seeking to undertake a definitive trial were set a priori. Criteria were met if each threshold was included in or lower than the 95% confidence interval (CI) of the estimate. Trial measures included health economic and outcome data completion rates (progression criterion #1 threshold: $\geq 70\%$), including biochemical validation rates (progression criterion #2 threshold: $\geq 70\%$), recruitment costs, app installation (progression criterion #3 threshold: $\geq 70\%$) and engagement rates (progression criterion #4 threshold: $\geq 60\%$), the app's effect on biochemically verified abstinence at 6 months (anticipated primary outcome of definitive trial) and hypothesised mechanisms of action. The qualitative process evaluation sought to identify participants' views of the trial and the Quit Sense app. The protocol and statistical and health economics analysis plan were pre-specified and published (open access).

Results

Of the people screened ($N = 323$), 299 (93%) were eligible and 209 (65% of screened) were consented and randomised either to the usual care arm ($n = 105$) or to the Quit Sense arm ($n = 104$). Completion of self-reported smoking questions was 71% (149/209; 95% CI 65% to 77%) and 77% (160/209; 95% CI 71% to 82%) at 6 weeks and 6 months, respectively, and at 6 months 70% provided both cessation support resource use data and EuroQol-5 Dimensions five level (EQ-5D-5L) data. Among those self-reporting abstinence at 6 months follow-up, 39% (95% CI 24% to 54%) returned a viable sample for biochemical verification, although return rates were higher in the Quit Sense than the usual care arm (52% vs. 19%). Online recruitment was completed successfully within the planned 6-week period, split into two campaigns, with a per-participant cost of £19.20, split into advert (£5.82) and running costs (£13.38). In the Quit Sense arm, 75% (95% CI 67% to 83%) of participants installed the app and, of these, 100% set a quit date within the app and 51% (95% CI 39% to 63%) engaged with it for more than 1 week.

At final follow-up, the rate of 6-month biochemically verified sustained abstinence, which we anticipated would be used as a primary outcome in a future study, was 11.5% (12/104) in the Quit Sense arm and 2.9% (3/105) in the usual care arm (estimated effect size: adjusted odds ratio = 4.57, 95% CI 1.23 to 16.94). Similar effects were observed for biochemically verified secondary abstinence outcomes at 6-month follow-up and sensitivity analyses. Effect sizes were smaller and non-significant for self-report only abstinence and there was no evidence of a between-arm difference in abstinence at 6-week follow-up. Participants in the Quit Sense arm had higher rates of lapse avoidance in the first 2 weeks of their quit attempt or post enrolment compared to usual care though this was not statistically significant (29.6% vs. 19.2%; $p = 0.14$). There was no evidence of between-arm differences in hypothesised mechanisms of action of the app, including the mean frequency of lapse prevention strategy use [mean

difference (MD) -0.07 ; $p = 0.46$], smoking cessation self-efficacy (MD 0.18 ; $p = 0.39$), strength ($p = 0.23$) and frequency ($p = 0.83$) of urges to smoke or the Wisconsin Inventory of Smoking Dependence Motives subscales of automaticity ($p = 0.51$) and associative processes ($p = 0.58$).

The qualitative process evaluation identified several potential pathways to abstinence among Quit Sense arm participants. Interviewed participants reported finding the insights gained from engaging with the smoking behaviour learning tool before their quit attempt started particularly valuable. They reported that this reinforced their commitment to quit, helped them better understand the drivers of their smoking behaviour and challenged the need for them to smoke. Some also reported finding regular and location-specific support messages encouraging and motivational and that this reinforced the goal of quitting and made them feel equipped when they spent time in locations that they used to smoke in. Participants highlighted several factors which led to disengagement with the app, including relapse, no longer feeling they needed support, not finding the app met their needs and technical issues. Participants also provided suggestions for app improvement relating to logging smoking, adding gamification elements and improved support triggering. Interviewed participants from both arms highlighted how COVID-19 measures had affected their smoking behaviour and restricted the time they spent outside of their home, which would have had implications for location-based cessation support.

In terms of the main cost-drivers, e-cigarettes/vaporisers and nicotine replacement therapy accounted for more than 70% of the total non-intervention costs. The total intervention cost (recruitment advertising and maintaining the Quit Sense app) was estimated to be £28.51 per participant. In both groups, the mean EQ-5D-5L score at both 6-week and 6-month follow-up was lower than that at baseline. A preliminary cost-effectiveness analysis using EQ-5D-5L score as the outcome estimated that the intervention was both more costly and less effective, compared to standard care, though there was no significant difference in cost or effect between the two groups.

The SWAT analysis indicated that increasing the incentive for completing follow-up from £10 to £20 did not increase response rates at 6 months (74% vs. 79%; $p = 0.36$) but did reduce the proportion of participants requiring manual follow-up (62% vs. 46%; $p = 0.018$) and the median response time to responding (15 days vs. 7 days; $p = 0.016$).

Conclusions

The Quit Sense RCT design and procedures demonstrated feasibility and generated preliminary efficacy evidence of the app on abstinence at 6-month follow-up, although how the app may achieve this is not clear. Three out of the four pre-specified feasibility progression criteria for moving to a definitive trial – completion rate of self-reported abstinence at final follow-up and the rate of Quit Sense installation and engagement – were met. The return of saliva samples among quitters was lower than anticipated, though this can likely be increased in a future trial through increased incentivisation and enhanced procedures. Progression to a definitive trial is warranted.

Trial registration

This trial is registered as ISRCTN12326962.

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