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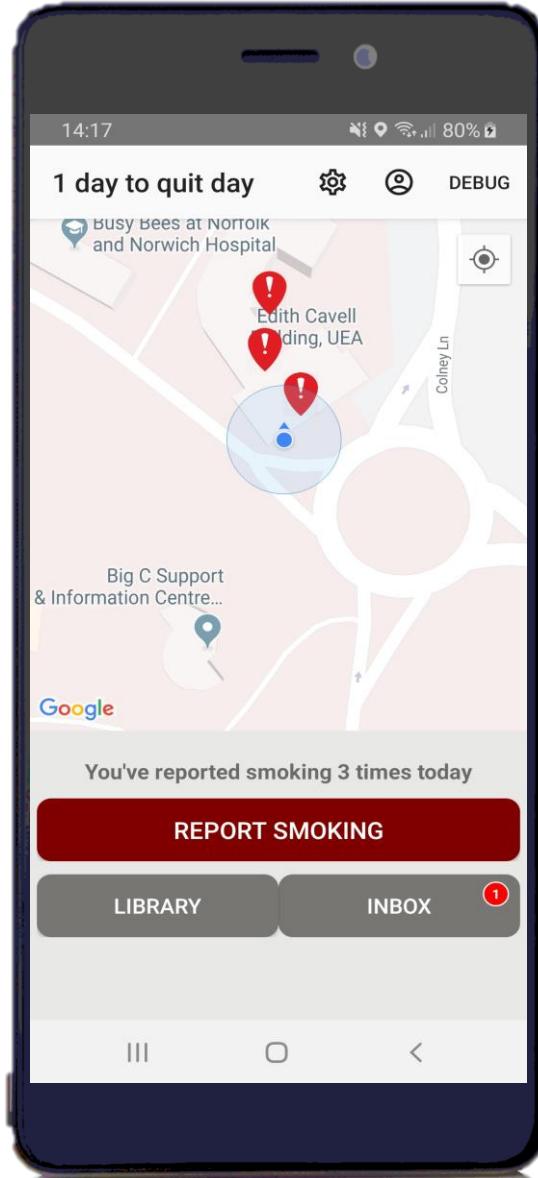


An automated, online RCT to evaluate a Just-In-Time Adaptive smoking cessation smartphone app (Quit Sense)

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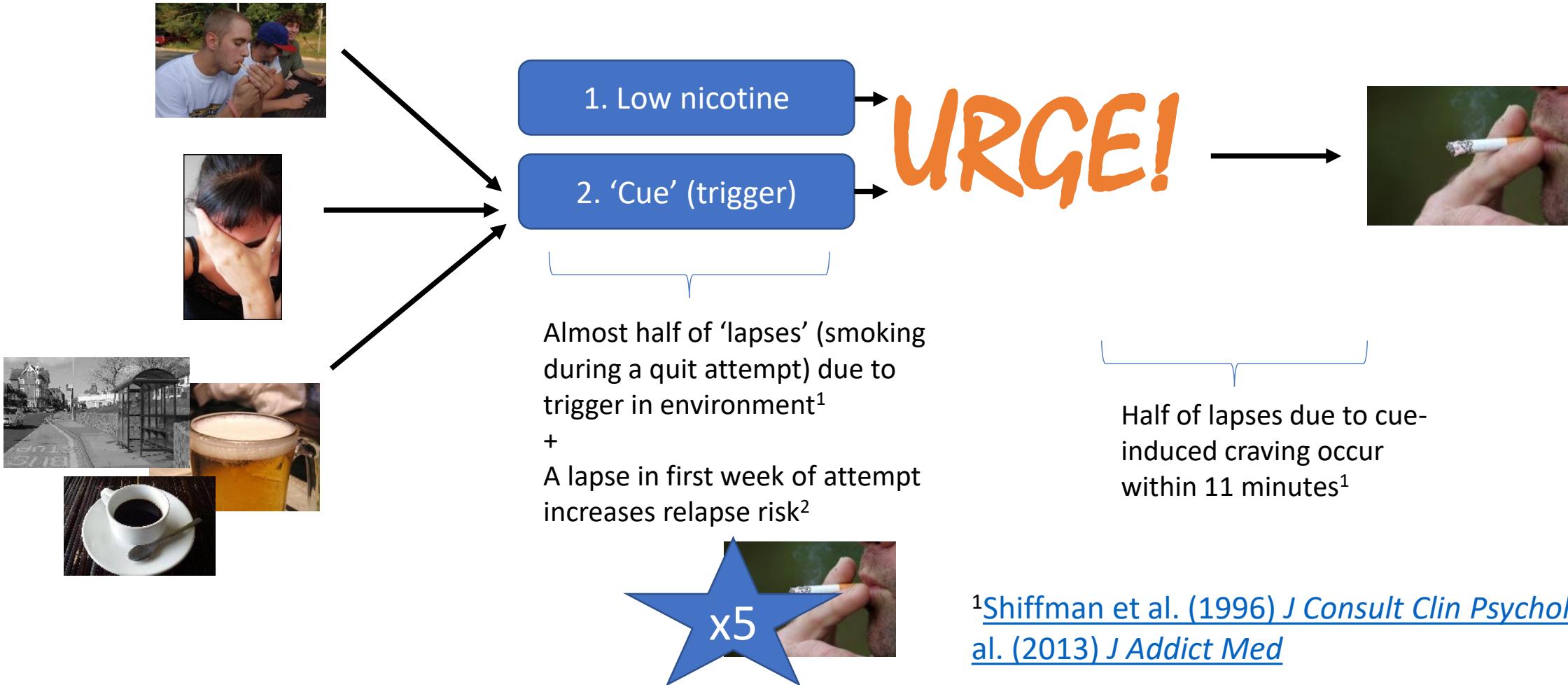


Team

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Tim Coleman
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Garry Barton
Felix Greaves

**Quit
Sense**

Key to helping people quit



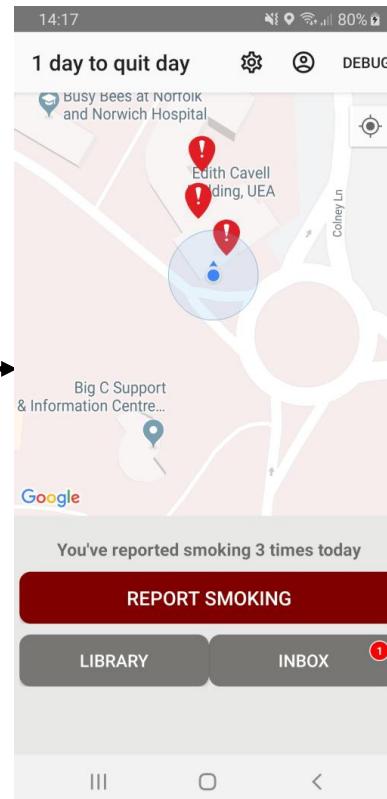
¹[Shiffman et al. \(1996\) J Consult Clin Psychol](#); ²[Ashare et al. \(2013\) J Addict Med](#)



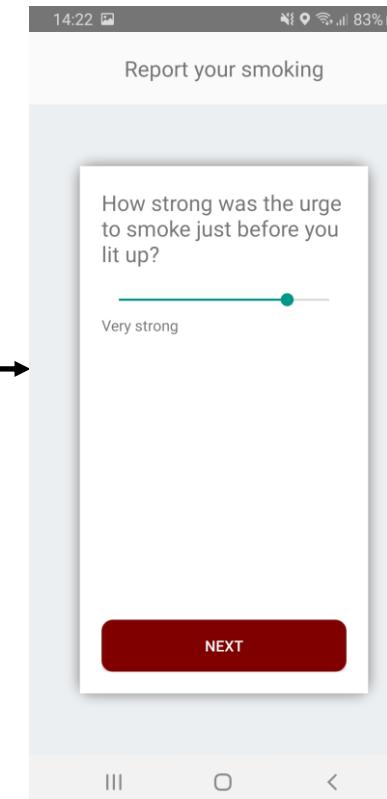
Initiation

Stage 1 – train the app (up to 4 weeks)

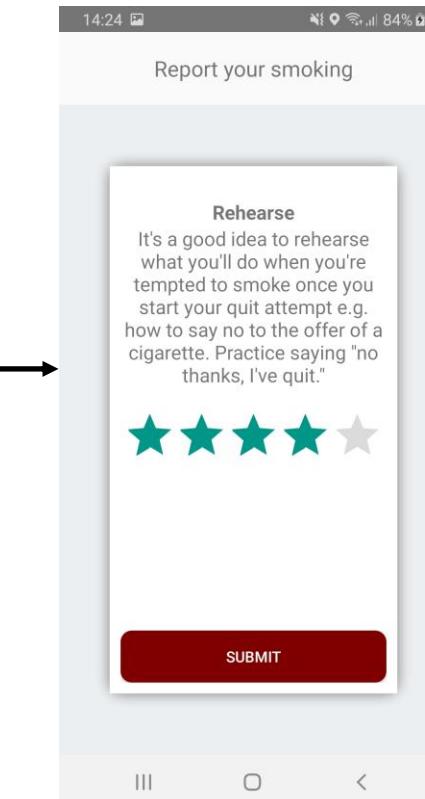
Set quit date



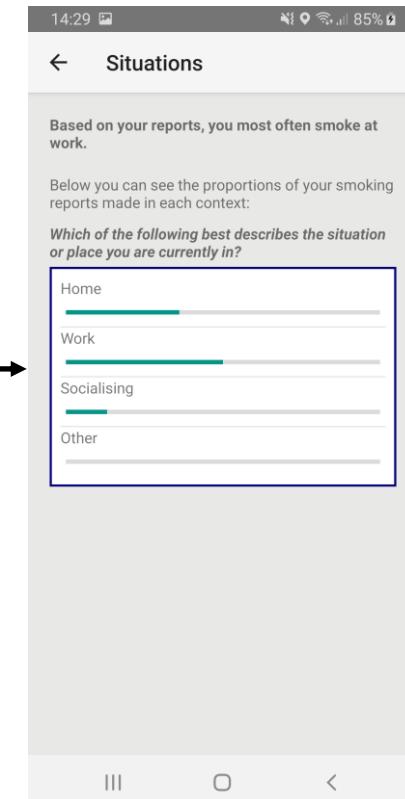
Homescreen
Users can train the app, view the library and check their messages via the inbox



Users try to log every time they smoke till their quit date. Each time they report smoking their geolocation is recorded



Smoking log feedback after reporting, users get advice to help them prepare, get motivated, feel confident and avoid lapse/relapse



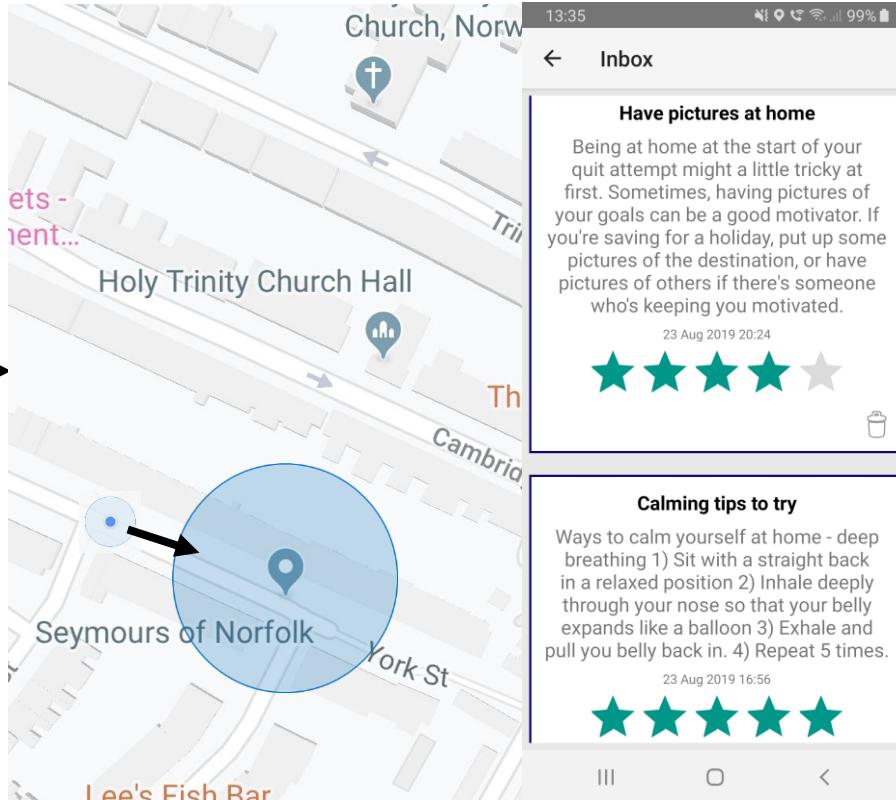
Smoking data feedback simple bar chart and text summaries on their triggers for smoking

Quit date arrives

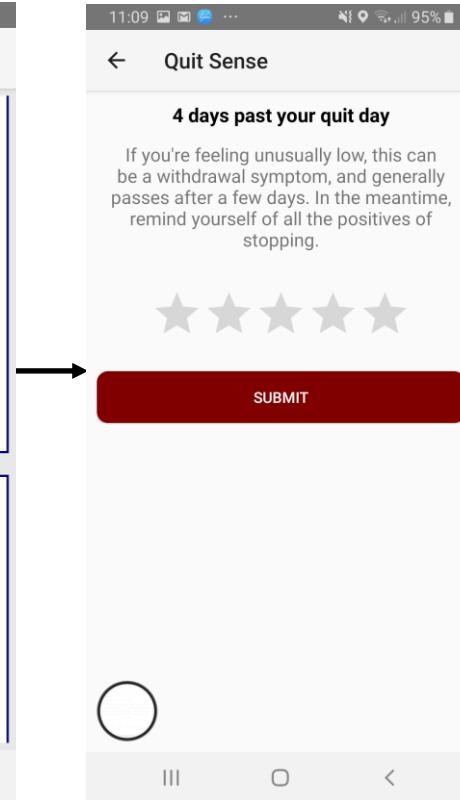


Stage 2 – commit to quit (4 weeks)

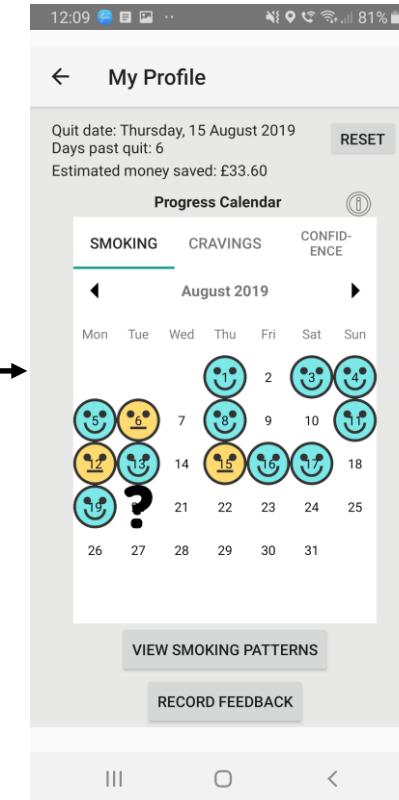
Quit date arrives



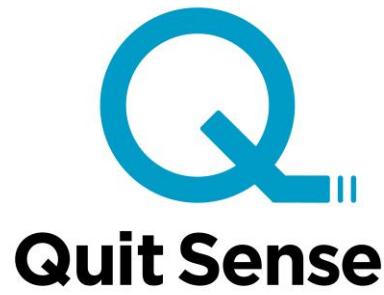
Support messages are delivered in real time when the user enters or spends time in a geofence (e.g. home), tailored to the likely smoking triggers in that location



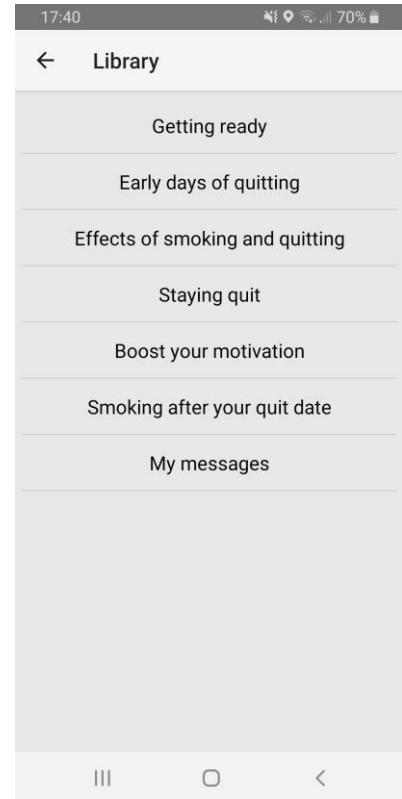
Daily support messages
targeting what to expect,
confidence to quit and
preventing lapses to
smoking



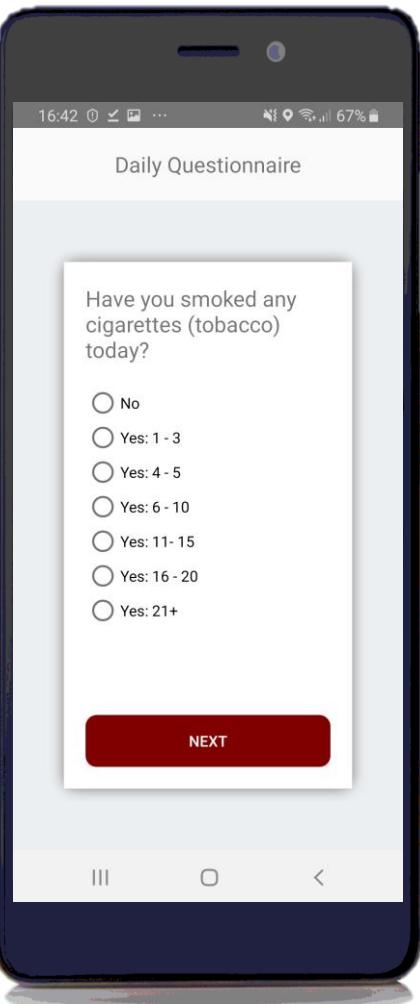
Progress calendar
users can look at their
progress over time by
completing end of day
surveys



Additional support



A library of support messages which can be viewed at any time tailored to the individual and categorised into key areas of support



End of day surveys recording any smoking, cravings, confidence to quit, most difficult situation

Maintenance

Stage 3 – maintain the change (8 weeks)

- In-the-moment messages reduce by 50% every 4 weeks and then end at 8 weeks
- If quit attempt is restarted, then can return back to stage 1 or stage 2

Quit Sense feasibility RCT

Objectives

1. Estimate completion rates for key outcome measures and key costs
2. Estimate rates of app installation, engagement and acceptability
3. Estimate the effect of Quit Sense on smoking behaviour
4. Assess participant views of Quit Sense

Overall aim – to inform and decide on a large ‘definitive’ trial

Trial registration [ISRCTN12326962](#). The trial protocol was published in [BMJ Open](#) and the Statistical and Health Economics Analysis Plan (SHEAP) was pre-registered on the [Open Science Framework](#)

Quit Sense feasibility RCT

Design

- A parallel, two-arm randomised controlled trial with a qualitative process evaluation and a 'Study Within A Trial' evaluating incentives on attrition
- The research team were blind to allocation except for the study statistician, database developers and lead researcher. Participants were not blind to allocation

Trial registration [ISRCTN12326962](#). The trial protocol was published in [BMJ Open](#) and the Statistical and Health Economics Analysis Plan (SHEAP) was pre-registered on the [Open Science Framework](#)

Quit Sense feasibility RCT

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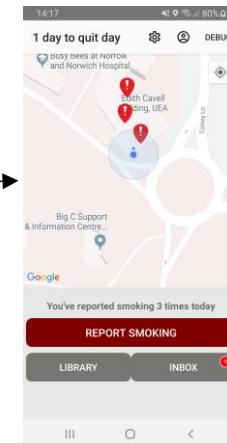
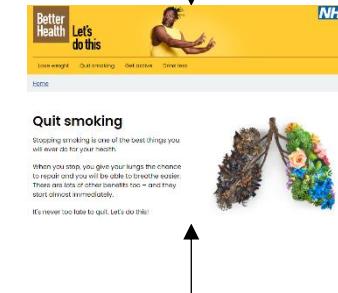
facebook



Google

Usual care (link to NHS smokefree website; n=105)

Quit Sense (n=104)



6 week follow up (n=78)

Qualitative interviews (n=20)

6 week follow up (n=71)

6 month follow up (n=81)

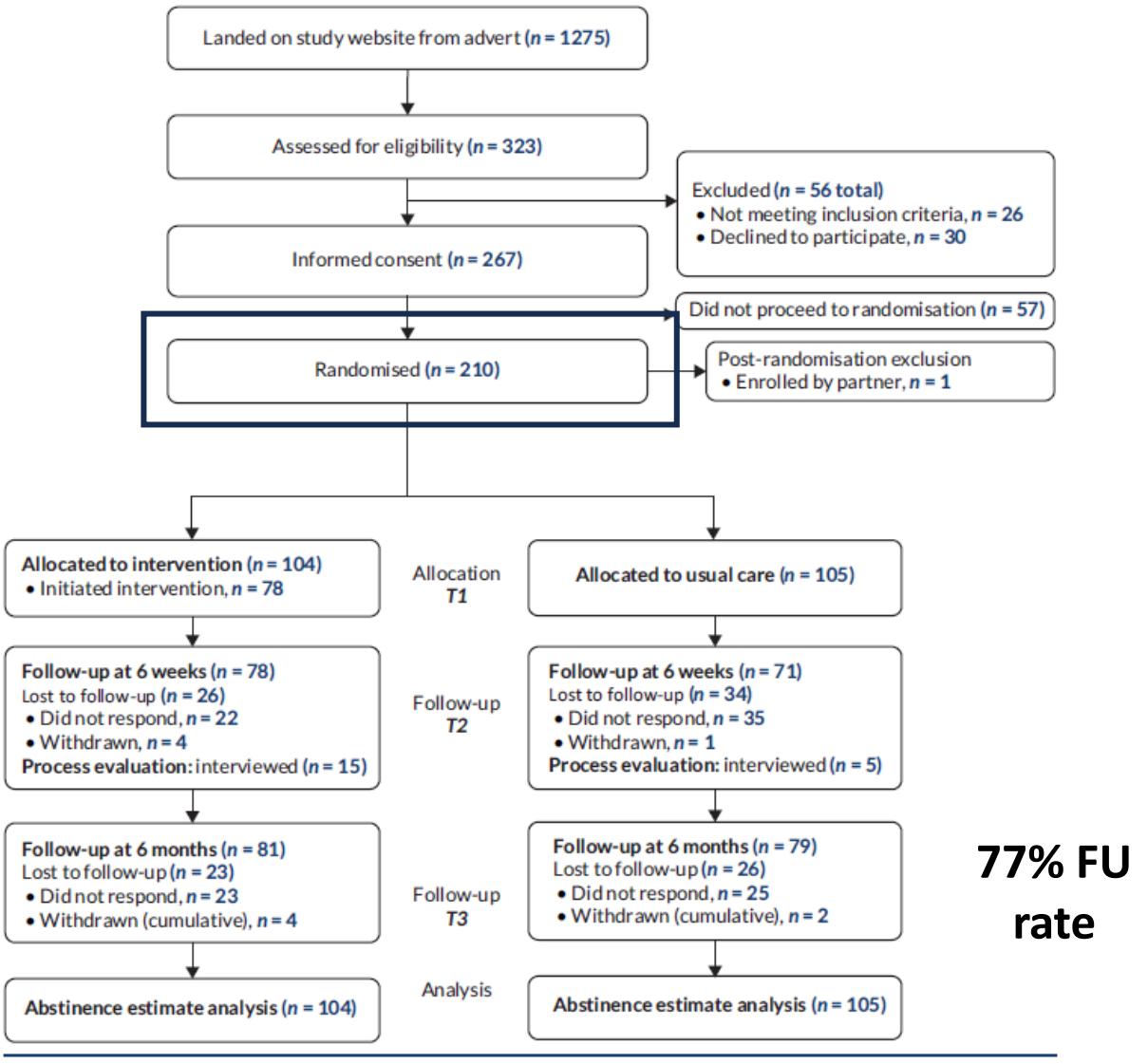


6 month follow up (n=79)

Fully automated

[Naughton et al. \(2023\) Nicotine Tob Res](#)

Trial flow



Sample

	Quit Sense arm (n=104)	Standard care (n=105)	Overall (N=209)
Age: mean (SD)	39.6 (10.0)	42.6 (10.0)	41.1 (10.0)
Female: n (%)	59 (56.7%)	57 (54.3%)	116 (55.5%)
Low socioeconomic status: n (%)	30 (28.9%)	31 (29.5%)	61 (29.2%)
White ethnicity: n (%)	95 (91.4%)	96 (91.4%)	191 (91.4%)
Cigarettes smoked p/d: mean (SD)	15.4 (7.6)	15.5 (6.5)	15.4 (7.1)

Completion rates and key costs

- Completion of smoking status (6m follow up):
 - Self-reported 76% (95% CI 70%, 81%)
 - Saliva sample returned 45% (95% CI 31%, 60%); (39% viable)
- Advertising spend:
 - Total cost £1,217 (per participant £5.82)
- Advertising spend including Nativve campaign fees:
 - 6-week campaign fees £2,796
 - Overall cost per participant £19.20



Recruitment costs

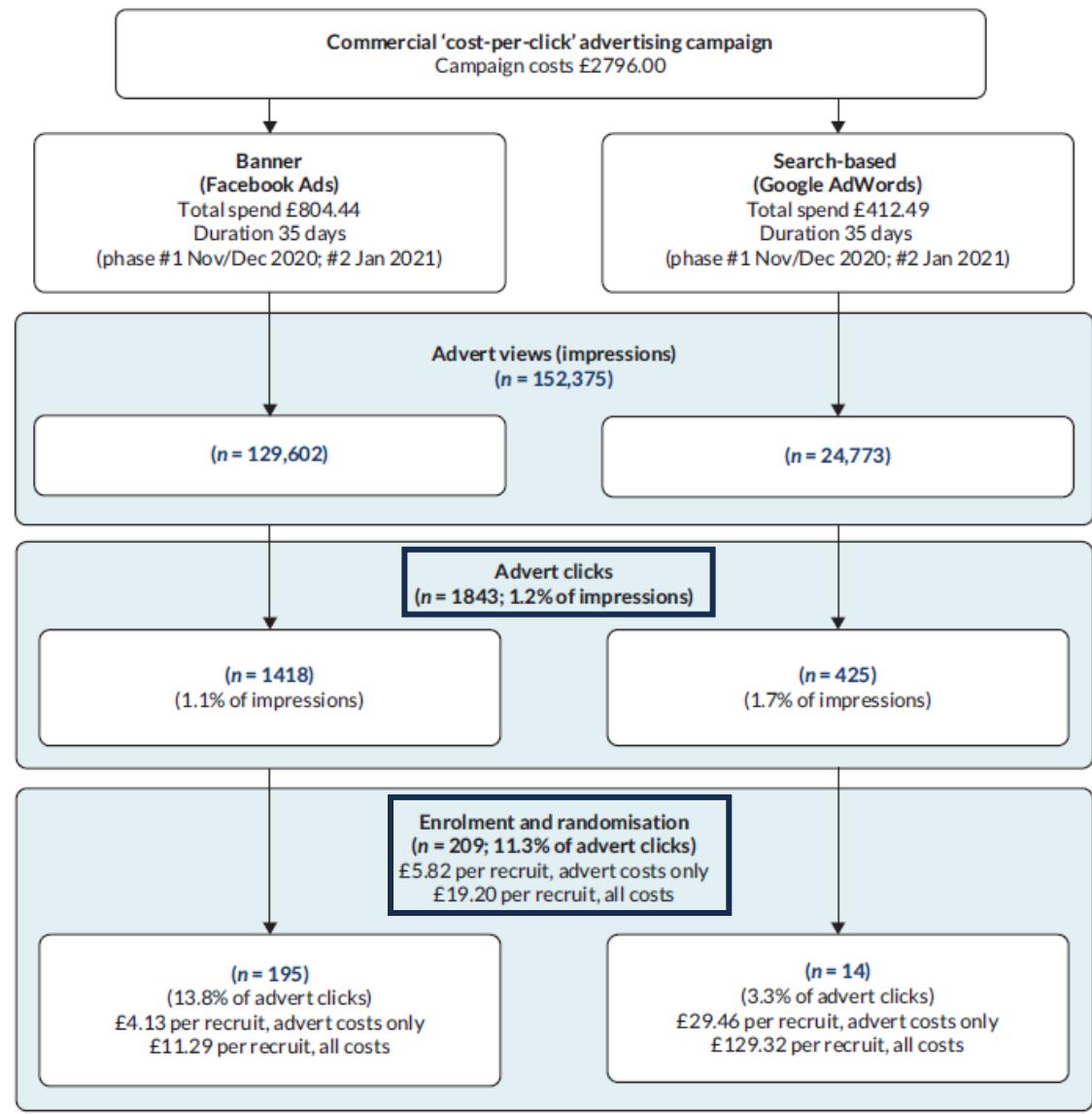


FIGURE 2 Flow diagram of advert reach, engagement and enrolment rates and costs.

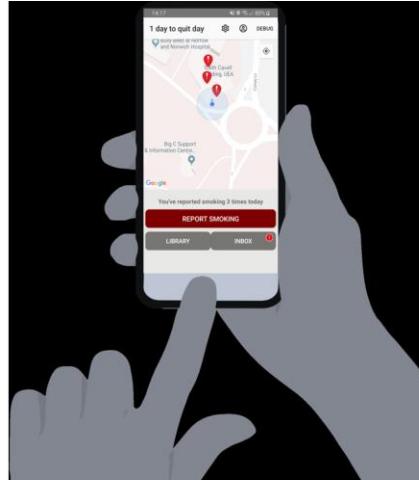
Quit Sense feasibility RCT

Uptake



75% installed app (intervention arm)

99% installed before 3-day app installation reminder.
Of the 28 participants sent a reminder, only one person installed



Engagement

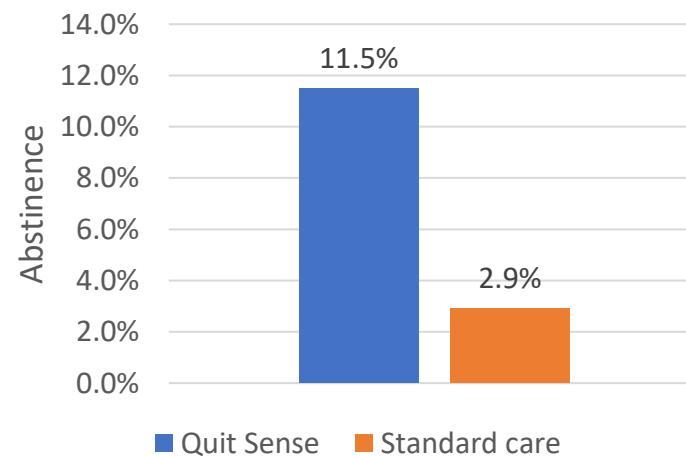
49% of installers engaged beyond quit date

Of these, median app engagement duration 27 days (IQR 91)

Estimate effect of Quit Sense

Primary smoking outcome: self-reported **abstinence over 6 months** (no more than 5 cigs in total) verified by a saliva biochemical test^a (with missing = smoking assumption)

	Quit Sense (n=104) % (n)	Standard care (n=105) % (n)	Difference	Odds ratio (95% CI)	P-value
Unadjusted	11.5% (12)	2.9% (3)	8.6%	4.44 (1.21, 16.21)	0.024
Adjusted***	-	-	-	4.57 (1.23, 16.94)	0.023



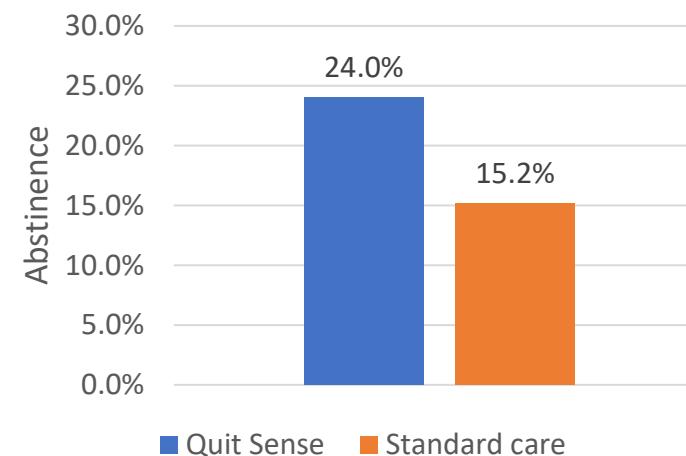
^aLow saliva return rate (39%) and potentially imbalanced between arms

*** Adjusted for stratification variables (socioeconomic status and smoking rate)

Estimate effect of Quit Sense

Post-hoc sensitivity analysis: self-reported **abstinence over 6 months** (no more than 5 cigs in total)
(with missing = smoking assumption)

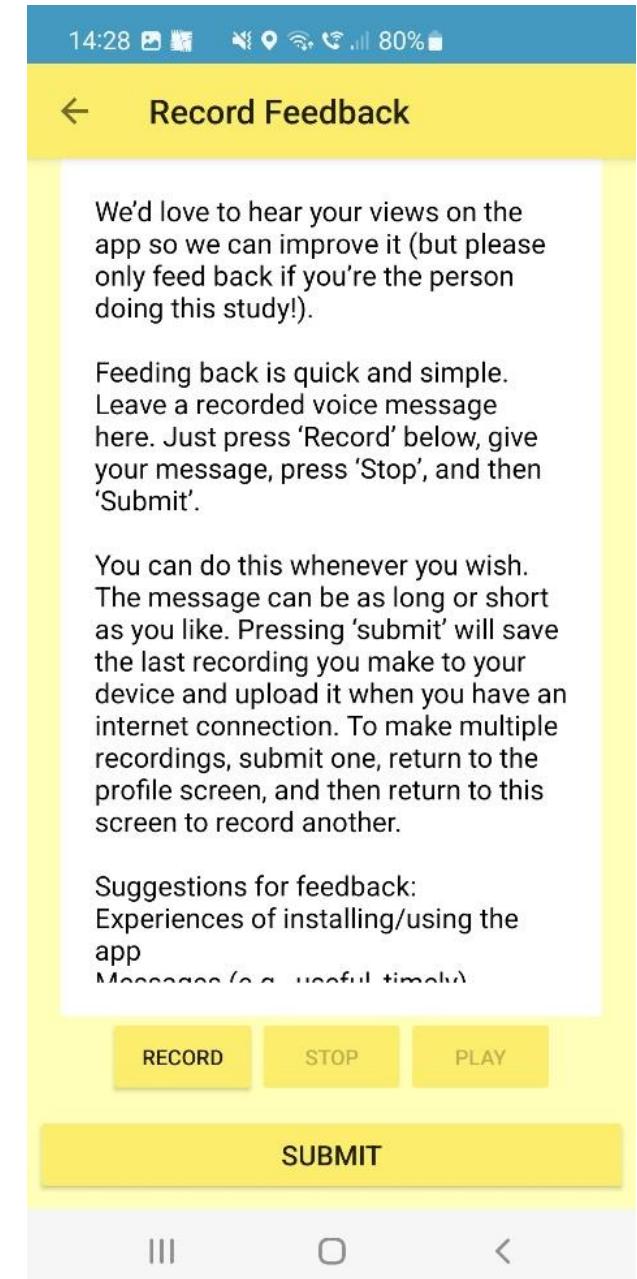
	Quit Sense (n=104) % (n)	Standard care (n=105) % (n)	Difference	Odds ratio (95% CI)	P-value
Unadjusted	24.0% (25)	15.2% (16)	8.8%	1.76 (0.88, 3.53)	0.11
Adjusted***	-	-	-		



*** Adjusted for stratification variables (socioeconomic status and smoking rate)

Auto-process evaluation

- Participants could orally describe their views of the app in a high ecologically valid context
- Of those who installed the app, six participants (7.7%; 6/78) submitted an audio recording
- Responses were focused on
 - Positive app improvement suggestions (e.g., logging unique contexts)
 - Issues/problems/limitations with the app



The retention problem

- Poor retention in trials compromises the science¹:
 - Potential attrition bias
 - Reduced statistical power
 - Potentially reduced reliability, validity and generalisability
- Most trials online/web cessation trials had loss between 20 – 50%²
- Reviews show incentives improve retention, particularly for remote trials³, but little known about automated or smoking cessation trials

¹ [Akl et al \(2012\) *BMJ*](#); ² [Taylor et al \(2017\) *Cochrane Database Syst Rev*](#);
³ [Gillies et al \(2021\) *Cochrane Database Syst Rev*](#)

Quit Sense Study Within A Trial (SWAT)



VS.



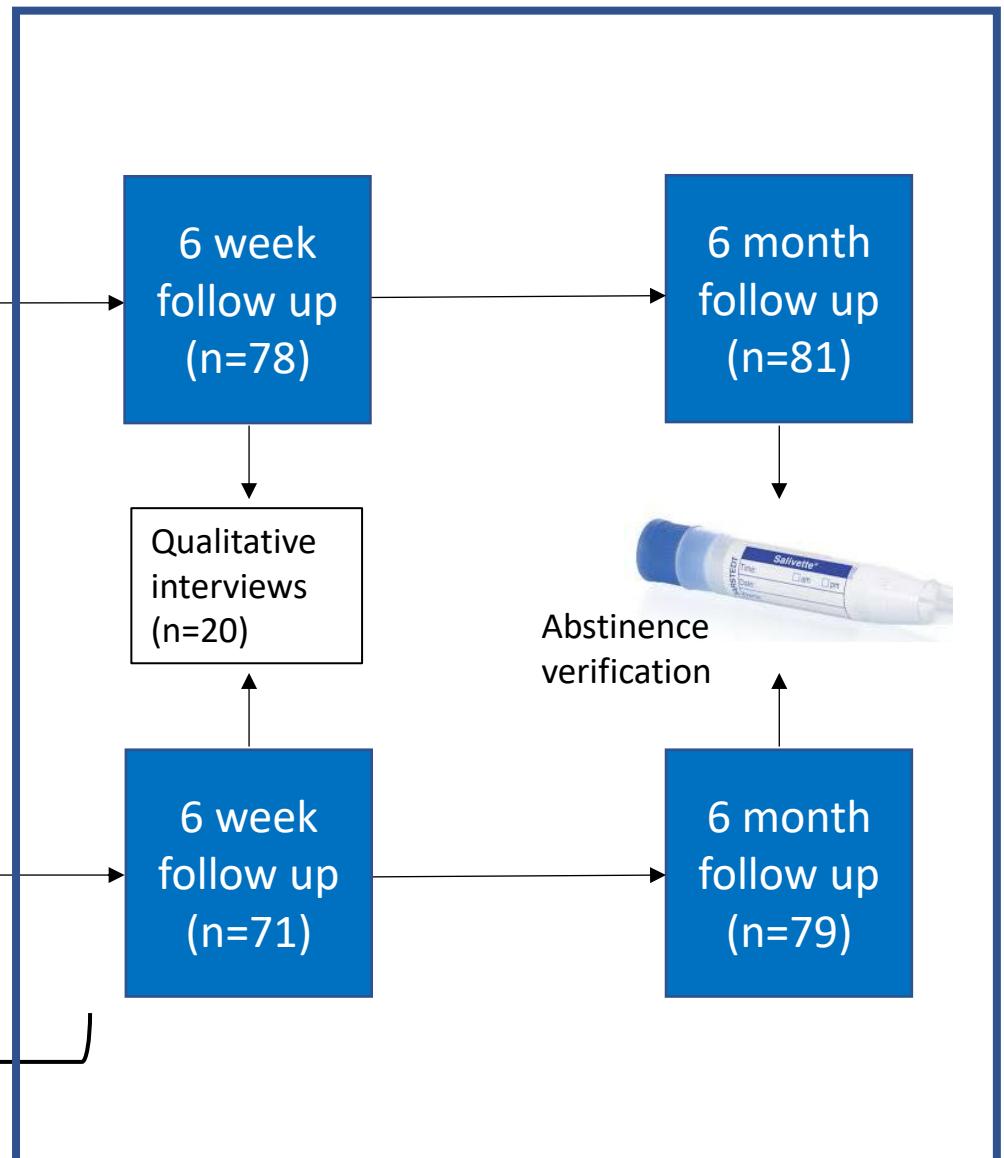
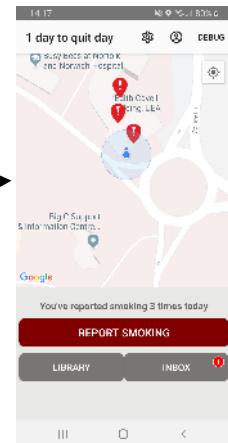
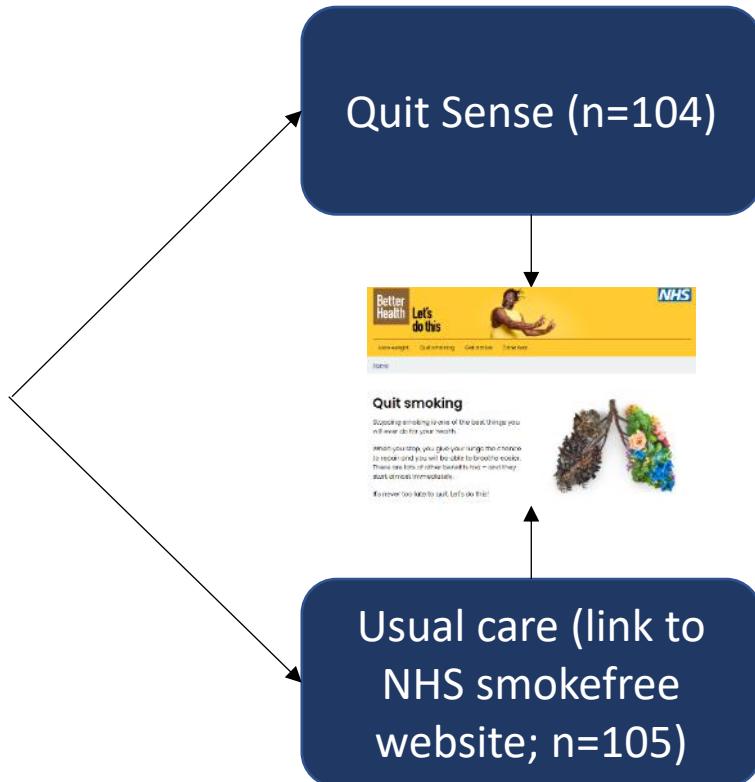
- Objectives – impact of £10 vs. £20 on:
 1. Overall 6m questionnaire follow up rate
 2. Proportion of participants requiring manual follow up & speed of response
 3. Completeness of responses

Quit Sense feasibility RCT

facebook

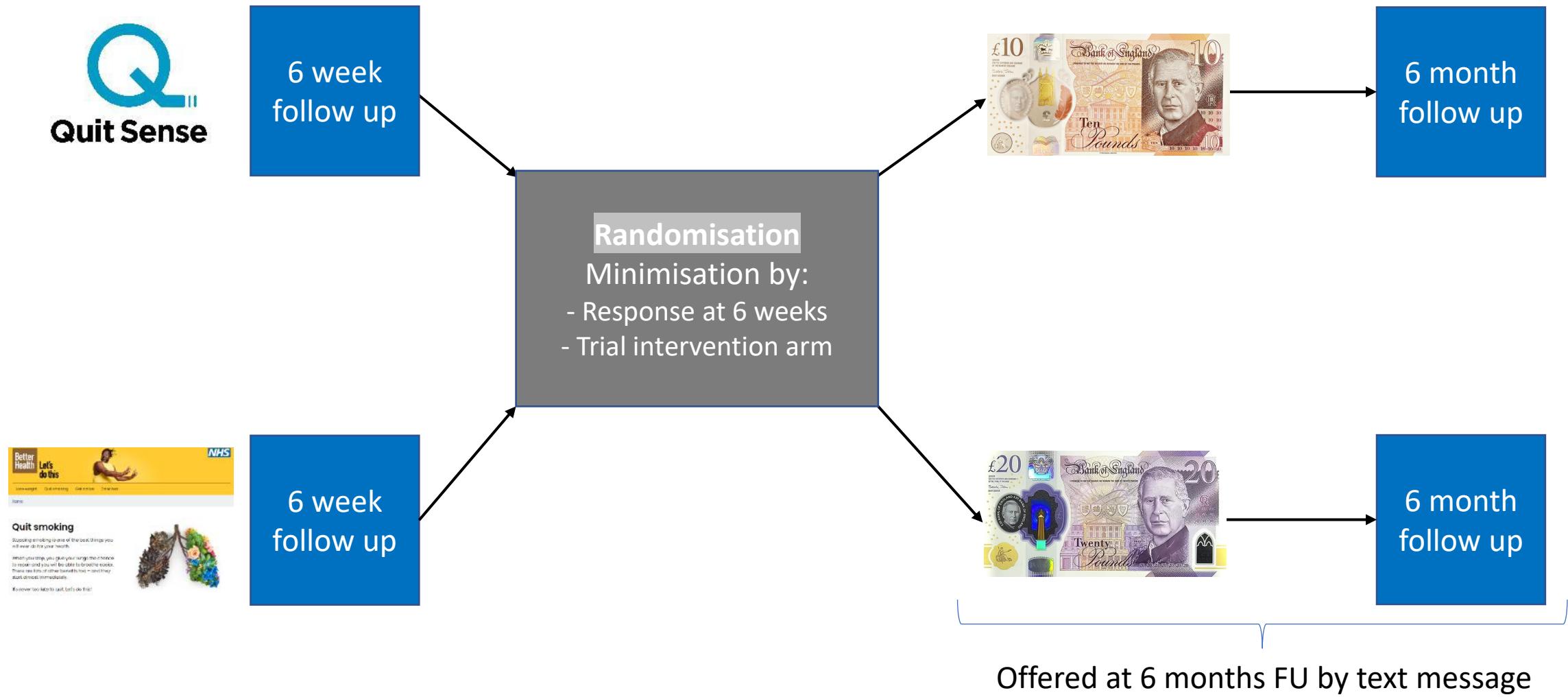


Google



Fully automated

Quit Sense Study Within A Trial (SWAT)



Quit Sense Study Within A Trial (SWAT)

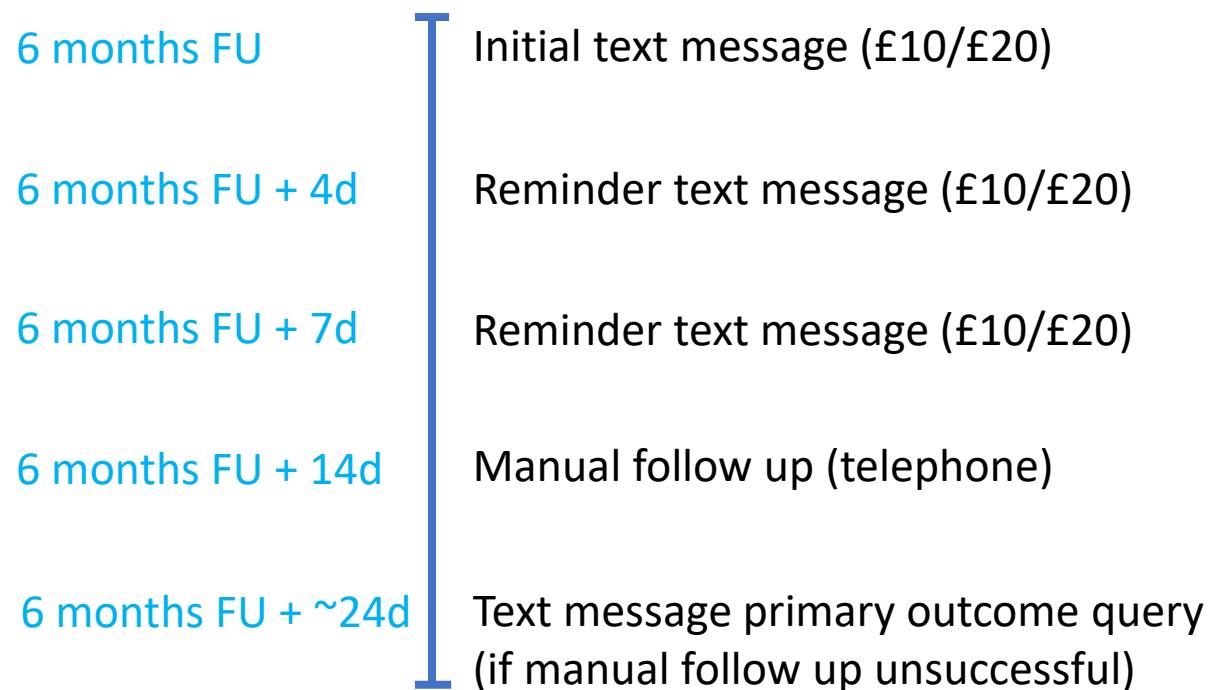
- Participant information sheet only referred to a 6m £10 incentive

Hi Felix. Here's the final survey for Quit Sense: [link](#)
Your response is very valuable to this study. You can take part whatever stage you're at (smoking or quit) and it doesn't matter how involved you've felt with the study so far. Takes around 10 mins. £[10/20] ←
Amazon voucher code on completion. We'll give you a call if we don't hear back, to see if you need any help.

This wording was the only manipulation (in the text messages)

Quit Sense Study Within A Trial (SWAT)

- Participant information sheet only referred to a 6m £10 incentive
- Researcher undertaking manual follow up blinded to allocation



Quit Sense Study Within A Trial (SWAT)

- Participant information sheet only referred to a 6m £10 incentive
- Researcher undertaking manual follow up blinded to allocation
- SWAT was pre-registered on the [SWAT Repository Store \(ID 164\)](#)

Findings – allocation and sample

- 103 randomised to £10 (51 from intervention arm, 52 control arm)
- 101 randomised to £20 (49 from intervention arm, 52 control arm)

Findings – objective 1

- At 6 months, no significant difference between incentive arms in **response rate**

74%



79%



Unadjusted OR=1.35 (95% CI 0.71, 2.60; p=0.36)
Adjusted* OR=1.29 (95% CI 0.66, 2.54; p=0.46)

* Adjusted for host trial stratification variables (smoking rate at baseline & socioeconomic status at baseline) and prognostic variables (heaviness of smoking index at baseline, gender)

Findings – objective 2

- At 6 months, **need for manual follow up** differed between incentive arms

62%



46%



Unadjusted OR=0.51 (95% CI 0.29, 0.89, p=0.018)
Adjusted* OR=0.53 (95% CI 0.29, 0.95; p=0.032)

* Adjusted for host trial stratification variables (smoking rate at baseline & socioeconomic status at baseline) and prognostic variables (heaviness of smoking index at baseline, gender)

Findings – objective 2

- Higher completion time for £10 incentive versus £20

14.9 days



7.0 days

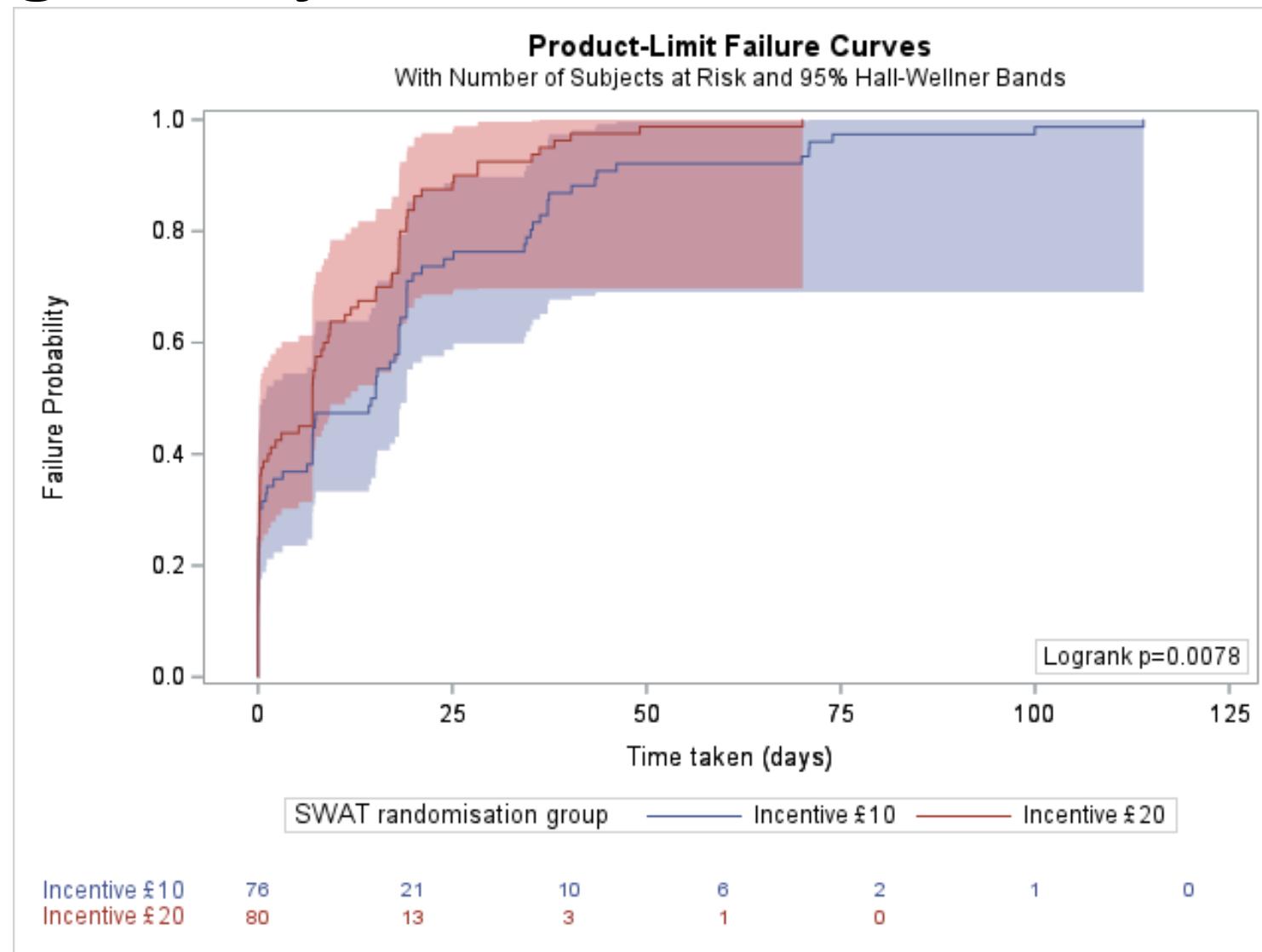


Unadjusted HR=1.55 (95% CI 1.12, 2.15, p=0.008)

Adjusted* HR=1.53 (95% CI 1.10, 2.13, p=0.012)

* Adjusted for host trial stratification variables (smoking rate at baseline & socioeconomic status at baseline) and prognostic variables (heaviness of smoking index at baseline, gender)

Findings – objective 2



Findings – objective 3

- Completeness of data was higher in £20 arm compared to £10 (inference tests not run/planned). Examples:

6m question	£10 incentive	£20 incentive
Are you currently smoking tobacco?	74%	81%
When did you last smoke a cigarette?	69%	78%
Strength of the urge to smoke (SUTS)	68%	78%
Smoking aid questions	66%	78%
EQ5D-5L questions	66%	78%

Summary/implications

- The automated trial design worked efficiently
- The Quit Sense app had promising uptake, engagement and potential for effectiveness
- Auto-process evaluation was not very promising
- Increasing a £10 incentive to £20:
 - Did not increase overall response rate
 - Did speed up response time and reduce manual follow up need (enhancing validity?)
 - May increase data completeness (increasing validity and power?)
- Findings may not generalise beyond sample and online trials



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Thank you

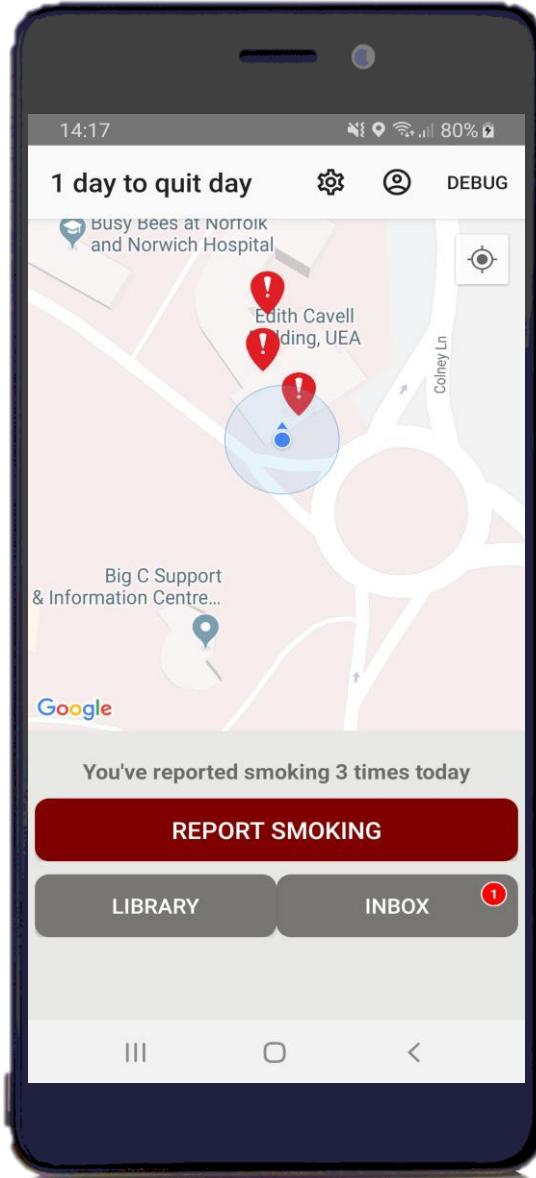
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