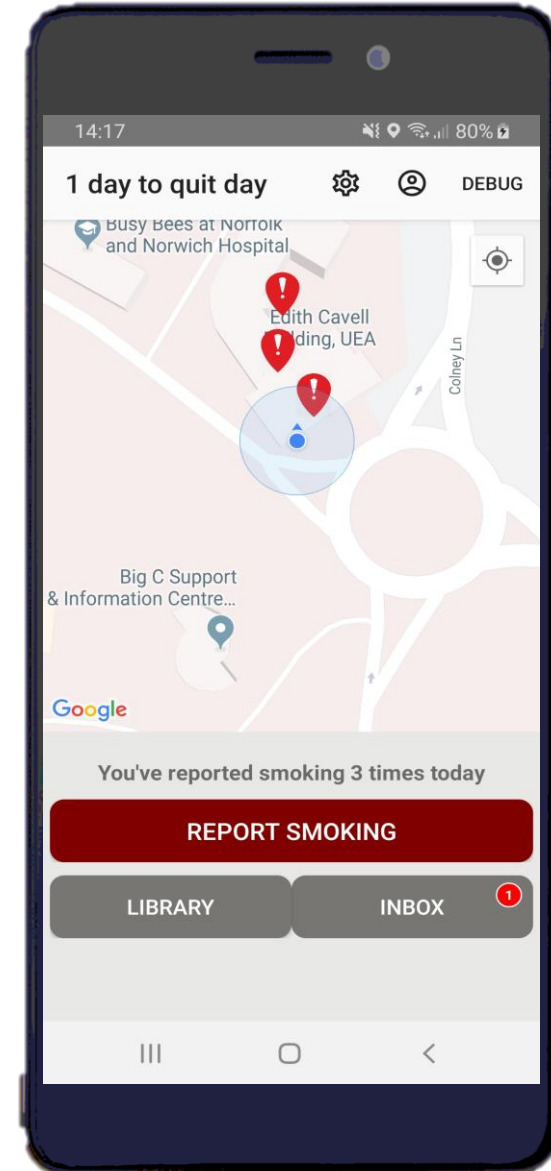


# An automated, online RCT to evaluate a Just-In-Time Adaptive smoking cessation smartphone app (Quit Sense)

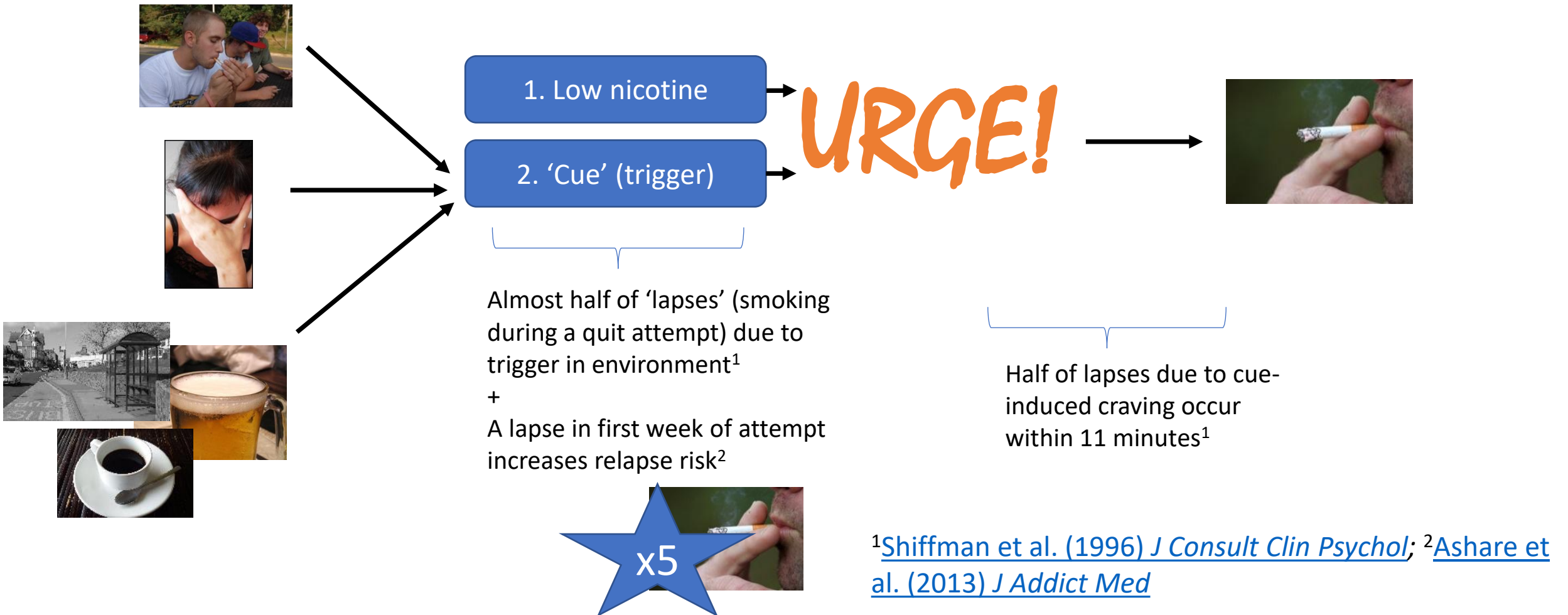
Felix Naughton  
[f.naughton@uea.ac.uk](mailto:f.naughton@uea.ac.uk)



## Team

Aimie Hope  
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Claire West  
Kelly Grant  
Tim Coleman  
Lee Shepstone  
Stephen Sutton  
Toby Prevost  
David Crane  
Garry Barton  
Felix Greaves

# Key to helping people quit

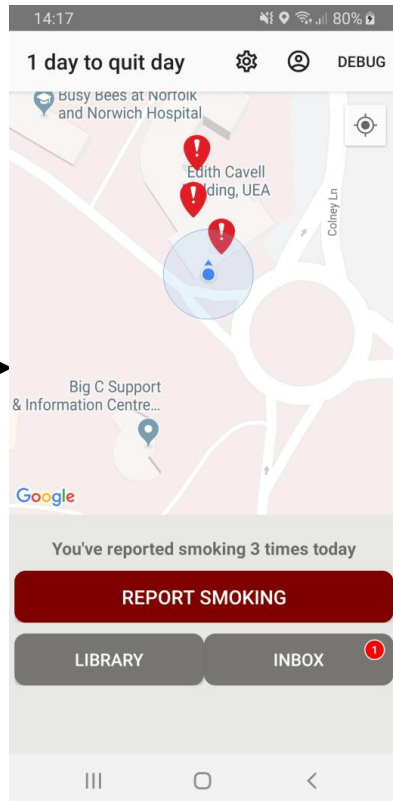




# Initiation

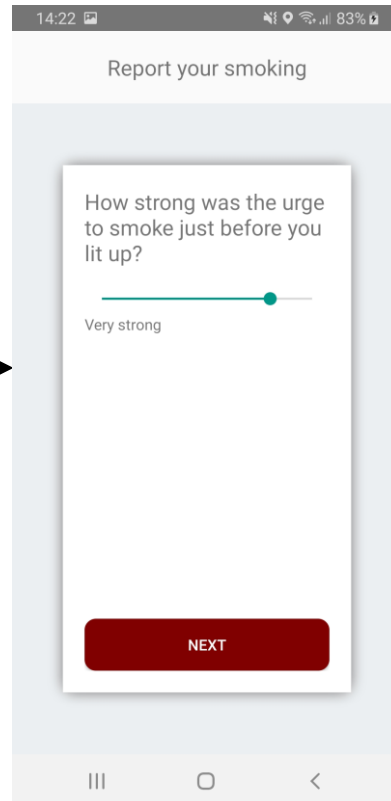
## Stage 1 – train the app (up to 4 weeks)

Set quit date

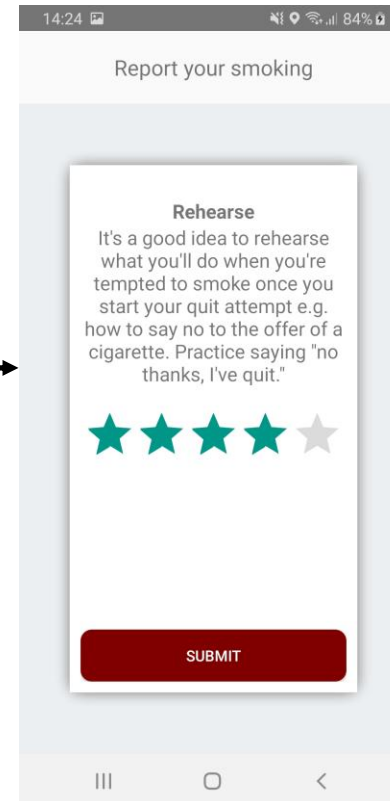


### Homescreen

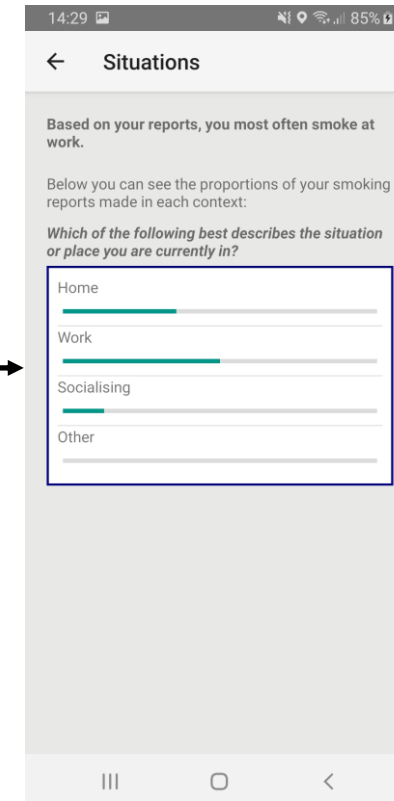
Users can train the app, view the library and check their messages via the inbox



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

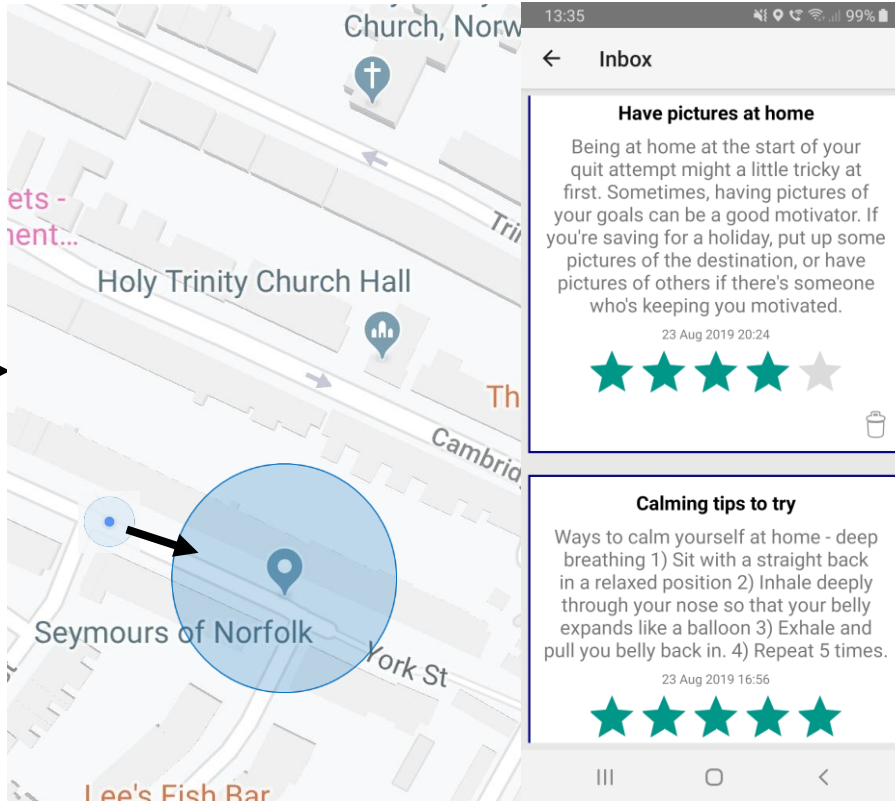


**Smoking data feedback** simple bar chart and text summaries on their triggers for smoking

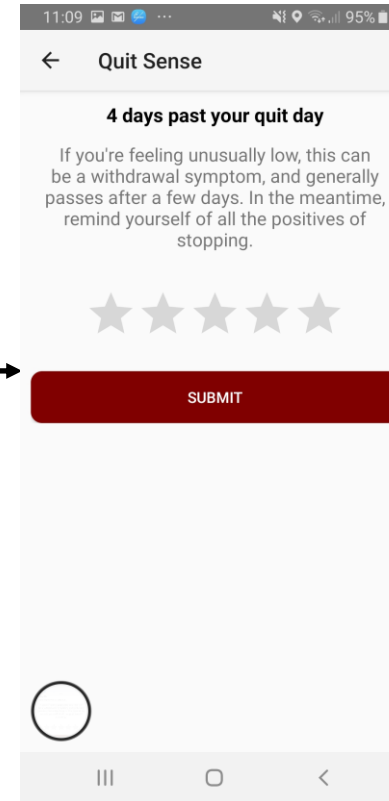
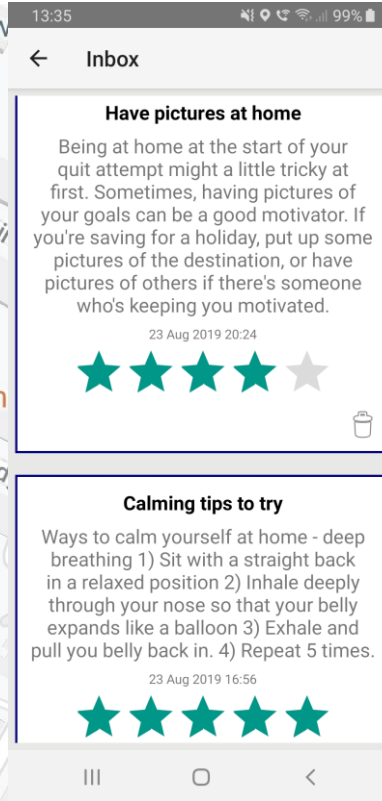
Quit date arrives

## Stage 2 – commit to quit (4 weeks)

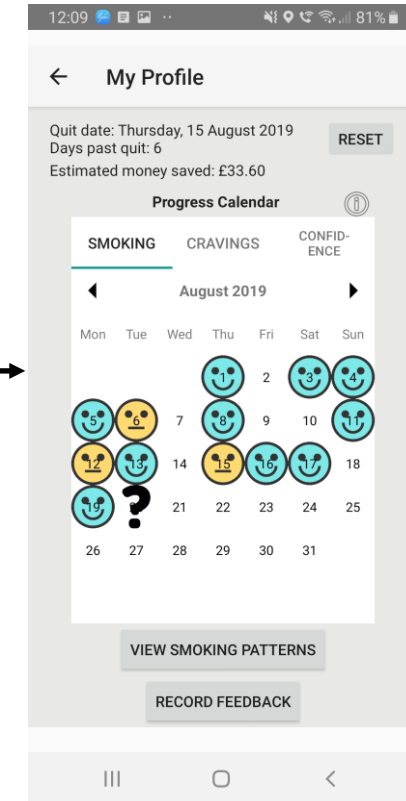
Quit date arrives



**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**



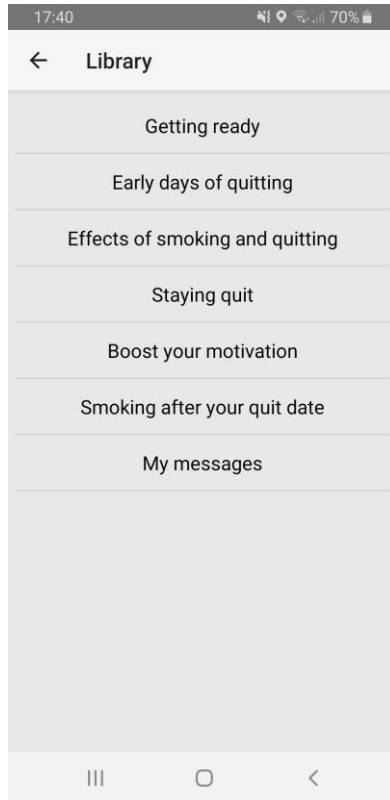
**Daily support messages targeting what to expect, confidence to quit and preventing lapses to smoking**



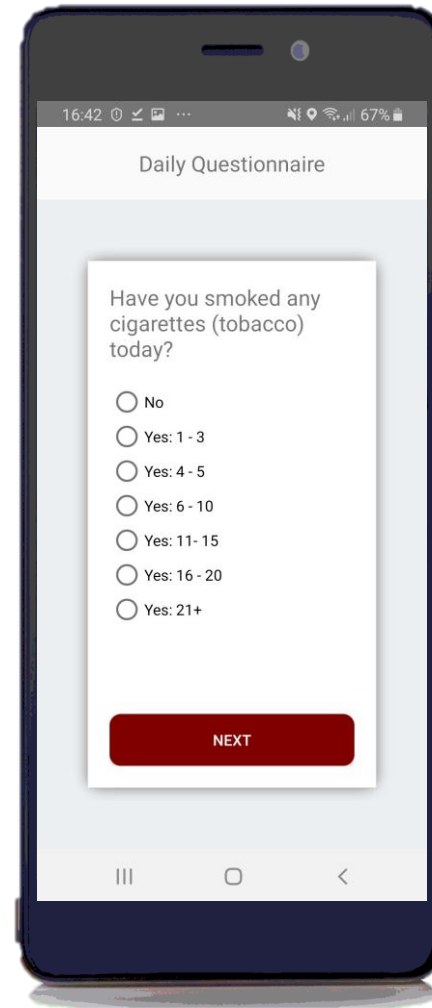
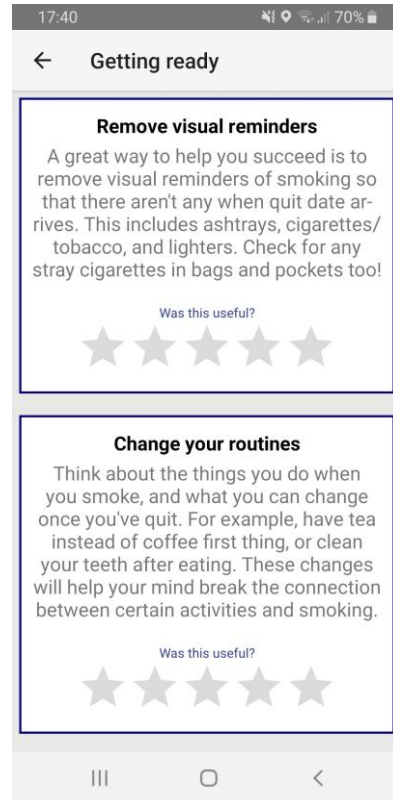
**Progress calendar**  
users can look at their progress over time by completing end of day surveys



# 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](https://www.isrctn.com/ISRCTN12326962). The trial protocol was published in [BMJ Open](https://bmjopen.bmj.com/) and the Statistical and Health Economics Analysis Plan (SHEAP) was pre-registered on the [Open Science Framework](https://www.openscienceframework.org/)



# Quit Sense feasibility RCT

## Design

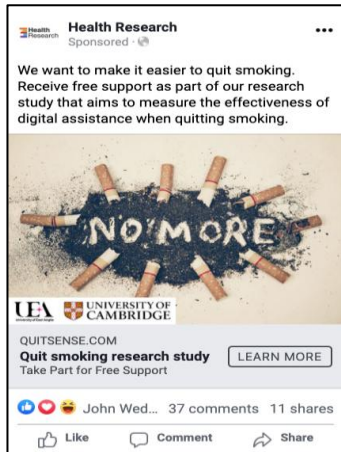
- A parallel, two-arm randomised controlled trial with a qualitative process evaluation and a 'Study Within A Trial' evaluating incentives on attrition
- The research team were blind to allocation except for the study statistician, database developers and lead researcher. Participants were not blind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

Trial registration [ISRCTN12326962](https://www.isrctn.com/ISRCTN12326962). The trial protocol was published in [BMJ Open](https://www.bmj.com/) and the Statistical and Health Economics Analysis Plan (SHEAP) was pre-registered on the [Open Science Framework](https://www.openscienceframework.org/)

# Quit Sense feasibility RCT

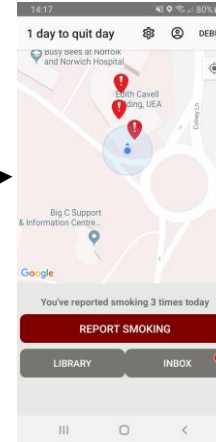
The trial protocol was published in [BMJ Open](#) and the Statistical and Health Economics Analysis Plan (SHEAP) was pre-registered on the [Open Science Framework](#)

facebook



Google

Quit Sense (n=104)



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

6 week follow up (n=78)

Qualitative interviews (n=20)

6 week follow up (n=71)

6 month follow up (n=81)

Abstinence verification



6 month follow up (n=79)

Fully automated

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



# Trial flow

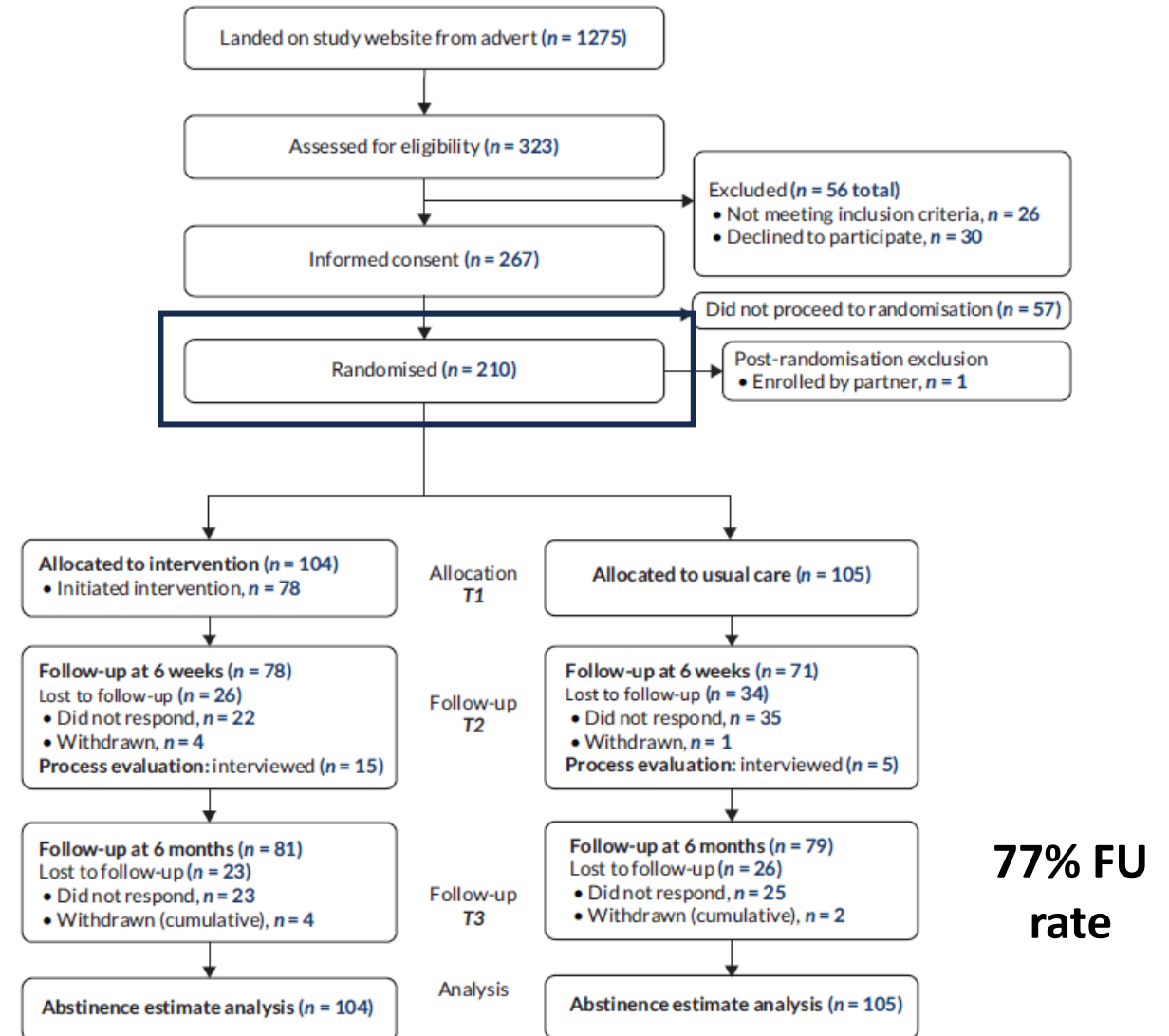


FIGURE 1 Trial flow.

# 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 Native campaign fees:
  - 6-week campaign fees £2,796
  - Overall cost per participant £19.20



# Recruitment costs

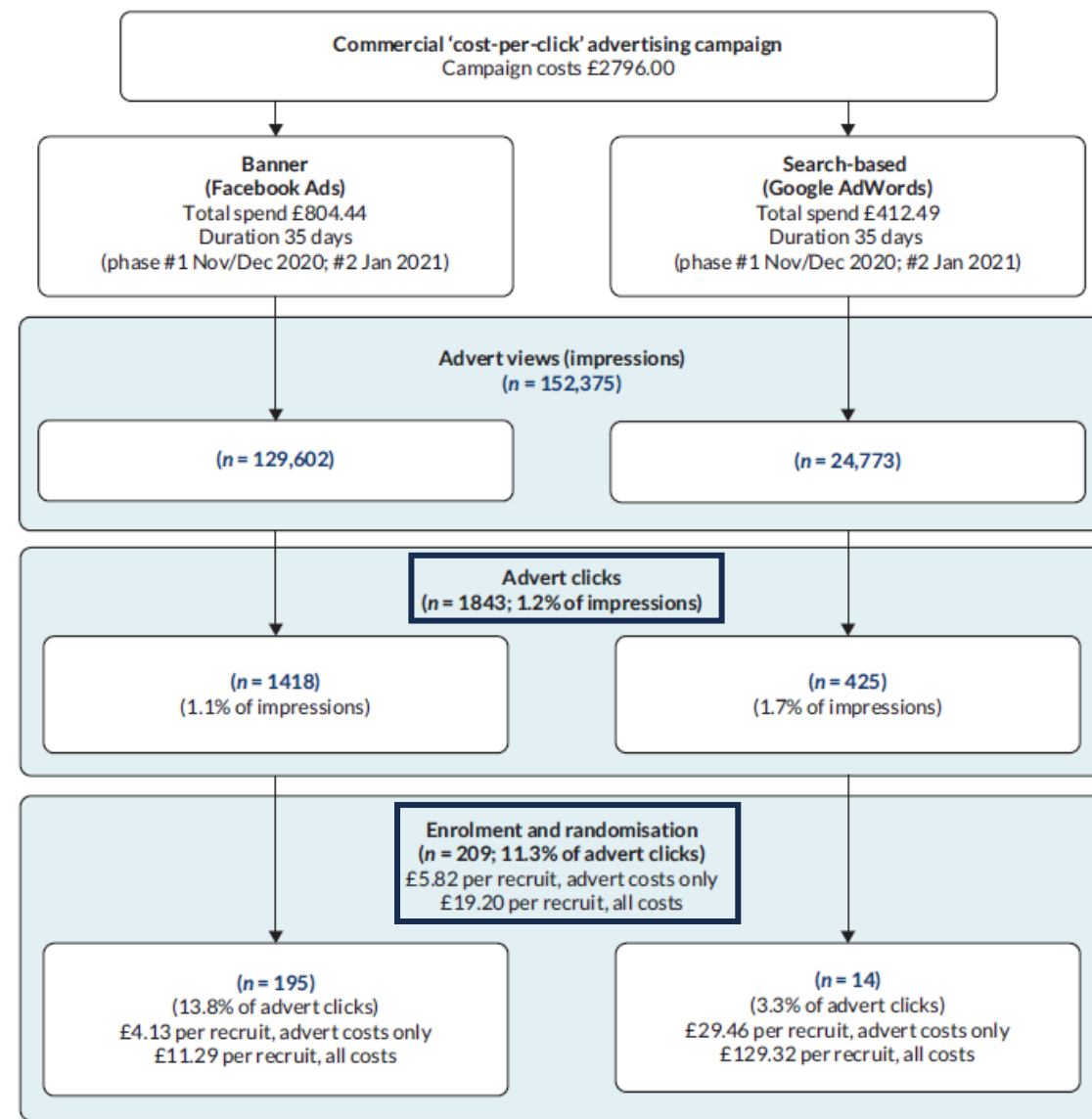


FIGURE 2 Flow diagram of advert reach, engagement and enrolment rates and costs.

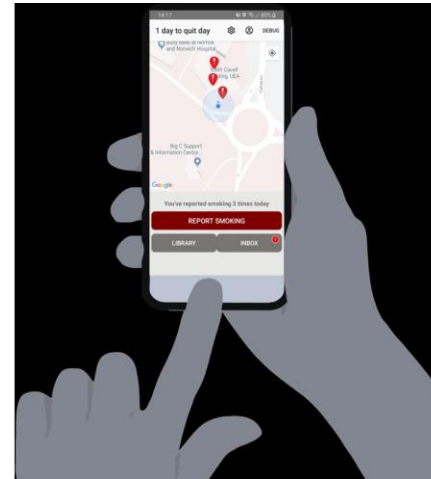
# Quit Sense feasibility RCT

## 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

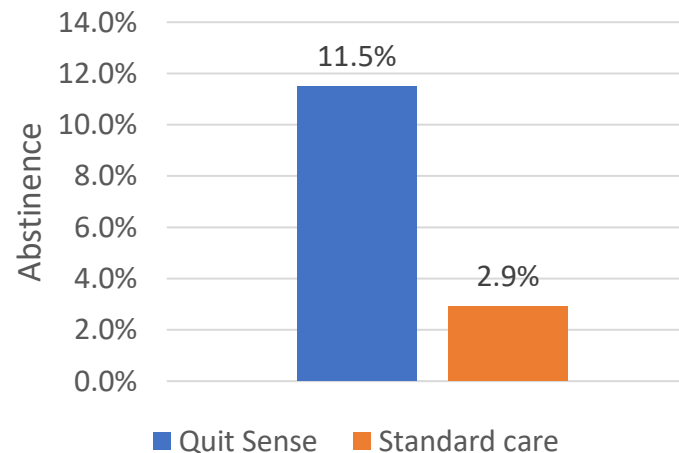
49% of installers  
engaged  
beyond quit  
date

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<sup>a</sup> (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



**!** <sup>a</sup>Low saliva return rate (39%) and potentially imbalanced between arms

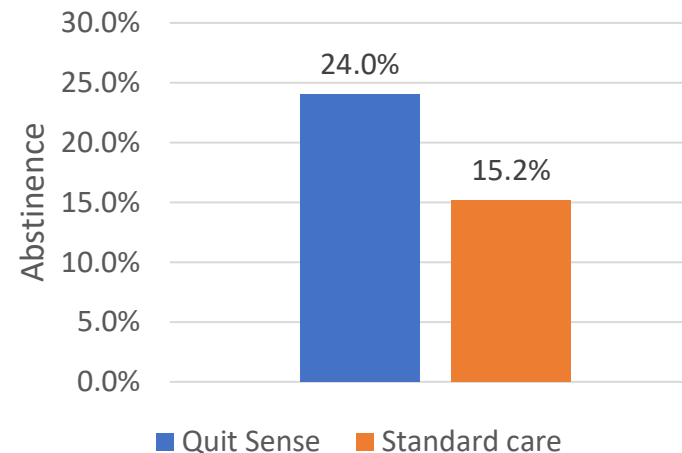
\*\*\* Adjusted for stratification variables (socioeconomic status and smoking rate)



# 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)

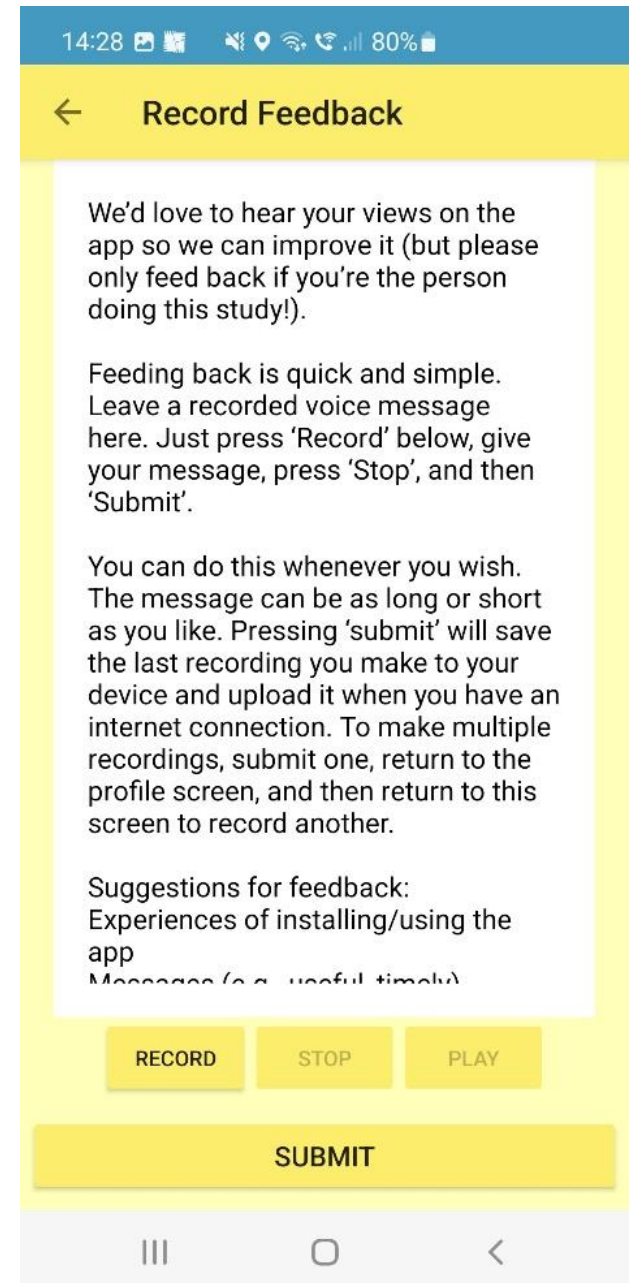
	Quit Sense (n=104) % (n)	Standard care (n=105) % (n)	Difference	Odds ratio (95% CI)	P-value
Unadjusted	24.0% (25)	15.2% (16)	8.8%	1.76 (0.88, 3.53)	0.11
Adjusted***	-	-	-		



\*\*\* 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 science<sup>1</sup>:
  - Potential attrition bias
  - Reduced statistical power
  - Potentially reduced reliability, validity and generalisability
- Most trials online/web cessation trials had loss between 20 – 50%<sup>2</sup>
- Reviews show incentives improve retention, particularly for remote trials<sup>3</sup>, but little known about automated or smoking cessation trials

<sup>1</sup> [Akl et al \(2012\) BMJ](#); <sup>2</sup> [Taylor et al \(2017\) Cochrane Database Syst Rev](#);

<sup>3</sup> [Gillies et al \(2021\) Cochrane Database Syst Rev](#)

# Quit Sense Study Within A Trial (SWAT)



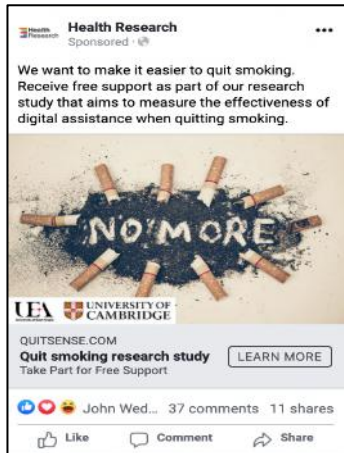
VS.



- 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

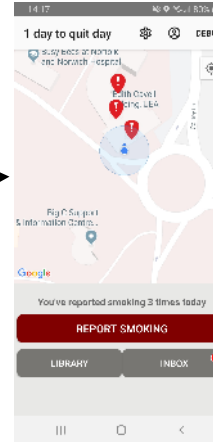
# Quit Sense feasibility RCT

facebook



Google

Quit Sense (n=104)



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

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6 month follow up (n=81)

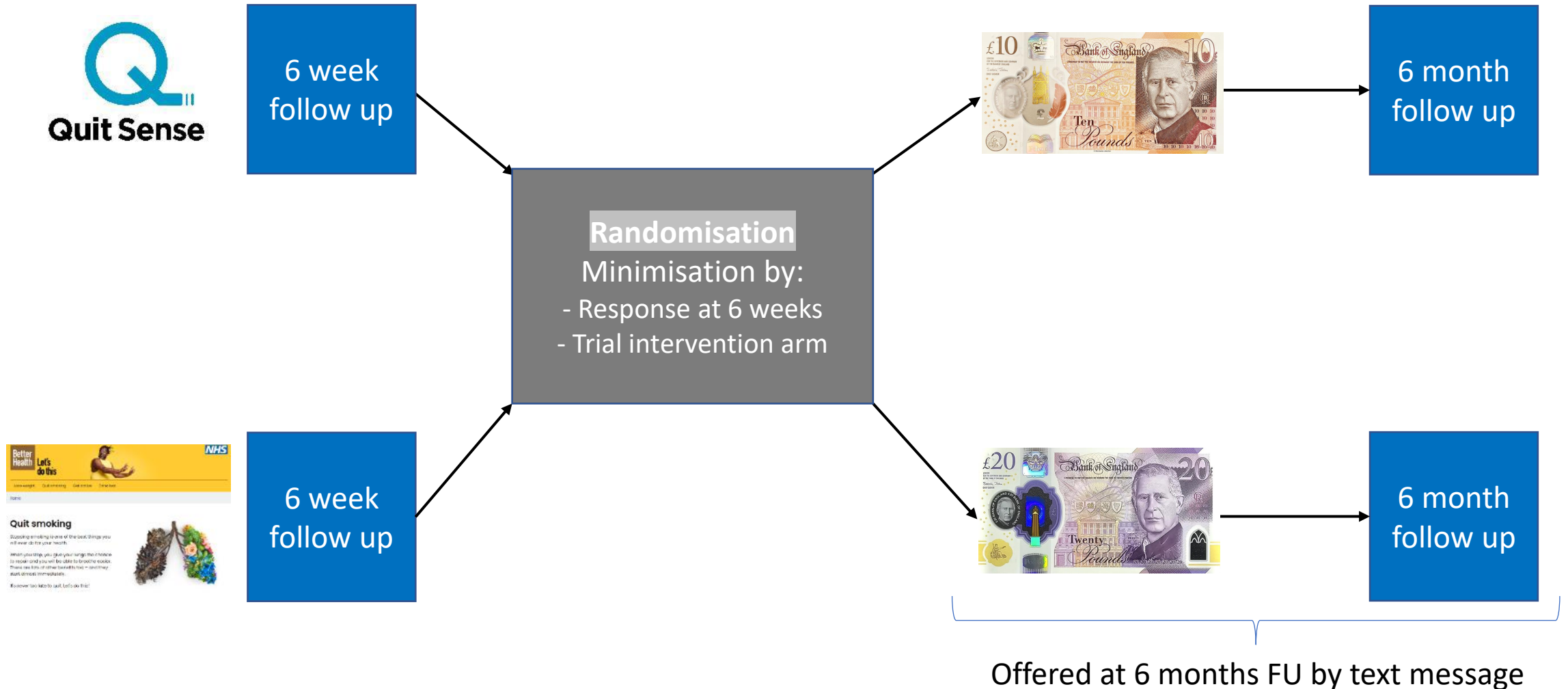


Abstinence verification

6 month follow up (n=79)

Fully automated

# Quit Sense Study Within A Trial (SWAT)





# Quit Sense Study Within A Trial (SWAT)

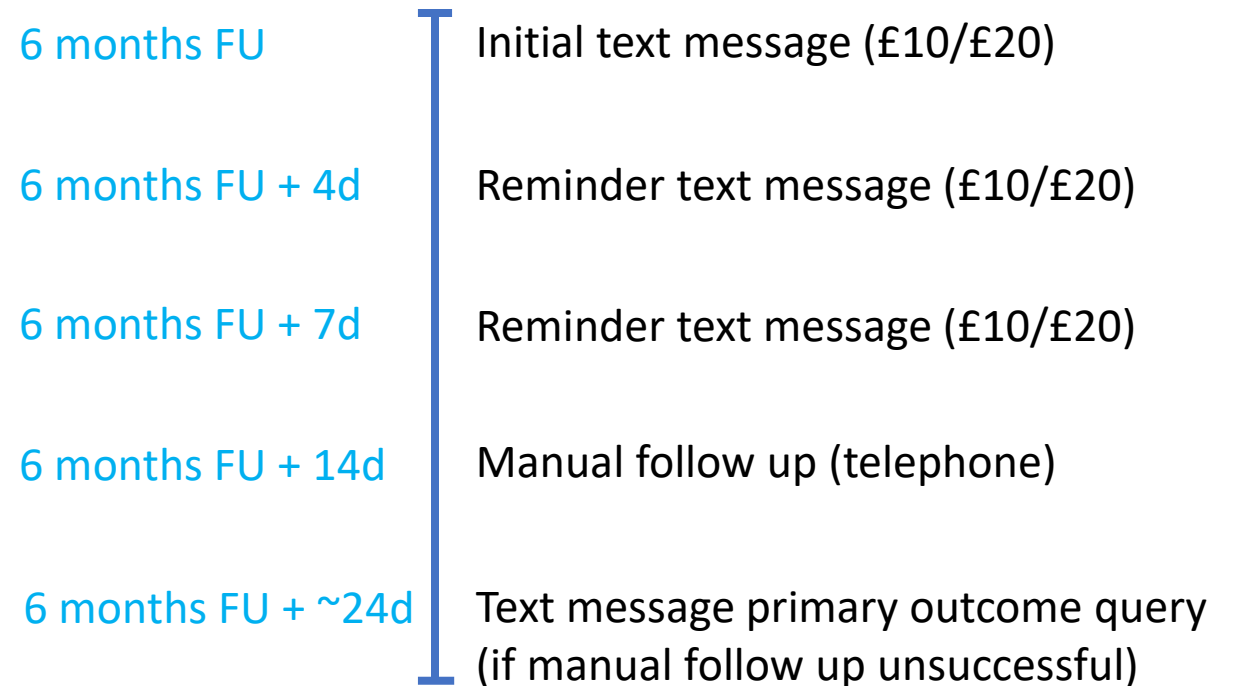
- Participant information sheet only referred to a 6m £10 incentive

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**

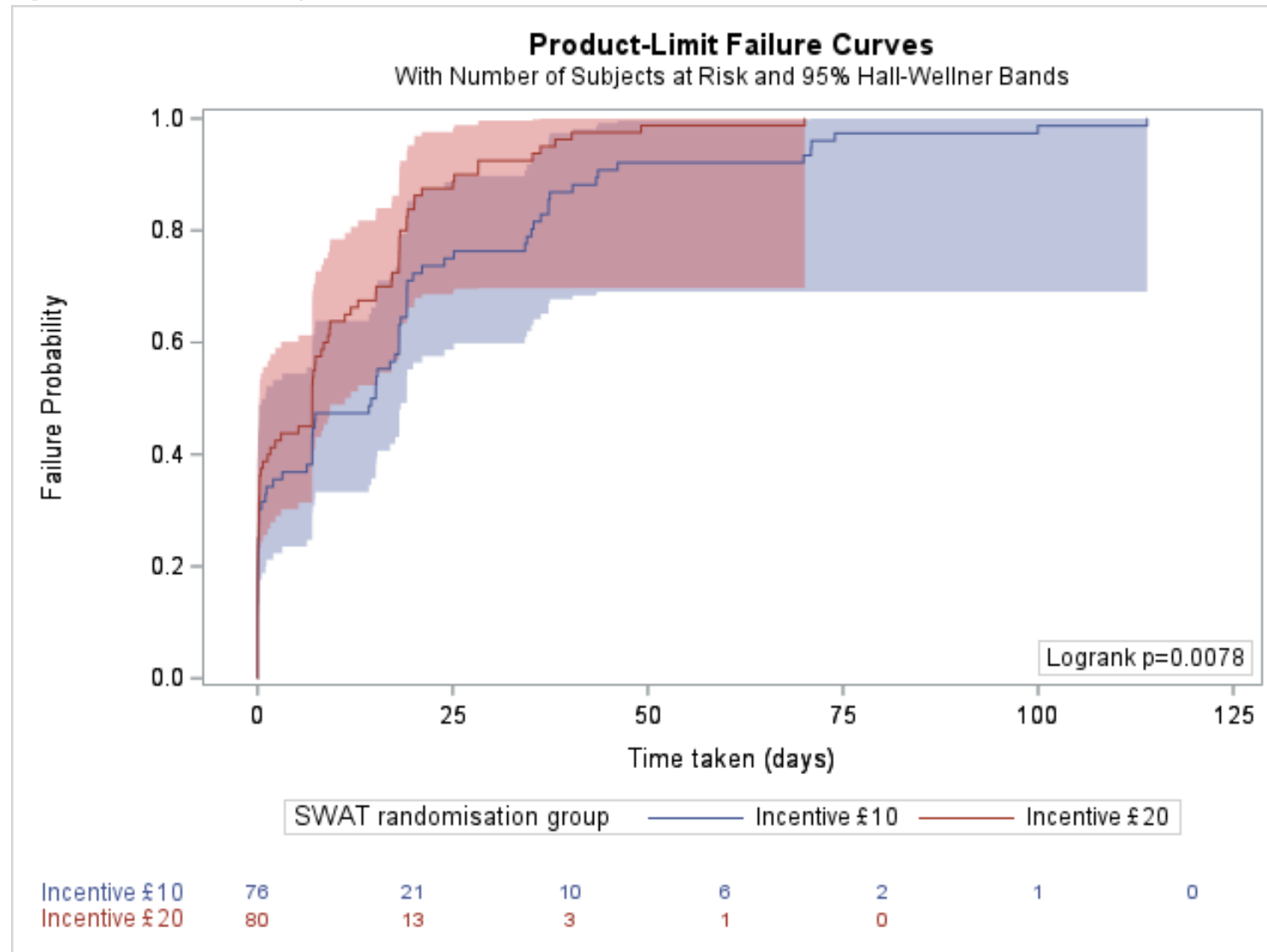


Unadjusted HR=1.55 (95% CI 1.12, 2.15, p=0.008)

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%

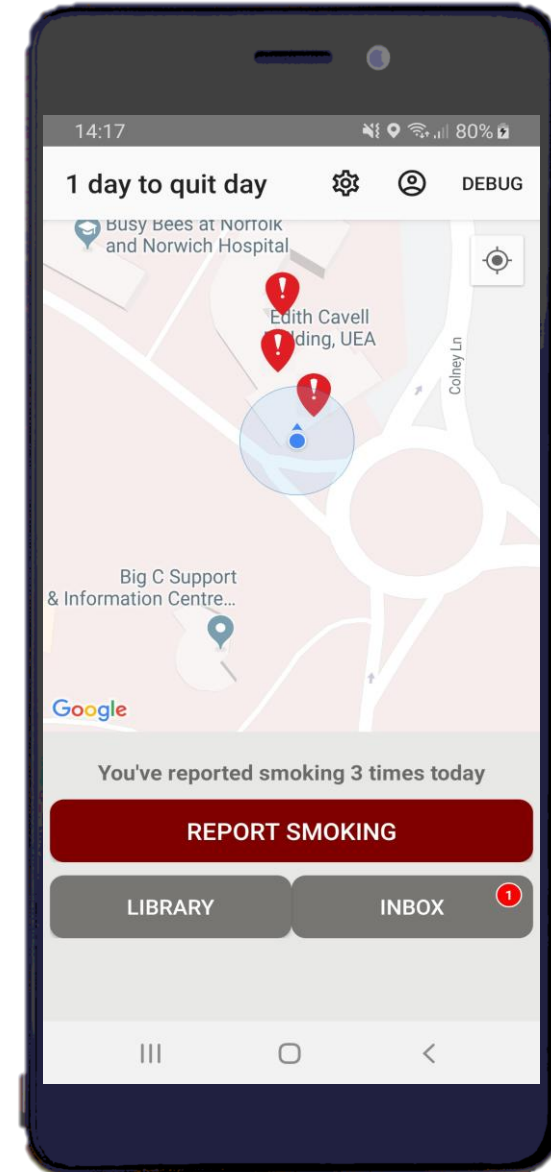
# Summary/implications

- 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

# Thank you

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