Study Title: Brief opportunistic Smoking cessation Advice for financially Vulnerable Individuals accessiNG financial Support (SAVINGS): a randomised controlled trial

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Funder:	National Institute for Health Research Public Health Research Programme (Grant Reference: NIHR158844).

Conflicts of interest

None of the investigators have financial links to the tobacco or vaping industry, or the Smoke Free app.

DoH Disclaimer

The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

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2. LAY SUMMARY

Aim of the research

We want to find out if offering people who smoke help to quit whilst they are accessing financial advice services makes them more likely to quit smoking than people who are not offered that help.

Background to the research

People with less money are more likely to smoke, and less likely to successfully quit, than people with more money. Over time, this means these people are more likely to become unwell due to their smoking. Giving advice and offering support to stop smoking can increase peoples' chances of quitting. Smoking is expensive, and providing support to quit through financial advice services could help more people.

Design of the research

We have worked with groups that provide social housing and financial guidance. They have helped find the best way to provide information and support for stopping smoking and to plan this study. We have also found financial support services who are willing to take part. During routine appointments financial support advisors will ask people if they smoke. If the answer is 'yes' advisors will explain the study and ask if they want to take part. We will put those who agree into one of two groups at random. One group will not receive guidance on their smoking. The other will receive advice and be offered the best ways to quit. This includes getting a nicotine vape and help to access behavioural support through a phone app or counselling from a stop smoking advisor. We will include 1,538 people accessing financial support who smoke in the study. We will follow up with them 12-weeks and nine months after they receive financial support to ask about changes in their smoking, wellbeing and money spent on tobacco. We will interview some people taking part and some people giving support about their experiences in the study.

Patient and public involvement in the research

We developed study methods by talking to people living with financial difficulties who smoke. We also talked to people who give financial guidance. We will ask two people who smoke and have had support with financial issues to join the study team. These people will help us work out the best ways to run the study. We will also ask more people with similar experiences for their advice on running the study and presenting results.

Sharing findings of the research

We will share our findings with everyone who takes part, including financial advisors. We will create a plan to share findings with more people who smoke and are experiencing financial problems. We will ask people with lived experience to review materials sharing our findings. We will also talk to people who work in relevant services to decide how to share this information with them. In the past we have used pictures, videos, and podcasts to share our findings. We might use these and other ways this time. We will work with Action on Smoking and Health (ASH) and the National Centre for Smoking Cessation and Training (NCSCT). They will also share our findings. The NCSCT will make a training programme based on this research and share this with more than 90,000 people.

Expected impact

If the intervention is effective, we hope it will contribute to helping people accessing financial advice services to quit smoking and improve their overall health, finances and well-being. On a population level, we hope that it will contribute to reducing health inequalities.

3. SYNOPSIS

Study Title	Brief opportunistic Smoking cessation Advice for financially Vulnerable Individuals accessiNG financial Support (SAVINGS): a randomised controlled trial		
Internal ref. no. / short title	IG138 / The SAVINGS trial		
Study registration	ISRCTN12504090		
Sponsor	University of Oxford RGEA, Joint Research Office, Churchill Drive, Headington, Oxford OX3 7GB T: +44 (0)1865 616480 E: rgea.sponsor@admin.ox.ac.uk		
Funder	National Institute for Health and Care Research Public Health Research Programme (Grant Reference: NIHR158844).		
Study Design	Two-arm, parallel group RCT with embedded pilot phase, economic, and process evaluations.		
Study Participants	Adult participants aged 18 years and over, who are receiving advice for financial difficulties and self-report daily tobacco smoking.		
Sample Size	**Trial**: 1,538 (769 in each arm). **Qualitative Process Evaluation:** Up to ~350 audio-recordings of intervention consultations, up to ~100 usual care recordings, up to ~30 interviews with intervention participants, up to ~20 interviews with financial services advisors.		
Planned Study Period	4 years. Individual participant involvement: 9 months Long-term follow-up: 9 months		
Planned Recruitment period	Dec 2025-Dec 2027		
	Objectives	Outcome Measures	Timepoint(s)
Primary	To undertake an RCT, with internal pilot, to evaluate the effectiveness and safety of very brief, opportunistic smoking cessation advice compared to usual care delivered in financial advice services.	biochemically validated four-week prolonged abstinence from tobacco (primary outcome)	12-weeks
		biochemically validated, prolonged abstinence from tobacco between the 12-week and 9-month follow-ups	9-months
		self-reported 7-day point prevalence tobacco abstinence	12-weeks 9-months
		number of participants reporting non-serious adverse reactions (ARs)	12-weeks
		number of participants reporting serious adverse events (SAEs)	12-weeks
Secondary	To estimate the intervention's cost-	financial well-being, measured using the abbreviated Consumer Financial Protection Bureau scale	12-weeks 9-months

	effectiveness relative to usual care from the public sector perspective.	health-related quality of life, measured using the EuroQol EQ-5D-5L	12-weeks 9-months
		incremental cost per QALY gained	12-weeks 9-months
		mental well-being, measured using the Warwick-Edinburgh Mental-Wellbeing Scale	12-weeks 9-months
	To carry out an embedded process evaluation investigating factors, e.g., number of quit attempts and intervention acceptability, influencing effects of the intervention.	proportion making at least one quit attempt (defined as 24-hours or more of abstinence) – self reported	12-weeks
		change in number of self-reported cigarettes smoked per day between baseline and follow-ups	12-weeks 9-months
		proportions of smoke-free households (defined as none of the members of a household currently smoking tobacco), self-reported	12-weeks 9-months
		self-reported change in tobacco expenditure from baseline to follow-ups	12-weeks 9-months
		reallocation of tobacco funds (in participants who report a reduction in expenditure) [1]	12-weeks 9-months
		intervention fidelity and acceptability [1]	12-weeks 9-months
		self-reported follow-on smoking cessation behavioural support, e-cigarette and medication use (including length of use) [1]	12-weeks 9-months
		participants' experiences of the intervention[2]	Post-baseline (during the follow-up period)
		service advisors' experiences of the intervention [2]	Post-baseline (during the follow-up period)
		if the intervention is delivered as intended (and what may hinder or support this) [2]	Post-baseline (during the follow-up period)
Intervention	Opportunistic, very brief advice on smoking, including information on the best ways to quit, the financial benefits of quitting and providing and referring participants to relevant support. A nicotine e-cigarette will be provided alongside information on		

	behavioural support available, including free access to a stop smoking app if preferred.
Comparator	Participants will be asked about their smoking to establish whether they are eligible for the study. Those randomised to the comparator group will receive no further intervention in line with usual care for this setting in the UK.

All outcomes are assessed quantitatively, unless otherwise specified:

[1] Assessed both qualitatively and quantitatively

[2] Assessed qualitatively only

4. ABBREVIATIONS

ARs	Non-Serious Adverse Reactions
ASH	Action on Smoking and Health
CFPB	Consumer Financial Protection Bureau
CONSORT	Consolidated Standards of Reporting
DMEC	Independent Data Monitoring and Ethics Committee
eCRF	Electronic Case Report Form
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
ISRCTN	International Standard Randomised Controlled Trial Number
NCSCT	National Centre for Smoking Cessation and Training
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Social Care Research
ORs	Odds Ratios
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
QALY	Quality-Adjusted Life Year
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Events
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
TMG	Trial Management Group
TSC	Independent Trial Steering Committee
VBA	Very Brief Advice
YTU	York Trials Unit

5. BACKGROUND AND RATIONALE

5.1. What is the Problem being Addressed?

Smoking prevalence increases with deprivation.(1) People living with socioeconomic disadvantage are just as motivated to quit smoking as more advantaged groups,(2-4) yet they are 16% less likely to attempt quitting and 41% less likely to succeed.(5)

5.2. Why is this Research Important in terms of Improving Public Health?

Smoking remains one of the single largest drivers of health inequalities in England, acting as a major mediator of the disparity in cancers, cardiovascular disease,(6, 7) and potentially contributing to mental wellbeing gaps.(8) Reducing smoking rates in socioeconomically disadvantaged groups is therefore essential to tackling preventable illness and premature death. Supporting people to quit could also offer financial relief for individuals and families, which may be especially meaningful during periods of financial strain.

Brief opportunistic smoking cessation interventions are effective and cost-efficient in healthcare settings,(9, 10) but access to these services is lower among people facing financial hardship.(11) Embedding smoking cessation support into financial support services—settings already accessed by the target population—could bridge this gap. Moreover, highlighting the financial burden of smoking may enhance motivation to quit within this context.(12)

Opportunistic very brief advice (VBA) can reach a wide range of people who smoke irrespective of their prior motivations to quit, including those not actively seeking help. This is particularly important given that motivation to quit fluctuates, and almost half of quit attempts are made on days when people had no prior intention to stop smoking.(13)

5.3. Review of Existing Evidence

We conducted a scoping review of the evidence for smoking cessation interventions delivered opportunistically within financial support settings.(14) From 6,043 screened records, we identified 25 eligible studies, covering a range of settings such as food banks, social housing, homeless support services, and cheque cashing locations. Seventeen of these studies explored the perspectives of service users and providers—who generally supported the integration of smoking cessation into financial services. Concerns from providers about people's receptiveness were not echoed by those who would receive the intervention who welcomed being asked about smoking and offered assistance to quit.

However, very few studies assessed smoking outcomes, and only six were RCTs. Most focused on comparing more versus less intensive interventions, rather than comparing against standard practice. No randomised controlled trials (RCTs) were conducted in the UK, follow-up durations were generally under six months, and none assessed cost-effectiveness. This highlights a significant evidence gap, particularly in relation to real-world UK settings.

One US-based field experiment in cheque cashing and grocery locations found that brochures emphasising the financial benefits of quitting were taken more frequently than those highlighting health gains—suggesting financial framing may enhance engagement in these contexts.(15)

5.4. Feasibility and Pilot Work

To inform this proposal, we evaluated the feasibility and acceptability of delivering VBA to quit smoking through Clarion Futures, a financial support service for social housing residents.(16) Among 369 residents assessed, 35% reported smoking—consistent with estimates for UK social housing populations (compared to 11.9% in the general UK population in 2023).(2, 17)

Financial advisors were trained to ask about smoking and deliver brief advice. Smoking was raised in 94% of recorded interactions, with an additional 2% of clients initiating the conversation themselves. Of those identified as smokers (n = 134), 97% received advice on how to quit and 89% were offered support via the Smoke Free app or local services. Among the residents surveyed, 75% were “very happy” and 19% “somewhat happy” to discuss their smoking during a financial advice session. These results suggest that not only is the intervention feasible, but that it aligns well with both the service context and user expectations.

5.5. Rationale for this Study

This study will evaluate whether delivering very brief, opportunistic smoking cessation advice through financial support services can promote meaningful quit attempts and abstinence among adults experiencing financial difficulty. Rather than creating a new intervention, the trial adapts an evidence-based VBA model, tailored to this setting by incorporating messaging about the financial benefits of quitting—an approach shown to resonate in early research and pilot work.

The SAVINGS trial will be the first large-scale UK RCT to test this model in real-world financial support settings. It will rigorously assess effectiveness, feasibility, acceptability, and cost-effectiveness, using a robust design that includes biochemical validation and process evaluation.

In doing so, the study addresses a critical public health question: can brief cessation advice embedded in routine financial support settings reduce smoking among those most affected by tobacco harm? The findings will directly inform national policy, offering an equity-focused, scalable approach to reducing smoking-related inequalities in England.

6. AIM, OBJECTIVES AND OUTCOME MEASURES

6.1. Aim

To assess the effects of very brief, opportunistic, smoking cessation advice compared to usual care, provided by financial guidance services to adults receiving support for financial difficulties who smoke tobacco.

6.2. Objectives and Outcome Measures

	Objectives	Outcome Measures	Timepoint(s)
Primary	To undertake an RCT, with internal pilot, to evaluate the effectiveness and safety of very brief, opportunistic smoking cessation advice compared to usual care delivered in financial advice services.	biochemically validated four-week prolonged abstinence from tobacco (primary outcome)	12-weeks
		biochemically validated, prolonged abstinence from tobacco between the 12-week and 9-month follow-ups	9-months
		self-reported 7-day point prevalence tobacco abstinence	12-weeks 9-months
		number of participants reporting non-serious adverse reactions (ARs)	12-weeks
		number of participants reporting serious adverse events (SAEs)	12-weeks
Secondary	To estimate the intervention's cost-effectiveness relative to usual care from the public sector perspective.	financial well-being, measured using the abbreviated Consumer Financial Protection Bureau scale	12-weeks 9-months
		health-related quality of life, measured using the EuroQol EQ-5D-5L	12-weeks 9-months
		incremental cost per QALY gained	12-weeks 9-months
		mental well-being, measured using the Warwick-Edinburgh Mental-Wellbeing Scale	12-weeks 9-months
	To carry out an embedded process evaluation investigating factors, e.g., number of quit attempts and intervention acceptability, influencing effects of the intervention.	proportion making at least one quit attempt (defined as 24-hours or more of abstinence) – self reported	12-weeks
		change in number of self-reported cigarettes smoked per day between baseline and follow-ups	12-weeks 9-months
		proportions of smoke-free households (defined as none of the members of a household currently smoking tobacco), self-reported	12-weeks 9-months
		self-reported change in tobacco expenditure from baseline to follow-ups	12-weeks 9-months

		reallocation of tobacco funds (in participants who report a reduction in expenditure)[1]	12-weeks 9-months
		intervention fidelity and acceptability[1]	12-weeks 9-months
		self-reported follow-on smoking cessation behavioural support, e-cigarette and medication use (including length of use)[1]	12-weeks 9-months
		participants' experiences of the intervention[2]	Post-baseline (during the follow-up period)
		service advisors' experiences of the intervention[2]	Post-baseline (during the follow-up period)
		if the intervention is delivered as intended (and what may hinder or support this)[2]	Post-baseline (during the follow-up period)

All outcomes are assessed quantitatively, unless otherwise specified:
[1]Assessed both qualitatively and quantitatively
[2]Assessed qualitatively only

7. STUDY DESIGN

A two-arm, multi-centre, parallel group RCT with embedded pilot phase, economic, and process evaluations assessing the effectiveness of very brief, opportunistic smoking cessation advice compared to usual care, delivered in financial advice services. The VBA intervention lasts approximately 1 minute. It will include participants being informed about behavioural support options they can access, including the availability of a licence to access a smoking cessation app free of charge, and that they will be sent a free e-cigarette/nicotine vape starter kit (including a vape and nicotine liquids).

Participants will be recruited by financial advice services when they are attending (either in-person or remotely) for routine reasons. Attendees will be screened for eligibility (including whether they smoke tobacco) and consent will take place at this point. People who consent will be 1:1 randomised to either the intervention group (N = 769), where they will receive very brief, opportunistic, smoking cessation advice, or the comparator group (N = 769), where they will receive no further intervention in line with usual care in the UK.

Participants will be asked to provide baseline data during the first recruitment contact with the financial service provider (in-person or remotely). Follow-up data will be collected via email and/or phone calls with the research team as soon as possible after this contact, at 12 weeks and 9 months following baseline. Therefore, each participant will be involved in the study for a total of 9 months, have one research related contact with the financial service provider, and three email/telephone contacts with the research team. Participants who claim to be abstinent from tobacco smoking at the 12-week and 9-month follow-ups will be mailed saliva sample test kits by the research team. They will be provided with the resources to mail this directly to the lab for analysis.

The process evaluation will include a conversation analysis of up to ~350 intervention group financial advice consultations, up to ~100 usual care consultations for fidelity testing, up to ~30 interviews with intervention participants, and up to ~20 interviews with financial service advisors. Recordings of financial advice consultations will start from approximately December 2025 and end in approximately December 2027 (i.e., throughout the recruitment phase). Interviews will start from approximately January 2025, four-to-six weeks after the participant has received the intervention, and end in approximately January 2028 (to account for participants recruited at the end of the recruitment period). Analysis will run concurrently with data collection and will end in approximately December 2028.

The entire study will take place over 48 months. A study Gantt chart can be found in Appendix A and a flowchart for the study in Appendix B.

This protocol has been developed in-line with the attached Equality Impact Assessment (EqIA) form (Appendix C). We will follow EqIA toolkit guidelines to ensure diversity.

8. PARTICIPANT IDENTIFICATION

8.1. Study Participants

Adults aged 18 and over, who are currently receiving advice or support for financial difficulties and self-report daily tobacco smoking. We aim to recruit 1538 participants in total.

8.2. Inclusion Criteria

- Adults aged 18 years and over.
- Able to give informed consent to participate.
- Currently receiving advice or support for financial difficulties by financial guidance services.
- Self-reported daily tobacco smoking, regardless of motivation to quit smoking.
- Able to provide both a contact telephone number and postal address (email address optional) for the purposes of follow-up.

8.3. Exclusion Criteria

- People using only cigars/cigarillos, smokeless tobacco, heated tobacco, shisha, cannabis, or non-tobacco nicotine products like e-cigarettes or nicotine pouches. People using these products alongside daily tobacco smoking will still be eligible.
- Other household member participating in the trial.

9. PROTOCOL PROCEDURES

A schedule of study procedures can be found in Appendix D and amendments to this protocol are in Appendix E.

9.1. Site Recruitment

We will identify services offering financial advice or specifically supporting people in financial difficulty (e.g., social housing, debt/financial advice services, job seeking services) through online searching and contacts with links to relevant organisations, e.g., our collaborators, Clarion Futures and ASH; local authorities. We will contact these services with information about the study and ask whether they would be interested in being involved. We will also work with National Institute for Health and Care Research (NIHR) Research Development Networks to identify and recruit sites, as needed. We will not recruit services solely assisting people experiencing homelessness, as this population have their own distinct needs, and is being addressed by other UK-research studies.

A lead person at each site will be assigned as the primary point of contact and asked to sign the appropriate page of the protocol to confirm that they have read the protocol and are happy to conform to the methods outlined. As we will be recording conversations between participants and their financial advisors, we will also seek informed consent from each advisor taking part in the trial to record their sessions with participants. This will take place prior to any sessions that the advisor has with participants.

9.2. Participant Recruitment

We will recruit participants from people accessing financial guidance or support services. Therefore, participants will be recruited opportunistically, rather than proactively, to ensure that people who smoke who are both motivated and unmotivated to stop are approached to take part. People using services will be consulting with a member of the financial service team as part of their routine contact. During the session, attendees will be advised that the service is taking part in a study that "is looking at whether it is helpful to offer support for changing a health behaviour within a financial support/social housing setting" and asked if they smoke tobacco cigarettes/roll-ups daily. If the attendee meets the eligibility criteria, they will be orally provided with information about the study –and asked if they would be happy to take part. It is important that the information is not too detailed as the description of the intervention could act as VBA itself.

9.3. Screening and Eligibility Assessment

Once a potential participant has confirmed that they smoke tobacco cigarettes or roll-ups daily (regardless of other tobacco/nicotine/cannabis use) and have confirmed their interest in the study, they will be asked for their birthdate (to confirm they are 18 years of age or over; if this is not already available to the advisor), if they are happy to be contacted about the study by phone/post, and their preferred time of day to be contacted by phone, for the purposes of follow-up. Each participant must satisfy all approved inclusion and exclusion criteria for the study. If an attendee does not meet all the criteria, they will be recorded as a screen failure for the CONSORT (Consolidated Standards Of Reporting Trials) diagram and informed that they cannot be included in the study. No exceptions will be made regarding eligibility.

9.4. Informed Consent

The financial services advisor will provide all potentially eligible service users with a Participant Information Sheet (PIS) – either as a paper copy or electronically, dependent on whether the session is in-person or remote. They will also read out the information on the PIS, if necessary, for example, if the potential participant is not able to access the PIS remotely immediately or if they prefer it. The PIS will be concise to fit within the context of the trial but will detail no less than: the nature of the study; what it will involve for the participant; the implications and constraints of the protocol; any risks involved in taking part; information on data protection procedures that will be followed. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal

The participant will be allowed time within the session to consider the information, and to question the financial service provider to decide whether they will participate in the study.

If the participant is happy to continue, the advisor will obtain consent from the participant to take part in the study by completing an online study consent form. To do this, the advisor will read out each consent statement, obtain verbal consent to each statement, directly record this into the online consent form and electronically sign the form. Providers who obtain the consent will be suitably trained and authorised to do so. A copy of the signed consent form will be sent to the participant via email (where provided), or by post, where necessary.

Where the participant attends the session with a companion (it is possible that people may include a friend, family member, carer in their appointment to offer support), we will also seek consent from the companion to be recorded as part of the process evaluation. Consent will be obtained using a different version of the consent form, but using the same processes as detailed above. Should a companion not consent to the session being recorded this will not prohibit the participant from taking part.

Baseline data will then be collected by the financial service providers (see 9.8 for further details).

9.5. Randomisation

Service users who have consented to participate, will be individually randomised by the financial service provider using a 1:1 ratio to either the intervention or usual care comparator group using simple randomisation. Randomisation will be carried out using a secure web-based randomisation system (REDCap) ensuring allocation concealment. Advisors will be trained on the course of action to be taken dependent on allocation (described in more detail below).

The randomisation service will require the recording of information and a check of participant eligibility to avoid inappropriate entry of individuals into the trial. The system will provide an immediate allocation and a confirmation email. The email confirming randomised allocation will be sent to appropriate and authorised users of the randomisation system.

An independent statistician at York Trials Unit (YTU), who is not involved in the recruitment of participants, will generate the allocation sequence which will be unmodifiable. There will be no paper based back up of randomisation for use in emergencies.

9.6. Blinding and Codebreaking

Due to the behavioural nature of the intervention, it will not be possible to blind the financial service providers, participants and trial staff to group allocation (although participants will not explicitly be told

their allocation they may be able to infer it). Efforts will be made to blind researchers to group allocation at the time of contacting participants to collect follow-up data; however, this may not always be possible due to the behavioural nature of the intervention and the wide-ranging responsibilities of trial's unit staff. It is also possible that participants could disclose information that will make their allocation known. To reduce bias in the measurement of the primary outcome, smoking status at the 12-week and 9-month follow-up will be biochemically verified; therefore, objectively measured. All patient-facing materials will be designed to put minimal emphasis on the exact nature of the intervention. It is possible that control group participants may experience more favourable outcomes compared to if they were not taking part in the trial, due to assessment reactivity. In order to control for this as much as possible trial procedures and contact time will be matched between study arms and the trial will assess the additive effect of the intervention. This will also be acknowledged as a limitation in the reporting of trial results.

9.7. Description of Study Intervention(s), Comparators and Study Procedures

9.7.1. Description of study intervention(s)

Participants randomised to the intervention will receive brief advice on smoking (lasting approximately one minute) delivered by the financial services provider, involving the following steps:

1) advice that the best way to stop smoking tobacco is with a combination of behavioural support and a switching aid, such as an e-cigarette;
2) advice on the amount of money that could be saved by stopping smoking/switching to another product;
3) information about the support available to help them switch from tobacco smoking, including the provision of an e-cigarette starter kit, and the various behavioural support options available.

For the third step, service users will be sent an e-cigarette/vape starter kit, including a vape and nicotine vape pods, unless they opt out. The vape kits will be purchased from independent suppliers who are not affiliated with the tobacco industry and will include a choice of pod flavours. We will aim to use a closed pod device that is straightforward to set up and operate, and which utilises pre-filled, non-refillable replacement pods containing nicotine salts. These replacement pods are available in a variety of flavours and nicotine strengths to enhance acceptability and appeal. The devices and pods are affordable and widely available from various outlets across the country, so this should help to encourage continued use and help avoid smoking relapse, where necessary. We will develop print materials with information on setting up the vapes and using them to switch away from combustible cigarettes, based on materials used and experiences and input from our patient and public involvement (PPI) panel. These will be sent out with the vape kits or via email.

Participants will be sent a voucher code that they can use to claim a vape kit via the supplier's website, alongside instructions on how to do so. Participants will be able to redeem this code at any time during their 9-month participation period in the study. .

Several modalities for offering behavioural support will be provided in the intervention to suit people's differing preferences and needs, and dependent on what is already on offer in the local area. Financial service providers will explain that there are several options available, with varying degrees of engagement and flexibility required, and explore the most appropriate one for each client. These will include:

1) **Referral to local authority commissioned stop smoking services**, which often involve face-to-face support. In some cases, the advisors may be able to assist the client in booking in, however, in other cases they may only be able to provide the information the client needs to pursue this themselves. Where a local authority commissioned service is not available only the two options below will be presented.
2) **A free access code for the Smoke Free smoking cessation app.**(18, 19) The app aims to help people trying to quit smoking to set goals, monitor their progress and be aware of the benefits they are achieving. It does this through a calculator that tracks the number of cigarettes not smoked and money not spent on buying cigarettes, a calendar that tracks the time since quitting, a scoreboard that awards 'badges' to users for not smoking, information on health improvements expected since the start of their quit attempt, and daily missions. As well as an AI chatbot, the app also has a chatroom for users with themed discussions, and the ability to contact smoking cessation advisors for support on an ad hoc basis.
3) **Signposting to National Health Service (NHS) resources**, i.e. the National Smokefree Helpline, the Quit Smoking Support Group on Facebook, and daily email support. With the client's permission the advisor can sign the client up for the email support during the call.

The details of the methods available will be emailed to the participants (or mailed where this is necessary).

Service providers delivering the intervention will be trained by the National Centre for Smoking Cessation and Training (NCSCT). They will deliver a half-day virtual training course on delivering the intervention when a new recruitment centre or centres are recruited into the trial. The course will be delivered via Zoom for up to 20 team members at a time, led by an NCSCT expert trainer and supported by the NCSCT Administration and Technical Support Officer. Informed by the Clarion Futures evaluation, course content will include: the health and financial impact of smoking, benefits of smoking cessation, understanding the very brief advice approach, modelling and practicing delivery of the intervention, support options available to participants in the intervention arm and frequently asked questions. A summary of the intervention and a short list of anticipated common issues will be provided to facilitate embedding the intervention into usual practice and equipping staff with the knowledge and confidence needed. NCSCT will contact trained staff by email one month after the training course to establish and address any implementation issues. This may include providing reminders and signposting to training materials and offering refreshers on parts of the training. Sites will be advised to contact the study team if more substantial refreshers are needed.

9.7.2. Description of comparator(s)

Participants randomised to the comparator group will receive no intervention for their smoking beyond being asked about their smoking (as part of the eligibility check). This is currently deemed usual care in the UK where generally no advice or assistance to quit smoking is provided as part of routine financial guidance services.

Following the 'End of Study' (defined below), when we distribute study findings, we will provide a leaflet signposting places where former participants (regardless of group allocation) can access support to quit smoking, e.g., the NHS search function for identifying local services, the NHS helpline, and the NHS Facebook group.

9.7.3. Adherence to study group allocation

To examine the fidelity of the intervention we will use the transcripts from intervention group consultation recordings, as well as transcripts of recordings from ~100 control group consultations, to investigate intervention fidelity alongside quantitative fidelity data (providers and participants will self-report whether they delivered and received the intervention as intended, respectively). Additional training on randomisation and intervention delivery will be provided should any concerns arise.

9.8. Baseline Assessments

Baseline data will be collected by the financial service providers after consent has been provided by participants and before randomisation taking place. Data will be input directly into the online database that will also be used for randomisation. The baseline data collected by providers will be minimal for reasons of pragmatism but will include the most essential data points to minimise missing data. Thus, the baseline data collected will be:

- Age
- Sex
- Gender
- Ethnicity
- Postcode (to determine index of multiple deprivation)
- Whether participants are receiving any income support benefits, universal credit or pension credits
- Self-reported cigarettes smoked per day. Where participants smoke roll-ups and provide their daily tobacco use in grams; 12.5 grams of tobacco will be deemed equivalent to 15 cigarettes, as in previous trials (20, 21)
- Motivation to stop smoking in the next 6-months, assessed through the following question: "How likely are you to try stopping smoking within the next six months?" Responses will be measured on a five-point Likert scale from "Very unlikely" to "Very likely"
- Current use of stop smoking aids, e.g., NRT, e-cigarettes, behavioural support (23)
- Self-reported weekly tobacco expenditure (measured in pounds sterling)
- Health-related quality of life measured using the EuroQol EQ-5D-5L (22)
- Healthcare resource use (numbers of primary care and hospital visits in past 12 weeks)

The research team will contact enrolled participants via an email and/or follow-up phone call as soon as possible after enrolment to collect intervention fidelity and satisfaction data, as detailed below. The intervention group will be asked to provide data for all three outcomes, whereas the control group will be asked for data on the third outcome only. Text messaging may also be used for follow-up contacts as necessary. Participants will be provided with a £10 incentive for completing this data collection. This data will be entered directly into the database, unless a participant specifically asks to complete the surveys on paper via post. A maximum of four attempts will be made in total to collect this data, over two weeks.

- Intervention fidelity – self-report of whether intervention was received as intended, by responding 'Yes' or 'No' to several questions asking about each intervention component (i.e., advice on how to quit, advice on financial benefits; information on e-cigarette provision; information on behavioural support options)
- Satisfaction with the part of the consultation focused on tobacco smoking. Participants will be asked how happy they were with the intervention and asked to assess this using a Likert scale, including the following options: very happy, somewhat happy, neutral, somewhat unhappy, very unhappy
- Satisfaction with the consultation as a whole. Participants will be asked how happy they were with the consultation and asked to assess this using a Likert scale, including the following options: very happy, somewhat happy, neutral, somewhat unhappy, very unhappy

Immediately after each session with participants randomised to the intervention group, financial service advisors will be asked whether they delivered the intervention as intended (i.e., the advice on how to quit, advice on financial benefits; information on e-cigarette provision; information on behavioural support options) by responding 'Yes' or 'No'. These questions will be prompted by the online database and responses logged directly into the database by the providers.

9.9. Subsequent Data Collection Contacts

Participants will be contacted by the research team for quantitative data collection on a further two occasions. These contacts will take place at approximately 12-weeks post-baseline and approximately 9-months post baseline. This data will be entered directly into the database. Attempts will be made to collect data via email, and these will be followed by attempts via phone. Text messaging may also be used for follow-up contacts as necessary. A maximum of four attempts will be made overall to collect the data at each time point. We will not limit the time period within which this is collected; however, we will record the date of collection so this can be taken into account during analysis; applying a sensitivity analysis to data collected more than four weeks after the follow-up point. The following data will be collected at both time points (unless otherwise stated):

- Self-report of whether anyone else in the participant's household smokes
- Motivation to stop smoking in the next 6 months (if still smoking), assessed through the following question: "How likely are you to try stopping smoking within the next six months?" Responses will be measured on a five-point Likert scale from "Very unlikely" to "Very likely".
- Use of stop smoking aids since last contact point, e.g., NRT, e-cigarettes, behavioural support, the Smoke Free app, NHS resources
- Self-reported cigarettes smoked per day. Where participants smoke roll-ups and provide their daily tobacco use in grams; 12.5 grams of tobacco will be deemed equivalent to 15 cigarettes, as in previous trials (20, 21)
- Whether at least one quit attempt has been made since baseline (at 12 weeks only)

- Self-reported prolonged smoking cessation (at 12-weeks this will be defined as abstinence from week 8 to week 12; at 9-months this will be defined as abstinence from week 12 to month 9). Participants will still be deemed abstinent if they have experienced limited lapses, i.e. if they have smoked no more than five cigarettes during the follow-up period, in-line with the Russell Standard (23)
- Self-reported 7-day (not-even-a-puff) point prevalence smoking cessation
- Self-reported weekly tobacco expenditure (measured in pounds sterling)
- Where a reduction in spend on tobacco is noted (data point above), where has this money been reallocated (participants will be able to choose from a list of options or specify other and give further details)
- Financial well-being measured using the abbreviated CFPB scale
- Health-related quality of life measured using the EuroQol EQ-5D-5L (22)
- Mental well-being measured using the Warwick-Edinburgh Mental-Wellbeing Scale (24)
- Broader resource use (e.g. GP/Nurse visits, hospital day-case, inpatient bed-days, medications, carer time)
- ARs; at 12 weeks only
- SAEs; at 12 weeks only.

Participants who provide fidelity and satisfaction data after enrolment will be reimbursed with a £10 voucher, and a £25 voucher for providing data at the 12 weeks follow-up and/or 9 months follow-up. If a participant is willing to provide self-report smoking cessation data at 12 weeks (to contribute to the primary outcome) and nine months, but not the other outcomes then we will provide them with a £5 voucher. They will receive this incentive regardless of whether they report smoking or not smoking.

After completing questionnaires at baseline, 12-weeks, and 9-months, all participants will be provided with a list of freely accessible mental health and wellbeing websites and contact information.

9.10. Sample Handling

The primary outcome is the proportion of participants who have achieved four weeks of prolonged biochemically confirmed abstinence from tobacco prior to the 12-weeks follow-up (with no more than five cigarettes smoked during this period). Abstinence will be validated using biochemical tests on saliva samples in those who self-report smoking abstinence. Abstinence will also be validated in this way at the nine-month follow-up. Participants will be mailed a saliva sample testing kit by the research team at week-12 and month nine, along with a pre-paid envelope to send the sample to the laboratory for subsequent testing. On return of their samples participants will receive a payment of £20 per sample.

Saliva samples will be pseudonymised and identified using the participant's study ID. In the first instance saliva will be tested for cotinine (a metabolite of nicotine), with a cut-point of 10 ng/ml. Where cotinine levels exceed 10 ng/ml the sample will also be tested for anabasine (a component of tobacco) with a cutpoint of 2 ng/ml. A sample testing positive for cotinine but negative for anabasine will indicate that the participant is abstinent from tobacco but using a nicotine-containing alternative product, i.e., e-cigarettes, NRT, or nicotine pouches (classed as abstinent from smoking for the purpose of our abstinence outcomes). Although anabasine can be detected in some e-cigarette e-liquids this is generally at much lower levels than those detected in cigarettes and lower than the cut point specified here.(25) It is unlikely we would see anabasine levels over 2ng/ml in the regulated e-liquids on the market in the UK. The analysed sample data will be sent by BioApp Solutions to the research team via email, with data

identified through the study ID, so that the research team can link it to the correct participants and enter the data into the study database.

9.11. Withdrawal of Participants

Participation in the study will be based upon participants' consent to take part. At the time of consent participants will be given/sent a PIS to keep. This PIS will state that participants can withdraw from the study at any point without it affecting the service they receive from the financial support service. They will be given information on what they should do if they no longer want to take part in the study. Thus, the PIS will include a telephone number and email address for participants to contact the researchers for this, or any other reasons. As the intervention is a one-off at the time of consent, withdrawal will mean withdrawal from all follow-ups, and not withdrawal from the intervention, as this will already have taken place. Participants will be informed that they do not have to give a reason for their decision to withdraw from the study. However, if the participant indicates the reason this will be recorded in the electronic case report from (eCRF) and documented in the CONSORT diagram. Data provided up to the time of withdrawal by participants who withdraw will be retained for analysis. Participants who withdraw will not be replaced. There will be no withdrawal criteria other than the participants request to withdraw.

9.12. Definition of End of Study

The end of study will be the point at which all the study data has been entered into the study database (i.e., the last participant has received their final follow-up at 9-months post-baseline, and their saliva sample result has been received) and any queries have been resolved.

10. SAFETY REPORTING

Adverse reactions (ARs) and serious adverse events (SAEs) will be assessed at the 12-week follow-up only, as follows.

10.1. Adverse Reactions

Based on the methods of two NIHR-funded studies(26, 27), we will assess potential side effects of e-cigarette use by asking participants whether they have experienced the following symptoms since randomisation: nausea, throat/mouth irritation, sleep disturbances, dizziness, headache, nervousness, sweating, weakness, pounding heart, shortness of breath, cough, wheezing and phlegm. If they respond in the affirmative, they will be asked whether this had stopped them from doing things they would usually do, as an indication of severity.

10.2. Serious Adverse Events

SAEs are defined as any untoward and unexpected medical occurrence that:

- results in death
- is life-threatening (this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe)
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- consists of a congenital anomaly or birth defect

Other 'important medical events' may also be considered an SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require an intervention to prevent one of the outcomes listed above.

Self-reported SAEs, occurring from the time of randomisation, will be collected by participant self-report at the 12-week follow-up point and followed up by members of the research team if further information is required. Self-reported SAEs advised by participants during other contact with researchers will also be documented. Once received, they will be recorded onto a study specific SAE form and causality and expectedness of SAEs only will be confirmed by an independent medical expert according to the following definitions.

Relationship to study intervention	Description
Unrelated	There is no evidence of any causal relationship
Unlikely to be related	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the study intervention or device). There is another reasonable explanation for the event
Possible relationship	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the study intervention or device). However, the influence of other factors may have contributed to the event
Probable relationship	There is evidence to suggest a causal relationship and the influence of other factors is unlikely
Definitely related	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out

SAEs that are deemed to be unexpected and related (i.e. resulted from administration of any of the research procedures) to the study will be notified to the Research Ethics Committee (REC) and sponsor within 15 days. All such events will be reported to the Trial Steering Committee (TSC)/Data Monitoring Committee (DMC) at their next meetings. Due to the low-risk nature of the intervention any related SAEs are likely to be extremely uncommon.

For each SAE the following information will be collected:

- Full details of the event and description of the case;
- Event duration (start / end dates);
- Action taken;
- Outcome.

11. STATISTICS AND ANALYSIS

11.1. Statistical Analysis Plan (SAP)

A SAP is to be produced separately, which will be reviewed and approved by the independent steering committees and finalised before the end of participant follow up.

11.2. Description of the Statistical Methods

Participant flow will be presented using a CONSORT diagram, with the number of participants withdrawing being summarised with reasons where available. Baseline data will be summarised descriptively by study arm. All outcome data at all timepoints will also be summarised descriptively by study arm. Abstinence outcomes will be analysed as intention-to-treat, using mixed effects logistic regression models, with allocation, and other important baseline variables as fixed effects and financial advisor as a random effect. Odds ratios (ORs) with 95% confidence intervals and estimated risk differences will be calculated.

Participants with missing primary outcome data will be assumed to be smokers as per the Russell Standard. The robustness of the primary analysis to deviations from the Russell Standard will be assessed via a sensitivity analysis using a pattern-mixture model and/or multiple imputation by chained equations.

All secondary effectiveness outcomes will be summarised descriptively by study arm and between group comparisons will be made using appropriate regression models adjusting for the same baseline factors as the primary analysis, as well as additional prognostic covariates where appropriate. All fitted models will be subjected to appropriate diagnostics analyses. Where these suggest violation of model assumptions, transformations (if appropriate) or non-parametric analyses will be considered.

11.3. Sample Size Determination

36% of people who smoke try to quit annually; ~3% per month(28), suggesting 6% would try to quit in the control group of the proposed study by week 8. Assuming quit attempts start approximately 4 weeks prior to the primary outcome period, then 18% of those who try to quit (18% of 6%) might be abstinent at 12 weeks (8 weeks later).(29) Thus, we expect 1% to attain the primary outcome in the control group. Offering support to quit increases the proportion attempting to quit (approximately 1.8-fold) (9) and increases the success of those attempting (up to 2-fold). Thus, we expect a 3-fold relative increase, i.e. 3% abstinence in the intervention arm. With a 5% alpha and 80% power, 1,538 participants are needed (769 in each arm). We have not inflated the sample size for dropout as all randomised participants will be included in our analyses, assuming missing equals smoking, as is standard in the field.(23)

11.3.1. Qualitative progression analysis

For the conversation analysis, ~350 intervention group financial advice sessions will be recorded. We will also record ~100 control group consultations for fidelity checking. For the interviews, we anticipate a sample of ~30 service users and ~20 financial services advisors but may stop sooner if ‘information power’ has been met.(30) Information power means that the higher quality the collected sample information is, the sooner data collection can be stopped.

11.4. Analysis Populations

The data of all participants, as randomised, will be included in quantitative analyses.

11.5. Decision Points/Stop–Go Rules

Taking the calculated sample size from above (N = 1,538), we will need to recruit an average of 62 participants/month over the 25-month recruitment period. We will conduct an internal pilot to assess the recruitment process nine months in. At this point, we will be a third of the way through recruitment but expect recruitment will be lower in the first few months as processes become embedded. Therefore, we will implement the following stop/go rules based on the NIHR standard approach of aiming to recruit at least one fifth of participants in the first third of the recruitment period. For our internal pilot trial, this will be a target of 308 participants:

- Green. Overall recruitment numbers: N ≥ 308; overall monthly recruitment numbers: ≥34 per month; monthly recruitment numbers per site: an average of ≥17 per site per month, based on two sites recruiting (during the pilot we will be investigating how many sites are required to recruit to target. Should more sites be needed, this target, and those for the amber and red criteria below, will be amended by dividing the overall monthly targets (e.g. n=34) by the number of sites recruiting).
- Amber. Overall recruitment numbers: N ≥ 195 and <300; overall monthly recruitment numbers: N ≥22 and <34 per month; monthly recruitment numbers per site: N ≥11 and <17 per site per month.
- Red. Overall recruitment numbers: N < 195; monthly recruitment numbers: < 22 per month; monthly recruitment numbers per site: < 11 per month.

We will also investigate intervention and usual care fidelity as part of the internal pilot. We will take advice of the TSC and where contamination has occurred, will conduct additional service provider training on trial processes (in particular the differentiation between the intervention and comparator groups). We will also continue monitoring fidelity throughout recruitment via weekly checks of the intervention fidelity outcome. We will implement the following stop/go rules:

- Green: 100% of assessments as intended
- Amber: ≥ 60% and < 100% of assessments as intended
- Red: < 60% of assessments as intended

Where green criteria are met, we will continue as planned. Where amber criteria are met, we will review procedures and devise new strategies with the approval of the TSC (for intervention fidelity this will include additional service provider training). Where red criteria are met, we will discuss potentially stopping the trial with the TSC and the funder (NIHR PHR). If there is inconsistency in the scoring of the progression criteria then overall the trial will be categorised according to the criterion that is furthest from achieving the progression threshold (e.g. if two criteria are green but one is amber, the trial will be categorised as amber).

11.6. The Level of Statistical Significance

Statistical significance will be set at the 5% level. Parameter estimates will be presented with corresponding 95% confidence intervals and p-values as appropriate.

11.7. Procedure for Accounting for Missing Data

For our smoking abstinence outcomes, participants with missing outcome data, including those who withdraw, will be assumed as non-abstinent and therefore all randomised participants will be included in our analyses, which is considered a standard approach in the field.(23) Applying this missing data assumption to our analyses would provide a conservative interpretation of the results, and so, sensitivity analyses involving multiple imputation methods will be conducted to evaluate the robustness of the results. The sensitivity analyses will aim to compare the results of the primary analysis, when imputing under both 'missing at random' and 'missing not at random' assumptions.

11.8. Procedures for Reporting any Deviation(s) from the Original Statistical Plan

Deviations from the original statistical analysis plan will be reported and justified at publication following the CONSORT guidelines.

12. HEALTH ECONOMICS ANALYSIS

We plan to examine the cost-effectiveness of the smoking cessation intervention at two levels. A preliminary within-trial analysis will establish the incremental cost per quitter (to compare across studies evaluating smoking cessation) and short-term (within trial) incremental cost per QALY gained from a societal perspective.

12.1. Preliminary Within-Trial Economic Evaluation

This analysis will take a societal perspective. Using a bottom-up costing method, we will estimate the costs of the SAVINGS intervention considering training of financial advisors, intervention delivery and any follow-up/management. Broader resource use and health-related quality of life outcomes (measured using the EQ-5D-5L) will be captured in questionnaires completed at baseline and at 12-weeks and 9-months post-randomisation. Unit costs for healthcare resources will largely be derived from local and national sources and estimated in-line with best practice; however, trial participants will also be asked to report their own smoking-related expenditures. The 9-month follow up data will be extrapolated for annual estimates. EQ-5D-5L responses will be used to generate quality-adjusted life-years (QALYs) using the area-under-the-curve method,(31) and the analyses will follow National Institute for Health and Care Excellence (NICE) guidance.(32) Utility weights will be estimated using recommended algorithms until a national tariff set for the EQ-5D-5L is available. Aligning with the main statistical analysis of the trial outcomes data, the first sets of within-trial analysis will be based on an intention-to-treat approach and those who were lost to follow-up will be assumed to be smokers. In addition, bivariate regression of costs and QALYs, with multiple imputation of missing data, will be conducted to generate within-trial estimates of incremental cost per QALY associated with the smoking cessation intervention.(33) These estimates of incremental cost-effectiveness will be subject to the NICE cost-effectiveness threshold (£20-30k/QALY). Sensitivity analyses will be undertaken to assess the impact of areas of uncertainty surrounding components of the economic evaluation. The sensitivity analyses will include re-estimation of cost-effectiveness based on cases with complete data, and re-estimation of cost-effectiveness assuming a public sector perspective. Cost-effectiveness acceptability curves will represent the effects of decision uncertainty surrounding the value of the cost-effectiveness threshold.

12.2. Long-term Cost-Utility Modelling

Taking a societal perspective and using a lifetime horizon, an existing Markov-based state transition model (EQUIPTMOD), previously used for the Preloading Trial, will be adapted to estimate the long-term incremental cost per QALY gained from the smoking cessation intervention compared with usual care.(34) The model has three states (current smokers, former smokers, never smokers) and four outcomes (lung cancer, chronic obstructive pulmonary disease, coronary heart disease, stroke) with death being the absorbing state. The model will calculate lifetime costs and QALYs with and without the intervention.(35) Intervention effect size data (quit rate) and intervention costs data will come from the SAVINGS trial as described above in the within-trial economic evaluation section. All other model input data (e.g. transition probabilities, relevant disease costs) will be sourced from the EQUIPTMOD itself or, where an update is deemed appropriate, through a rapid review of the literature including NICE guidance on smoking cessation and harm reduction interventions.(36) To adapt EQUIPTMOD to this specific context, we will use Nemeth et al.(34) 's essential model input list to update specific data and re-programme the model. While updating these input data, we will include the data that are specific to this sub-group (rather than the general adult population) where available. We will use a discount rate of 3.5% for base case estimates. We will report estimates of incremental cost per QALY gained, which will be subject to NICE cost-effectiveness threshold of £20-30k/QALY. This estimate will be evaluated for

uncertainty through a probabilistic sensitivity analysis, as originally implemented in the EQUIPTMOD model. Subject to data availability, an attempt will be made to also model the life-course financial gains among those who successfully quit smoking.(37)

12.3. Both Types of Economic Evaluation

Approaches for characterising uncertainty, heterogeneity, and distributional effects within the economic evaluation will adhere to the recommendations of the NICE reference case. This component of the study will be detailed within a 'Health Economic Analysis Plan' and signed off by the TSC.

13. QUALITATIVE PROCESS EVALUATION

We will conduct a parallel qualitative process evaluation to understand: (a) participants' and financial advisors' experiences of the intervention, (b) if the intervention is delivered as intended (and what may hinder or support this), and (c) identify learning for future implementation. We will contextualise participants' experiences within their social, economic, and cultural contexts, dependent on the data collected. We will follow Lincoln and Guba's established approach to maintaining quality, trustworthiness, and rigour throughout.(38)

13.1. Conversation Analysis

With the consent of the participant and financial services advisor, we will record the entirety of all financial advice sessions and then sample up to ~350 intervention consultations.(39) Where appropriate and feasible, we will use a purposive sample for conversation analysis,(40) a well-established approach to understanding communication, and its effects, to identify if: the intervention is delivered as intended; common pitfalls which may hinder delivery; and how these might be best managed or avoided. Supporting implementation beyond the trial we may also quantitatively link conversation analysis with participant responses during the intervention and, where possible and appropriate, longer-term outcomes, to understand which ways of communicating intervention delivery may be best received (and by whom).(41, 42)

We will purposively sample the transcripts from the above intervention group consultation recordings as well as transcripts of recordings from up to ~100 control group consultations to investigate intervention fidelity alongside the quantitative data collected (see secondary outcomes above), i.e. whether VBA is being delivered as intended in the intervention arm and whether smoking is being discussed in the control arm. We will aim to sample up to ~10% of consultations per provider for fidelity checking, or up to ~2 per provider where that is greater than 10%. We will analyse these by listening to the audio recordings and assessing the content against a framework outlining the key elements of the intervention. Control group consultations will not necessarily be transcribed, unless something becomes especially intriguing in the data to warrant a more detailed analysis.

We will discuss potential changes to processes, including the randomisation strategy and training, and deliver targeted top-up training if evidence of low adherence to intervention components or contamination is identified during the study (even if this is low overall but concentrated at particular sites or advisors).

13.2. Qualitative Interviews

To understand participants' and service advisors' experiences of the intervention (including experiences and contextual factors that affected behaviour) we will carry out 1-to-1 remote semi-structured interviews. We will use a purposive maximum variation sample of up to ~30 participants. Sampling will be guided by a frame of personal characteristics, including sex, age, ethnicity, study site, and Index of Multiple Deprivation decile, alongside outcome data including cigarettes smoked per day and receipt of income support (yes/no). We will primarily sample those at the lower ends of Index of Multiple Deprivation decile, as the intervention aims to benefit this group most. However, we will also include deviant cases with higher Index of Multiple Deprivation deciles to understand distinct challenges that might not be apparent in the target population.

We will also individually interview up to ~20 service providers to understand their perceptions of their role, organisational factors and, where possible, examine issues relevant to integrating the intervention

into routine service provision. For this, we will use a sampling frame to collate a diverse sample based on sex, site, number of participants recruited from that site at the time of the interview, and their site's Index of Multiple Deprivation decile. AT will conduct most interviews, with another researcher with experience of qualitative interviews filling in for absences. Another researcher may also observe the interviews for training purposes, but they will not be involved in conducting the interview itself.

Service advisor interviews will be conducted over Microsoft Teams using audio only. Participant interviews will be over telephone using the built-in telephone function on Microsoft Teams.

. The Microsoft Teams transcription function will be used to generate an initial transcription for both service advisor and participant interviews. However, a researcher will listen to the interviews and refine the transcriptions as needed to ensure accuracy.

Participants will be interviewed approximately four-to-six weeks after randomisation and advisors will be interviewed after they have completed at least one advisory session. Reflecting our learning from previous qualitative process evaluations, this time period was selected to reduce recall bias, balancing participants' ability to remember the details of their consultations with the opportunity to notice behaviour and financial changes. AT will be notified once a participant has been randomised to the intervention so that she can organise with the participant over email, post or telephone a date for interview and send over the interview PIS.

Open-ended questions will be asked, aiming to elicit detailed reports, but also using prompts and follow-up questions, to encourage elaboration. Topic guides have been developed by AT with support from CA, NL, and ADW and based on their expertise and knowledge of the literature. Overviews of the topics that will be covered will be sent to participants in advance of the interview. Following-best practice we will iterate the topic guides after every couple of interviews as we learn from participants and based on piloting with PPI and their recommendations.(43) We will also take reflexive field notes during and after the interviews to supplement interview data and engage in regular team discussion about the findings.

We will analyse interviews using reflexive thematic analysis; an established method for identifying, analysing and reporting patterns in data,(44) interviewing until reaching appropriate ‘information power’ or justifying why it has not been reached.(30) We will discuss data with our PPI group, exploring their perspectives on potential areas of analytic focus. We will also present our analytic interpretations to our PPI group, to understand if they resonate with their lived experiences. We will aim to draw on social, behavioural, and/or implementation theories to interpret our data.

13.3. Mixed Methods Matrix

We will aim to develop a mixed-methods matrix to integrate any relevant qualitative and quantitative (such as, uptake of smoking cessation support) analyses and results from across the process evaluation. This will be informed by the study team and our PPI and advisory panels.(58) Where possible we will integrate analyses from the advice sessions, interviews and relevant quantitative data, to triangulate what works for who, and why; identifying learning for subsequent implementation. Drawing together learning from different sources, as previously (45), may develop a more complete picture of the different processes.

14. DATA MANAGEMENT

The University of York and the University of Oxford will be joint data controllers for this study. Quantitative study data will primarily be collected by YTU, University of York. Qualitative process evaluation data will be collected by the University of Oxford. Data will be shared between both universities, and a data sharing agreement will be in place.

14.1. Source Data

Source documents are identified as those where data are first recorded, and from which participants' eCRF data are obtained. Quantitative data in this study will primarily be entered directly into the REDCap data collection system by participants, financial advisors at study sites and YTU research staff. The REDCap eCRFs will therefore be the source documents. Where participants explicitly ask to complete a survey on paper and return by post these will be entered into REDCap by YTU study staff. We only expect the latter to take place on rare occasions.

14.2. Access to Data

14.2.1. University of York

Quantitative data will be held securely for the duration of the project on the cloud-hosted REDCap server at YTU at the University of York. Access to REDCap will be restricted to named, authorised individuals granted user rights by YTU YorQuit trial management team. Paper documents held at YTU will be retained in a secure (kept locked when not in use) location for the duration of the study. All work will be conducted following the University of York's data protection policy which is publicly available (https://www.york.ac.uk/records-management/dp/).

Data shared with the University of Oxford will be both identifiable and pseudonymised. Identifiable data will be shared for the purposes of the process evaluation; the process evaluation researcher will therefore be given direct access to the REDCap system to obtain the contact details of study participants who have agreed to be contacted to take part in an interview. Pseudonymised data will be shared with the health economics team at University of Oxford.

The final trial dataset held in Stata format (as a .dta file) will be accessible subject to a completed YTU Data Request form, and Chief Investigator confirmation.

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

14.2.2. University of Oxford

All qualitative data will be password-protected where possible, with access restricted to the Oxford research team. Data will be accessed and used on University premises and remotely in accordance with the University's remote working guidance and Department policy.

The PIS states that participants' financial advice audio recordings may be transferred to a transcribing company to facilitate the planned conversation analysis. The specialist transcribing company holds an agreement with the University of Oxford. Transfers will be through a secure communications procedure in-line with the University of Oxford's Information Security Handling Rules.

Reports containing anonymised data for the purpose of dissemination may also be uploaded to the secure Oxford University-managed OneDrive. This OneDrive has visibility and access restricted to members of the study team and requires two-factor authentication.

The University of Oxford will share non-identifiable, aggregated summary data with Brunel University of London.

14.3. Data Recording and Record Keeping

Data collected as part of this research includes questionnaires and qualitative data from interviews/ observations. All study files will be stored in accordance with Good Clinical Practice (GCP) guidelines.

14.3.1. Questionnaire data

Participant data will be kept confidential and managed in accordance with the Data Protection Act and University of York's data protection policy. Questionnaire data will be collected via electronic data collection forms. These can be completed online by the participant themselves or over the phone at the participant's preference. On rare occasions they may be completed on paper and returned by post. Every attempt will be made to ensure the data are accurate, complete and reliable:

- The staff involved in any data collection will be trained in the collection of it, including assisting participants with their questionnaires where required.
- Care will be taken to ensure participants are given clear instructions when completing the questionnaires and these will be checked for missing data by staff at YTU.
- Two email reminders will be sent to non-responding participants, with a minimum of one attempt to obtain data by a telephone interview. A maximum of four attempts will be made in total, across mediums, to collect each data point.

14.3.2. Qualitative data

The financial advice consultation recordings and interviews will be audio-recorded (with all parties' consent). Each recording will be pseudonymised by participants assigned study ID, rather than participant name. Recordings will be saved in a password-protected file in a folder, with restricted access, on the University of Oxford's secure network (from here referred to as SAVINGS file).

The financial advice consultation recordings will be collected directly by the financial service advisors. There are two options for recording: (a) The consultation is on an online meeting software and the advisor has approval to use the embedded recording feature; (b) The consultation is in person, over the phone, or an online meeting software and the advisor does not have approval to use the embedded recording feature. Most will go through option B, which in this case, they will use a voice recorder (Dictaphone) and in-ear piece to audio-record the consultation. Only the advisors will have access to the voice recorder, and it will be stored securely at their site. They will receive training on how to use it and will be able to contact the study's qualitative team if there are questions.

Each site will have their own SAVINGS file on the University of Oxford OneDrive only accessible to themselves and the research team. The advisors will upload audio-recordings of the consultations to this file as soon as is practical. They will notify the research team at Oxford (over email or Teams) that they have sent the consultation recording and then delete the audio from the Dictaphone. This process will happen as soon as is practical. Advisors will have training on this protocol and have top-up training where needed.

Consultation recordings of those in the intervention group require specialist Jefferson transcription for the planned conversation analysis. Therefore, they will be sent to and transcribed by an approved University and specialist transcriber with whom appropriate information security and confidentiality agreements are in place. File transfer (of initial audio, then transcriptions) will take place using encrypted files over a OneDrive file only accessible to the company and the research team with encryption password sent separately via different means. The transcriptions will undergo pseudonymisation, meaning such as names and contact details will not be included in the transcript, by the transcription company. Once returned, they will be checked for accuracy by the research team and then the transcript and audio will be uploaded to the SAVINGS file, with the OneDrive copy deleted.

Conversation analysis requires analysis of intonations, speed, emphasis, and pauses to understand the way conversations are delivered. Therefore, it is necessary to retain intervention recordings for ongoing analysis throughout the course of this study. The audio recordings will not be anonymised; this is not possible due to the large number of recordings. Adjusted voice clips of the recordings may be used to share results about the study (which will be publicly available). Participants, however, will not be identifiable from these clips.

The usual care and intervention consultation recordings and transcriptions will be deleted 5 years after the final publication from this trial (approximately 2035), except where participants and advisors have provided consent for recording and transcript retention for use on other ethically approved studies.

The audio recordings of the interviews will be transcribed using intelligent verbatim at the same time as the interview using Microsoft Team's embedded transcription feature, which has been approved for use at Oxford. Transcripts of the interviews will have identifying information (such as names and places) removed. Transcripts will be uploaded to the SAVINGS file, checked for accuracy, and pseudonymised, using the participant's assigned study ID, by an approved member of the research team. Once checked, the audio file will be permanently deleted. This process will happen as soon as is practical. Interview transcripts will be deleted 5 years after the final publication from this trial (approximately 2035), except where participants and advisors have provided consent for recording and transcript retention for use on other ethically approved studies.

During analysis, transcribed data will be managed and handled using NVivo (Lumivero) software (v11 onward), and audio data from the consultations will be managed and handled using Adobe.

The participants will be identified by a unique trial specific number and/or code in any database. The name and any other identifying detail will NOT be included in any trial data electronic file.

15. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures (SOPs).

15.1. Risk Assessment

A risk assessment and monitoring plan will be prepared before the study opens and will be reviewed as necessary over the course of the study to reflect significant changes to the protocol or outcomes of monitoring activities.

15.2. Study Monitoring

Regular monitoring will be performed according to the study specific Monitoring Plan. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents as these are defined in the study specific Monitoring Plan. Missing data will be chased until received or confirmed as non-available. Reminders will be sent to participants if questionnaires are not completed. Following written SOPs, the monitors will verify that the study is conducted, and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

15.3. Study Committees

We have formed four oversight committees to approve the protocol and oversee conduct:

15.3.1. Independent Trial Steering Committee (TSC)

The TSC will be led by an independent Chair, who has experience of appropriate behaviour change trials in the UK. Additional members are as follows: a health economist, statistician, qualitative expert, a financial support organisation representative and two PPI representatives. The overall responsibilities of the TSC are to approve the study protocol and any amendments and to monitor and supervise the overall running of the trial ensuring adherence to the protocol and overall objectives. The TSC will endeavour to ensure that the Trial is always conducted to the standards set out in the Medical Research Council (MRC) guidelines for Good Clinical Practice (GCP).

15.3.2. Independent Data Monitoring and Ethics Committee (DMEC)

The DMEC will monitor the trial data and make recommendations to the TSC on whether there are any ethical or safety reasons why the study should not continue. This is particularly important due to the vulnerable population being recruited. The committee will be formed of three experts in the field, including a statistician and health economist.

15.3.3. Trial Management Group (TMG)

The TMG will be formed of co-investigators, key study staff, YTU and PPI representatives and will hold regular meetings throughout the period of the research. Recruitment, research processes, and milestones will be monitored by YTU and reported at these meetings.

15.3.4. Representative Patient Public Involvement Panel (PPI)

The PPI panel will consist of individuals with lived experience of financial difficulty and smoking (current or past). The panel will provide input throughout the trial by guiding adaptation suggestions, overseeing the assessment of adaptation sufficiency, and co-designing the definitive trial and dissemination plans. The panel will meet bi-annually to review trial progress and provide feedback, which will be reported to the TSC and TMG.

Two members of the panel will act as PPI co-leads and sit on both the TSC and TMG to ensure consistent representation and integration of panel perspectives. They will be supported by the researcher PPI lead (ADW), who has completed training in PPI involvement and will undertake further specialist training in effective community engagement.

Recruitment will follow the Centre for Ethnic Health Research guidance. A sampling frame will ensure that the panel reflects the diversity of the target population in terms of ethnicity, gender, and socioeconomic background. Recruitment will draw on social media, community organisations, social housing resident groups, and voluntary sector partners. To address attrition, all eligible applicants will be invited to join so that workload is shared. Barriers to participation such as digital exclusion will be considered, with support provided where needed.

Structured training and support will be offered to PPI co-leads, including 50 hours of contact/training time, access to specialist training courses, and reimbursement of travel and caring costs. Training will combine formal workshops and informal peer support, tailored to individual needs and supported by voluntary sector opportunities where appropriate.

We have allocated specific budget for PPI training, support and expenses, and 0.2 FTE of the researcher PPI lead's time to coordinate activities. Feedback from the panel will be integrated systematically into TSC and TMG agendas, delivered in written or verbal formats as preferred by the panel.

By embedding PPI at multiple levels of trial governance and ensuring inclusive recruitment and support, the study will align with research inclusion and produce evidence relevant and applicable to diverse UK populations.

16. PROTOCOL DEVIATIONS

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from GCP or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file. A SOP is in place describing the procedure for identifying non-compliances, escalation to the central team and assessment of whether a non-compliance/deviation may be a potential Serious Breach.

17. SERIOUS BREACHES

A "serious breach" is a breach of the protocol or of the conditions or principles of GCP which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

If a serious breach is suspected the Sponsor will be contacted within 1 working day. In collaboration with the Principal Investigator, the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee within seven calendar days.

18. ETHICAL AND REGULATORY CONSIDERATIONS

18.1. Declaration of Helsinki

The Principal Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

18.2. Guidelines for Good Clinical Practice

The Principal Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

18.3. Approvals

Following Sponsor approval, the protocol, informed consent forms and PIS will be submitted to the University of Oxford Medical Sciences Division REC. The Principal Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

18.4. Other Ethical Considerations

The study has been ethically approved by the University of Oxford's ethics committee [MS IDREC 2338392]. As the study will not take place in a clinical setting NHS ethics is not required.

18.4.1. Qualitative Interviews

We expect the interviews to be low risk. However, we have developed a risk assessment and prevention plan, submitted with our ethics application. This ensures that the researchers have a clear plan to follow should a participant shows signs of distress and to safeguard the researcher. In addition, our qualitative team have completed Oxfordshire Safeguarding Adults Board Level 1 and 2.

Our process evaluation lead (CA) and qualitative researcher (AT) have experience of carrying out interviews in vulnerable populations.

18.5. Reporting

The Principal Investigator shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, Sponsor and NIHR (where required). In addition, an End of Study notification and final report will be submitted to the same parties.

18.6. Transparency in Research

Prior to the recruitment of the first participant, the trial will have been registered on the International Standard Randomised Controlled Trial Number (ISRCTN) Registry; the UK's primary clinical study registry. The study information will be kept up to date during the trial, and the Principal Investigator, or their delegate, will upload results to the public registry (where this is possible) within 12 months of the end of the trial declaration.

18.7. Participant Confidentiality

All study data will be stored in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 for the duration of the study. The processing of the personal data of participants will be minimised by making use of a unique participant study number on all study documents, apart from the secure and encrypted eCRFs, where participant identifiable information (e.g. names, contact details, consent form) will be stored. Electronic data will be securely stored on password protected systems at University of Oxford and the University of York, and the cloud-hosted REDCap system at the University of York. Only relevant members of the study team will have access to REDCap. All paper documents will be stored securely and only accessible by study staff and authorised personnel. All study staff will safeguard the privacy of participants' personal data.

18.7.1. University of York

Access to the study interface containing participant identifiable information and research data will be restricted to named authorised individuals granted user rights by a REDCap administrator at YTU. All work will be conducted following the University of York's data protection policy.

18.7.2. University of Oxford

Qualitative data (consultation recordings, interview recordings, field notes, transcripts, NVivo and Adobe files) will be stored securely on the Nuffield Department of Primary Health Care Sciences network drives at the University of Oxford. This data will be kept in a specific folder within the 'SAVINGS trial' folder. Visibility and access to this folder is limited to the Oxford research team only, and files will be password-protected wherever possible. Data will be accessed and used on university premises and remotely in accordance with the University's remote working guidance and Department policy. Reports containing anonymised data for the purpose of dissemination may also be uploaded to the secure study team's Oxford University-managed OneDrive. This OneDrive has visibility and access restricted to members of the study team and requires two-factor authentication.

For transcribing the intervention consultation recordings for conversation analysis, audio files will be temporarily stored in a separate, secure OneDrive folder. This folder will only be visible and accessible to the Oxford qualitative team and a transcription company who has a formal third-party agreement with the University of Oxford. Once the transcription is finished, the audio and transcription file will be moved to the 'SAVINGS trial' folder on the network drives, and then permanently deleted from the OneDrive location. Adjusted voice clips of the recordings may be used to share results about the study (which will be publicly available). Participants, however, will not be identifiable from these clips.

Psydonymised participant self-reported data (using participant ID) exported from REDCap will be securely transferred to the University of Oxford for inclusion in the study's health economic evaluation.

18.8. Expenses and Benefits

We will provide the following expenses and benefits, which will be made clear on the relevant PIS:

- Participants who complete the post-consultation questionnaire immediately after baseline will be reimbursed with **£10** shopping vouchers
- Participants who complete 12-week and 9-month follow-up measures will be reimbursed with **£25** shopping vouchers (per timepoint). Where a person does not want to (or cannot) provide all required data at the 12-week or 9-month point but is happy to provide self-reported smoking cessation data they will be reimbursed **with £5** shopping vouchers at each relevant timepoint (rather than £25).
- Participants who return saliva samples at the 12-week and/or 9-month follow-up points will be reimbursed with **£20** shopping vouchers (per timepoint)
- Service users and financial service advisors (where this is permitted by employers) who take part in the interviews will be reimbursed with **£20** shopping vouchers.

PPI members will be reimbursed at a rate of £25 per hour + £5 internet costs (for online meetings), either through bank transfer or shopping voucher depending on their preference. They will also be offered travel expenses and costs for carers at £150 per PPI panel member for attendance at in-person workshops.

19. FINANCE AND INSURANCE

19.1. Funding

This study is funded by the NIHR under the Public Health Research Programme (Grant Reference Number: NIHR158844).

19.2. Insurance

The University of Oxford has a specialist insurance policy in place which would operate in the event of any participant suffering harm because of their involvement (Newline Underwriting Management Ltd, at Lloyd's of London).

19.3. Contractual Arrangements

Appropriate contractual arrangements will be put in place with all third parties.

20. PUBLICATION POLICY

Dissemination of the study may include:

Participants: We will send study results to each participant and other stakeholders. Previously we have produced videos, podcasts, and infographics and will do this here, as appropriate. The PI hosts the podcast 'Let's Talk E-cigarettes' where investigators of relevant studies are interviewed about their work. Members of the public are one of the key audiences for this podcast and it has over 9,000 listeners in more than 53 countries. The proposed work would be a relevant study that could be featured.

Implementation: With NCSCT, we will produce an intervention manual for our new brief intervention for financial advice settings, using insights from our process evaluation, and disseminating to >95,000 health and social care professionals.

We will work with ASH to disseminate our findings to contacts across health and social care through direct communications, webinars, and briefing documents developed through collaboration. We will work with our financial advice partners to find the best ways to reach others in the sector. ASH provide the secretariat for the All-Party Parliamentary Group on Smoking and Health and so where relevant can provide advice on engaging with parliamentarians regarding our findings.

Scientific community: We will present at academic conferences and publish our findings in peer-reviewed journals.

Members of the public: we will use insights from previous PPI work on tobacco control dissemination, our PPI contributors, and our process evaluation to inform communication to the public. Our PPI contributors will aid us in co-creation of dissemination materials and strategy.

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the NIHR Public Health Research Programme (Grant Reference Number NIHR158844). They will also acknowledge that the views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged (with consent). All conflicts will be declared.

21. THE GENERATION OF INTELLECTUAL PROPERTY

We do not expect to generate any new IP as a result of this study. However, ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the study.

22. ARCHIVING

22.1. University of York

Data will be archived in accordance with YTU's SOPs. All paper records will be stored in secure storage facilities. Personal identifiable paper records will be stored separately from pseudonymised paper records.

All electronic data will be stored on a password protected server within YTU and de-identified as soon as it is practical to do so. The online data collection system (REDCap) will be locked and the project taken offline at the end of the study, after a suitable period the data will then be exported and transferred to the YTU archiving file store. REDCap data and files will be archived in a format that can be reconstructed as needed according to YTU archiving policy.

Data will be archived by the University of York for a minimum period of 5 years following the end of the study and then securely deleted. Anonymised quantitative data may be stored in a publicly available research repository and may also be shared (where participant consent given) with other researchers to support future learning.

22.2. University of Oxford

Audio recordings of qualitative interviews will be deleted once their transcripts have been checked for accuracy. Consultation recordings associated pseudonymised transcripts and pseudonymised interview transcripts will be kept securely at the University of Oxford for a minimum period of 5 years following the end of the study, and then securely deleted. Where a participant provides informed consent, these recordings and pseudonymised transcripts will be kept indefinitely for the purpose of training and future research. These will be stored securely on the Nuffield Department of Primary Health Care Sciences' 'Z Drive' at the University of Oxford, within the 'SAVINGS trial' folder. Visibility and access to this folder will be limited to the Oxford team only, and files will be password-protected wherever possible. Qualitative data from this study will not be deposited in a repository. If there is a request for data sharing, this will occur over a University of Oxford information governance approved system with bona fide commercial organisations or researchers.

The quantitative health economic datasets stored at the University of Oxford will consist of cleaned raw data in a format accessible from the remote server. The use of these datasets will be approved and will be securely stored (Z drive) at the main server of the University of Oxford. Data will be stored on a secure project folder ('SAVINGS trial' folder), following the University of Oxford Data Protection policy. The Nuffield Department of Primary Care Health Sciences (NDPCHS) meets the standards of the Data Security and Protection Toolkit administered by NHS Digital. Access is provided by an encrypted remote desktop application. No individual-level data will leave the Oxford servers.

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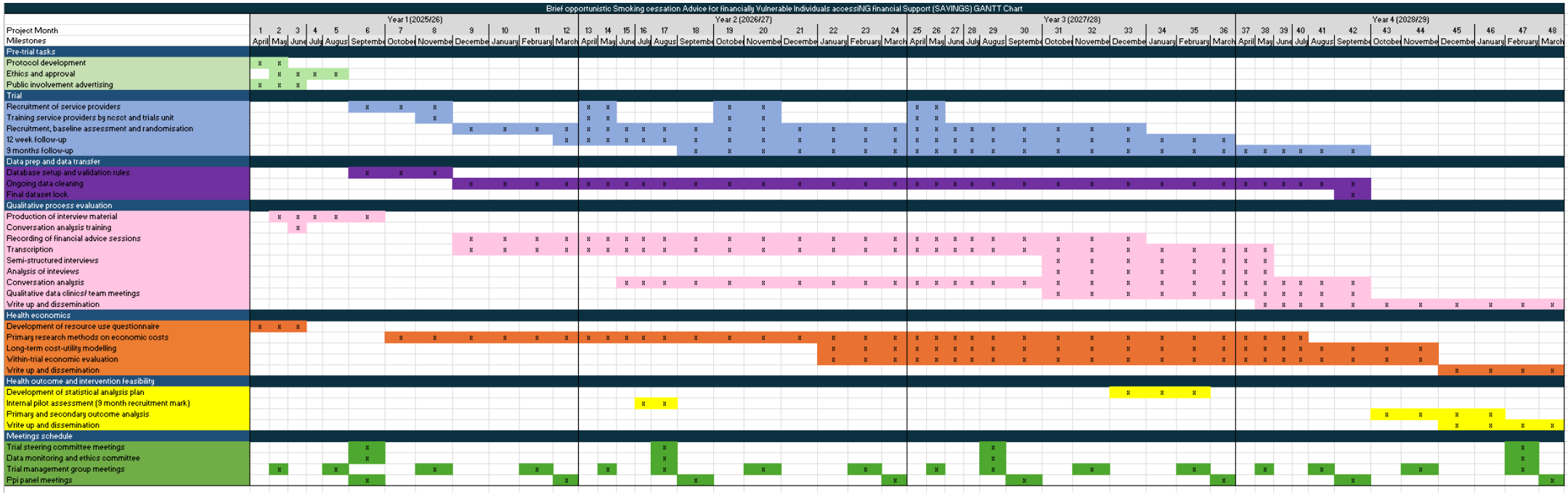
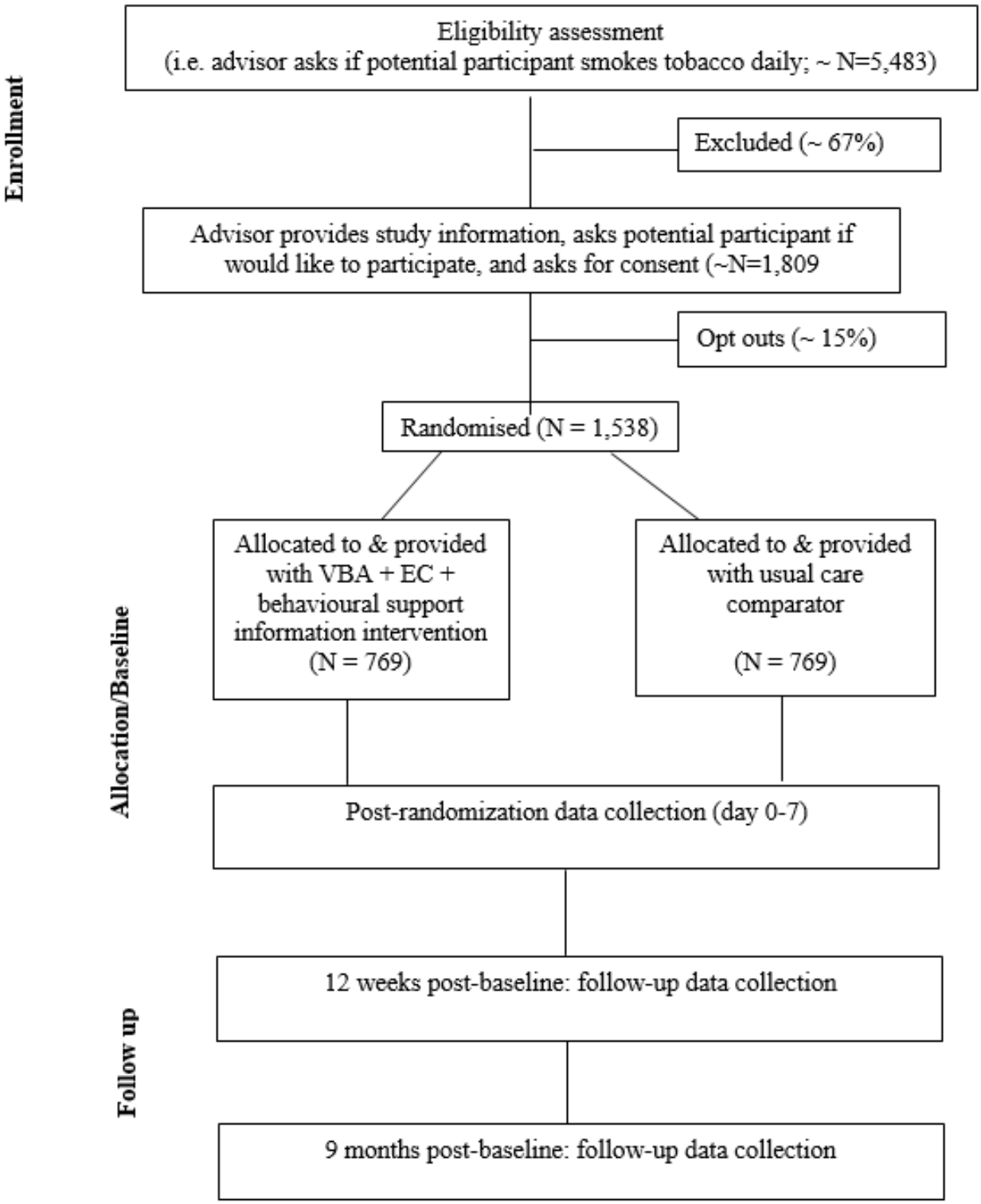
24. APPENDIX A: STUDY GANTT CHART



25. APPENDIX B: STUDY FLOW CHART



26. APPENDIX C: EQUALITY IMPACT ASSESSMENT FORM (EqIA)

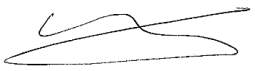
ACTION PLAN

What actions do you intend to take (or have you taken) to address the findings arising from the EqIA?

Action	By when?	Responsibility of?	Monitored through (by and when)?	Impact?
1. Recruit a diverse PPI panel for guidance.	Prior to start of project	• ADW • AT	Regular PPI panel meetings and reporting to Trial Management Group (TMG)	Provide guidance on how to include, recruit, and retain from underrepresented groups throughout the study.
2. Ensure participant facing materials are available in a range of languages.	Month 1 (these languages will be selected in collaboration with the social housing organisations, we will only include languages that they provide services in)	• ADW • AT	Reporting to TMG.	Study participation is more accessible and inclusive.
3. Monitor recruitment.	Throughout	• ADW • AT • CA	Reporting to PPI panel, advisory panel, and to TMG.	Ongoing monitoring will highlight potential areas for action.
4. (a) Ensure people are aware that we will reimburse carers/support workers for their time to support participation in the study. (b)Ensure that, for people participating in qualitative interviews which require additional commitment over and above usual consultation time, we will make sure people are aware we will additionally provide childcare vouchers and replacement carer costs (for people who are carers).	Throughout	• ADW • AT	Reporting to TMG.	Study participation is more accessible and inclusive.

5. Understand that alternative study communication methods might be preferred by participants, and offer alternatives (e.g. when inviting participants for interviews we will offer to post additional materials, discuss on the telephone, or send by email).	Throughout	• ADW • AT	Reporting to TMG.	Study participation is more accessible. Supports follow-up and retention.
6. Consider some participants will take more or less time to complete study activities, and support them to do this.	Throughout	• ADW • AT	Research team meetings, and reporting to TMG.	Study participation is more accessible; builds trust; and supports further participation.
7. Highlight 'next steps' areas, for further research and for implementation.	End of project	• ADW • NL	End of project report to NIHR.	Ensure NIHR are aware of potential avenues for further research and implementation.
8. Ensure meetings, and participatory workshops are accessible, including offering hybrid options, and mutually convenient locations (considering digital exclusion, and preferences of our population).	Throughout	• ADW	Reporting to TMG.	Team members/ workshop attendees can fairly access these events and are not excluded unnecessarily.
9. Consider accessibility in design of documents and materials.	Throughout	• ADW	Report to TMG, end of project report to NIHR, final outputs.	Documents and materials are accessible.
10. Remain alert to additional ways to enhance equality, diversity, and inclusion, across the project implementing these where possible and sharing learning.	Throughout	• All (ADW will lead in adding this as a standing action in meetings.)	TMG , Advisory and PPI Panel discussions.	Ongoing learning and improvement.

Assessor's Name: Dr Charlotte Albury

Assessor's Signature: 

Date 27/03/24

27. APPENDIX D: SCHEDULE OF STUDY PROCEDURES

Procedures	TimeLine				
	Day 0	Day 0-7	Week 4-6	Week 12	Month 9
Eligibility assessment	X				
Informed consent	X				
Demographic data collection	X				
Income support/benefits data collection	X				
Cigarettes per day data collection	X			X	X
Motivation to stop smoking data collection	X			X	X
Current use of stop smoking aids data collection	X			X	X
Weekly tobacco expenditure data collection	X			X	X
EuroQol EQ-5D-5L scale	X			X	X
Randomisation	X				
Delivery of intervention*	X				
Recording of consultations	X				
Financial advisor reported intervention fidelity	X				
Participant reported intervention fidelity		X			
Participant satisfaction with intervention		X			
Qualitative interviews*			X		
Consumer Financial Protection Bureau Scale				X	X
Warwick-Edinburgh Mental-Wellbeing Scale				X	X
Broader resource use data collection	X			X	X
Data on whether other household members smoke				X	X
Quit attempts				X	
Prolonged smoking cessation				X	X
7-Day point prevalence smoking cessation				X	X
Reallocation of funds				X	X
Non-serious adverse reaction reporting				X	
Serious adverse event reporting				X	
Qualitative fidelity checking	Throughout the trial				
Advisor qualitative interviews	Throughout the trial				
Saliva sample analysis	End of trial				
*Intervention group only					

28. APPENDIX E: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made