Examples of study advertisements

Smokers required for ground breaking study - ONLY X MONTHS LEFT TO SIGN UP!

Stop Smoking Study - Barts & The London School Of Medicine

If you are a smoker interested in quitting click for more information (London based)

Study on e-cigarettes

If you are a smoker interested in quitting, call Barts and The London School of Medicine on

020 7882 XXXX

Or email

health-research@qmul.ac.uk

Barts and The London
School of Medicine and Dentistry

TEC advertisements v3.0, 01 July 2015

Front **Back**

Barts and The London
School of Medicine and Dentistry

Smokers required for ground breaking study

If you are a smoker interested in quitting call **0207 882 5747**

or email

health-research@qmul.ac.uk

Interested in quitting smoking?

We are investigating whether electronic cigarettes are as effective in helping smokers to quit as nicotine replacement treatment (e.g. nicotine patches, gum, mouthspray etc.).

This is a ground breaking study, the first of its kind, and your participation could provide vital information about how we help people to quit smoking in the future. The study is run by the Health and Lifestyle Research Unit at Queen Mary University of London, a world leader in this field.

If you choose to take part you will receive:

• 6 weeks of specialist stop-smoking support from health psychologists

• an e-cigarette starter pack OR your choice of nicotine replacement treatment on prescription (decided at random by a computer)

Study sessions will take place once a week but appointments can be flexible to suit you. Our clinic is based 2 minutes' walk from Stepney Green underground station and we also have free parking for participants.

If you are interested in taking part please call: 0207 882 5747 (lines are open Monday-Friday, 9-5pm)
Or email us: health-research@qmul.ac.uk

TEC advertisement version 5.0, 12 April 2016

STUDY ON E-CIGARETTES

If you are a smoker interested in quitting, call the East Sussex Stop Smoking Service on

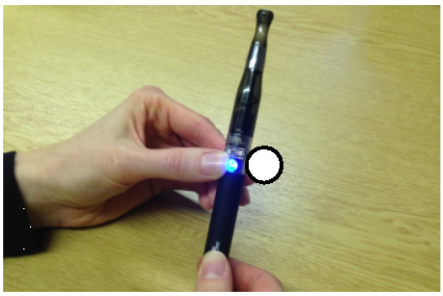
0800 622 6968

How to use your electronic cigarette (EC)

1: Battery
2: Tank
3: Charger
4: Button on battery
5: Connector
6: E-liquid bottle
7: Atomiser head

Charging the EC

Unscrew the battery (1) from the tank (2) and screw it into the charger (3). The charger connects to a USB computer port, or an adaptor which can be charged from a wall plug.

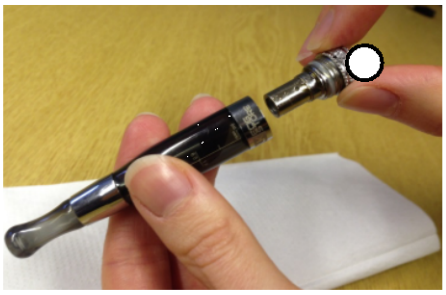


The EC needs about 30 minutes to charge. A red light on the charger will turn green when the battery is fully charged.

When your EC is charged, the button on the battery (4) glows when pressed.

Your EC will need to be charged about once a day.

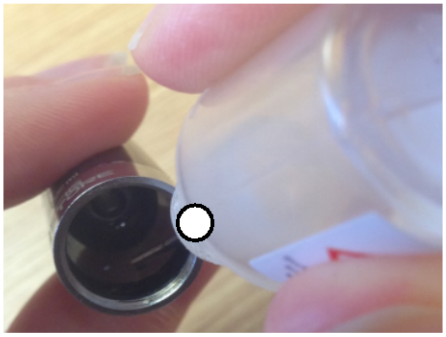
When using your EC for the first time or sometimes after charging, the button (4) needs to be pressed five times quickly to unlock it. The button will glow once it's unlocked.



Filling the EC

E-liquid bottles (6) have child-proof caps which need to be pushed down before unscrewing them.

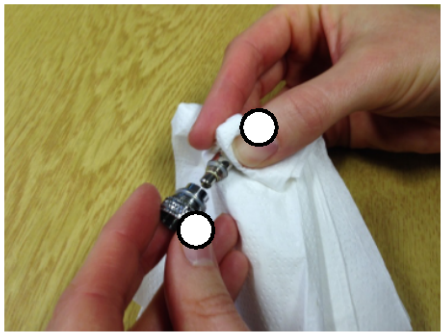
Unscrew the tank (2) from the battery (1) and hold it so that the mouthpiece is pointing down. Next, a connector (5) which connects the tank to the battery needs to be unscrewed and removed. Put the connector on a piece of tissue paper.



Insert the bottle nozzle (6) into the tank aiming it at the side of the tank , avoid getting any liquid into the central tube. Squeeze the bottle to fill the tank to just over half way full; do not fill above the top of the central tube.

Screw the connector back on to the tank and then back onto the battery and you can start vaping. Do not overtighten the connections.

Your EC will need refilling about once or twice a day.

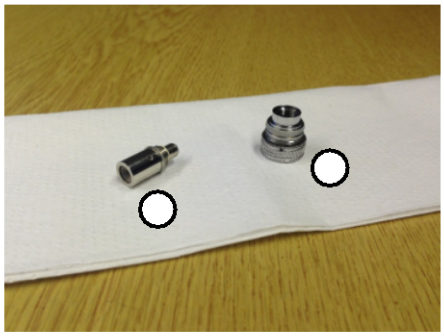


Replacing the atomiser head

The tank contains the atomiser head (7) which is attached to the connector (5). The head needs to be replaced about once every 1-2 weeks. If the vapour starts to taste different it may be a sign that the atomiser head needs changing.

Remove the connector (5) from the tank and using a tissue, unscrew the atomiser (7).

Empty any remaining e-liquid from the tank into a tissue or down the sink, wash the tank with hot water and rinse and dry it. Attach a new atomiser head (sometimes also called replacement coil).



General tips

If you get e-liquid on your skin, wipe it off and wash the area.

Condensation can sometimes gather where the connector (5) and battery connect. To keep your EC in good working order, this can be cleaned using a cotton bud. If any dirt gets stuck here tooth picks can be handy for removal.

As you hold down the button to vape, you may hear a little crackling: this is a normal sound of the EC vaporising the e-liquid.

If you encounter any problems, call us on 0207 882 8230.

A randomised controlled trial to examine the efficacy of e-cigarettes compared with nicotine replacement therapy, when used within the UK stop smoking service

Informed Consent Form

Principal Investigator:

Participant Name:
Participant Number:
Site Number: London

	Please initial each line
I confirm that I have read (or someone else has read to me) and I understand the Participant Information Sheet (version 4.0, 29 May 2015)	
I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.	
I understand that my participation is voluntary (my choice) and that I may withdraw from the study at any time without giving reason, and that my medical care or legal rights will not be affected because of this.	
Unless I explicitly state otherwise, I agree to be contacted for follow up data after my withdrawal and I agree for the data collected up to the point of my withdrawal to be used for the study.	
I understand that all information collected will be in accordance to the Data Protection Act of 1998.	
I understand that all study related data will be anonymised (will not identify me in any way) and I agree to my personal identifiable information to be stored (separately to my anonymised study data) for the purposes of contacting me throughout the study. I understand that all information collected will be stored in the Barts Health Trust archive facility for 20 years.	
I agree to my GP being informed about my participation in this study.	
I agree to take part in the above study.	
I understand that the research data collected during the study may be looked at by other individuals from the research team, sponsor, or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	

Participant Name (please print)	Signature of Participant	Date
Name of person explaining consent	Signature of person explaining consent	Date

Please complete two forms (one for the participant and one for the study file)

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

Trial of Electronic Cigarettes (TEC)

Barts and The London School of Medicine and Dentistry, Queen Mary, University of London

We would like to invite you to take part in a research study. The information which follows tells you about it. It is important that you understand what is in this leaflet. Please ask any questions you want to about the research and we will try our best to answer them.

The Study

Current treatments for smokers do not typically address the behaviours and sensations associated with the act of smoking (e.g. handling a cigarette, inhaling, taste and feel of smoke on the throat).
Electronic cigarettes (EC) are battery-operated devices that attempt to mimic the act of smoking and thus provide these effects. We already know that EC can alleviate urges to smoke, but do not know if they are as effective in helping smokers quit as the existing stop-smoking medicines (e.g. nicotine replacement treatment, NRT).
Half of the people in the study will receive an EC to use, whilst the other half will receive NRT via the stop smoking services' usual practice. A computer will decide at random which group you will be allocated to.
Regardless of which group you are in you will receive treatment from specialist stop smoking advisors and psychologists. Smokers who use this treatment are some four-five times more likely to quit compared with no support.
Study sessions begin one week prior to your agreed quit date and continue for four weeks thereafter.

What will happen if you take part?

You will be asked to attend one of our clinics in London, Leicestershire or East Sussex weekly for 6 weeks. On the next page are details of the treatment.

Baseline session	We will describe the study and go through this information sheet. You will then have the opportunity to ask any questions. We will ask you to sign a consent form to show that you have agreed to take part. Information about your smoking, mood, health and lifestyle will be collected. We will also measure the amount of carbon monoxide (CO) in your breath (this shows how much smoke you inhale). We will discuss how best to stop smoking.
Target Quit Date (TQD)	You will receive either an EC starter kit with a 2 week supply of refills, or NRT via the stop smoking services' usual practice and we will explain how to use the product you have been given. We will collect some information about your mood and smoking over the previous week and measure the amount of CO in your breath. You will be asked to stop smoking after this session.
1, 2, 3 and 4 weeks after TQD	We will discuss your progress, record your EC/NRT use and provide advice and guidance. We will also record whether you smoked or not, whether you found the EC/NRT helpful, ask some questions about your health and measure the amount of CO in your breath. If you were allocated to receive NRT you will be given more as needed, via the stop smoking services' usual practice. If you were allocated to the EC you will

	purchase any additional refills yourself. At 1 and 4 weeks after your TQD we will also ask you to answer some questions about your mood and your experience with EC/NRT.
6 months after TQD	We will telephone you and complete a short questionnaire about your smoking, health, lifestyle and EC/NRT use.
12 months after TQD	We will telephone you and complete a short questionnaire about your smoking, health, lifestyle and EC/NRT use. If you report that you are not smoking, or have reduced your smoking by 50% or more, we will ask you to provide a CO reading. You will receive £20 travel expenses for attending this extra session.

Who can take part?
You will be able to take part if you are:

- Aged 18 years or over

You will **not** be able to take part if you:

- Are pregnant or breast feeding
- Are unable to read/write/understand English
- Have a strong preference to use or not to use NRT or EC in your quit attempt
- Are currently involved in another treatment based research project
- Are currently using EC or NRT

Risks/Side effects
We do not expect there to be any risks from using EC. EC do not contain tobacco, and therefore do not deliver the many harmful substances found in normal cigarettes. As a result they pose no increased risk compared to your normal cigarettes. The most common side effects that people report experiencing when using EC are mouth/throat irritation, nausea and sleep disturbance. EC are not currently licensed as a medicine, but they are currently regulated as a consumer product.

Data Protection
If you agree to take part any information you give us will be kept confidential, and only study staff at your local site, and the main site (Queen Mary, University of London) will have access to this data. We will inform your GP, with your consent, that you are taking part in this study. Should you choose to withdraw from the study and do not wish for us to contact you for any follow up data, you can let us know and we will only use data collected up until the point of your withdrawal (unless you would like us not to). The results of this study may be presented to other individuals working in the field of smoking cessation or may be printed in journals. However, all data will be anonymised and there will be no information included which could identify you. After the study is completed the university will store all data collected from this study for 20 years, as per standard practice.

Your Rights
Your participation in this study is entirely voluntary, and you are free to drop out of the study at any time. Your records will be kept strictly confidential and your ordinary medical care will not be put at risk if you decide not to take part or drop out.

What happens if you are concerned or have any questions?
You will be able to contact Katie Myers Smith (0207 882 8230) if you are worried about anything or have any questions. The Chief Investigator of this study is Professor Peter Hajek, Tobacco Dependence Research Unit, Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry, 2 Stayner's Road, London, E1 2AH, Tel: 020 7882 8230.
A summary of the results of this study will be available upon request.
We believe that this study is safe and do not expect you to suffer any harm or injury because of your participation in it. However, Queen Mary University of London has agreed that if you are harmed as

a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.
If you wish to raise a complaint or would like to seek independent advice outside the study team, you can call the local patient advice and liaison service (PALS) on 0203 594 2040/2050 or you can email them at pals@bartshealth.nhs.uk.

This study has been reviewed by the NRES Committee London - Camden and Islington REC.

We would like to thank you for your interest in this study.

TEC Participant Information SheetVersion 4.0 29 May 2015

Clinic No: **Clinician Initials:** **CLIENT TREAT NO: 201 _ : _ _ _**

_

Smokers Clinic Questionnaire

Please complete this form and bring it to your first appointment. If you have any problems with the questions, please don't worry or be put off coming. We will help you if necessary. The information collected is strictly confidential, for use by Trust staff. Some items, e.g. age and ethnicity, are required by the Department of Health to monitor the service we provide. Other items, including those obtained from all sessions and follow-ups, will be used by the clinic to guide your treatment, and may be used in research on smoking. No names or information that might identify you will be used in any reports, only figures from many smokers together. The information will be stored in accordance with the Data Protection Act and you have the right to review it, or withdraw your permission for us to use it. Your participation in this work is voluntary and your treatment at the clinic will not be affected if you refuse. Please discuss any concerns you may have regarding this information with the clinic staff. Signing below indicates that you have read this notice and agree to your information being used in this way.

Signature _____ **Date** _____

In addition, Public Health England would like to collect service users' feedback. A company called Encouraging Lifestyle Change have been asked to do this. Please sign below to indicate that you are happy for them to contact you. If you do not wish to be contacted, this will not affect your treatment in any way.

Signature _____ **Date** _____

Please write where you see the lines. Circle the word which applies to you

Your name: _____ **Are you? Male Female (*circle ONE*)**

Your date of Birth: _____ **Your age?** _____ **years**

Your address: _____

_____ **Post Code:** _____

Home tel no: _____ **Work tel no:** _____

Mobile tel no: _____ **Email:** _____

Person to contact if we cannot reach you: _____ **Tel No:** _____

Name/Address of your GP: _____

_____ **Post Code:** _____ **Tel No:** _____

1. **Are you? Married Divorced Separated Widowed Single (never married) (*circle ONE*)**

2. **Do you live? With your spouse/partner Family/friends On your own Hostel/residential home (*circle ONE*)**

3. **Are you? (*circle ONE*)**

Working in a routine or manual occupation
Working in an intermediate occupation
Working in a managerial or professional occupation
Unemployed / not working for a year or more
Full time student
Retired
Sick / Disabled / Unable to return to work
Home carer (unpaid)
None of these

4a. **What is your most recent or current occupation?** _____

4b. Do you work within one of the following areas: City of London LBO Hackney LBO Tower Hamlets Another area (circle one)

5. **Which qualifications do you have? None GCSE/CSE A-Level Diploma/HND Degree Other_____**

6. **Are you entitled to free prescriptions? Yes No (*circle one*)**

7. **Which of these best describes your ethnic origin?** (*circle ONE category below*)

WHITE - British	WHITE - Irish	WHITE - other background
MIXED - White and Black Caribbean	MIXED - White and Black African	MIXED - White and Asian
MIXED - other background	ASIAN Indian	ASIAN Pakistani
ASIAN Bangladeshi	ASIAN other	BLACK Caribbean
BLACK African	BLACK other	CHINESE
Another ethnic group: _____		Don't wish to answer

Questions about your smoking

8. **How many cigarettes do you usually smoke each day?** _____ (*write a SINGLE average number*)

9. **How many of these are hand-rolled cigarettes?** _____ (*write a single average number*)

10. **How soon after waking up do you usually smoke?** (*circle one*)

Within 5 mins | 6-30 mins | 31-60 mins | After 1 hour

11. **Do you find it difficult not to smoke in places where smoking is not allowed?** Yes | No (*circle one*)

12. **Do you smoke more in the first hours after waking up than during the rest of the day?** Yes | No (*circle one*)

13. **Which cigarette would you hate most to give up?** The first of the morning | Another one (*circle one*)

14. **Do you smoke if you are so ill that you are in bed most of the day?** Yes | No (*circle one*)

15. **How often do you wake up at night and smoke?** (*circle one*)

Never | Less than once a month | 1 or 2 times a month | 1 or 2 times a week | Most nights

16. **How old were you when you first started smoking regularly?** _____ years old

17. **Does your spouse or partner smoke?** Yes | No | No spouse/partner (*circle one*)

18. **How many times have you tried to stop smoking in the last 5 years?** (*circle one*)

Not at all | Once | 2 or 3 times | 4 or 5 times | More than 5 times

19. **What is the longest time you've succeeded in giving up smoking in the last 5 years?** (*circle one*)

Few hours | 1 day | 2 -3 days | 4 -7 days | 1-3 weeks | 1-3 months | More than 3 months | Not tried

20. **How long ago was your last serious attempt to stop?** (*circle one*)

1 - 3 weeks | 1 - 6 months | More than 6 months | More than a year | Never tried before

21. **What was the ONE MAIN THING that led you back to smoking last time?** (*circle JUST ONE reason below*)

Never stopped before | Got too miserable | Craved too much | Put on too much weight | Got too bad-tempered
Got too stressed | Thought I could smoke and stop easily | Cannabis smoking | Getting drunk | Something else

22. **How recently has your GP advised you to stop?** In the last year | More than a year ago | Never (*circle one*)

23. **What is your ONE MAIN REASON for wanting to stop now?** (*circle JUST the most important ONE*)

To save money | To stop being addicted | To protect my health | To please others | It's anti-social | Another reason

24. **Which of these methods have you tried before to help you stop? (*circle ALL THE ONES you have ever tried*)**

(a) **None** (b) **Nicotine Gum** (c) **Nicotine Inhalator** (d) **Nicotine Patch** (e) **Nicotine Microtab**

(f) **Nicotine Lozenge** (g) **Nicotine Nasal Spray** (h) **Nicotine Minis** (i) **Nicotine Mouth Spray** (j) **Champix**

(k) **Zyban** (l) **Electronic Cigarette** (m) **Hypnosis** (n) **Acupuncture** (o) **Herbal cigarettes** (p) **Nicotine mouth strips**

25. **Have you ever suffered any unpleasant reactions to any of the above medications?** (a) **Yes** **No**

If yes,

(b) **Which medication?** _____

(c) **What reaction?** _____

26 a. **If you have taken Champix before, please answer the following questions:**

(a) How long ago did you last try Champix? _____

(b) How long did you use it for when you last tried Champix? _____

(c) For how long did you manage to stop smoking?

Less than 24 hours **More than 24 hours** (state how long) _____

26 b. **If you have used Nicotine Replacement Therapy (NRT) before, please answer the following questions**

(a) How long ago did you last try NRT? _____

(b) How long did you use it for when you last tried NRT? _____

(c) What type/s of NRT did you use? (List all products that you used) _____

(d) For how long did you manage to stop smoking?

Less than 24 hours **More than 24 hours** (state how long) _____

26 c. **If you have used Zyban before, please answer the following questions**

(a) How long ago did you last try Zyban? _____

(b) How long did you use it for when you last tried Zyban? _____

(c) For how long did you manage to stop smoking?

Less than 24 hours **More than 24 hours** (state how long) _____

26 d. **If you have used e-cigarettes (EC) before, please answer the following questions**

(a) How long ago did you last try EC? _____

(b) How long did you use it for when you last tried EC? _____

(c) What type of EC did you use? (List all products that you used) _____

(d) For how long did you manage to stop smoking?

Less than 24 hours **More than 24 hours** (state how long) _____

27. **Have you been to this Smokers' Clinic before?** (a) **Yes** **No** (b) **If Yes, which year was it?** _____

28. **Do you regularly use cannabis?** **No** **Yes, with tobacco** **Yes, but not with tobacco** **(*circle one*)**

29. **How many units of alcohol do you drink during a typical WEEK?** _____ **units** *
(one unit = glass of wine / half pint of beer / single spirit)

30. **If you are female, are you?** **Pregnant** (expected delivery date _____) **Trying to conceive**
Breast Feeding **None of these** *

If you join the clinic programme, you may be prescribed a medicine to help. Some medicines can be harmful for some people, so we ask everyone to complete the medical checklist below. If you don't understand some of the questions, a therapist at the clinic will help you.

Have you EVER suffered from these illnesses?			**&**	**Do you currently take any medicines for these illnesses?**		
	(*circle one*)			**(*circle one*)**		**Name of any medicine you are taking**
31. **Heart disease or condition?**	**YES**	**NO**		**YES**	**NO**	
32. **Chronic Obstructive Pulmonary Disease (COPD)?**	**YES**	**NO**		**YES**	**NO**	

33. **Alcohol problems?**	**YES**	**NO**		**YES**	**NO**	
34. **Drug problems?**	**YES**	**NO**		**YES**	**NO**	
35. **Depression?**	**YES**	**NO**		**YES**	**NO**	
36. **Bi-polar disorder?**	**YES**	**NO**		**YES**	**NO**	
37 **Any form of schizophrenia?**	**YES**	**NO**		**YES**	**NO**	
38 **Any other form of psychosis?**	**YES**	**NO**		**YES**	**NO**	
39. **Skin allergies or eczema?**	**YES**	**NO**		**YES**	**NO**	
40. **Nasal problems or nose bleeds?**	**YES**	**NO**		**YES**	**NO**	
41. **A stroke?**	**YES**	**NO**		**YES**	**NO**	*
42. **An eating disorder?**	**YES**	**NO**		**YES**	**NO**	*
43. **Liver disease?**	**YES**	**NO**		**YES**	**NO**	*
44. **Kidney disease?**	**YES**	**NO**		**YES**	**NO**	
45. **A brain tumour?**	**YES**	**NO**		**YES**	**NO**	*
46. **A head injury?**	**YES**	**NO**		**YES**	**NO**	*
47. **Fits or seizures or epilepsy?**	**YES**	**NO**		**YES**	**NO**	*
48. **Diabetes?**	**YES**	**NO**		**YES**	**NO**	*
Other CURRENT illness:	**Name of other medicines / tablets / injections taken for this illness:**					
49.						
50.						
51.						

52. **Do you have any allergies to any medicines? YES NO** *(circle one)*

If Yes, please write which ones below and your reactions to them

Medication	**Reaction**
52.	
53.	
54.	

If you are currently under psychiatric care, **Name of your Psychiatrist:**

_____

Address: _____ **Post Code:**

_____

Tel No: _____

52. **Do you consider yourself to have a disability? YES NO PREFER NOT TO SAY** *(circle one)*

Please check that you have included ALL the medicines you are currently taking somewhere above

Thank you very much. Please remember to bring this form with you to the clinic

Office Use Only ELIG FOR NRT? Y N NK ELIG FOR CHAMPIX Y N ELIG FOR ZYB? Y N NK

PATIENT REFERRED FROM:

Medication option 1_____
Medication option 2_____

If NRT dispensed at S1 please specify -

Product 1:	Dosage:	Quantity:
Product 2:	Dosage:	Quantity:

Clinical Notes:

Screened by: _____ Date: _____

Signature

CASE REPORT FORM

TEC STUDY

Participant number			
Participant initials			

Screening and Session 1 – eligibility questions

Date | | | | | | | |

D D M M M Y Y

1.	**Inclusion Criteria**	Circle ONE	
	Are you aged 18 or over?	YES	NO
	Are you able to read/write/understand English?	YES	NO
	Are you a current smoker accessing a stop smoking service?	YES	NO
2.	**Exclusion Criteria**	Circle ONE	
	Are you currently using EC or NRT?	YES	NO
	Do you have a strong preference to use or not to use NRT or EC in your quit attempt?	YES	NO
	Are you pregnant/breastfeeding?	YES	NO
	Are you enrolled in other interventional research?	YES	NO
3.	**Eligible for study?** (participant is eligible if they answer yes to all inclusion criteria and no to all exclusion criteria)	YES	NO
4.	**Consent form completed and participant given a copy?**	YES	NO
5.	**Do you wish to receive the results of the study when they are available?**	YES	NO

6. Completed baseline and health questions? (tick box) ☐

7. Completed the EQ-5D questionnaire? (tick box) ☐

8. Completed the Health Service Use Questionnaire? (tick box) ☐

Screening and Session 1 - baseline questions

1. Are you? Male ☐ Female ☐ **Your age?** ____ years

2. What is your highest level of education? (*tick ONE*)

Primary school ☐ Secondary school ☐ Further education/diploma ☐ Higher Education ☐

3. Are you? (*circle ONE*) Married Divorced Separated Widowed Single (never married)

4. Are you? (*circle ONE*)

Working in a routine or manual occupation
Working in an intermediate occupation
Working in a managerial or professional occupation
Unemployed / not working for a year or more
Full time student
Retired
Sick / Disabled / Unable to return to work
Home carer (unpaid)
None of these

5. Are you entitled to free prescriptions? (*circle ONE*) Yes No

6. Which of these best describes your ethnic origin? (*circle ONE category below*)

WHITE - British WHITE - Irish WHITE - other background

MIXED - White and Black Caribbean MIXED - White and Black African MIXED - White and Asian

MIXED - other background ASIAN Indian ASIAN Pakistani

ASIAN Bangladeshi ASIAN other BLACK Caribbean

BLACK African BLACK other CHINESE

Another ethnic group: _____ Don't wish to answer

7. On average, how many cigarettes do you usually smoke each day? _____

8. How soon after waking up do you usually smoke? (tick ONE)

Within 5 mins ☐ 6-30 mins ☐ 31-60 mins ☐ After 1 hour ☐

9. Do you find it difficult not to smoke in places where smoking is not allowed? Yes ☐ No ☐

10. Do you smoke more during the first hours after waking than the rest of the day? Yes ☐ No ☐

11. Which cigarette would you hate most to give up? The first of the morning ☐ Another one ☐

12. Do you smoke if you are so ill that you are in bed most of the day? Yes ☐ No ☐

13. Have you tried any of the following methods to help you quit smoking before?

Method	**Tried it?** (Circle ONE)	**If yes, how many weeks ago did you last try it?** (write below)	**If yes, how many days did you use it for when you last tried it?** (write below)	**If yes, for how long did you manage to quit smoking when you last tried it?** (write below)
Nicotine replacement therapy	**Yes/No**			
Champix	**Yes/No**			
Zyban	**Yes/No**			
Electronic cigarette	**Yes/No**			

14. How old were you when you first started smoking regularly? _____ years old

15. Does your spouse or partner smoke? (circle ONE) Yes No No spouse/partner

Screening and Session 1 - health and medication questions

Have you EVER suffered from these illnesses? (circle ONE response for each illness)			**&**	**Do you CURRENTLY take any medicines for these illnesses?** (circle ONE response for each illness and write name of any medicine and start date below, if known)		
1. **Heart disease or condition?**	**YES**	**NO**		**YES**	**NO**	
2. **Chronic Obstructive Pulmonary Disease (COPD)**	**YES**	**NO**		**YES**	**NO**	
3. **Alcohol problems?**	**YES**	**NO**		**YES**	**NO**	
4. **Drug problems?**	**YES**	**NO**		**YES**	**NO**	
5. **Depression?**	**YES**	**NO**		**YES**	**NO**	
6. **Any form of psychosis?**	**YES**	**NO**		**YES**	**NO**	
7. **Skin allergies or eczema?**	**YES**	**NO**		**YES**	**NO**	
8. **A stroke?**	**YES**	**NO**		**YES**	**NO**	
9. **Liver disease?**	**YES**	**NO**		**YES**	**NO**	
10. **Kidney disease?**	**YES**	**NO**		**YES**	**NO**	
11. **Diabetes?**	**YES**	**NO**		**YES**	**NO**	

Do you suffer from any other CURRENT illness not listed above? (if yes, list below)	**Do you currently take any other medicines / tablets / injections not listed above (if yes, list below with their start date, if known)**
12.	
13.	
14.	
15.	
16.	
17.	
18.	
19.	
20.	
21.	

22. Over the last week, have you experienced any of the following health problems? If yes, study staff to assess severity below.

Health problem	Has the participant experienced the health problem? (tick ONE box)	Severity - Has the health problem stopped the participant doing things they would normally do? (tick ONE box)
Nausea	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot
Sleep disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot
Throat/mouth irritation	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot
Dizziness	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot
Headache	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot
Visual disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot
Shortness of breath	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot
Wheezing	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot
Cough	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot
Phlegm	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot

Session 1 - current smoking questions

1. **Record carbon monoxide in expired breath (ppm)** ____

2. **About how many cigarettes have you smoked <u>per day</u> in the last week?** ____

3. **For each of the following rate how you have been feeling <u>over the past week</u>** (circle ONE box on each line)

	Not at all	Slightly	Somewhat	Very	Extremely
Depressed	1	2	3	4	5
Irritable	1	2	3	4	5
Restless	1	2	3	4	5
Hungry	1	2	3	4	5
Poor concentration	1	2	3	4	5

4. **How much of the time have you felt the urge to smoke over the past week?** (circle ONE)

1. Not at all	2. A little of the time	3. Some of the time	4. A lot of the time	5. Almost all of the time	6. All of the time

5. **How strong have these urges been?** (circle ONE)

1. No urges	2. Slight	3. Moderate	4. Strong	5. Very strong	6. Extremely strong

6. **Set target quit date (clinician use only)** ____ ____ ____ ____ ____ ____ ____

D D M M M Y Y

Session 2: Quit date

1. **Date** ____ ____ ____ ____ ____ ____ ____

D D M M M Y Y

2. **Record carbon monoxide in expired breath (ppm)** ____

3. **About how many cigarettes have you smoked <u>per day</u> in the last week?** ____ **cpd**

4. **For each of the following rate how you have been feeling <u>over the past week</u>** (circle ONE box on each line)

	Not at all	Slightly	Somewhat	Very	Extremely
Depressed	1	2	3	4	5
Irritable	1	2	3	4	5
Restless	1	2	3	4	5
Hungry	1	2	3	4	5
Poor concentration	1	2	3	4	5

5. **How much of the time have you felt the urge to smoke over the past week?** (circle ONE)

1. Not at all	2. A little of the time	3. Some of the time	4. A lot of the time	5. Almost all of the time	6. All of the time

6. How strong have these urges been? (circle ONE)

1. No urges	2. Slight	3. Moderate	4. Strong	5. Very strong	6. Extremely strong

7. Record randomisation number ☐

8. Record treatment arm (tick appropriate box) ☐ **EC** ☐ **NRT**

9a. Commitment form signed? (tick box) ☐

10a. For EC arm participants only: **EC provided?** (tick box) ☐

10b. For EC arm participants who were dispensed an LOR at baseline visit: **NRT collected in exchange for EC?** (tick box) ☐

11. For NRT arm participants only: **NRT/LOR provided?** (tick box) ☐

17a. If NRT/LOR provided, specify which:
NRT1: (product and strength)
NRT2: (product and strength)

Session 3: 1-week post-quit date

1. Date

D	**D**	**M**	**M**	**M**	**Y**	**Y**

2. Record carbon monoxide in expired breath (ppm)

3. Have you smoked regular cigarettes at all since your last visit? (circle ONE)

1. Not a single puff
2. Just a few puffs
3. ≤ 5 cigs in total
4. > 5 cigs in total

3a. If smoked > 5 cigarettes: on average, how many days a week did you smoke since your last visit?

3b. If smoked > 5 cigarettes, how many cigarettes did you smoke per day on average? **cpd**

4. For each of the following rate how you have been feeling since your last visit (circle ONE box on each line)

	Not at all	Slightly	Somewhat	Very	Extremely
Depressed	1	2	3	4	5
Irritable	1	2	3	4	5
Restless	1	2	3	4	5
Hungry	1	2	3	4	5
Poor concentration	1	2	3	4	5

5. How much of the time have you felt the urge to smoke over the past week? (circle ONE)

1. Not at all	2. A little of the time	3. Some of the time	4. A lot of the time	5. Almost all of the time	6. All of the time

7. How strong have these urges been? (circle ONE)

1. No urges	2. Slight	3. Moderate	4. Strong	5. Very strong	6. Extremely strong

8. Have you used your allocated product since your last visit? (If yes, please complete the following.) ☐ **Yes** ☐ **No**

			How many days per week did you use your product since your last visit?	On average, how many mls of EC liquid, number of cartridges, patches, oral NRT did you use per day?
☐ **EC brand provided OR**	**Brand:**	**Strength:**		
NRT 1:	**Product:**	**Strength:**		
NRT 2:	**Product:**	**Strength:**		

9. If you stopped using your allocated product since your last visit, what was the main reason? (tick ONE)

☐ **Cost**

☐ **Did not like the taste**

☐ **Adverse reaction (nausea, throat/mouth irritation and/or sleep disturbance – if yes, complete further details on health problems page)**

☐ **Not satisfying**

☐ **Difficult to use**

☐ **Embarrassing to use**

☐ **Difficult to obtain them**

☐ **Smoking normal cigarettes now**

☐ **To quit nicotine**

☐ **Other reason (specify):**

10. Since your last visit how helpful did you find your allocated product(s) (e-cigs or NRT) in keeping you away from normal cigarettes? (circle ONE response on each line, or tick box if they did not use allocated product **at all** since last visit) ☐ **Did not use product since last visit**

	Not at all	Slightly	Somewhat	Very	Extremely
EC	1	2	3	4	5
NRT 1 ***(specify)***	1	2	3	4	5
NRT 2 ***(specify)***	1	2	3	4	5

Thinking about your allocated product (e-cigs or oral NRT only), since your last visit, how was it compared to your normal cigarettes in terms of the following (circle ONE response on each line, or tick box if they did not use allocated product **at all** since last visit) ☐ **Did not use product since last visit**

	Much less than normal cigs	A little less than normal cigs	The same as normal cigs	A little more than normal cigs	Much more than normal cigs
11. How good did it taste?	1	2	3	4	5
12. How satisfying was it?	1	2	3	4	5

13. Have you used any other products since your last visit? (if yes, please answer Q13a and 13b) ☐ **Yes** ☐ **No**

13a. If you used another product, what did you use? (tick ALL that apply)

☐ **EC** ☐ **NRT** ☐ **Varenicline** ☐ **Bupropion**

13b. If you used another product(s), for how many days in a row did you use it? ☐

14. Since your last visit have you purchased any of the following? (Please tick ALL that apply)

EC device	☐ **No** ☐ **Yes (approx. how much spent; go to 14a)**	**£**
EC liquid	☐ **No** ☐ **Yes (approx. how much spent; go to 14b)**	**£**
NRT product(s)	☐ **No** ☐ **Yes (approx. how much spent; go to 14c)**	**£**

14a. What type of EC device did you purchase? (tick ALL that apply)

☐ **A disposable e-cigarette (non-rechargeable)**

☐ **A rechargeable e-cigarette without a 'tank'**

☐ **A rechargeable e-cigarette with a 'tank'**

☐ **A modular system (your own combination of separate parts: battery, atomizer, fluid etc).**

14b. Which strength and flavor EC liquid(s) did you buy?

EC liquid 1: Strength_____% or mg/ml Flavour:_____

EC liquid 2: Strength_____% or mg/ml Flavour:_____

EC liquid 3: Strength_____% or mg/ml Flavour:_____

14c. Which NRT product(s) and strengths did you buy?

NRT Product 1:_____(name) _____ (strength)

NRT Product 2:_____(name) _____ (strength)

NRT Product 3:_____(name) _____ (strength)

15. Since your last visit have there been any changes to your health conditions or medicines taken? ☐ **No** ☐ **Yes** (if yes, update S1 health and medication questions)

16. Completed health problems questions overleaf? (tick box) ☐

17. For NRT arm participants only: **NRT/LOR provided?** (tick ONE) ☐ **No** ☐ **Yes**

17a. If NRT/LOR provided, specify which:
NRT1: (product and strength)
NRT2: (product and strength)

18. Since your last visit, have you experienced any of the following health problems? If yes, study staff to assess severity, seriousness and action required.

Health problem	**Has the participant experienced the health problem?**	***Severity - has the health problem stopped the participant doing things they would normally do? (tick one box)**	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness – without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or getting a permanent disability?**	***Action taken**
Nausea	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Sleep disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Throat/mouth irritation	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Dizziness	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Headache	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

Continued overleaf

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an intervention to the health problem the answer is**

Health problem	Has the participant experienced the health problem?	*Severity - has the health problem stopped the participant doing things they would normally do? (tick one box)	**Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?	**Seriousness – without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or getting a permanent disability?	*Action taken
Visual disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Shortness of breath	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Wheezing	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Cough	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Phlegm	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

'yes' then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.

☐ **No** ☐ **Yes**

19. Have you seen a GP, or had an unplanned admission to hospital about a health problem since your last visit? If yes, what was the health problem? (Write below. Study staff to assess severity and seriousness etc. below)

Health Problem (write in boxes below)	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness –without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or got a permanent disability?**	***Action taken**
1.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
2.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
3.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an intervention to the health problem the answer is 'yes' then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.**

Session 4: 2-weeks post-quit date

1. Date | | | | | | | | **D D M M M Y Y**

2. Record carbon monoxide in expired breath (ppm) | |

3. Have you smoked regular cigarettes at all since your last visit/contact? (circle ONE)

1. Not a single puff
2. Just a few puffs
3. ≤ 5 cigs in total
4. > 5 cigs in total

3a. If smoked > 5 cigarettes: on average, how many days a week did you smoke since your last visit? |

3b. If smoked > 5 cigarettes, how many cigarettes did you smoke per day on average? | cpd

4. Have you used your allocated product since your last visit/contact? (If yes, please complete the following.) ☐**Yes** ☐**No**

			How many days per week did you use your product since your last visit?	**On average, how many mls of EC liquid, number of cartridges, patches, oral NRT did you use per day?**
☐**EC brand provided OR**	**Brand:**	**Strength:**		
NRT 1:	**Product:**	**Strength:**		
NRT 2:	**Product:**	**Strength:**		

5. If you stopped using your allocated product since your last visit/contact what was the main reason? (tick ONE)

☐**Cost**

☐**Did not like the taste**

☐**Adverse reaction (nausea, throat/mouth irritation and/or sleep disturbance – if yes, complete further details on health problems page)**

☐**Not satisfying**

☐**Difficult to use**

☐**Embarrassing to use**

☐**Difficult to obtain them**

☐**Smoking normal cigarettes now**

☐**To quit nicotine**

☐**Other reason (specify):**

6. Since your last visit/contact how helpful did you find your allocated product(s) (ecigs or NRT) in keeping you away from normal cigarettes? (circle ONE response on each line, or tick box if they did not use allocated product **at all** since last visit) ☐ **Did not use product since last visit**

	Not at all	**Slightly**	**Somewhat**	**Very**	**Extremely**
EC	1	2	3	4	5
NRT 1 ***(specify)***	1	2	3	4	5
NRT 2 ***(specify)***	1	2	3	4	5

7. Have you used any other products since your last visit/contact? (if yes, please answer to Q7a and Q7b) ☐**Yes** ☐**No**

7a. If you used another product, what did you use? (tick ALL that apply)

☐ **EC** ☐ **NRT** ☐ **Varenicline** ☐ **Bupropion**

7b. If you used another product(s), for how many days <u>in a row</u> did you use it? ☐

8. Since your last visit/contact have you purchased any of the following? (Please tick ALL that apply)

EC device	☐**No** ☐**Yes (approx. how much spent; go to 8a)**	**£**
EC liquid	☐**No** ☐**Yes (approx. how much spent; go to 8b)**	**£**
NRT product(s)	☐**No** ☐**Yes (approx. how much spent; go to 8c)**	**£**

8a. What type of EC device did you purchase? (tick ALL that apply)

☐**A disposable e-cigarette (non-rechargeable)**

☐**A rechargeable e-cigarette without a 'tank'**

☐**A rechargeable e-cigarette with a 'tank'**

☐**A modular system (your own combination of separate parts: battery, atomizer, fluid etc).**

8b. Which strength and flavor EC liquid(s) did you buy?

EC liquid 1: Strength_____% or mg/ml Flavour:_____

EC liquid 2: Strength_____% or mg/ml Flavour:_____

EC liquid 3: Strength_____% or mg/ml Flavour:_____

8c. Which NRT product(s) and strengths did you buy?

NRT Product 1:_____(name) _____ (strength)

NRT Product 2:_____(name) _____ (strength)

NRT Product 3:_____(name) _____ (strength)

9. Since your last visit/contact have there been any changes to your health conditions or medicines taken? ☐ **No** ☐ **Yes** (if yes, update S1 health and medication questions)

10. Completed health problems questions overleaf? (tick box) ☐

11. For EC arm participants only: **additional e-liquid dispensed?** (tick ONE) ☐ **No** ☐ **Yes**

12. For NRT arm participants only: **NRT/LOR provided?** (tick ONE) ☐ **No** ☐ **Y**

12a. If NRT/LOR provided, specify which:
NRT1: (product and strength)
NRT2: (product and strength)

13. Since your last visit/contact, have you experienced any of the following health problems? If yes, study staff to assess severity, seriousness and action required.

Health problem	**Has the participant experienced the health problem?**	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness – without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or getting a permanent disability?**	***Action taken**
Nausea	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Sleep disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Throat/mouth irritation	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Dizziness	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Headache	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

Continued overleaf

Health problem	**Has the participant experienced the health problem?**	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick onebox)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness – without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or getting a permanent disability?**	***Action taken**
Visual disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Shortness of breath	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Wheezing	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Cough	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Phlegm	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an intervention to the health problem the answer is 'yes' then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.**
Continued overleaf

☐ **No** ☐ **Yes**

14. Have you seen a GP, or had an unplanned admission to hospital about a health problem since your last visit/contact? If yes, what was the health problem? (Write below. Study staff to assess severity and seriousness etc. below)

Health Problem (write in boxes below)	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness –without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or got a permanent disability?**	***Action taken**
1.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
2.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
3.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an intervention to the health problem the answer is 'yes' then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.**

Session 5: 3-weeks post-quit date

1. **Date** | | | | | | | | | D D M M M Y Y

2. **Record carbon monoxide in expired breath (ppm)** |

3. **Have you smoked regular cigarettes at all since your last visit/contact?** (circle ONE)

1. Not a single puff
2. Just a few puffs
3. ≤ 5 cigs in total
4. > 5 cigs in total

3a. If smoked > 5 cigarettes: on average, how many days a week did you smoke since your last visit/contact?

3b. If smoked > 5 cigarettes, how many cigarettes did you smoke per day on average? cpd

4. **Have you used your allocated product since your last visit/contact?** (If yes, please complete the following) ☐**Yes** ☐**No**

			How many days per week did you use your product since your last visit?	**On average, how many mls of EC liquid, number of cartridges, patches, oral NRT did you use per day?**
☐**EC brand provided OR**	**Brand:**	**Strength:**		
NRT 1:	**Product:**	**Strength:**		
NRT 2:	**Product:**	**Strength:**		

6. If you stopped using your allocated product since your last visit/contact, what was the main reason? (tick ONE)

☐ **Cost**

☐ **Did not like the taste**

☐ **Adverse reaction (nausea, throat/mouth irritation and/or sleep disturbance – if yes, complete further details on health problems page)**

☐ **Not satisfying**

☐ **Difficult to use**

☐ **Embarrassing to use**

☐ **Difficult to obtain them**

☐ **Smoking normal cigarettes now**

☐ **To quit nicotine**

☐ **Other reason (specify) :**

7. Since your last visit/contact how helpful did you find your allocated product (ecigs or NRT) in keeping you away from normal cigarettes? (circle ONE response on each line, or tick box if they did not use allocated product **at all** since last visit) ☐ **Did not use product since last visit**

	Not at all	**Slightly**	**Somewhat**	**Very**	**Extremely**
EC	1	2	3	4	5
NRT 1 ***(specify)***	1	2	3	4	5

NRT 2 *(specify)*	1	2	3	4	5

8. Have you used any other products since your last visit/contact? (if yes, please answer Q8a and 8b) ☐**Yes** ☐**No**

8a. If you used another product, what did you use? (tick ALL that apply)

☐ **EC** ☐ **NRT** ☐ **Varenicline** ☐ **Bupropion**

8b. If you used another product(s), for how many days <u>in a row</u> did you use it?

9. Since your last visit/contact have you purchased any of the following? (tick ALL that apply)

EC device	☐**No** ☐**Yes (approx. how much spent; go to 9a)**	**£**
EC liquid	☐**No** ☐**Yes (approx. how much spent; go to 9b)**	**£**
NRT product(s)	☐**No** ☐**Yes (approx. how much spent; go to 9c)**	**£**

9a. What type of EC device did you purchase? (tick ALL that apply)

☐**A disposable e-cigarette (non-rechargeable)**

☐**A rechargeable e-cigarette without a 'tank'**

☐**A rechargeable e-cigarette with a 'tank'**

☐**A modular system (your own combination of separate parts: battery, atomizer, fluid etc).**

9b. Which strength and flavor EC liquid(s) did you buy?

EC liquid 1: Strength_____% or mg/ml Flavour:_____

EC liquid 2: Strength_____% or mg/ml Flavour:_____

EC liquid 3: Strength_____% or mg/ml Flavour:_____

9c. Which NRT product(s) and strengths did you buy?

NRT Product 1:_____(name) _____ (strength)

NRT Product 2:_____(name) _____ (strength)

NRT Product 3:_____(name) _____ (strength)

10. Since your last visit/contact have there been any changes to your health conditions or medicines taken? ☐ **No** ☐ **Yes** (if yes, update S1 health and medication questions)

11. Completed health problems questions overleaf? (tick box) ☐

12. NRT arm participants only: **NRT/LOR provided?** (tick ONE) ☐**No** ☐**Yes**

12a. If NRT/LOR provided, specify which:
NRT1: **(product and strength)**
NRT2: **(product and strength)**

13. Since your last visit/contact, have you experienced any of the following health problems? If yes, study staff to assess severity, seriousness and action required.

Health problem	**Has the participant experienced the health problem?**	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness – without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or getting a permanent disability?**	***Action taken**
Nausea	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Sleep disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Throat/mouth irritation	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Dizziness	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Headache	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

Continued overleaf

Health problem	**Has the participant experienced the health problem?**	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness – without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or getting a permanent disability?**	***Action taken**
Visual disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Shortness of breath	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Wheezing	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Cough	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Phlegm	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an intervention to the health problem the answer is 'yes' then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.**
Continued overleaf.

☐ **No** ☐ **Yes**

14. Have you seen a GP, or had an unplanned admission to hospital about a health problem since your last visit/contact? If yes, what was the health problem? (Write below. Study staff to assess severity and seriousness etc. below)

Health Problem (write in boxes below)	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness –without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or got a permanent disability?**	***Action taken**
1.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
2.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
3.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an intervention to the health problem the answer is 'yes' then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.**

Session 6: 4-weeks post-quit date

1. Date | | | | | | | | D D M M M Y Y

2. Record carbon monoxide in expired breath (ppm) | |

3. Have you smoked regular cigarettes at all since your last visit/contact? (circle ONE)

1. Not a single puff
2. Just a few puffs
3. ≤ 5 cigs in total
4. > 5 cigs in total

3a. If smoked > 5 cigarettes: on average, how many days a week did you smoke since your last visit/contact? |

3b. If smoked > 5 cigarettes, how many cigarettes did you smoke per day on average? | cpd

4. If you have smoked since your last visit/contact, did you smoke at all in the last 7 days? ☐ **Yes** ☐ **No**

5. For each of the following rate how you have been feeling <u>since your last visit/contact</u> (circle ONE box on each line)

	Not at all	Slightly	Somewhat	Very	Extremely
Depressed	1	2	3	4	5
Irritable	1	2	3	4	5
Restless	1	2	3	4	5
Hungry	1	2	3	4	5
Poor concentration	1	2	3	4	5

6. How much of the time have you felt the urge to smoke since your last visit/contact? (circle ONE)

1. Not at all	2. A little of the time	3. Some of the time	4. A lot of the time	5. Almost all of the time	6. All of the time

8. How strong have these urges been? (circle ONE)

1. No urges	2. Slight	3. Moderate	4. Strong	5. Very strong	6. Extremely strong

9. Have you used your allocated product since your last visit/contact? (If yes, please complete the following) ☐ **Yes** ☐ **No**

			How many days per week did you use your product since your last visit?	On average, how many mls of EC liquid, number of cartridges, patches, oral NRT did you use per day?
☐ **EC brand provided OR**	**Brand:**	**Strength:**		
NRT 1:	**Product:**	**Strength:**		

NRT 2:	Product:	Strength:		

10. If you stopped using your allocated product since your last visit/contact, what was the main reason? (tick ONE)

☐ **Cost**

☐ **Did not like the taste**

☐ **Adverse reaction (nausea, throat/mouth irritation and/or sleep disturbance – if yes, complete further details on health problems page)**

☐ **Not satisfying**

☐ **Difficult to use**

☐ **Embarrassing to use**

☐ **Difficult to obtain them**

☐ **Smoking normal cigarettes now**

☐ **To quit nicotine**

☐ **Other reason (specify) :**

11. Since your last visit/contact how helpful did you find your allocated product(s) in keeping you away from normal cigarettes? (circle ONE response on each line, or tick box if they did not use allocated product **at all** since last visit) ☐ **Did not use product since last visit**

	Not at all	Slightly	Somewhat	Very	Extremely
EC	1	2	3	4	5
NRT 1 ***(specify)***	1	2	3	4	5
NRT 2 ***(specify)***	1	2	3	4	5

Thinking about your allocated product (e-cigs or oral NRT only), since your last visit/contact, how was it compared to your normal cigarettes in terms of the following (circle ONE response on each line, or tick box if they did not use allocated product **at all** since last visit) ☐ **Did not use product since last visit**

	Much less than normal cigs	A little less than normal cigs	The same as normal cigs	A little more than normal cigs	Much more than normal cigs
12. How good did it taste?	**1**	**2**	**3**	**4**	**5**
13. How satisfying was it?	**1**	**2**	**3**	**4**	**5**

14. Have you used any other products since your last visit/contact? (if yes, please answer Q14a and 14b) ☐ **Yes** ☐ **No**

14a. If you used another product, what did you use? (tick ALL that apply)

☐ **EC** ☐ **NRT** ☐ **Varenicline** ☐ **Bupropion**

14b. If you used another product(s), for how many days in a row did you use it?

15. Since your last visit/contact have you purchased any of the following? (tick ALL that apply)

EC device	☐ **No** ☐ **Yes (approx. how much spent; go to 15a)**	**£**
EC liquid	☐ **No** ☐ **Yes (approx. how much spent; go to 15b)**	**£**
NRT product(s)	☐ **No** ☐ **Yes (approx. how much spent; go to 15c)**	**£**

15a. What type of EC device did you purchase? (tick ALL that apply)

☐ A disposable e-cigarette (non-rechargeable)

☐ A rechargeable e-cigarette without a 'tank'

☐ A rechargeable e-cigarette with a 'tank'

☐ A modular system (your own combination of separate parts: battery, atomizer, fluid etc).

15b. Which strength and flavour EC liquid(s) did you buy?

EC liquid 1: Strength_____% or mg/ml Flavour:_____

EC liquid 2: Strength_____% or mg/ml Flavour:_____

EC liquid 3: Strength_____% or mg/ml Flavour:_____

15c. Which NRT product(s) and strengths did you buy?

NRT Product 1:_____(name) _____ (strength)

NRT Product 2:_____(name) _____ (strength)

NRT Product 3:_____(name) _____ (strength)

16. Since your last visit/contact have there been any changes to your health conditions or medicines taken? ☐ **No** ☐ **Yes** (if yes, update S1 health and medication questions)

17. Completed health problems questions overleaf? (tick box) ☐

18. For participants in NRT arm only: **NRT/LOR provided?** ☐ **No** ☐ **Yes**

18a. If NRT/LOR provided, specify which:
NRT1: (product and strength)
NRT2: (product and strength)

19. Since your last visit/contact, have you experienced any of the following health problems? If yes, study staff to assess severity, seriousness and action required.

Health problem	**Has the participant experienced the health problem?**	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness – without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or getting a permanent disability?**	***Action taken**
Nausea	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Sleep disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Throat/mouth irritation	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Dizziness	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Headache	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

Continued overleaf

Health problem	**Has the participant experienced the health problem?**	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness – without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or getting a permanent disability?**	***Action taken**
Visual disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Shortness of breath	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Wheezing	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Cough	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Phlegm	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an intervention to the health problem the answer is 'yes' then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.**
Continued overleaf

☐ No ☐ Yes

20. Have you seen a GP, or had an unplanned admission to hospital about a health problem since your last visit/contact? If yes, what was the health problem? (Write below. Study staff to assess severity and seriousness etc. below)

Health Problem (write in boxes below)	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness –without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or got a permanent disability?**	***Action taken**
1.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
2.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
3.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an intervention to the health problem the answer is 'yes' then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.**

Session 7: 24-weeks post-quit date (telephone call)

1. **Date** | | | | | | | | |
D D M M M Y Y

2. **Have you smoked regular cigarettes at all since your last visit/contact?** (circle ONE)
1. Not a single puff
2. Just a few puffs
3. ≤ 5 cigs in total
4. > 5 cigs in total

2a. If smoked > 5 cigarettes: on average, how many days a week did you smoke since your last visit/contact?

2b. If smoked > 5 cigarettes, how many cigarettes did you smoke per day on average? cpd

3. **If you have smoked since your last visit, did you smoke at all in the last 7 days?** ☐ **Yes** ☐ **No**

5. **Have you used your allocated product since your last visit/contact?** (if yes, please complete the following) ☐ **Yes** ☐ **No**

			How many days did you use your product per week?	**On average, how many mls of EC liquid, number of cartridges, patches, oral NRT did you use per day?**
☐ **EC brand provided OR**	**Brand:**	**Strength:**		
NRT 1:	**Product:**	**Strength:**		
NRT 2:	**Product:**	**Strength:**		

6. If you stopped using your allocated product since your last visit/contact, what was the main reason? (tick ONE)

☐ **Cost**

☐ **Did not like the taste**

☐ **Adverse reaction (nausea, throat/mouth irritation and/or sleep disturbance – if yes, complete further details on health problems page)**

☐ **Not satisfying**

☐ **Difficult to use**

☐ **Embarrassing to use**

☐ **Difficult to obtain them**

☐ **Smoking normal cigarettes now**

☐ **To quit nicotine**

☐ **Other reason (specify):**

7. Since your last visit/contact how helpful did you find your allocated product(s) (ecigs or NRT) in keeping you away from normal cigarettes? (circle ONE response on each line, or tick box if they did not use allocated product **at all** since last visit) ☐ **Did not use product since last visit**

	Not at all	Slightly	Somewhat	Very	Extremely
EC	1	2	3	4	5
NRT 1 ***(specify)***	1	2	3	4	5
NRT 2 ***(specify)***	1	2	3	4	5

8. Have you used any other products since your last visit/contact? (if yes, please answer Q8a and 8b) ☐ **Yes** ☐ **No**

8a. If you used another product, what did you use? (tick ALL that apply)

☐ **EC** ☐ **NRT** ☐ **Varenicline** ☐ **Bupropion**

8b. If you used another product(s), for how many days <u>in a row</u> did you use it? ☐

9. Since your last visit/contact have you purchased any of the following? (tick ALL that apply)

EC device	☐ **No** ☐ **Yes (approx. how much spent; go to 9a)**	**£**
EC liquid	☐ **No** ☐ **Yes (approx. how much spent; go to 9b)**	**£**
NRT product(s)	☐ **No** ☐ **Yes (approx. how much spent; go to 9c)**	**£**

9a. What type of EC device was purchased? (tick ALL that apply)

☐ **A disposable e-cigarette (non-rechargeable)**

☐ **A rechargeable e-cigarette without a 'tank'**

☐ **A rechargeable e-cigarette with a 'tank'**

☐ **A modular system (your own combination of separate parts: battery, atomizer, fluid etc).**

9b. Which strength and flavor EC liquid(s) did you buy?

EC liquid 1: Strength_____% or mg/ml Flavour:_____

EC liquid 2: Strength_____% or mg/ml Flavour:_____

EC liquid 3: Strength_____% or mg/ml Flavour:_____

9c. Which NRT product(s) and strengths did you buy?

NRT Product 1:_____(name) _____ (strength)

NRT Product 2:_____(name) _____ (strength)

NRT Product 3:_____(name) _____ (strength)

10. Have there been any changes to your health conditions or medicines taken since your last visit/contact? ☐ **No** ☐ **Yes** (if yes, update S1 health and medication questions)

11. Completed health problems questions overleaf? (tick box) ☐

12. Completed EQ 5D questionnaire? (tick box) ☐

13. Complete the Health Service Use Questionnaire? (tick box) ☐

14. Since your last visit/contact, have you experienced any of the following health problems? If yes, study staff to assess severity, seriousness and action required.

Health problem	**Has the participant experienced the health problem?**	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness – without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or getting a permanent disability?**	***Action taken**
Nausea	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Sleep disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Throat/mouth irritation	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Dizziness	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Headache	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

Continued overleaf

Health problem	**Has the participant experienced the health problem?**	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness – without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or getting a permanent disability?**	**Action taken**
Visual disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Shortness of breath	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Wheezing	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Cough	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
Phlegm	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an intervention to the health problem the answer is 'yes' then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.**
Continued overleaf.

☐ **No** ☐ **Yes**

15. Have you seen a GP, or had an unplanned admission to hospital about a health problem since your last visit/contact? If yes, what was the health problem? (Write below. Study staff to assess severity and seriousness etc. below)

Health Problem (write in boxes below)	***Severity - has the health problem stopped the participant doing things they would normally do? (tick one box)**	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousness –without an intervention to this health problem, is/was the participant at risk of death, being admitted to hospital, or got a permanent disability?**	**Action taken**
1.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
2.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study
3.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes	☐ None ☐ Stopped product ☐ Withdrawn from study

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an intervention to the health problem the answer is 'yes' then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.**

Session 8: 52-weeks post-quit date (telephone call)

1. Date

D	**D**	**M**	**M**	**M**	**Y**	**Y**

2. Since two weeks after your quit date, have you smoked regular cigarettes at all? (circle ONE)

1. Not a single puff
2. Just a few puffs
3. ≤ 5 cigs in total
4. > 5 cigs in total

2a. If smoked > 5 cigarettes: on average, how many days a week did you smoke since your last contact?

2b. If smoked > 5 cigarettes, how many cigarettes did you smoke per day on average?

cpd

3. Have you smoked regular cigarettes at all in the last 6 months? (circle ONE)

1. Not a single puff
2. Just a few puffs
3. ≤ 5 cigs in total
4. > 5 cigs in total

4. Have you smoked at all in the last 7 days?

☐ **Yes** ☐ **No**

Advisor to calculate reduction (where applicable) in number of cigarettes smoked from the start of the study.

Record baseline CPD from S1 form:

5. Has there been a 50% reduction or more in baseline CPD, or has the participant been abstinent from smoking for the last 6 months?

☐**Yes** ☐**No**

If abstinent since quit date or in the last 6 months, or if ≥ 50% reduction then participant is eligible for validation visit (complete remaining questions over the telephone and book appointment at the end).

6. Have you used your allocated product since your last contact? (If yes, please complete the following).

☐ **Yes** ☐ **No**

			How many days did you use your product per week?	**On average, how many mls of EC liquid, number of cartridges, patches, oral NRT did you use per day?**
☐**EC brand provided OR**	**Brand:**	**Strength:**		
NRT 1	**Product:**	**Strength:**		
NRT 2	**Product:**	**Strength:**		

8. If you stopped using your allocated product since your last visit, what was the main reason? (tick ONE)

☐ **Cost**

☐ **Did not like the taste**

☐ **Adverse reaction (nausea, throat/mouth irritation and/or sleep disturbance – if yes, complete further details on health problems page)**

☐ **Not satisfying**

☐ **Difficult to use**

☐ **Embarrassing to use**

☐ **Difficult to obtain them**

☐ **Smoking normal cigarettes now**

☐ **To quit nicotine**

☐ **Other reason (specify):**

9. Since your last contact how helpful did you find your allocated product(s) (e-cigs or NRT) in keeping you away from normal cigarettes? (circle ONE response on each line, or tick box if they did not use allocated product **at all** since last visit) ☐ **Did not use product since last visit**

	Not at all	Slightly	Somewhat	Very	Extremely
EC	1	2	3	4	5
NRT 1 ***(specify)***	1	2	3	4	5
NRT 2 ***(specify)***	1	2	3	4	5

10. Have you used any other products since your last contact? (if yes, please answer Q10a and 10b) ☐**Yes** ☐**No**

10a. If you used another product, what did you use? (tick ALL that apply)

☐ **EC** ☐ **NRT** ☐ **Varenicline** ☐ **Bupropion**

10b. If you used another product(s), for how many days in a row did you use it?

11. Since your last contact have you purchased any of the following? (tick ALL that apply)

EC device	☐**No** ☐**Yes (approx. how much spent; go to 11a)**	**£**
EC liquid	☐**No** ☐**Yes (approx. how much spent; go to 11b)**	**£**
NRT product(s)	☐**No** ☐**Yes (approx. how much spent; go to 11c)**	**£**

11a. What type of EC device was purchased? (tick ALL that apply)

☐ **A disposable e-cigarette (non-rechargeable)**

☐ **A rechargeable e-cigarette without a 'tank'**

☐ **A rechargeable e-cigarette with a 'tank'**

☐ **A modular system (your own combination of separate parts: battery, atomizer, fluid etc).**

11b. Which strength and flavor EC liquid(s) did you buy?

EC liquid 1: Strength_____% or mg/ml Flavour:_____

EC liquid 2: Strength_____% or mg/ml Flavour:_____

EC liquid 3: Strength_____% or mg/ml Flavour:_____

11c. Which NRT product(s) and strengths did you buy?

NRT Product 1:_____(name) _____ (strength)

NRT Product 2:_____(name) _____ (strength)

NRT Product 3:_____(name) _____ (strength)

12. Have there been any changes to your health conditions or medicines taken since your last contact? ☐ **No** ☐ **Yes** (if yes, update S1 health and medication questions)

13. Completed health problems questions overleaf? (tick box) ☐

14. Completed EQ 5D questionnaire? (tick box) ☐

15. Completed the Health Service Use Questionnaire? (tick box) ☐

16. Eligible for validation visit? (tick ONE) ☐ **No** ☐ **Yes** (if yes, complete q17, 18 and 19)

17. Date of validation visit

D	**D**	**M**	**M**	**M**	**Y**	**Y**

18. Record carbon monoxide in expired breath (ppm) at validation visit

19. Participants attending validation visit only: **payment received and signed for?** (tick box) ☐

20. Since your last contact, have you experienced any of the following health problems? If yes, study staff to assess severity, seriousness and action required.

Health problem	**Has the participant experienced the health problem?**	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousne intervention problem participant a being admitte getting a disa**
Nausea	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes
Sleep disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes
Throat/mouth irritation	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes
Dizziness	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes
Headache	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes

Continued overleaf

Visual disturbances	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes
Shortness of breath	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes
Wheezing	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes
Cough	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes
Phlegm	☐ No ☐ Yes	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an intervention to the health problem the answer is 'yes' then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.**
Continued overleaf.

21. Have you seen a GP, or had an unplanned admission to hospital about a health problem since your last visit? I health problem? (Write below. Study staff to assess severity and seriousness etc. below)

Health Problem (write in boxes below)	***Severity - has the health problem stopped the participant doing things they would normally do?** (tick one box)	****Seriousness – has the participant died, been admitted to hospital, or got a permanent disability due to this health problem?**	****Seriousnes intervention problem, participant at being admitted got a permane**
1.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes
2.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes
3.	☐ No ☐ A little ☐ A lot	☐ No ☐ Hospitalised ☐ Death ☐ Disability	☐ No ☐ Yes

*** If the severity of any health problem is 'a little' or 'a lot' report to and discuss action to be taken with Principal Investigator**
**** If the seriousness of any health problem is 'hospitalised', 'death' or 'disability' or if without an**

intervention to the health problem the answer is ‘yes’ then a Serious Adverse Event form must be completed and forwarded immediately to the Chief Investigator.

Site number:	L	O	N	Participant number:	

Health Questionnaire

English version for the UK

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

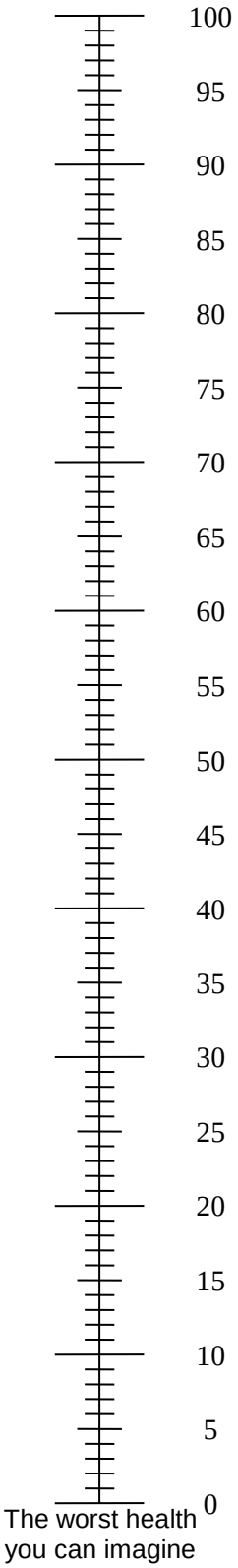
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



SMOKING CESSATION SERVICES AND HEALTH SERVICE USE

To be completed at baseline, 6 and 12 month follow up

Please complete the following questions about smoking cessation help you have received and health care contacts you have made.

Section I: SMOKING CESSATION HELP

Please list the services you have used <u>excluding</u> the six weekly support sessions arranged by our study

Q1. In the last **six months** how many times have you: *(if none insert zero).*

a) Sought help or advice to quit smoking from your GP?

b) Attended a Specialist Smoking Cessation Service?

c) Telephoned the NHS Smoking Helpline service for advice or support?

d) Telephoned any other smoking helpline e.g. Quitline for advice or support?

Section II: SMOKING CESSATION PRODUCTS

EXCLUDING THE SIX WEEKLY SUPPORT SESSIONS ARRANGED BY OUR STUDY:

2.a) In the last six months, have you used e-cigarettes to help you to quit or reduce your smoking?

Yes ☐ Go to Q2b

No ☐ Go to Q3a

2.b) For how long did you use e-cigarettes?

Days ☐

OR weeks ☐

2.c) How many e-cigarettes have you purchased in the last six months?

2.d) How many e-cigarette refills have you purchased in the last six months?

2.e) Approximately how much money have you spent on e-cigarette products in the last six months?

NICOTINE REPLACEMENT THERAPY

EXCLUDING THE SIX WEEKLY SUPPORT SESSIONS ARRANGED BY OUR STUDY:

3.a) In the last six months, have you used Nicotine Replacement Therapy products?

Yes ☐ Go to Q3b

No ☐ Go to Q4a

3.b) Approximately how many of the following did you receive?

Nicotine patches ☐ [packs] Packs received on prescription ☐☐

Packs bought over the counter ☐☐

Nicotine gum ☐ [packs] Packs received on prescription ☐☐

Packs bought over the counter ☐☐

Nicotine tablets (microtab) ☐ [packs] Packs received on prescription ☐☐

Packs bought over the counter ☐☐

Nicotine inhalers ☐ [cartridges] Cartridges received on prescription ☐☐

Cartridges bought over the counter ☐☐

Nicotine lozenges	[packs]	Packs received on prescription	
		Packs bought over the counter	
Nicotine sprays	[bottles]	Bottles received on prescription	
		Bottles bought over the counter	
Nicotine mouth strips	[packs]	Packs received on prescription	
		Packs bought over the counter	

3.c) For how long did you use Nicotine Replacement Therapy on prescription?

Days
OR
weeks

3.d) For how long did you use Nicotine Replacement Therapy purchased over the counter?

days
OR
weeks

3.e) Are you currently using Nicotine Replacement Therapy?

Yes
No

ZYBAN

EXCLUDING THE SIX WEEKLY SUPPORT SESSIONS ARRANGED BY OUR STUDY:

4.a) In the last six months, have you used Zyban to help you to quit smoking?

Yes — Go to Q4b
No — Go to Q5a

4.b) For how long did you use it?

Days
OR weeks

4.c) How many packs have you received?

packs

CHAMPIX

EXCLUDING THE SIX WEEKLY SUPPORT SESSIONS ARRANGED BY OUR STUDY:

5.a) In the last six months, have you used Champix to help you to quit smoking?

Yes — Go to Q5b
No — Go to Q6

5.b) For how long did you use it?

Days
OR weeks

5.c) How many packs have you received?

packs

Section III: GENERAL HEALTH CARE

The following questions relate to contacts with health care services in the previous six months.

6. **In the last six months**: *(if none please enter zero)*

a)	How many times have you visited a hospital A & E dept. as a patient?		
b)	How many times have you visited hospital as an outpatient?		
c)	How many nights have you stayed in hospital as a patient?		
d)	How many times have you visited hospital for a day case (attended hospital for a procedure but have not stayed overnight)?		
e)	How many times have you been taken to hospital by an emergency ambulance?		
f)	How many times have you visited your GP?		
g)	How many times have you seen a practice nurse at a GP surgery?		
h)	How many times has your GP visited you at home?		
i)	How many times has a practice nurse visited you at home?		
j)	How many prescriptions have you received (excluding prescriptions to help you stop smoking)?		