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Research Article

Cost-effectiveness of e-cigarettes for smoking cessation at homeless support centres: SCeTCH cRCT

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Abstract

Background: While smoking is common among those experiencing homelessness, the effectiveness of an e-cigarette intervention to reduce smoking in this population is unclear.

Objective: To determine the cost-effectiveness of providing an e-cigarette for smoking cessation in homeless support centres compared to usual care.

Design and methods: A multicentre two-arm cluster randomised controlled trial, with data collection time points at baseline, 4, 12 and 24 weeks post baseline.

Setting and participants: Adults (aged 18+) who smoked daily and accessed 32 homeless support centres across six areas of Great Britain received either e-cigarette intervention ($n = 239$ in 16 centres) or usual care ($n = 236$ in 16 centres) by centre (cluster) randomisation.

Intervention: The intervention was the provision of an e-cigarette starter kit plus 4 weeks' supply of e-liquids. The usual care comprised very brief advice for smoking cessation and signposting to local Stop Smoking Services.

Main outcome measures: The total costs included costs of intervention/usual care, costs of smoking cessation outside of the trial and costs of general healthcare services use over 24 weeks. Quality-adjusted life-years were derived from EuroQol-5 Dimensions, five-level version administered at each data collection point. An incremental cost-effectiveness ratio was calculated for 24 weeks using the difference between groups in total costs and quality-adjusted life-years, with cost-effectiveness acceptability curve constructed based on bootstrap to examine uncertainty. A long-term model was employed to project a lifetime incremental cost-effectiveness ratio with probabilistic sensitivity analysis to examine uncertainty.

Data sources: The analysis over 24 weeks was based on research team records and data collected via self-reported questionnaires. Unit costs for valuation were extracted from published secondary sources. The parameters of the long-term model were based on the 24-week results and published secondary sources.

Results: Mean intervention costs were estimated at £92 [standard error (SE) £0] per participant and mean usual care costs at £50 (SE £0) per participant. Mean total costs per participant were estimated at £3859 (SE £441) in the e-cigarette group and £2716 (SE £386) in the usual care group. Mean quality-adjusted life-years were estimated at 0.303 (SE 0.008) in the e-cigarette group and 0.295 (SE 0.010) in the usual care group. Adjusting for baseline covariates and respective baseline values, e-cigarette group were £1267 (95% confidence interval £600 to £1938) more costly and yielded 0.007 (95% confidence interval -0.017 to 0.027) more quality-adjusted life-years than usual care. The incremental cost-effectiveness ratio was calculated at £181,000 per quality-adjusted life-year gain, with probability of intervention being cost-effective between the incremental cost-effectiveness ratio thresholds of £20,000–30,000 per quality-adjusted life-year gain at 0.9–3.5%. The lifetime model projected the incremental cost-effectiveness ratio at £38,360 per quality-adjusted life-year gained, with the probability of intervention being cost-effective between £20,000 and £30,000 from 47.6% to 49.6%.

Limitations: The imbalance in missing data led to some uncertainty in the results, and healthcare costs recorded in the trial may not reflect the health needs of this population.

Conclusions: Providing e-cigarettes for smoking cessation in homeless support centres was more costly than usual care, but the small increase in quality-adjusted life-years was not significant.

Future work: Future work should aim to maximise quit rates while being cost-effective and therefore implementable.

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Background

Between 2011 and 2022, the proportion of current smokers among adult population in the UK declined from 20.2% to 11.9%.¹ In contrast to this, a review showed that the prevalence of smoking among people experiencing homelessness ranged between 57% and 82%.² People who experience homelessness have poor health, to which smoking significantly contributes, especially respiratory and lung health outcomes.³ Conservative estimates put costs of secondary and emergency care among people experiencing homelessness four times the level of the general population.⁴ The health inequality between those experiencing homelessness and the general population is evident. There is an urgent need to help people accessing homelessness support to stop smoking so to reduce the inequality gaps.

Behavioural support and nicotine replacement therapy (NRT) has long been proved effective and cost-effective in smoking cessation and has become conventional in the UK.⁵ However, one report shows that while half of the smokers experiencing homelessness expressed wish to quit, only 14% took up the support offered, with the rest either not being offered support or not taking it up.⁶ Since the wide use of e-cigarettes, multiple trials demonstrated that they are effective as a smoking cessation aid in the general population.⁷ One economic evaluation in general population reported an incremental cost-effectiveness ratio (ICER) at £1100 per quality-adjusted life-year (QALY) gain over 12 months and £65 per QALY gain over lifetime, with over 80% probability of being cost-effective against £20,000 per QALY gain threshold in both cases.⁸ Another economic evaluation reported ICER over the 6 months at £7750 per QALY gain

(72% probability of cost-effectiveness at £20,000 threshold) and lifetime ICER at £1131 per QALY (54% probability of cost-effectiveness at £20,000 threshold) in those visiting emergency care department.⁹ However, the prices of e-cigarette (EC) starter kit in the aforementioned studies ranged from £20 to £30 each, in addition to subsequent expenses on e-liquids or replacement accessories, which might put deterrent for those in a financially difficult position. Evidence on the effectiveness of smoking cessation methods remains unclear in those experiencing homelessness,¹⁰ let alone cost-effectiveness.

The Stop Smoking Trial for people experiencing homelessness (SCeTCH) trial was a multicentre two-arm cluster randomised controlled trial comparing the effectiveness and cost-effectiveness of provision of EC starter kit at homeless support centres and usual care (UC) for smoking cessation.¹¹ Taking advantage of the sample size and data collection, a cost-effectiveness analysis was conducted alongside the effectiveness analysis. The effectiveness results are reported elsewhere.¹² The current manuscript presents the results of the cost-effectiveness analysis.

Aim and objectives

The aim of the economic evaluation was to determine the cost-effectiveness of the provision of an EC and e-liquids compared to the offer of UC for smoking cessation in homeless support centres.

Specific objectives were to estimate the costs of the EC intervention in the trial and assess the costs of healthcare

service use following the intervention. Combined with health-related outcome measures, we were to conduct a cost-effectiveness analysis of EC comparing to UC for smoking cessation in homeless support centres from an NHS and Personal Social Services (PSS) perspective. The final objective was to explore the cost-effectiveness of EC comparing to UC from a societal perspective.

Methods

Trial design

The SCeTCH trial was conducted in 32 homeless support centres across six areas of Great Britain. Target sample size was 480 participants in total (15 per centre).

The centres were eligible if they were not exclusively residential, primarily targeting people experiencing homelessness, not already providing EC to potential participants, within 2 hours of travelling distance from the university area, and agreed to be randomised to either group. Centres (clusters) were randomised at 1 : 1 ratio to either EC group or UC group.

In each centre, people were eligible if they were adults (aged 18+), self-reported smokers verified by staff, known to centre staff and willing and able to provide written informed consent. Those who were currently using a smoking cessation aid were excluded. In the centres allocated to the EC group only, those who were allergic to any of the e-liquid ingredients were also excluded. The scheduled data collection time points were baseline, 4, 12 and 24 weeks post baseline.

For detailed information on trial procedures, please see the published protocol.¹¹ The analyses followed a pre-specified analysis plan which is available at <https://osf.io/yhmk9/>.

E-cigarette and usual care costs

The EC group were provided a tank-style refillable EC starter kit (the PockeX device, Shenzhen Eigate Technology Co., Ltd., Shenzhen, Guangdong Province, China), e-liquids (five 10 ml bottles per week) supply for 4 weeks regardless of actual usage, an EC fact/help sheet and a brief introduction session to the use of EC and relevant knowledge. Participants were encouraged to use EC as an aid to quit smoking, but they did not necessarily have to be motivated to quit. Unless they enquired, participants were not actively signposted to local Stop Smoking Service (SSS). As accessories, each participant was also provided with one USB wall plug to charge the device and replacement coils upon request.

The UC group were offered very brief advice plus (VBA+) about smoking cessation from centre staff, a leaflet adapted for this population from 'NHS choices' and signposting to local SSS, to encourage them to seek help about their smoking.

The staff in participating centres in both groups were responsible for delivery and therefore required training beforehand. EC and UC costs included their respective costs of training the trainers, training the staff and delivery.

Costs of training

Twelve trainers, who were members of the research team, attended a 1-day (7 hours) training programme and delivered training to participating staff within 2 weeks before baseline assessments commenced. Centre staff in both groups received education and training course which followed National Centre for Smoking Cessation and Training recommendations.¹³ Staff in the EC group were trained in EC use and introduced to the relevant information needed to deliver the intervention, including a demonstration of the device. Staff in the UC group received information about how to signpost participants to their local SSS.

The number and duration of the training events were recorded. Numbers of trainers and attendees were logged for each occasion. The opportunity costs of time were estimated by multiplying the trainers' and staff's hourly costs by their respective time spent, including travel time for trainers. Costs or prices of materials used during the training were also recorded. Other costs, such as refreshments, venue and accommodation, were added if applicable. Staff and trainers' hourly costs were estimated using their respective salary with an additional 30% to account for salary oncosts.

Costs of delivery

The EC device, e-liquids, USB wall plugs, coils and printing of fact sheets were costed using the prices at which the study acquired them. The quantities of devices, e-liquids and coils given out were originally planned to be logged by centre staff. However, it proved infeasible for them to keep track of this owing to work pressures. We, therefore, used the stock inventory at the end of the intervention period (4 weeks) to estimate the EC-related costs by centres and then allocated evenly to the participants in each centre. The leaflets adapted from 'NHS choice' were costed at the price of printing. The number and duration of introduction sessions in the EC group and VBA+ sessions in the UC group were recorded and costed using duration of session multiplied by staff hourly costs.

Smoking cessation costs

Smoking cessation support received was reported by participants via case report forms (CRFs) administered at baseline, 4, 12 and 24 weeks. This included advice sessions with local SSS, general practitioners (GPs), practice nurses, pharmacists and NHS Stop Smoking Helpline. The unit costs of these services are presented in [Table 1](#).

Quantities of NRT products received by participants on prescription or from SSS/GP free of charge were collected at each time point. The weighted average costs of these products were extracted from English Prescribing Dataset, October 2021 ([Table 2](#)).²³

TABLE 1 Unit costs of smoking cessation and general healthcare services

Service	Unit cost (2021–2)
<i>Smoking cessation services</i>	
Sessions in SSS	£22/session ^{14,15,16}
GP	£38/session ^{14,17}
Practice nurse	£8/session ^{14,17}
Pharmacist	£5/session ^{14,17}
NHS Stop Smoking Helpline	£8/call ^{14,18,19}
<i>General healthcare services</i>	
A&E attendance	£113/attendance ²⁰
A&E admission	£303/admission ²⁰
A&E visit (admission unspecified)	£247/visit ²⁰
Outpatient	£165/appointment ²⁰
Inpatient	£4845/episode ²⁰
Daycase	£1038/episode ²⁰
Ambulance to the scene	£268/occasion ²⁰
Ambulance to hospital	£390/journey ²⁰
GP	£38/consultation ¹⁴
Practice nurse	£13/consultation ^{14,21}
Prescription	£20/prescription ²²
Drug and Alcohol service	£81/contact ²⁰
Adult mental health team	£276/contact ²⁰
Crisis team	£117/contact ²⁰
Housing team	£21/contact ¹⁴
A&E, accident and emergency.	

General healthcare costs

Following National Institute for Health and Care Excellence (NICE) guidance,²⁵ general healthcare service utilisation data were collected using a service use questionnaire (piloted in the feasibility study and revised accordingly afterwards).²⁶ The questionnaire was part of the self-reported CRFs at baseline, 4-, 12- and 24-week follow-ups. The services included primary and community care services, secondary and emergency care services and social care. Quantities reported were multiplied by a set of national average unit costs derived from public sources.^{14–22} Services and their respective unit costs are presented in [Table 1](#).

Participants’ spending and lost income

Participants’ purchases of NRT products, EC, e-liquids and other accessories (outside of those provided by the trial) were collected in CRFs at baseline, 4-, 12- and 24-week follow-ups. The quantities of NRT products purchased were collected. We used the quantities and associated average prices from a shopping website (Sainsbury’s grocery) to estimate participants’ spending on NRT. Consumer Price Inflation Index²⁴ was used to deflate the prices from current year (2024) to 2021–2 (see [Table 2](#)). Participants’ spending on EC-related purchases could not be estimated due to an error in CRFs, which only asked whether purchases were made without quantity information. The weekly average spending on tobacco-related products and the payment for travelling to receive health care were collected. Hours off paid work due to ill health were combined with national minimum wage²⁷ of 2021 to estimate the lost income. The stipulated minimum wage was £6.56 per hour for employees aged 18–20, £8.36 per hour for employees aged 21–22, and £8.91 per hour for employees aged 23 and over.

Effectiveness

Quality of life

EuroQol-5 Dimensions, five-level version (EQ-5D-5L)²⁸ was administered as a part of the CRFs at baseline, 4-, 12- and 24-week follow-ups. It consists of five domains and a visual analogue scale (VAS). The mapping function recommended by the latest NICE guidance was used to convert complete profiles to utility values.^{25,29} Using area under the curve approach,³⁰ the utility values at multiple time points were used to derive QALYs. The VAS values participants’ self-perception of overall health on the day of administering, ranging from 0 (worst imaginable health) to 100 (best imaginable health).

Smoking cessation outcomes

Participants were defined as sustained carbon monoxide (CO)-validated abstainers if, to the question ‘in the last

TABLE 2 Unit costs and estimated prices of NRT products

NRT	Costs per package (2021–2) ²³	Estimate prices per package (2021–2)	Sources for estimated prices
Patch	£11.07/package	£12.46/package	Average prices on Sainsbury's grocery online store, deflated using CPI ²⁴
Gum	£12.80/package	£14.63/package	
Tablet (microtab)	£14.88/package	£16.50/package	
Inhaler	£0.84/cartridge	£22.23/20-cartridge; £1.11/cartridge	
Lozenge	£9.77/package	£14.25/package	
Nasal spray	£15.81/bottle	£24.37/bottle	
Mouth spray	£14.05/bottle	£18.39/bottle	

CPI, Consumer Price Inflation Index.

2 weeks/2 months/3 months, have you smoked regular cigarettes/roll-ups at all? (tick ONE; note: please include tobacco with other substances, e.g. cannabis)', they reported 'not a puff' or 'just a few puffs' at all three follow-ups, and each accompanied by a CO reading < 8 ppm. Participants who reported smoking no more than five cigarettes in total and had CO reading < 8 ppm at all follow-ups were also defined as abstainers. If CO readings or information on the number of cigarettes smoked was missing, they were considered non-abstainers.

Self-reported sustained abstinence was defined similarly as above but without requirements of CO readings. Self-reported 7-day point prevalence abstinence was defined as a self-report of smoking 'not a puff' or 'a few puffs' of regular cigarettes/roll-ups or zero cigarettes or joints per day in the last 7 days. This measure was collected at 4-, 12- and 24-week follow-ups.

Participants lost to follow-up were considered non-abstainers.¹¹

Missing data

Missing data for smoking status were handled as described in smoking cessation outcomes. Missing values at baseline assessment were expected to be rare and unrelated to the intervention and therefore imputed by the mean of the measure of the pooled sample of both groups.³¹ Missing values at follow-ups were handled using multiple imputation with chained equations, following Rubin's rule and assuming missing at random (MAR).³² The association of missingness of each measure with group allocation and baseline covariates, and with observed values of the same measure at other follow-ups, was examined using statistical tests (univariate logistic regression for continuous and binary variables, χ^2 tests for discrete

variables). An imputation model was developed, including all the measures necessary to the analysis or associated with missingness identified by the statistical tests. The number of imputations was set as approximately the highest percentage figure of the missing data.³¹ The imputation was performed by allocation group. Unless otherwise specified, all analyses were performed on multiple imputed data.

Analysis

All analyses were carried out following an intention-to-treat principle. While the appropriate currency year is 2022–3 Great British pounds, multiple public sources of service costs were unavailable for this year at the time of analysis. We therefore presented all monetary outcomes in 2021–2 Great British pounds.

Primary analysis

The primary analysis was an incremental cost-effectiveness analysis of the EC intervention over and above UC, from the NHS and PSS perspective over the 24-week trial period, following the reference case of NICE guidance.²⁵ Total costs included costs of EC/UC, smoking cessation advice and NRT prescription outside of the study, emergency and secondary care, and primary and community care over 24 weeks. The effectiveness measure was QALYs. No discounting was applied to either costs or QALYs, as the trial period was shorter than 1 year. Using stepwise approach and comparing the likelihood of models ($\alpha = 0.05$), a mixed-effects generalised linear regression model was selected to estimate the incremental costs and QALYs by the EC group over the UC group. The incremental costs were estimated adjusting for gender, pre-existing chronic illness or mental health conditions (none, either or both), smoking cessation and healthcare costs at baseline as fixed effects, and centre as random effects. The incremental QALYs were estimated

adjusting for Fagerstrom Test for Cigarette Dependence (FTCD) at baseline, pre-existing chronic illness or mental health conditions, EQ-5D-5L utility at baseline as fixed effects, and centre as random effects. The ICER was calculated by dividing incremental costs by incremental QALYs. The ICER was compared against the maximum acceptable ICER thresholds of £20,000–30,000 per QALY, as suggested by NICE.²⁵

Uncertainty surrounding the point estimate was assessed using non-parametric bootstrap re-sampling technique.³³ Validity of estimates generated by this technique does not depend upon any specific form of underlying distribution. We used the bootstrap to generate 5000 replicates of sample with replacement to create a distribution for incremental costs and QALYs, respectively. The regression model used remained the same as the point estimate without stepwise selection of covariates for each replicate. The 95% CIs for incremental costs and QALYs based on the bootstrapping results were derived using the 2.5th and 97.5th percentiles of the respective distribution. Cost-effectiveness acceptability curves (CEACs)³⁴ were constructed using the bootstrap iterations to estimate the probability that EC was cost-effective at different threshold values, compared to UC.

Sensitivity analyses

To assess the impact of missing data, a complete-case analysis (CCA) was undertaken following the same approach as the primary analysis, but only on those who had complete data on both costs and QALYs at all time points as well as the baseline covariates needed in the regression model.

To examine the MAR assumption, sensitivity analyses were carried out using pattern mixture modelling.³⁵ This method assumes that data are missing not at random (MNAR) and sets rules for imputing to reflect this assumption. In the current analysis, we assumed that those who had missing values at follow-ups either needed more health care or experienced worse health, or both at the same time. To examine how these scenarios affected the results based on MAR assumption, the incremental costs and QALYs were re-estimated based on data with (1) imputed costs were increased by 10%, 20% and 30%; (2) imputed EQ-5D-5L utility values were reduced by 10%, 20% and 30%; (3) the combination of (1) and (2).

Secondary analyses

A set of secondary analyses using smoking cessation outcomes as an effectiveness measure were undertaken to provide a comparable figure with existing literature. The costs of smoking cessation included costs of treatment

(EC and UC, where applicable), smoking cessation advice and NRT prescription. The analyses presented a set of cost per quitter by each outcome measure.

A further secondary analysis was undertaken as an incremental cost-effectiveness analysis over the 24-week trial period from a societal perspective. In addition to the costs included in the primary analysis, the societal perspective also included participants' spending on NRT, tobacco and lost income due to illness. The effectiveness measure remained QALYs. No discounting was applied to either costs or QALYs. As in the primary analysis, the incremental costs were estimated using a mixed-effects regression model, with centres as random effects and allocation group and baseline covariates as fixed effects. An ICER was calculated by dividing the adjusted incremental total societal costs by the adjusted incremental QALYs. The 95% CIs and CEACs were constructed following bootstrapping 5000 replicates as described in the primary analysis. However, as there is no authoritative maximum acceptable ICER threshold from the societal perspective, no conclusion could be drawn from this analysis.

Finally, quitting smoking has been demonstrated to reduce the risks of developing smoking-related diseases later in life.^{36–38} The long-term benefits of quitting may not be fully captured by clinical trials given the short follow-up periods. Therefore, a decision-analytic model, adapted from a model developed by several of the coauthors,³⁹ was employed to project the lifetime cost-effectiveness of the EC compared to UC from secondary care services perspective. The overall assumption is that after the initial (study) intervention, participants would not receive further smoking cessation interventions or aids in their lifetimes.

The model used in the analysis is a three-state Markov model based on 1-year cycles, considering the potential transitions among smokers, ex-smokers and deaths (*Figure 1*). The cycles run until all individuals enter the death state or reach 90 years, which is considered lifetime. Each state is associated with corresponding age- and gender-specific EQ-5D utilities,⁴⁰ and smoking-attributable secondary care costs over 1 year. Smoking-attributable costs were estimated using incidence and relative risks, hospital episodes and inpatient costs of smoking-related diseases inflated to the analysis year.^{14,41–43} The mortality rates of the homeless population were derived from the 2021 census and the registrations of deaths of homeless people in England and Wales.^{44,45} These rates were then combined with the relative risks of smoking-related mortality to estimate the mortality rates for smokers and ex-smokers within this population.⁴⁶ Given the low quit rates observed in the homeless population in this trial,

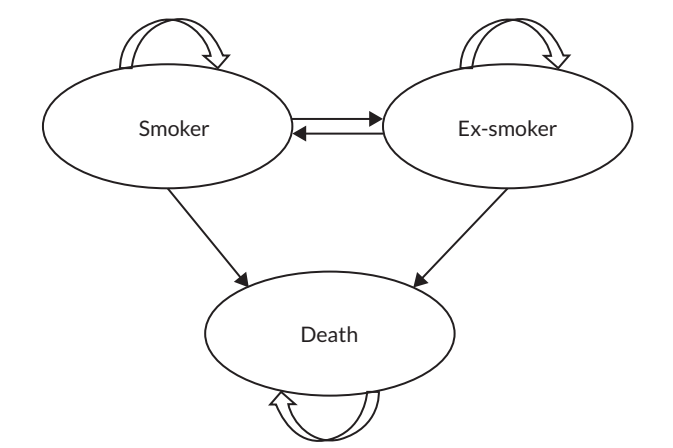


FIGURE 1 The Markov model structure.

the model did not consider spontaneous quitting without any smoking cessation aids after the initial treatment.⁴⁷ The relapse rate of 10% following cessation of smoking was applied for the first 10 years.^{48,49} If an ex-smoker does not relapse for 10 years, they are assumed to be lifetime abstinent. The transition probabilities are presented in [Table 3](#). A discount rate of 3.5% per annum was applied to all costs and QALYs.²⁵ A probabilistic sensitivity analysis

TABLE 3 Transition probabilities in the Markov model

Parameters	Probability	
Probability of relapse for the first 10 years ^{48,49}	10%	
Age group	Male	Female
Mortality among smokers^{44,45,50}		
40–44	10.6%	9.1%
45–49	21.8%	7.1%
50–54	21.1%	5.6%
55–59	21.2%	3.6%
60–64	20.3%	16.4%
65–69	37.3%	7.4%
70 and over	8.7%	16.0%
Mortality among ex-smokers^{44,45,50}		
40–44	7.8%	6.8%
45–49	13.9%	4.5%
50–54	13.4%	3.5%
55–59	13.6%	2.3%
60–64	13.0%	10.5%
65–69	22.3%	4.4%
70 and over	5.2%	9.6%

was conducted using Monte Carlo simulation to assess the uncertainty of the model parameters. For more details on the original model, please see the published article.³⁹

The model cohort of 1000 was specified with the study sample mean age and gender proportion. The results from the primary analysis, including the abstinence rate, mean costs and mean QALYs for each group during the trial period, were entered to define the conditions for the initial cycle in the model. The estimated ICER was compared to maximum acceptable ICER thresholds. The uncertainty surrounding the estimated lifetime ICER was presented in a CEAC based on the results of probabilistic sensitivity analysis.

All analyses but the lifetime modelling was performed in Stata MP18.0 (StataCorp LP, College Station, TX, USA). The lifetime modelling was performed in Microsoft Excel (Microsoft Corporation, Redmond, WA, USA).

Results

A total of 477 participants were randomised (239 EC vs. 238 UC). Excluding one participant who died during the follow-up period and one who withdrew their consent for any data to be used, 239 participants in 16 centres in the EC group and 236 participants in 16 centres in the UC group were included in analyses. Males made up 81% (193/239) of the EC group and 86% (202/236) of the UC group. Apart from the binary identification, one participant identified as non-binary, and one as transgender in the EC group and one participant in the UC group preferred not to say. Three participants had missing values on age. The mean age was 42.1 [standard deviation (SD) 11.0] years in the EC group (*n* = 237) and 45.3 (SD 12.2) years in the UC group (*n* = 235).

Costs

E-cigarette/usual care costs

E-cigarette/UC costs included their respective costs of training the trainer event, staff training events and delivery (staff time and materials used during delivery). Twelve staff were involved in training the trainer event, whose hourly costs ranged from £21.98 to £52.75 ([Table 4](#)). The opportunity costs of trainers’ time in receiving their training were estimated at £2865 in total. Allocating equally to all participants, it resulted in £6 per participant.

[Table 5](#) presents the estimation of costs of staff training and EC/UC session delivery. The mean duration of training was longer in the EC group while trainers travelled farther

TABLE 4 Staff costs of training the trainer events

	Annual pay + 30% salary oncosts ^a	Hourly costs	Number of staff	Staff costs of training the trainer
Grade 5	£40,000	£21.98	1	£153.85
Grade 6	£48,000	£26.37	3	£553.85
Grade 7	£54,000	£29.67	1	£207.69
Grade 8	£66,000	£36.26	5	£1269.23
Grade 10	£81,000	£44.51	1	£311.54
Grade 11	£96,000	£52.75	1	£369.23
Total				£2865
Average per participant (N = 475)				£6

^a With approximate reference to the pay grade of University of York.

TABLE 5 Costs of staff training and treatment delivery

	EC		UC	
Staff training	Staff hours	N = 239	Staff hours	N = 236
Staff time in training sessions	2.3 hours/centre	£7847	1.8 hours/centre	£5735
Trainers time in travelling	1.8 hours/trainer	£2580	2.2 hours/trainer	£2916
Refreshments, travel and hotel	–	£1179	–	£1324
Total		£11,607		£9975
Average per centre		£725 (SD £300)		£623 (SD £310)
Average per participant		£49		£42
Delivery – sessions	Staff hours	N = 238	Staff hours	N = 225
Centre staff per centre	3.6 hours/centre	£101 (SD £45)	0.9 hours/centre	£19 (SD £16)
Research team members per centre	0.2 hours/centre	£6 (SD £9)	0.3 hours/centre	£8 (SD £8)
Total		£1715		£442
Average per centre		£107 (SD £46)		£28 (SD £15)
Average per participant		£7 (SD £3)		£2 (SD £1)
Devliery – EC related ^a	Unit	N = 239	–	–
EC device	Per centre	£209 (SD £17)	–	–
E-liquids	Per centre	£171 (SD £47)	–	–
USB wall plugs	Per centre	£45 (SD £4)	–	–
Coils	Per centre	£20 (SD £22)	–	–
Total	16 centres	£7109	–	–
Average per centre		£444 (SD £58)	–	–
Average per participant		£30 (SD £3)	–	–
Leaflets/factsheets	Quantity	N = 239	Quantity	N = 236
Printing	270 copies	£92	270 copies	£49
Average per participant		£0.34		£0.17

^a Excluding 20% VAT as per NICE guidance.¹⁴

in the UC group. Due to incomplete or missing keyworker logs, the treatment delivery information was only available for 225 participants in the UC group and 238 in the EC group. The duration of session delivery was much longer in the EC group.

For details of estimation of EC and UC, please see [Appendix 1](#).

Smoking cessation costs

Among those who completed the CRF at each time point, very few participants reported use of smoking cessation services (see [Appendix 2, Table 13](#)). Mean costs of NRT prescription were £0.00 (SD £0.05) for inhaler in the UC group at baseline at the lowest and £4.19 (SD 22.98) for patches in the UC group at week 24 at the highest (see [Appendix 2, Table 14](#)).

General healthcare costs

[Appendix 3](#) presents the number of participants who reported any healthcare service use and their respective mean number of use and costs in each group. The mean costs of secondary and emergency care [accident and emergency (A&E), hospital-based care and ambulance] and of primary and community care (GP-based care, drug and alcohol service, adult mental health team, crisis team and housing team) are presented in [Table 6](#).

Participants’ spending and lost income

Participants’ spending included purchases of NRT products and tobacco-related products, and travel fares to receive health care. The purchase of NRT products were very rare in both groups (see [Appendix 4, Table 21](#)). This led to negligible mean spending on NRT products in both groups. In contrast, the average spending on tobacco-related products was considerably higher ([Table 7](#) and see [Appendix 4, Table 22](#)). The spending on travelling to receive care was also negligible.

Although we were unable to estimate spending on EC-related products, the number of participant-reported purchases is presented in [Appendix 4, Table 23](#). Contrary to the increase in the number of participants who reported purchasing EC-related products in the EC group from baseline to 24 weeks, this number in the UC group was consistent over the time. However, it should be kept in mind that these only covered those who were followed up.

At baseline, only 11 participants in the EC group and 13 in the UC group were in paid employment or self-employment. Very few participants reported taking leave from paid work due to ill health. The lost income due to ill health was therefore, on average, very low in each group (see [Appendix 4, Table 24](#)).

TABLE 6 Mean costs of secondary and emergency care and primary and community care at all time points by group

Costs	EC (n = 239)		UC (n = 236)	
	N	Mean (SD)	N	Mean (SD)
Baseline				
Secondary and emergency care	238	£567 (£2418)	232	£582 (£2216)
Primary and community care	239	£520 (£1156)	233	£403 (£1167)
Week 4				
Secondary and emergency care	190	£316 (£1173)	154	£352 (£1876)
Primary and community care	190	£507 (£772)	155	£199 (£281)
Week 12				
Secondary and emergency care	156	£494 (£1812)	125	£587 (£2354)
Primary and community care	155	£507 (£772)	126	£343 (£631)
Week 24				
Secondary and emergency care	160	£1157 (£4801)	111	£416 (£2651)
Primary and community care	159	£997 (£2085)	109	£849 (£2132)

TABLE 7 Mean participants' spending (SD) over the data collection period at each time point by group

Participants' spending over specified period	EC (n = 239)		UC (n = 236)	
	N	Mean (SD)	N	Mean (SD)
On NRT products				
Week 4–baseline	239	£0.86 (£8.43)	236	£0.15 (£1.65)
Baseline–week 4	190	£0.52 (£7.11)	155	£0.52 (£3.42)
Week 4–week 12	156	£0.32 (£3.99)	126	£0.61 (£4.69)
Week 12–week 24	162	£0.70 (£4.87)	111	£0.35 (£2.79)
On tobacco-related products				
Week 4–baseline	238	£428.85 (£479.30)	235	£411.08 (£439.00)
Baseline–week 4	170	£261.65 (£247.17)	149	£287.95 (£331.50)
Week 4–week 12	141	£988.26 (£1038.64)	121	£1142.29 (£1062.41)
Week 12–week 24	148	£2471.82 (£2563.61)	107	£2634.46 (£2155.71)
On travelling to receive care				
Week 4–baseline	238	£0.79 (£3.50)	233	£1.77 (£7.39)
Baseline–week 4	190	£0.93 (£5.37)	155	£0.88 (£3.69)
Week 4–week 12	155	£1.38 (£6.81)	125	£1.17 (£4.79)
Week 12–week 24	162	£1.10 (£6.07)	111	£4.62 (£29.37)

Effectiveness

Quality of life

The mean utility value derived from EQ-5D-5L of participants who had complete profile of the five domains remained above 0.6 among those followed up in both groups at all time points (see [Appendix 5](#), [Table 25](#)). [Appendix 5](#) presents further details of EQ-5D-5L pattern.

Smoking cessation outcomes

The CO-validated sustained abstinence at week 24 was 2.09% in the EC group and 0.85% in the UC group. The self-reported 7-day point prevalence of abstinence in the EC group was 8.37% at week 4, dropped to 4.60% at week 12 and rose to 6.28% at week 24. In the UC group, it was 2.54% at week 4 and 12, then dropped slightly to 2.12% at week 24, consistently lower than in the EC group. The self-reported sustained abstinence was the same as the CO-validated sustained abstinence at week 24 (see [Appendix 6](#)).

Missing data

Most missing data were due to participants not completing any of the sections of the CRFs. Single items missing were present but rare. Participants returned to follow up even if they missed the previous one. Missing data were more

prominent in the UC group than in the EC group, as by week 24 over half of the UC group were lost to follow-up (see [Appendix 7](#)).

The missing values at baseline were first imputed with the mean of the respective variable across the whole sample, except for EC/UC costs. The costs of EC/UC were imputed with the mean values within the same centre (cluster). Upon examining the missing data (see [Appendix 7](#)), the imputation model was developed to include the baseline covariates (age, gender, whether chronic illness or mental health conditions exist, drug use status, FTCD and centre), costs of EC and UC, cost variables (smoking cessation advice, NRT prescription, emergency and secondary care, primary and community care), EQ-5D-5L utility and VAS, participants' spending (NRT, cigarettes and travelling to receive care) and their lost income due to ill health. Except for baseline covariates, all were collected at baseline, week 4, 12 and 24. In addition, CO-validated sustained abstinence at week 24 was also included. The imputation approach was predictive mean matching with 10 closest neighbours to draw from. Due to too few non-zero observations available in participants' spending and lost income, the set of predictors used in each imputation varied. Cost variables and participants' spendings and lost income were therefore not used to predict each other.

The highest percentage of missing was 46% of spending on cigarettes at week 24. The number of imputations was therefore set at 46.

Analysis

Primary analysis

The costs of EC were estimated at £92 (SE £0) per participant and that of UC was estimated at £50 (–) per participant (Table 8). The total costs were estimated at £3859 (SE £441) per participant in the EC group and £2716 (SE £386) per participant in the UC group. The adjusted incremental costs were £1267 (95% CI £600 to £1938). The mean QALYs were estimated at 0.303 (SE 0.008) in the EC group and 0.295 (0.010) in the UC group. The adjusted incremental QALYs were 0.007 (95% CI –0.017 to 0.027). The ICER was calculated at £181,000 per QALY gain, much higher than the upper limit of maximum acceptable ICER threshold of £30,000 per QALY gain. Figure 2 presents the CEAC of the primary analysis, showing the probability of EC being cost-effective at 0.9–3.5% between £20,000 and

£30,000 per QALY gain. For detailed results and additional information, please see Appendix 8.

Sensitivity analyses

In total, 106 participants (44%) in the EC group and 77 participants (33%) in the UC group had complete costs and QALYs at all time points. Contrary to the primary analysis, at baseline, both the mean costs and mean EQ-5D-5L utility appeared higher in the UC group than in the EC group (Table 9). The complete cases in the EC group showed lower mean estimates of both costs and QALYs than in the primary analysis, while the reverse was observed for those in the UC group.

Given the limited number of participants remaining in some centres (cluster), the centre as random effects was removed from the generalised linear regression model. The resulting adjusted incremental costs were £1023 (95% CI –£100 to £1823) and adjusted incremental QALYs were 0.010 (95% CI –0.021 to 0.035). The positive incremental QALYs by the EC group, despite the lower mean QALYs,

TABLE 8 Results of primary analysis

	EC (n = 239)	UC (n = 236)
Baseline	Mean (SE)	
Total costs	£1096 (£184)	£988 (£162)
Trial period	Mean (SE)	
Costs of EC/UCs	£92 (£0)	£50 (–)
Cost of smoking cessation advice	£13 (£3)	£25 (£5)
Costs of NRT prescription	£5 (£2)	£12 (£4)
Costs of emergency and secondary care	£1898 (£385)	£1173 (£324)
Costs of primary and community care	£1851 (£194)	£1456 (£185)
Total costs	£3859 (£441)	£2716 (£386)
EQ-5D-5L utility	Mean (SE)	
Baseline	0.621 (0.020)	0.603 (0.022)
Week 4	0.648 (0.023)	0.623 (0.025)
Week 12	0.656 (0.024)	0.640 (0.031)
Week 24	0.677 (0.023)	0.662 (0.030)
QALYs	0.303 (0.008)	0.295 (0.010)
Adjusted incremental	Mean (95% CI)	
Incremental costs	£1267 (£600 to £1938)	
Incremental QALYs	0.007 (–0.017 to 0.027)	
ICER	£181,000 (uncertainty see Figure 2)	

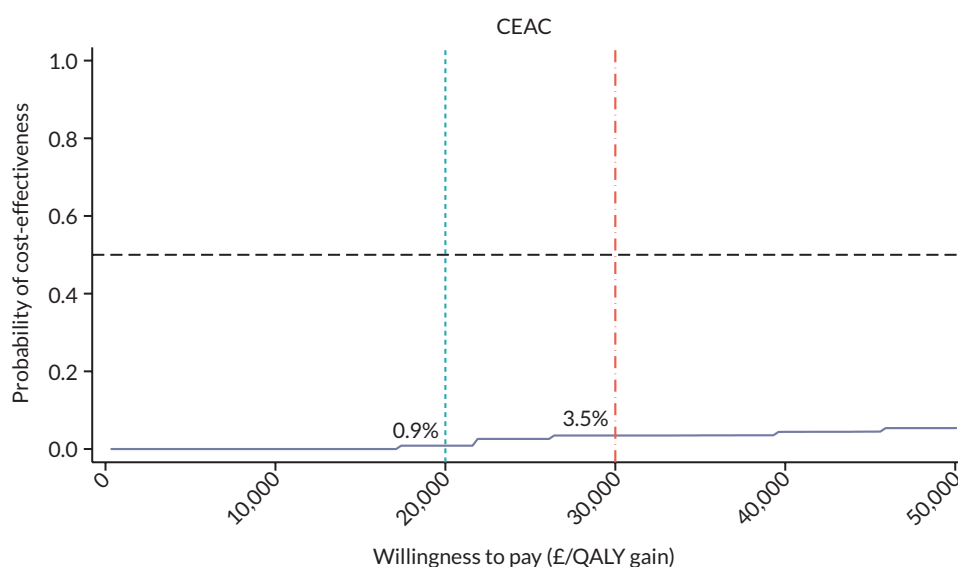


FIGURE 2 Cost-effectiveness acceptability curve of the primary analysis.

TABLE 9 Results of primary analysis and CCA

	Primary analysis		CCA	
	EC (n = 239)	UC (n = 236)	EC (n = 106)	UC (n = 77)
Baseline	Mean (SE)			
Total costs	£1096 (£184)	£988 (£162)	£861 (£177)	£1040 (£359)
EQ-5D-5L utility	0.621 (0.020)	0.603 (0.022)	0.603 (0.032)	0.645 (0.038)
Trial period	Mean (SE)			
Total costs	£3859 (£441)	£2716 (£386)	£3197 (£464)	£2805 (£897)
QALYs	0.303 (0.008)	0.295 (0.010)	0.301 (0.013)	0.310 (0.015)
Adjusted incremental	Mean (95% CI)			
Incremental costs	£1267 (£600 to £1938)		£1023 (–£100 to £1823)	
Incremental QALYs	0.007 (–0.017 to 0.027)		0.010 (–0.021 to 0.035)	
ICER	£181,000 (uncertainty see Figure 2)		£102,300 (uncertainty see Figure 3)	

was accounted for by the lower baseline value and sharper rise of the utility values. [Figure 3](#) illustrates that the probability of EC being cost-effective, comparing to UC, was 10.9–17.3% between £20,000 and £30,000 per QALY gain thresholds. The conclusion is consistent with that of the primary analysis.

Under the MNAR assumption, the increase in adjusted incremental costs with imputed cost increase were negligible ([Table 10](#)). On the other hand, with imputed utility decrease, the adjusted incremental QALYs became larger. The ICER range under the MNAR assumption

was £70,444 per QALY gain to £115,545 per QALY gain. Both were lower than the estimated £181,000 per QALY gain under the MAR assumption in the primary analysis, but still much higher than the maximum acceptable ICER thresholds.

Secondary analyses

Costs per quitter

Costs of smoking cessation over the 24 weeks were £110 (SE £4) in the EC group and £87 (SE £8) in the UC group. The 24-week CO-validated sustained abstinence rate

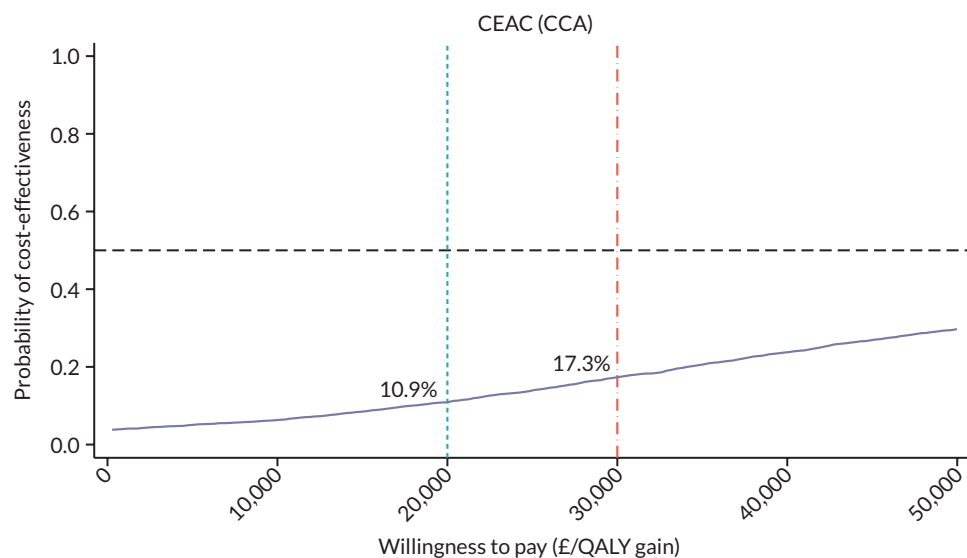


FIGURE 3 Cost-effectiveness acceptability curve of the CCA.

TABLE 10 Incremental costs and QALYs re-estimated based on MNAR assumptions

Mean (SE)	Total costs		QALYs	
	EC (n = 239)	UC (n = 236)	EC (n = 239)	UC (n = 236)
Primary analysis	£3859 (£441)	£2716 (£386)	0.303 (0.008)	0.295 (0.010)
Incremental	£1267		0.007	
	Scenario (1)		Scenario (2)	
	Imputed costs increased by 10%		Imputed utility decreased by 10%	
Mean (SE)	£3973 (£456)	£2836 (£398)	0.294 (0.008)	0.283 (0.009)
Incremental	£1268		0.011	
	Imputed costs increased by 20%		Imputed utility decreased by 20%	
Mean (SE)	£4088 (£473)	£2957 (£411)	0.286 (0.008)	0.271 (0.009)
Incremental	£1270		0.014	
	Imputed costs increased by 30%		Imputed utility decreased by 30%	
Mean (SE)	£4203 (£491)	£3077 (£425)	0.277 (0.008)	0.259 (0.009)
Incremental	£1271		0.018	

was 2.09% (SE 0.93%) in the EC group and 0.85% (SE 0.60%) in the UC group. The costs of smoking cessation per CO-validated 24-week sustained abstinence were £5260 (SE £2286) in the EC group and £10,310 (SE £7208) in the UC group. EC group cost £1743 more on smoking cessation to achieve one additional CO-validated abstainer at 24 weeks. The probability of EC being cost-effective reached 50% at around £2450 for an additional CO-validated abstainer and then plateaued at 90.8% from £9900 onwards (*Figure 4*).

As the self-reported sustained abstinence was the same as CO-validated sustained abstinence, the costs per self-reported abstinence were the same as above. *Figure 5* illustrates the 7-day quit rate and the corresponding costs per quit at each follow-up. In the UC group, the costs per quitter rose over time. In the EC group, the costs per quitter peaked at week 12, reflecting the lower quit rate at this time point compared with at 4 and 24 weeks (for details, see *Appendix 9*).

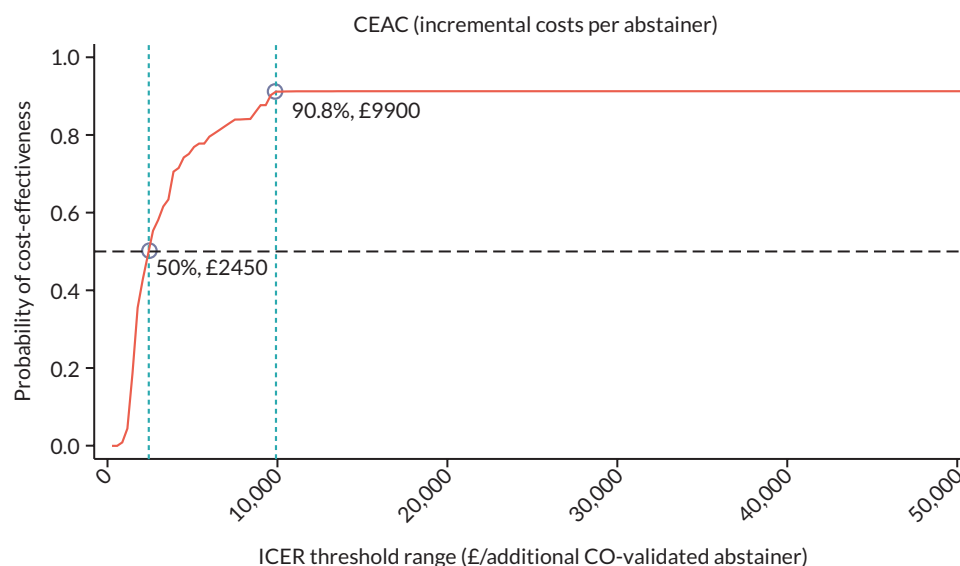


FIGURE 4 Cost-effectiveness acceptability curve for incremental cessation costs per additional CO-validated abstainer.

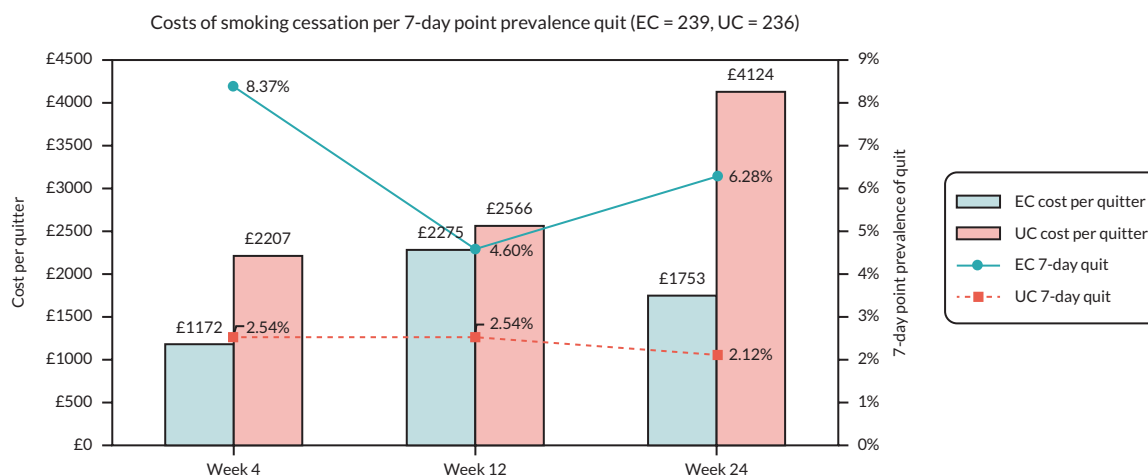


FIGURE 5 Costs per 7-day point prevalence quitter at week 4, 12 and 24 by group.

Incremental cost-effectiveness analysis from a societal perspective

Overall, the spending and lost income was mostly constituted by spending on tobacco ([Table 11](#) and see [Appendix 9, Table 34](#)). The incremental total societal costs were estimated using mixed-effects generalised linear regression model, adjusting for existing chronic illness or mental health conditions and total societal costs at baseline as fixed effects and centre as random effects. The resulting adjusted incremental total societal costs were £674 (95% CI –£256 to £2040). The ICER was calculated at £96,286 per QALY gain. [Figure 6](#) illustrates the probability of EC being cost-effective at ICER thresholds from £0 to £50,000 per QALY gain at £10,000 intervals.

Long-term cost-effectiveness extrapolation

The lifetime cost-effectiveness of EC compared to UC was estimated using the Markov model that utilised input parameters from both the literature and the trial, as shown in [Table 3](#) and [Appendix 9, Table 35](#). As the CO-validated sustained abstinence was the same as the self-reported one, the results projected from them were identical.

Compared to UC, the EC was associated with incremental costs of £1142 per person while yielding an additional 0.030 QALYs over the lifetime horizon ([Table 12](#)). The lifetime ICER was calculated at £38,360 per QALY gain, with the probability of the EC being cost-effective between ICERs of £20,000 and £30,000 ranging from 47.6% to 49.6% ([Figure 7](#)).

TABLE 11 Results of incremental cost-effectiveness analysis from a societal perspective

	EC (n = 239)	UC (n = 236)
Baseline	Mean (SE)	
Spending on NRT	£1 (£1)	£0 (£0)
Spending on tobacco	£429 (£31)	£411 (£29)
Spending on travelling to receive care	£1 (£0)	£2 (£0)
Lost income	£0 (£0)	£8 (£6)
Total spending and lost income	£430 (£31)	£421 (£30)
Total NHS/PSS costs	£1096 (£184)	£988 (£162)
Total societal costs	£1527 (£186)	£1409 (£165)
Trial period	Mean (SE)	
Spending on NRT	£1 (£1)	£1 (£1)
Spending on tobacco	£3707 (£230)	£4187 (£243)
Spending on travelling to receive care	£3 (£1)	£7 (£2)
Lost income	£12 (£10)	£13 (£9)
Total spending and lost income	£3724 (£231)	£4208 (£242)
Total NHS/PSS costs	£3859 (£441)	£2716 (£386)
Total societal costs	£7583 (£485)	£6924 (£453)
EQ-5D-5L	Mean (SE)	
QALYs	0.303 (0.008)	0.295 (0.010)
Adjusted incremental estimates	Mean (95% CI)	
Incremental costs	£674 (–£256 to £2040)	
Incremental QALYs	0.007 (–0.017 to 0.027)	
ICER	£96,286 (uncertainty see Figure 6)	

Discussion

From April 2021 to March 2022, the NHS SSS reported a median costs per quitter of £601, ranging from £23 to £6192.¹⁶ The definition of quit was defined as self-reported sustained abstinence for the past 2 weeks at 4-week follow-up. Our study reported smoking cessation costs per self-reported 7-day point prevalence of quit at £1172 (SE £247) in the EC group and £2207 (SE £888) in the UC group at week 4. While they are within the range of costs from SSS, they are much higher than the median values. As the period of sustained abstinence measured in the study was only half of that measured by the NHS SSS, the comparable figures in our study might be higher than reported above. Despite seemingly moderate average smoking cessation costs per participant, the low quit rates in our study led to a substantial cost per quitter.

The results of the within-trial cost-effectiveness analysis from the NHS/PSS perspective and the long-term model projection both indicate that it is unlikely that the EC was cost-effective when compared to the UC in the current trial setting and population. For within-trial analysis, the choice of cost scope and QALY as effectiveness measure was outlined by the NICE guidance,²⁵ but the short follow-up period of 24 weeks might have limited the sensitivity with respect to the effects of stopping smoking which are not realised immediately. However, with such low quit rates in both groups, the impact of the few successful quitters was likely negligible at a group level.

As for the projections of the long-term model, the less-than-favourable results could be attributed to the very low quit rate at the beginning of the projection cycle and the high mortality rates in the homeless population, with about 80% of the model cohort having

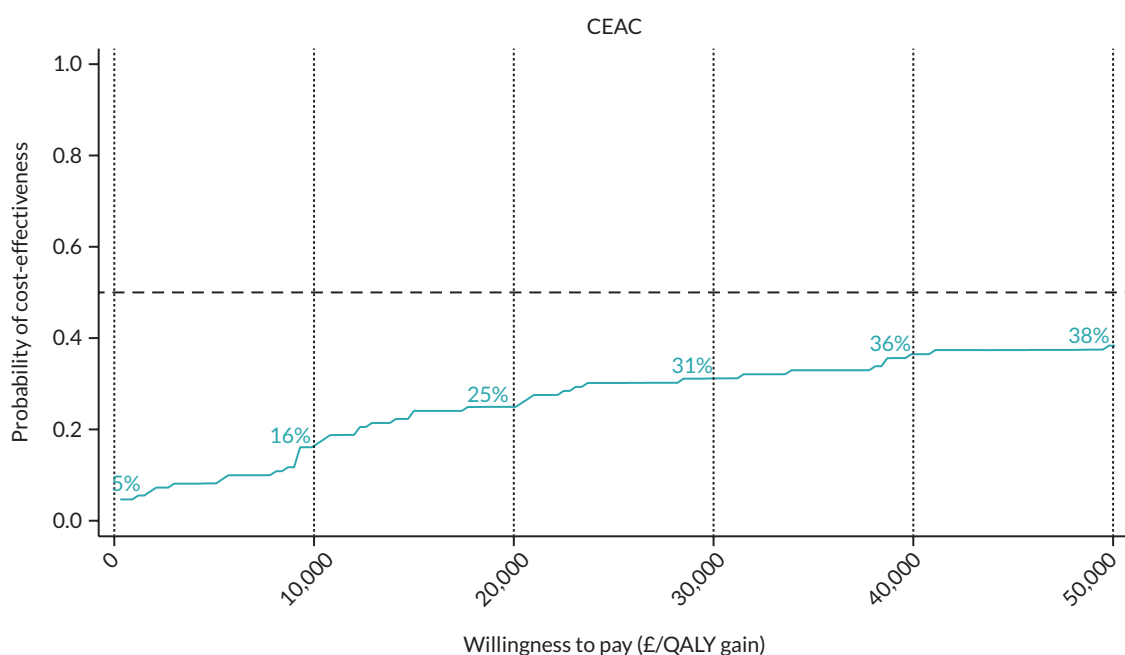


FIGURE 6 Cost-effectiveness acceptability curve from a societal perspective.

TABLE 12 Results of model-based incremental cost-effectiveness analysis

	EC Mean (SE)	UC Mean (SE)	Incremental outcomes Mean (95% CI)
Costs	£4179 (£79)	£3037 (£55)	£1142 (£1 to £2320)
QALYs	4.008 (0.023)	3.978 (0.023)	0.030 (−0.616 to 0.712)
ICER	£38,360 per QALY gained (uncertainty see Figure 7)		

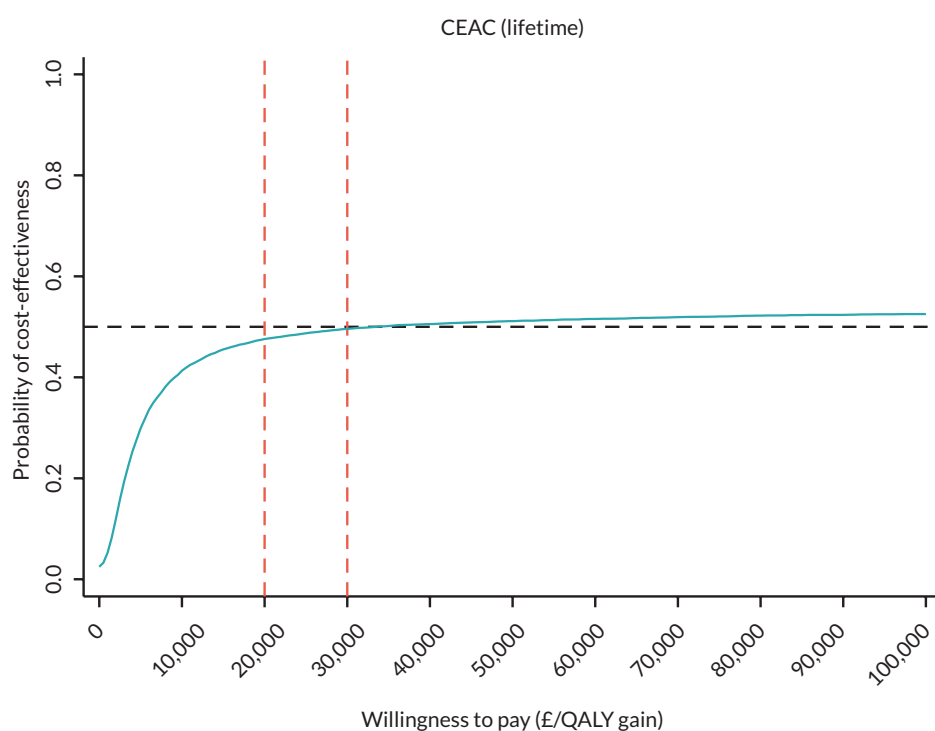


FIGURE 7 Cost-effectiveness acceptability curve of model-projected results.

died after 10 years. It should also be noted that, except for mortality rates, other parameters in the model were not specific to a homeless population. For instance, the incidence of respiratory diseases is higher, while quality of life is worse in people experiencing homelessness than in the securely housed population, even comparing to the most deprived housed population.⁵¹ Therefore, the results of the model projection should be treated with caution.

In contrast to the current study, previous evidence suggests that providing ECs for smoking cessation may be cost-effective. One study based on the general population provided behavioural support accompanying EC (£105 per participant), resulting in a 12-month CO-validated quit rate at 18.0% compared to 9.9% in the control group.⁸ Another study set in emergency departments adopted a similar format but only with a brief session (£48 per participant), resulting in a 6-month CO-validated quit rate at 7.2% compared to 4.1% in the control group.⁹ Both studies recruited a slightly younger sample (41 years old), with a lower dependence on nicotine/cigarettes (Fagerstrom Test for Nicotine/Cigarette Dependence 4.6 and 4.9) than the current study (43 years old, FTCD 5.3). These differences may partially explain the low quit rates in the current study. Ideally, effective interventions or policies should increase the sustained abstinence, thereby reducing the healthcare costs. However, maintaining long-term abstinence among people experiencing multiple disadvantages is notoriously difficult to achieve.² Substantially improved abstinence rates will likely demand more intensive, and therefore more costly, support. Future policies should prioritise resource-intensive interventions for people experiencing homelessness, recognising that investing in effective, long-term solutions is crucial for closing the health inequality gap.

The costs of healthcare service use were high in both groups, but the mean costs of secondary and emergency care and primary and community care were over £1800 in the EC group, while both were below £1500 in the UC group. The higher costs of inpatient care and alcohol/drug services contributed primarily to the increased overall cost of EC compared to UC. The CCA showed the same pattern but to a lesser extent. Altering the imputed values under MNAR assumptions did not affect the incremental costs either. The reason for the EC group's higher healthcare service utilisation was unclear.

Although we originally planned to estimate costs of e-liquids and coils based on keyworkers' dispensing logs, this proved difficult for the centre staff to record. As a result of the level of missing keyworkers' logs, we used

the stock inventory at the end of the intervention period (4 weeks) to estimate the costs of e-liquids and coils given to the participants in each centre in the EC group. The downside of this approach was that we were not able to match the quantities to each participant but only estimate the costs on a centre level. Though it reduced participant variance, assuming uniform costs within each centre prevented underestimating mean costs and avoided the substantial missing data from incomplete keyworker logs.

While we were unable to estimate the amount of money spent by participants on the EC-related purchases, the data showed that among those responding at each time point, a higher proportion of the EC group made relevant purchases compared with the UC group. This was expected as participants in the EC group initiated EC use as part of the intervention.

Weekly spending on tobacco averaged £100–200 but ranged broadly from £0 to £1400. During the first 4 weeks of treatment, tobacco spending fell below £100 per week in both groups but rose above £200 in the final 12 weeks, suggesting a short-term impact that did not endure. The high mean spending on tobacco not only overshadowed the spending on NRT products and travelling to care but also reached the level of the mean NHS/PSS costs. The higher mean tobacco spending in the UC group offset the higher mean NHS/PSS costs in the EC group, resulting in smaller incremental societal costs.

The missing data level was around 10% higher in the UC group than in the EC group at weeks 4 and 12, increasing to about 20% at week 24. The comparison of primary analysis and CCA showed an opposite picture of EC and UC groups. In the EC group, those who followed up throughout the trial incurred lower healthcare costs and slightly lower QALYs than the estimated costs based on the imputed data. In the UC group, those who remained followed up had similar levels of healthcare costs but slightly higher QALYs comparing to the estimated costs and QALYs based on the imputed data. The MNAR examinations had a larger impact on incremental QALYs than incremental costs. It might be due to atypical utilisation, as the population is characterised by poorer physical and mental health while having less access to health care.⁵²

People experiencing homelessness face barriers to access health care, not only posed by service supply but also by their own preparedness. A disconnect exists between their healthcare needs and actual utilisation, leading to care being sought only when health issues have reached a critical, cumulative stage.⁶ More efforts should be made towards retaining participants and collecting accurate

cost information from both participants and staff so that the results of the analysis could be of higher certainty. The specific design or administering approach of CRFs might be needed to cater for participants undergoing unstable life or with complex needs. When data collection relies on non-research staff, better facilitation should be considered.

Conclusions

The results from the SCeTCH trial should be interpreted solely within the context of the population in which the study was undertaken. Given the atypical nature of the population in terms of access to health care and existing conditions which may have a ceiling effect on health gains, the results should not be extrapolated to the wider population. The results from a societal perspective are also atypical due to low rates of employment limiting the scope for productivity gains.

Costs per CO-validated sustained 24-week abstinence were high in both the EC and UC groups, but the EC intervention was estimated at only half of that of UC. Nevertheless, from an NHS/PSS perspective, the ICER far exceeded the maximum threshold set by NICE for cost-effectiveness, mainly due to the higher healthcare service utilisation in the EC group and negligible difference in QALYs. We therefore conclude that, in this context, the EC intervention was not cost-effective, compared to the UC. More effective interventions that produce higher long-term abstinence rates are required and would, in turn, improve cost-effectiveness.

Additional information

CRediT contribution statement

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Lynne Dawkins (<https://orcid.org/0000-0003-1236-009X>): Conceptualisation (lead), Funding acquisition (lead), Investigation, Methodology (lead), Project administration (lead), Supervision (lead), Writing – reviewing and editing (equal).

Data-sharing statement

The underpinning anonymised data and data dictionary are available on the SCeTCH OSF project page at the time of publication on <https://osf.io/yhmk9/>. Along with the study protocol, Statistical Analysis Plan, Health Economic Analysis Plan, participant information sheet, consent form, CRFs and other study materials.

Ethics statement

Ethical approval has been gained from London South Bank University (17/08/2021, Ref: ETH2021–0176). The results from the project will be published as open access and made available to the centres taking part.

Information governance statement

London South Bank University is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, LSBU is the sponsor and data controller, and University of York is the data processor. University of York did not handle any personal data. You can find out more about how LSBU handles personal data, including how to exercise your individual rights and the contact details for LSBU's Data Protection Officer here dpa@lsbu.ac.uk.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at <https://doi.org/10.3310/GJLD2428>.

Primary conflicts of interest: Jinshuo Li, Qi Wu, Steve Parrott, Sharon Cox, Francesca Pesola, Rachel Brown, Allison Ford, Peter Hajek, Deborah Robson, Emma Ward, Anna Varley, Charlotte Mair, Lauren McMillan, Jessica Lennon, Janine Brierley, Amy Edwards, Bethany Gardner and Allan Tyler declare no competing interests. Kirstie Soar has acted as a paid consultant for National Centre for Smoking Cessation and Training for tobacco harm reduction and Pharmastrat Ltd a healthcare consulting company who deliver SSSs. Caitlin Notley has received an honorarium from Vox media company for filming a 'nicotine explainer' on the role of nicotine in addiction. Linda Bauld is seconded part time to Scottish Government as their Chief Social Policy Adviser and in that role serve as Senior Responsible Officer for the Place and Wellbeing Programme. Lynne Dawkins has acted as a paid consultant for Johnson and Johnson who manufactured smoking cessation medications.

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This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Trial registration

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List of abbreviations

A&E	accident and emergency
CCA	complete-case analysis
CEAC	cost-effectiveness acceptability curves
CRF	case report form
EC	e-cigarette
FTCD	Fagerstrom Test for Cigarette Dependence
GP	general practitioner
ICER	incremental cost-effectiveness ratio
MAR	missing at random
NICE	National Institute for Health and Care Excellence
MNAR	missing not at random
NRT	nicotine replacement therapy
PSS	Personal Social Services
QALY	quality-adjusted life-year
SCETCH	Stop Smoking Trial for people experiencing homelessness

SSS	Stop Smoking Service
UC	usual care
VAS	visual analogue scale
VBA+	very brief advice plus

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Appendix 1

Details of e-cigarette/usual care costs estimation

In total, 184 staff were trained in 32 participating centres, from 2 to 19 per centre. Most centres only held training once, but two required twice. In the EC group, the training sessions took from 1.5 to 3 hours, while in the UC group, they took 1–2.5 hours. The number of trainers for each session varied between 1 and 4 trainers. Return journeys that the trainers took to the sites ranged from 10 minutes' walk to 5 hours' train. It was also necessary for the trainers to stay overnight for some sites. The fees or penalty for train and hotel cancellation were also included where applicable. A total of 65 different titles of positions were logged, from unpaid volunteers and students in placement to centre managers. The hourly pay of some staff was logged, and others were not. Efforts were made to search for advertisements of similar positions in homeless support centres or charity to obtain their respective hour pay or annual pay. The hourly costs were estimated using the equivalent hour pay plus 30% oncosts. The staff of unknown positions were costed using the average hourly costs of the others. The resulting hourly costs ranged from £13 to £71, with an average of £25 per hour.

In the UC group, 151 sessions were delivered by centre staff, with a mean duration of 5.0 (SD 2.8) minutes, and 73 were delivered by members of the research team, with a mean duration of 4.7 (SD 2.1) minutes. One participant did not receive any session due to early withdrawal. In the

EC group, centre staff delivered 208 individual sessions and 4 group sessions, with a mean duration of 10.3 (SD 4.4) minutes, covering 220 participants, while the research team members delivered 18 sessions, with a mean duration of 9.1 (SD 3.2) minutes. The weekly e-liquid dispense sessions at weeks 2–4 delivered by centre staff amounted to 303 in total, with a mean duration of 5.1 (SD 1.6) minutes. The research team members also delivered 14 e-liquid dispense sessions in one centre, with the duration assumed to be 5 minutes.

All but one participant received at least the starter kit (EC device, USB wall plug and five bottles of e-liquid). The one participant refused to use EC and therefore did not receive any supply of e-liquid afterwards either. The mean number of bottles of e-liquids per participant within each centre in the EC group ranged from 7 to 18 bottles. The mean number of coils per participant within each centre ranged from nearly 0 (0.1) to 4 coils. The EC devices were purchased at £13.97 per unit. The e-liquids were ordered in different batches, with the weighted average costs of e-liquid at £1 per bottle. The USB wall plugs were purchased at £3 each, and the coils were £1.76 each. All costs excluded VAT.

Based on comments from the available keyworkers' log and follow-up checking, some participants in the UC group might not have been given the leaflet of SSS signposting and tips. We assumed that all participants received the leaflet to avoid underestimating the costs. In total, 270 pieces of EC tips and instructions and 290 pieces of local SSS signposting and tips were printed. The former costed £91.87, and the latter costed £49.35, excluding VAT.

Appendix 2

Smoking cessation costs estimation

The smoking cessation costs included costs of smoking cessation advice from local SSS, GPs, practice nurses, pharmacists, NHS Stop Smoking Helpline service and other smoking helpline, and costs of NRT products on

prescription or given by local SSS. Participants' attendance of SSS was only collected at follow-ups, while the smoking cessation advice from other professionals was collected at baseline and follow-ups. The highest mean costs were £9.93 (£47.44) for SSS sessions attended in the UC group at week 24. Most of the mean costs, if not zero, were below £1 per participant. The mean costs of each smoking cessation service use were low with a huge SD (*Table 13*).

TABLE 13 Number of contacts and mean costs (SD) with professionals for smoking cessation at all time points by group

	EC (n = 239)			UC (n = 236)		
	N of null use	N of any use, Mean (SD)	N of costs, Mean (SD)	N of null use	N of any use, Mean (SD)	N of costs, Mean (SD)
Baseline	N = 239			N = 236		
GP	225	14 1.8 (1.9)	239 £3.97 (£23.16)	230	6 1.0 (0.0)	236 £0.97 (£5.99)
Practice nurse	233	6 1.7 (1.2)	239 £0.33 (£2.52)	231	4 1.0 (0.0)	235 £0.14 (£1.04)
Pharmacist	236	3 15.3 (21.5)	239 £0.96 (£13.03)	230	5 1.0 (0.0)	235 £0.11 (£0.72)
NHS Stop Smoking Helpline	239	0 –	239 –	234	1 1 (–)	235 £0.03 (£0.52)
Other helpline	236	3 1.0 (0.0)	–	235	0 (–)	–
Week 4	N = 191			N = 156		
Sessions in SSS	186	3 7.7 (7.4)	189 £2.68 (£26.95)	146	10 1.8 (1.0)	156 £2.54 (£11.17)
GP	185	6 1.7 (1.2)	191 £1.99 (£13.36)	152	4 1.0 (0.0)	156 £0.97 (£6.03)
Practice nurse	187	3 1.0 (0.0)	190 £0.13 (£1.00)	150	6 1.0 (0.0)	156 £0.31 (£1.54)
Pharmacist	186	4 1.8 (1.0)	190 £0.18 (£1.40)	151	4 1.8 (1.5)	155 £0.23 (£1.74)
NHS Stop Smoking Helpline	189	1 1 (–)	190 £0.04 (£0.58)	152	3 1.7 (1.2)	155 £0.26 (£2.12)
Other helpline	188	2 1.5 (0.7)	–	155	0 –	–
Week 12	N = 157			N = 126		
Sessions in SSS	152	5 1.6 (1.4)	157 £1.12 (£7.80)	118	7 3.0 (2.6)	125 £3.70 (£19.90)
GP	149	7 2.1 (1.9)	156 £3.65 (£21.92)	121	5 1.0 (0.0)	126 £1.51 (£7.45)
Practice nurse	151	5 2.0 (2.2)	156 £0.51 (£4.03)	126	0 –	126 –
Pharmacist	153	3 1.7 (0.6)	156 £0.16 (£1.19)	122	4 3.3 (1.7)	126 £0.52 (£3.15)
NHS Stop Smoking Helpline	156	0 –	156 –	124	2 4.5 (4.9)	126 £0.57 (£5.74)
Other helpline	155	1 1 (–)	–	125	0 –	–
Week 24	N = 162			N = 111		
Sessions in SSS	159	3 2.0 (1.0)	162 £0.81 (£6.43)	101	10 2.9 (3.3)	111 £5.75 (£27.94)
GP	148	14 1.0 (0.0)	162 £3.28 (£10.71)	98	13 2.2 (3.1)	111 £9.93 (£47.44)

TABLE 13 Number of contacts and mean costs (SD) with professionals for smoking cessation at all time points by group (*continued*)

	EC (n = 239)			UC (n = 236)		
	N of null use	N of any use, Mean (SD)	N of costs, Mean (SD)	N of null use	N of any use, Mean (SD)	N of costs, Mean (SD)
Practice nurse	158	4 1.3 (0.5)	162 £0.25 (£1.65)	108	3 1.7 (1.2)	111 £0.36 (£2.50)
Pharmacist	155	7 1.1 (0.4)	162 £0.25 (£1.22)	107	4 4.5 (1.9)	111 £0.81 (£4.50)
NHS Stop Smoking Helpline	162	0 –	162 –	111	0 –	111 –
Other helpline	162	0 –	–	111	0 –	–

At baseline, 15/239 participants in the EC group and 15/236 participants in the UC group reported using NRT. At week 4, 4/190 participants in the EC group and 14/155 participants in the UC group reported using NRT. At week 12, 6/156 participants in the EC group and 11/126 participants in the UC group reported using NRT. At week 24, 14/162 participants in the EC group and 13/111 participants in the UC group reported using NRT. Given the numbers included those who purchased products, the number of participants using NRT on

prescription or from SSS free of charge was very low. This resulted in low mean costs of the products with high SDs (*Table 14*). Nasal spray use was not reported by any participants, while patches were reported in both groups at all time points.

Overall, the mean costs of smoking cessation advice and NRT prescription in both groups were low with large SDs, consistent with the pattern of use of each individual service or product (*Table 15*).

TABLE 14 Costs of NRT products at all time points by group

Prescription costs Mean (SD)	EC (n = 239)	UC (n = 236)
Baseline	N = 239	N = 236
Patch	£2.22 (£22.49)	£0.24 (£2.98) ^a
Gum	£1.93 (£29.81)	£0.11 (£1.18)
Tablet (microtab)	–	–
Inhaler	–	£0.00 (£0.05)
Lozenge	– ^b	£0.04 (£0.64)
Nasal spray	–	–
Mouth spray	£0.06 (£0.91)	–
Week 4	N = 190	N = 155
Patch	£1.86 (£24.14)	£2.57 (£25.19)
Gum	–	£0.08 (£1.03)
Tablet (microtab)	–	–
Inhaler	–	£0.02 (£0.15)
Lozenge	–	–
Nasal spray	–	–
Mouth spray	£0.30 (£4.08)	£0.09 (£1.13)

continued

TABLE 14 Costs of NRT products at all time points by group (*continued*)

Prescription costs Mean (SD)	EC (n = 239)	UC (n = 236)
Week 12	N = 156	N = 126
Patch	£0.14 (£1.25)	£2.28 (£20.93)
Gum	£2.05 (£24.61)	£0.20 (£2.28)
Tablet (microtab)	–	–
Inhaler	–	£0.52 (£5.84)
Lozenge	£0.13 (£1.10)	£0.16 (£1.74)
Nasal spray	–	–
Mouth spray	–	–
Week 24	N = 162	N = 111
Patch	£0.75 (£4.64)	£4.19 (£22.98)
Gum	£0.16 (£1.42)	–
Tablet (microtab)	–	£0.27 (£2.82)
Inhaler	£0.01 (£1.71)	–
Lozenge	£0.18 (£1.71)	£0.70 (£5.70)
Nasal spray	–	–
Mouth spray	–	£0.89 (£8.10)
a Two participants missing. b One participant missing.		

TABLE 15 Mean costs of smoking cessation advice and NRT prescription at all time points by group

Costs	EC (n = 239)		UC (n = 236)	
	N	Mean (SD)	N	Mean (SD)
Baseline				
Smoking cessation advice	239	£5 (£27)	235	£1 (£6)
NRT prescription	238	£4 (£38)	234	£0 (£3)
Week 4				
Smoking cessation advice	188	£5 (£41)	155	£4 (£14)
NRT prescription	190	£2 (£28)	155	£3 (£25)
Week 12				
Smoking cessation advice	156	£5 (£24)	125	£6 (£28)
NRT prescription	156	£2 (£25)	126	£3 (£31)
Week 24				
Smoking cessation advice	162	£5 (£14)	111	£17 (£66)
NRT prescription	162	£1 (£6)	111	£6 (£31)

Appendix 3

General healthcare costs estimation

While only a small group of participants had visited A&E, the mean costs per participant were consistently

over £10 ([Table 16](#)). One participant in the EC group at baseline reported 10 visits to A&E but did not specify if any of them entailed admission. The weighted average costs per visit was applied to the quantity, resulting costs of £2470.

TABLE 16 Number of contacts and mean costs (SD) of A&E services at all time points, by group

	EC (n = 239)			UC (n = 236)		
	N of null use	N of any use Mean (SD)	N of costs Mean (SD)	N of null use	N of any use Mean (SD)	N of costs Mean (SD)
Baseline	N = 239			N = 236		
A&E attendance	213	25 1.2 (0.6)	238 £14.24 (£47.69)	203	31 2.0 (2.8)	234 £30.42 (£139.29)
A&E admission	229	9 2.7 (4.6)	238 £30.55 (£300.81)	218	16 1.1 (0.3)	234 £23.31 (£90.13)
Week 4	N = 191			N = 157		
A&E attendance	180	10 2.1 (1.6)	190 £12.49 (£66.10)	142	14 1.5 (1.1)	156 £15.57 (£61.08)
A&E admission	182	8 1.0 (0.0)	190 £12.76 (£61.01)	150	7 1.4 (0.8)	157 £19.30 (£101.09)
Week 12	N = 157			N = 126		
A&E attendance	144	12 1.2 (0.4)	156 £10.14 (£37.14)	108	18 1.8 (1.2)	126 £29.60 (£87.15)
A&E admission	150	6 4.2 (7.3)	156 £48.56 (£464.96)	119	7 1.6 (1.1)	126 £26.45 (£132.88)
Week 24	N = 162			N = 111		
A&E attendance	146	15 2.5 (3.6)	161 £25.97 (£146.38)	99	12 1.3 (0.7)	111 £16.29 (£52.44)
A&E admission	143	18 1.8 (1.4)	161 £62.11 (£222.45)	106	5 1.6 (1.3)	111 £21.84 (£127.32)

[Table 17](#) presents participants' use of hospital-based care. Similar to the A&E services, a small number of participants used the services, resulting in high SDs of the mean costs. The mean costs of outpatient appointments at most time

points were above £50 in both groups. The mean costs of inpatient were above £200 at all time points in either group, with the highest at £902.80 (SD £4440.68) at week 24 in the EC group.

TABLE 17 Number of contacts and mean costs (SD) of hospital-based care at all time points by group

	EC (n = 239)			UC (n = 236)		
	N of null use	N of any use Mean (SD)	N of costs Mean (SD)	N of null use	N of any use Mean (SD)	N of costs Mean (SD)
Baseline	N = 239			N = 236		
Outpatient	216	23 2.3 (2.6)	239 £35.90 (£169.34)	202	32 2.4 (2.3)	234 £54.29 (£193.26)
Inpatient	226	13 1.6 (1.3)	239 £425.71 (£2246.20)	219	14 1.1 (0.4)	233 £332.70 (£1382.82)
Daycase	229	9 1.3 (0.5)	238 £52.34 (£281.21)	223	10 2.4 (3.4)	233 £106.92 (£866.12)
Week 4	N = 191			N = 157		
Outpatient	169	21 1.7 (2.4)	190 £31.26 (£156.11)	140	15 2.6 (3.1)	155 £40.98 (£199.75)
Inpatient	182	8 1.0 (0.0)	190 £204.00 (£975.59)	150	5 1.6 (0.9)	155 £250.06 (£1541.40)
Daycase	188	2 1.5 (0.7)	190 £16.39 (£168.03)	151	4 1.0 (0.0)	155 £26.79 (£165.12)
Week 12	N = 157			N = 126		
Outpatient	138	18 2.7 (3.6)	156 £50.77 (£243.38)	107	19 2.5 (5.2)	126 £62.86 (£360.20)
Inpatient	149	7 1.3 (0.5)	156 £279.52 (£1374.83)	120	6 1.5 (0.8)	126 £346.07 (£1752.64)
Daycase	152	4 2.3 (1.9)	156 £59.88 (£460.30)	118	7 1.0 (0.0)	125 £58.13 (£239.62)
Week 24	N = 162			N = 111		
Outpatient	136	25 2.2 (2.5)	161 £57.39 (£207.29)	95	16 3.8 (8.7)	111 £89.19 (£574.08)
Inpatient	146	15 2.0 (2.4)	161 £902.80 (£4440.68)	109	2 2.5 (2.1)	111 £218.24 (£1892.02)
Daycase	154	7 1.0 (0.0)	161 £45.13 (£212.34)	108	3 1.0 (0.0)	111 £28.05 (£169.09)

At weeks 4 and 12, no participants reported being treated by an ambulance at scene, and no more than two participants did so at baseline and week 24 ([Table 18](#)).

At all time points, some participants in each group were taken to hospital by ambulance.

TABLE 18 Number of contacts and mean costs (SD) of ambulance services at all time points by group

	EC (n = 239)			UC (n = 236)		
	N of null use	N of any use Mean (SD)	N of costs Mean (SD)	N of null use	N of any use Mean (SD)	N of costs Mean (SD)
Baseline	N = 239			N = 236		
Ambulance to the scene	236	2 2.0 (0.0)	238 £4.50 (£49.03)	232	1 2 (–)	233 £2.30 (£34.11)
Ambulance to hospital	224	14 2.9 (4.2)	238 £65.55 (£468.00)	216	17 1.2 (0.4)	233 £33.48 (£126.18)

TABLE 18 Number of contacts and mean costs (SD) of ambulance services at all time points by group (*continued*)

	EC (n = 239)			UC (n = 236)		
	N of null use	N of any use Mean (SD)	N of costs Mean (SD)	N of null use	N of any use Mean (SD)	N of costs Mean (SD)
Week 4	N = 191			N = 157		
Ambulance to the scene	190	–	–	155	–	–
Ambulance to hospital	176	14 1.4 (1.1)	190 £39.00 (£177.39)	147	8 1.6 (0.7)	155 £32.71 (£153.67)
Week 12	N = 157			N = 126		
Ambulance to the scene	156	–	–	126	–	–
Ambulance to hospital	146	10 1.8 (1.5)	156 £45.00 (£221.33)	116	10 2.1 (1.4)	126 £65.00 (£264.51)
Week 24	N = 162			N = 111		
Ambulance to the scene	159	1 1 (–)	160 £1.68 (£21.19)	111	–	–
Ambulance to hospital	144	16 2.0 (1.3)	160 £78.00 (£282.79)	103	8 1.5 (0.5)	111 £56.14 (£91.49)

Contrary to other services, a higher proportion of participants reported accessing primary care. The mean costs of GP contacts at all time points were higher than £20, reaching £56.14 (SD £91.49) in the UC group at

week 24 (*Table 19*). Over half of those who completed the questions reported receiving prescriptions for some medicines. The mean number of prescriptions was over two at any point, mostly over three.

TABLE 19 Number of contacts and mean costs (SD) primary care services at all time points by group

	EC (n = 239)			UC (n = 236)		
	N of null use	N of any use Mean (SD)	N of costs Mean (SD)	N of null use	N of any use Mean (SD)	N of costs Mean (SD)
Baseline	N = 239			N = 236		
GP	123	116 2.0 (2.9)	239 £37.05 (£81.61)	151	83 2.4 (3.7)	234 £32.15 (£94.48)
Practice nurse	182	57 1.9 (2.0)	239 £5.93 (£16.71)	192	42 1.7 (1.3)	234 £4.06 (£11.24)
Prescription	72	167 3.2 (5.7)	239 £45.19 (£99.90)	87	146 3.0 (4.3)	233 £37.94 (£74.13)
Week 4	N = 191			N = 157		
GP	129	62 1.7 (1.1)	191 £20.49 (£37.95)	88	67 1.4 (0.7)	155 £23.29 (£32.52)
Practice nurse	149	42 1.7 (1.9)	191 £4.97 (£14.70)	131	25 1.5 (0.9)	156 £3.17 (£8.53)
Prescription	56	135 3.9 (6.5)	191 £54.61 (£114.78)	65	91 2.9 (3.6)	156 £33.46 (£61.22)
Week 12	N = 157			N = 126		
GP	83	73 2.8 (3.3)	156 £49.94 (£100.47)	68	58 2.2 (1.7)	126 £38.60 (£60.80)

continued

TABLE 19 Number of contacts and mean costs (SD) primary care services at all time points by group (*continued*)

	EC (n = 239)			UC (n = 236)		
	N of null use	N of any use Mean (SD)	N of costs Mean (SD)	N of null use	N of any use Mean (SD)	N of costs Mean (SD)
Practice nurse	117	39 2.4 (3.1)	156 £7.83 (£24.12)	97	29 1.4 (0.9)	126 £4.33 (£9.73)
Prescription	40	116 5.0 (9.4)	156 £73.97 (£167.31)	49	77 3.3 (4.1)	126 £40.63 (£71.73)
Week 24	N = 162			N = 111		
GP	79	81 2.6 (3.1)	160 £50.11 (£96.47)	55	56 2.9 (2.7)	111 £56.14 (£91.49)
Practice nurse	114	46 4.0 (6.9)	160 £14.79 (£53.20)	79	32 3.5 (4.1)	111 £13.12 (£35.30)
Prescription	34	126 6.6 (9.8)	160 £103.38 (£182.58)	38	72 5.8 (10.8)	110 £76.00 (£182.52)

The most often used community care was drug and alcohol services ([Table 20](#)). This might correspond to the number of prescriptions in [Table 19](#), as participants experiencing drug or alcohol problems were likely to be prescribed medicines to help them quit. In the EC group, the mean costs of drug and alcohol service use were always higher than £100, while in the UC group, except for week 24, it was always below £100. Given the nature of the sample

population, the contacts with adult mental health team and housing team were not unexpected either. Except for in the UC group at week 4, the mean costs of adult mental health team were also higher than £100. The mean costs of crisis team remained below £50, except for in the UC group at week 24. Except for week 24 in the UC group, the mean costs of housing team were between £10 and £30 per participant.

TABLE 20 Number of contacts and mean costs (SD) of other community care at all time points by group

	EC (n = 239)			UC (n = 236)		
	N of null use	N of any use Mean (SD)	N of costs Mean (SD)	N of null use	N of any use Mean (SD)	N of costs Mean (SD)
Baseline	N = 239			N = 236		
Drug and alcohol service	145	94 4.0 (6.0)	239 £127.43 (£341.10)	174	60 4.0 (6.2)	234 £82.38 (£287.82)
Adult mental health team	178	61 3.5 (6.3)	239 £243.67 (£962.22)	179	55 2.7 (4.4)	234 £174.56 (£664.45)
Crisis team	224	15 4.5 (7.2)	239 £33.29 (£240.86)	216	18 4.9 (9.3)	234 £44.00 (£330.30)
Housing team	193	46 6.8 (8.6)	239 £27.50 (£96.63)	169	65 4.6 (7.0)	234 £26.56 (£77.32)
Week 4	N = 191			N = 157		
Drug and alcohol service	124	67 4.3 (7.0)	191 £122.56 (£372.85)	118	38 1.9 (1.5)	156 £37.90 (£89.89)
Adult mental health team	155	36 2.2 (1.4)	191 £112.71 (£290.26)	131	25 1.7 (1.2)	156 £74.31 (£213.43)
Crisis team	186	5 1.8 (1.8)	191 £5.51 (£45.37)	150	6 2.3 (1.2)	156 £10.50 (£58.50)
Housing team	163	27 4.9 (6.6)	190 £14.76 (£63.05)	127	29 4.4 (6.9)	156 £17.37 (£71.37)

TABLE 20 Number of contacts and mean costs (SD) of other community care at all time points by group (*continued*)

	EC (n = 239)			UC (n = 236)		
	N of null use	N of any use Mean (SD)	N of costs Mean (SD)	N of null use	N of any use Mean (SD)	N of costs Mean (SD)
Week 12	N = 157			N = 126		
Drug and alcohol service	99	57 7.4 (10.4)	156 £219.12 (£584.62)	105	21 5.6 (12.8)	126 £75.21 (£447.21)
Adult mental health team	128	27 2.6 (2.3)	155 £122.86 (£377.62)	99	27 2.9 (2.4)	126 £168.67 (£440.18)
Crisis team	151	5 5.8 (8.2)	156 £21.75 (£195.69)	124	2 1.0 (0.0)	126 £1.86 (£14.68)
Housing team	133	23 3.4 (4.9)	156 £10.50 (£46.22)	93	33 2.6 (2.5)	126 £14.17 (£35.82)
Week 24	N = 162			N = 111		
Drug and alcohol service	105	55 13.6 (22.5)	160 £379.18 (£1186.33)	85	26 7.3 (12.4)	111 £139.38 (£540.63)
Adult mental health team	123	38 6.5 (10.6)	161 £425.15 (£1602.52)	90	21 7.1 (13.2)	111 £372.97 (£1739.08)
Crisis team	155	6 1.3 (0.5)	161 £5.81 (£31.51)	104	6 18.8 (32.5)	110 £120.19 (£956.37)
Housing team	138	23 4.4 (6.5)	161 £13.17 (£59.76)	76	34 9.4 (17.9)	110 £60.90 (£226.00)

Appendix 4

Participants' spending and lost income

TABLE 21 Mean spending (SD) on NRT products at all time points by group

Out-of-pocket spending, mean (SD)	EC (n = 239)	UC (n = 236)
Baseline	N = 239	N = 236
Patch	£0.36 (£3.68)	£0.05 (£0.81)
Gum	£0.18 (£2.11)	–
Inhaler	–	£0.09 (£1.45)
Mouth spray	£0.31 (£4.76)	–
Week 4	N = 190	N = 155
Patch	£0.07 (£0.90)	£0.24 (£2.23)
Gum	–	£0.28 (£2.62)
Lozenge	£0.45 (£6.20)	–
Mouth spray	–	£0.09 (£1.13)

continued

TABLE 21 Mean spending (SD) on NRT products at all time points by group (*continued*)

Out-of-pocket spending, mean (SD)	EC (n = 239)	UC (n = 236)
Week 12	N = 156	N = 126
Patch	£0.32 (£3.99)	£0.59 (£4.69)
Inhaler	–	£0.02 (£0.20)
Week 24	N = 162	N = 111
Patch	£0.08 (£0.98)	£0.22 (£1.66)
Gum	£0.18 (£1.62)	–
Tablet (microtab)	£0.10 (£1.30)	–
Lozenge	–	£0.13 (£1.35)
Mouth spray	£0.34 (£4.33)	–

[Table 21](#) presents the negligible mean spending on different NRT products at each time point by group. The average weekly spending on tobacco-related purchases was relatively high in both groups ([Table 22](#)). Around half of the participants who answered this question reported an average spending below £200 per week. However, some participants reported spending far more, with a highest spend of £1400. It is unclear whether the participants misunderstood the question or included something that was not intended for this question. Multiplying the

weekly spending with the time period covered by each time point, the mean spendings on tobacco-related purchases are presented in [Table 7](#). [Table 23](#) presents the proportion of participants who reported making e-cigarette-related purchases.

All participants reported spending on travelling to receive care with a maximum of £60, except one in the UC group reported as high as £300 at week 24.

TABLE 22 Mean weekly spending on tobacco-related purchases at each time point by group

Weekly spending on tobacco	EC (n = 239)		UC (n = 236)	
	N of null spending	N of spending > 0 Mean (SD)	N of null spending	N of spending > 0 Mean (SD)
Baseline	9	229 £111.13 (£120.22)	19	216 £111.81 (£109.97)
Week 4	26	144 £77.22 (£59.95)	19	130 £82.51 (£83.70)
Week 12	23	118 £147.61 (£128.78)	14	107 £161.47 (£130.08)
Week 24	14	134 £227.51 (£213.33)	12	95 £247.27 (£171.64)

TABLE 23 Number (%) of participants reported purchase of EC-related products at each time point by group

E-cigarette	EC (n = 239) n, %			UC (n = 236) n, %		
	Device	Accessories	E-liquid	Device	Accessories	E-liquid
Week 4	N = 190			N = 155		
	24, 13%	6, 3%	25, 13%	32, 21%	11, 7%	16, 10%
Week 12	N = 156			N = 126		
	54, 35%	23, 15%	43, 28%	33, 26%	11, 9%	16, 13%
Week 24	N = 162			N = 111		
	55, 34%	25, 15%	42, 26%	34, 31%	14, 13%	21, 19%

At baseline, one participant in the EC group took 1 hour off paid work, and six participants in the UC group took off from 1 to 160 hours. At week 4, one participant in each group took leave (24 hours in the EC group and 7 hours in the UC group). At week 12, one participant in the EC group

took 200 hours off work, while one participant in the UC group took 3 hours off work. At week 24, three participants in the EC group lost 3–8 hours' wage, while four participants in the UC group lost 6–120 hours' wage. [Table 24](#) presents the mean lost income at each time point by group.

TABLE 24 Mean loss of income (SD) at each time point by group

Lost income	EC (n = 239)		UC (n = 236)	
	N	Mean (SD)	N	Mean (SD)
Week 4–baseline	237	£0.04 (£0.58)	233	£8.22 (£95.35)
Baseline–week 4	188	£1.14 (£15.60)	155	£0.40 (£5.01)
Week 4–week 12	154	£11.57 (£143.60)	123	£0.22 (£2.41)
Week 12–week 24	159	£1.06 (£8.23)	110	£13.77 (£105.04)

Appendix 5

Quality of life

At baseline, most participants in both groups reported no problems in mobility, self-care and usual activities. Fifty-one per cent in the EC group (122/239) and 44% (101/232) in the UC group reported no problems in pain/discomfort. The main issue was in the anxiety/

depression domain, where only 29% (70/239) of the EC group and 38% (87/232) of UC participants reported no problems.

This pattern remained among those who were followed up at week 4, 12 and 24. Most participants had no problems in mobility, self-care and usual activities. Around half the participants in each group reported not experiencing pain/discomfort. Lower than half of the participants did not feel anxious/depressed.

TABLE 25 Mean (SD) of EQ-5D-5L utility values and EQ-5D VAS values at all time points by group

	EC (n = 239)				UC (n = 236)			
	N	Utility Mean (SD)	N	VAS Mean (SD)	N	Utility Mean (SD)	N	VAS Mean (SD)
Baseline	235	0.621 (0.315)	239	51.8 (23.0)	233	0.603 (0.343)	232	54.5 (24.2)
Week 4	186	0.664 (0.317)	189	57.5 (22.6)	154	0.636 (0.318)	156	56.8 (22.2)
Week 12	153	0.664 (0.329)	154	58.4 (23.5)	125	0.665 (0.343)	125	57.5 (22.2)
Week 24	159	0.666 (0.328)	161	58.2 (23.2)	111	0.681 (0.335)	111	59.8 (20.0)

[Table 25](#) presents the mean EQ-5D-5L utility values and VAS values among those who responded at each time point. In total, 121 participants in the EC group and 86 participants in the UC group had utility values at all time

points. The mean QALYs among these participants were 0.303 (SD 0.128) in the EC group and 0.312 (SD 0.126) in the UC group.

Appendix 6

Smoking cessation outcomes

TABLE 26 Summary of primary and secondary smoking cessation outcomes by group

	EC (n = 239)		UC (n = 236)	
	N of abstainer	Proportion (%)	N of abstainer	Proportion (%)
Sustained abstinence at week 24				
CO-validated	5	2.09	2	0.85
Self-reported	5	2.09	2	0.85
Self-reported 7-day point prevalence of abstinence				
Week 4	20	8.37	6	2.54
Week 12	11	4.60	6	2.54
Week 24	15	6.28	5	2.12

Appendix 7

Missing data examination

The most significant loss was at week 4, followed by week 12 ([Table 27](#)). The missing level between weeks 12 and 24 was similar. By group, the missing data level shows an imbalance ([Table 28](#)).

TABLE 27 Number (%) of missing values of each variable

Variables	n of missing	% of missing
Age	3	1
Gender	0	0
Chronic illness and mental health	0	0
Drug use	0	0
FTCD	37	8
Treatment costs	12	3
Usual care costs	0	0
Baseline		
Costs of smoking cessation advice	1	0
Costs of NRT prescription	3	1
Costs of emergency and secondary care	5	1
Costs of primary and community care	3	1
EQ-5D-5L utility	7	1
EQ-5D-5L VAS	3	1

TABLE 27 Number (%) of missing values of each variable (*continued*)

Variables	n of missing	% of missing
Spending on NRT	0	0
Spending on cigarettes	2	0
Spending on travelling to receive care	4	1
Lost income	5	1
Week 4		
Costs of smoking cessation advice	132	28
Costs of NRT prescription	130	27
Costs of emergency and secondary care	131	28
Costs of primary and community care	130	27
EQ-5D-5L utility	135	28
EQ-5D-5L VAS	127	27
Spending on NRT	130	27
Spending on cigarettes	156	33
Spending on travelling to receive care	130	27
Lost income	132	28
Week 12		
Costs of smoking cessation advice	194	41
Costs of NRT prescription	193	41
Costs of emergency and secondary care	194	41
Costs of primary and community care	194	41
EQ-5D-5L utility	197	41
EQ-5D-5L VAS	194	41
Spending on NRT	193	41
Spending on cigarettes	213	45
Spending on travelling to receive care	195	41
Lost income	198	42
Week 24		
Costs of smoking cessation advice	202	43
Costs of NRT prescription	202	43
Costs of emergency and secondary care	204	43
Costs of primary and community care	207	44
EQ-5D-5L utility	205	43
EQ-5D-5L VAS	203	43
Spending on NRT	202	43
Spending on cigarettes	220	46
Spending on travelling to receive care	202	43
Lost income	206	43

TABLE 28 Number (%) of missing values of each variable by group

	EC (n = 239)		UC (n = 236)	
	n of missing	% of missing	n of missing	% of missing
Age	2	1	1	0
Gender	0	0	0	0
Chronic illness and mental health	0	0	0	0
Drug use	0	0	0	0
FTCD	21	9	16	7
EC/UC costs	1	0	11	5
Usual care costs	0	0	0	0
Baseline				
Costs of smoking cessation advice	0	0	1	0
Costs of NRT prescription	1	0	2	1
Costs of emergency and secondary care	1	0	4	2
Costs of primary and community care	0	0	3	1
EQ-5D-5L utility	4	2	3	1
EQ-5D-5L VAS	0	0	3	1
Spending on NRT	0	0	0	0
Spending on cigarettes	1	0	1	0
Spending on travelling to receive care	1	0	3	1
Lost income	2	1	3	1
Week 4				
Costs of smoking cessation advice	51	21	81	34
Costs of NRT prescription	49	21	81	34
Costs of emergency and secondary care	49	21	82	35
Costs of primary and community care	49	21	81	34
EQ-5D-5L utility	53	22	82	35
EQ-5D-5L VAS	48	20	79	33
Spending on NRT	49	21	81	34
Spending on cigarettes	69	29	87	37
Spending on travelling to receive care	49	21	81	34
Lost income	51	21	81	34
Week 12				
Costs of smoking cessation advice	83	35	111	47
Costs of NRT prescription	83	35	110	47
Costs of emergency and secondary care	83	35	111	47
Costs of primary and community care	84	35	110	47
EQ-5D-5L utility	86	36	111	47

TABLE 28 Number (%) of missing values of each variable by group (*continued*)

	EC (n = 239)		UC (n = 236)	
	n of missing	% of missing	n of missing	% of missing
EQ-5D-5L VAS	83	35	111	47
Spending on NRT	83	35	110	47
Spending on cigarettes	98	41	115	49
Spending on travelling to receive care	84	35	111	47
Lost income	85	36	113	48
Week 24				
Costs of smoking cessation advice	77	32	125	53
Costs of NRT prescription	77	32	125	53
Costs of emergency and secondary care	79	33	125	53
Costs of primary and community care	80	33	127	54
EQ-5D-5L utility	80	33	125	53
EQ-5D-5L VAS	78	33	125	53
Spending on NRT	77	32	125	53
Spending on cigarettes	91	38	129	55
Spending on travelling to receive care	77	32	125	53
Lost income	80	33	126	53

Most of the missingness at follow-up variables was significantly associated with group allocation and age, except for spending on NRT at week 4 and spending on cigarettes at week 12 ([Table 29](#)). The missingness of follow-up variables was not associated with FTCD at baseline, week 12 and week 24 but was significantly associated with it at week 4. The missingness of follow-up variables was not associated with gender, chronic illness or mental health conditions, or drug use status ([Tables 29](#) and [30](#)). As for the association between

missingness of variables and the values of the variables at other time points, the significance was only shown in missing on costs of emergency and secondary care at week 4 and its values at week 24, missing on EQ-5D-5L utility at week 4 and its values at baseline and week 24, missing on costs of emergency and secondary care at week 12 and its values at week 24, costs of primary and community care at week 12 and its values at week 4, and missing on spending on cigarettes and its values at baseline ([Table 31](#)).

TABLE 29 Univariate logistic regressions on association between missingness of follow-up variables and baseline covariates (continuous and binary)

Missing on	Allocation OR (Z, p)	Age OR (Z, p)	FTCD OR (Z, p)	Drug use OR (Z, p)
Week 4				
Costs of smoking cessation advice	1.92 (Z = 3.14, p = 0.002)	0.98 (Z = -2.52, p = 0.012)	1.09 (Z = 1.86, p = 0.063)	1.42 (Z = 1.70, p = 0.090)
Costs of NRT prescription	2.03 (Z = 3.35, p = 0.001)	0.98 (Z = -2.61, p = 0.009)	1.09 (Z = 1.70, p = 0.088)	1.37 (Z = 1.50, p = 0.133)
Costs of emergency and secondary care	2.06 (Z = 3.44, p = 0.001)	0.98 (Z = -2.41, p = 0.016)	1.09 (Z = 1.70, p = 0.088)	1.33 (Z = 1.40, p = 0.163)

continued

TABLE 29 Univariate logistic regressions on association between missingness of follow-up variables and baseline covariates (continuous and binary) (*continued*)

Missing on	Allocation OR (Z, p)	Age OR (Z, p)	FTCD OR (Z, p)	Drug use OR (Z, p)
Costs of primary and community care	2.03 (Z = 3.35, p = 0.001)	0.98 (Z = -2.78, p = 0.005)	1.08 (Z = 1.56, p = 0.118)	1.42 (Z = 1.71, p = 0.088)
EQ-5D-5L utility	1.87 (Z = 3.02, p = 0.003)	0.97 (Z = -3.17, p = 0.002)	1.10 (Z = 1.96, p = 0.050)	1.33 (Z = 1.38, p = 0.168)
EQ-5D-5L VAS	2.00 (Z = 3.27, p = 0.001)	0.97 (Z = -3.09, p = 0.002)	1.10 (Z = 1.85, p = 0.064)	1.40 (Z = 1.62, p = 0.105)
Spending on NRT	2.03 (Z = 3.35, p = 0.001)	0.98 (Z = -2.61, p = 0.009)	1.09 (Z = 1.70, p = 0.088)	1.37 (Z = 1.50, p = 0.133)
Spending on cigarettes	1.44 (Z = 1.85, p = 0.064)	0.98 (Z = -2.73, p = 0.006)	1.03 (Z = 0.65, p = 0.517)	1.09 (Z = 0.43, p = 0.670)
Spending on travelling to receive care	2.03 (Z = 3.35, p = 0.001)	0.98 (Z = -2.81, p = 0.005)	1.09 (Z = 1.80, p = 0.072)	1.37 (Z = 1.50, p = 0.133)
Lost income	1.93 (Z = 3.14, p = 0.002)	0.97 (Z = -3.00, p = 0.003)	1.08 (Z = 1.50, p = 0.134)	1.36 (Z = 1.49, p = 0.135)
Week 12				
Costs of smoking cessation advice	1.67 (Z = 2.72, p = 0.007)	0.96 (Z = -4.49, p = 0.000)	1.11 (Z = 2.32, p = 0.020)	1.32 (Z = 1.49, p = 0.137)
Costs of NRT prescription	1.64 (Z = 2.63, p = 0.009)	0.96 (Z = -4.49, p = 0.000)	1.10 (Z = 2.21, p = 0.027)	1.30 (Z = 1.40, p = 0.162)
Costs of emergency and secondary care	1.67 (Z = 2.72, p = 0.007)	0.96 (Z = -4.49, p = 0.000)	1.10 (Z = 2.07, p = 0.039)	1.28 (Z = 1.30, p = 0.193)
Costs of primary and community care	1.61 (Z = 2.53, p = 0.011)	0.96 (Z = -4.41, p = 0.000)	1.10 (Z = 2.15, p = 0.031)	1.28 (Z = 1.30, p = 0.193)
EQ-5D-5L utility	1.58 (Z = 2.44, p = 0.015)	0.96 (Z = -4.67, p = 0.000)	1.10 (Z = 2.11, p = 0.035)	1.21 (Z = 1.02, p = 0.309)
EQ-5D-5L VAS	1.67 (Z = 2.72, p = 0.007)	0.96 (Z = -4.49, p = 0.000)	1.10 (Z = 2.07, p = 0.039)	1.28 (Z = 1.30, p = 0.193)
Spending on NRT	1.64 (Z = 2.63, p = 0.009)	0.96 (Z = -4.49, p = 0.000)	1.10 (Z = 2.21, p = 0.027)	1.30 (Z = 1.40, p = 0.162)
Spending on cigarettes	1.38 (Z = 1.69, p = 0.091)	0.96 (Z = -4.66, p = 0.000)	1.10 (Z = 2.28, p = 0.023)	1.05 (Z = 0.25, p = 0.799)
Spending on travelling to receive care	1.64 (Z = 2.63, p = 0.009)	0.96 (Z = -4.39, p = 0.000)	1.10 (Z = 2.01, p = 0.044)	1.25 (Z = 1.21, p = 0.227)
Lost income	1.66 (Z = 2.71, p = 0.007)	0.97 (Z = -4.06, p = 0.000)	1.08 (Z = 1.84, p = 0.065)	1.27 (Z = 1.29, p = 0.196)
Week 24				
Costs of smoking cessation advice	2.37 (Z = 4.54, p = 0.000)	0.97 (Z = -4.23, p = 0.000)	1.05 (Z = 1.20, p = 0.229)	1.41 (Z = 1.84, p = 0.065)
Costs of NRT prescription	2.37 (Z = 4.54, p = 0.000)	0.97 (Z = -4.23, p = 0.000)	1.05 (Z = 1.20, p = 0.229)	1.41 (Z = 1.84, p = 0.065)
Costs of emergency and secondary care	2.28 (Z = 4.35, p = 0.000)	0.97 (Z = -4.21, p = 0.000)	1.05 (Z = 1.06, p = 0.289)	1.41 (Z = 1.84, p = 0.066)
Costs of primary and community care	2.32 (Z = 4.44, p = 0.000)	0.97 (Z = -4.19, p = 0.000)	1.04 (Z = 0.98, p = 0.328)	1.43 (Z = 1.92, p = 0.054)
EQ-5D-5L utility	2.24 (Z = 4.26, p = 0.000)	0.96 (Z = -4.38, p = 0.000)	1.05 (Z = 1.13, p = 0.257)	1.34 (Z = 1.56, p = 0.119)
EQ-5D-5L VAS	2.32 (Z = 4.44, p = 0.000)	0.97 (Z = -4.17, p = 0.000)	1.05 (Z = 1.06, p = 0.289)	1.38 (Z = 1.75, p = 0.081)
Spending on NRT	2.37 (Z = 4.54, p = 0.000)	0.97 (Z = -4.23, p = 0.000)	1.05 (Z = 1.20, p = 0.229)	1.41 (Z = 1.84, p = 0.065)
Spending on cigarettes	1.96 (Z = 3.61, p = 0.000)	0.97 (Z = -4.21, p = 0.000)	1.02 (Z = 0.40, p = 0.690)	1.26 (Z = 1.26, p = 0.208)
Spending on travelling to receive care	2.37 (Z = 4.54, p = 0.000)	0.97 (Z = -4.23, p = 0.000)	1.05 (Z = 1.20, p = 0.229)	1.41 (Z = 1.84, p = 0.065)
Lost income	2.28 (Z = 4.35, p = 0.000)	0.97 (Z = -4.25, p = 0.000)	1.04 (Z = 0.92, p = 0.358)	1.41 (Z = 1.83, p = 0.067)
Bold indicates a statistically significant difference (p < 0.05).				

TABLE 30 Chi-square (χ^2) test on association between missingness of follow-up variables and baseline covariates (discrete)

Missing on	Gender	Chronic illness and mental health
Week 4		
Costs of smoking cessation advice	$\chi^2 = 1.3438, p = 0.854$	$\chi^2 = 1.1331, p = 0.567$
Costs of NRT prescription	$\chi^2 = 1.2515, p = 0.870$	$\chi^2 = 0.7348, p = 0.693$
Costs of emergency and secondary care	$\chi^2 = 1.1604, p = 0.885$	$\chi^2 = 0.9211, p = 0.631$
Costs of primary and community care	$\chi^2 = 1.2515, p = 0.870$	$\chi^2 = 0.7348, p = 0.693$
EQ-5D-5L utility	$\chi^2 = 7.6202, p = 0.107$	$\chi^2 = 1.5054, p = 0.471$
EQ-5D-5L VAS	$\chi^2 = 1.1427, p = 0.887$	$\chi^2 = 1.2312, p = 0.540$
Spending on NRT	$\chi^2 = 1.2515, p = 0.870$	$\chi^2 = 0.7348, p = 0.693$
Spending on cigarettes	$\chi^2 = 3.0588, p = 0.548$	$\chi^2 = 2.0136, p = 0.365$
Spending on travelling to receive care	$\chi^2 = 1.2515, p = 0.870$	$\chi^2 = 0.7348, p = 0.693$
Lost income	$\chi^2 = 1.1787, p = 0.882$	$\chi^2 = 1.1331, p = 0.567$
Week 12		
Costs of smoking cessation advice	$\chi^2 = 2.9771, p = 0.562$	$\chi^2 = 2.6475, p = 0.266$
Costs of NRT prescription	$\chi^2 = 3.0115, p = 0.556$	$\chi^2 = 3.0418, p = 0.219$
Costs of emergency and secondary care	$\chi^2 = 2.9771, p = 0.562$	$\chi^2 = 3.2210, p = 0.200$
Costs of primary and community care	$\chi^2 = 2.9771, p = 0.562$	$\chi^2 = 2.6475, p = 0.266$
EQ-5D-5L utility	$\chi^2 = 4.6140, p = 0.329$	$\chi^2 = 2.0776, p = 0.354$
EQ-5D-5L VAS	$\chi^2 = 2.9771, p = 0.562$	$\chi^2 = 3.2210, p = 0.200$
Spending on NRT	$\chi^2 = 3.0115, p = 0.556$	$\chi^2 = 3.0418, p = 0.219$
Spending on cigarettes	$\chi^2 = 3.2977, p = 0.509$	$\chi^2 = 1.9351, p = 0.380$
Spending on travelling to receive care	$\chi^2 = 3.1839, p = 0.528$	$\chi^2 = 3.6427, p = 0.162$
Lost income	$\chi^2 = 3.7815, p = 0.436$	$\chi^2 = 2.9654, p = 0.227$
Week 24		
Costs of smoking cessation advice	$\chi^2 = 3.4724, p = 0.482$	$\chi^2 = 1.2696, p = 0.530$
Costs of NRT prescription	$\chi^2 = 3.4724, p = 0.482$	$\chi^2 = 1.2696, p = 0.530$
Costs of emergency and secondary care	$\chi^2 = 3.4834, p = 0.480$	$\chi^2 = 1.4219, p = 0.491$
Costs of primary and community care	$\chi^2 = 3.3855, p = 0.496$	$\chi^2 = 1.5630, p = 0.458$
EQ-5D-5L utility	$\chi^2 = 4.0456, p = 0.400$	$\chi^2 = 0.8872, p = 0.642$
EQ-5D-5L VAS	$\chi^2 = 3.4334, p = 0.488$	$\chi^2 = 1.3346, p = 0.513$
Spending on NRT	$\chi^2 = 3.4724, p = 0.482$	$\chi^2 = 1.2696, p = 0.530$
Spending on cigarettes	$\chi^2 = 3.3367, p = 0.503$	$\chi^2 = 0.6842, p = 0.710$
Spending on travelling to receive care	$\chi^2 = 3.4724, p = 0.482$	$\chi^2 = 1.2696, p = 0.530$
Lost income	$\chi^2 = 3.5687, p = 0.468$	$\chi^2 = 1.4879, p = 0.475$
Bold indicates a statistically significant difference.		

TABLE 31 Univariate logistic regressions on associations between missingness of variable at one time point and their respective values at other time points

Missing on	OR (Z, p)		
	Values of		
Week 4	Baseline	Week 12	Week 24
	Costs of smoking cessation advice		
Costs of smoking cessation advice	1.00 (Z = 0.43, p = 0.667)	1.00 (Z = 0.02, p = 0.982)	1.01 (Z = 1.84, p = 0.065)
	Costs of NRT prescription		
Costs of NRT prescription	0.99 (Z = -0.67, p = 0.503)	0.99 (Z = -0.33, p = 0.742)	0.99 (Z = -0.39, p = 0.698)
	Costs of emergency and secondary care		
Costs of emergency and secondary care	1.00 (Z = 0.36, p = 0.719)	1.00 (Z = -0.63, p = 0.530)	1.00 (Z = -0.22, p = 0.823)
	Costs of primary and community care		
Costs of primary and community care	1.00 (Z = 1.02, p = 0.307)	1.00 (Z = 1.20, p = 0.230)	1.00 (Z = 2.03, p = 0.043)
	EQ-5D-5L utility		
EQ-5D-5L utility	0.54 (Z = -2.03, p = 0.043)	0.48 (Z = -1.33, p = 0.183)	0.22 (Z = -2.68, p = 0.007)
	EQ-5D-5L VAS		
EQ-5D-5L VAS	1.00 (Z = -1.06, p = 0.288)	0.99 (Z = -1.31, p = 0.189)	0.99 (Z = -0.59, p = 0.557)
	Spending on NRT		
Spending on NRT	0.99 (Z = -0.31, p = 0.760)	0.94 (Z = -0.40, p = 0.689)	1.02 (Z = 0.59, p = 0.558)
	Spending on cigarettes		
Spending on cigarettes	1.00 (Z = 1.00, p = 0.316)	1.00 (Z = 0.67, p = 0.505)	1 (Z = 0.00, p = 0.996)
	Spending on travelling to receive care		
Spending on travelling to receive care	1.02 (Z = 0.98, p = 0.328)	1.02 (Z = 1.03, p = 0.305)	1.00 (Z = -0.03, p = 0.972)
	Lost income		
Lost income	1.00 (Z = -0.35, p = 0.724)	1.00 (Z = 0.35, p = 0.725)	–
Week 12	Baseline	Week 4	Week 24
	Costs of smoking cessation advice		
Costs of smoking cessation advice	1.01 (Z = 1.24, p = 0.213)	1.00 (Z = -0.63, p = 0.528)	1.00 (Z = -0.55, p = 0.579)
	Costs of NRT prescription		
Costs of NRT prescription	0.98 (Z = -0.79, p = 0.431)	1.00 (Z = 0.67, p = 0.500)	1.00 (Z = -0.09, p = 0.931)
	Costs of emergency and secondary care		
Costs of emergency and secondary care	1.00 (Z = 1.20, p = 0.231)	1.00 (Z = 0.38, p = 0.706)	1.00 (Z = 2.05, p = 0.040)
	Costs of primary and community care		
Costs of primary and community care	1.00 (Z = 1.22, p = 0.222)	1.00 (Z = 2.39, p = 0.017)	1.00 (Z = 1.64, p = 0.100)
	EQ-5D-5L utility		
EQ-5D-5L utility	0.60 (Z = -1.76, p = 0.078)	0.98 (Z = -0.06, p = 0.950)	0.84 (Z = -0.37, p = 0.709)
	EQ-5D-5L VAS		
EQ-5D-5L VAS	1.00 (Z = -0.87, p = 0.382)	1.00 (Z = -0.12, p = 0.905)	0.99 (Z = -1.38, p = 0.168)

TABLE 31 Univariate logistic regressions on associations between missingness of variable at one time point and their respective values at other time points (*continued*)

Missing on	OR (Z, p)		
	Values of		
	Spending on NRT		
Spending on NRT	0.98 (Z = -0.77, p = 0.443)	1.04 (Z = 1.20, p = 0.231)	–
	Spending on cigarettes		
Spending on cigarettes	1.00 (Z = 0.76, p = 0.446)	1.00 (Z = 0.91, p = 0.365)	1.00 (Z = -0.64, p = 0.520)
	Spending on travelling to receive care		
Spending on travelling to receive care	1.01 (Z = 0.79, p = 0.428)	0.99 (Z = -0.42, p = 0.678)	1.01 (Z = 1.26, p = 0.207)
	Lost income		
Lost income	1.00 (Z = -0.61, p = 0.544)	–	–
Week 24	Baseline	Week 4	Week 12
	Costs of smoking cessation advice		
Costs of smoking cessation advice	0.99 (Z = -1.51, p = 0.130)	0.99 (Z = -1.11, p = 0.266)	0.99 (Z = -0.89, p = 0.371)
	Costs of NRT prescription		
Costs of NRT prescription	0.98 (Z = -0.81, p = 0.418)	0.99 (Z = -0.64, p = 0.521)	0.99 (Z = -0.53, p = 0.597)
	Costs of emergency and secondary care		
Costs of emergency and secondary care	1.00 (Z = 0.06, p = 0.956)	1.00 (Z = -1.02, p = 0.306)	1.00 (Z = 0.15, p = 0.884)
	Costs of primary and community care		
Costs of primary and community care	1.00 (Z = 0.45, p = 0.652)	1.00 (Z = 0.60, p = 0.546)	1.00 (Z = -0.78, p = 0.438)
	EQ-5D-5L utility		
EQ-5D-5L utility	0.73 (Z = -1.11, p = 0.269)	1.07 (Z = 0.18, p = 0.856)	1.38 (Z = 0.69, p = 0.488)
	EQ-5D-5L VAS		
EQ-5D-5L VAS	1.00 (Z = -0.62, p = 0.535)	0.99 (Z = -0.98, p = 0.329)	1.00 (Z = -0.66, p = 0.509)
	Spending on NRT		
Spending on NRT	0.91 (Z = -1.29, p = 0.197)	1.03 (Z = 1.16, p = 0.246)	1.03 (Z = 1.13, p = 0.259)
	Spending on cigarettes		
Spending on cigarettes	1.00 (Z = 2.34, p = 0.019)	1.00 (Z = 0.84, p = 0.401)	1.00 (Z = 0.16, p = 0.873)
	Spending on travelling to receive care		
Spending on travelling to receive care	1.03 (Z = 1.62, p = 0.105)	0.98 (Z = -0.72, p = 0.472)	0.99 (Z = -0.26, p = 0.792)
	Lost income		
Lost income	1.00 (Z = -0.63, p = 0.530)	–	–
Bold indicates a statistically significant difference (p < 0.05).			

Appendix 8

Detailed results of the primary analysis and complete case analysis

The mean VAS score was 51.8 (SE 1.5) at baseline, 57.0 (SE 1.6) at week 4, 58.1 (SE 1.8) at week 12, and 58.4 (1.6) at week 24 in the EC group. It was 54.5 (SE 1.6) at baseline,

55.5 (SE 1.7) at week 4, 57.8 (SE 1.9) at week 12, and 58.8 (1.6) at week 24 in the UC group.

The mean EQ-5D-5L utility was higher than 0.600 in both groups at all time points ([Table 32](#)). It showed an upward trend in both groups from baseline to week 24 while consistently higher in the EC group than in the UC group at each time point. [Table 33](#) presents the detailed results of the complete case analysis.

TABLE 32 Results of primary cost–utility analysis

	EC (n = 239)	UC (n = 236)
Baseline	Mean (SE)	
Cost of smoking cessation advice	£5 (£2)	£1 (£0)
Costs of NRT prescription	£4 (£2)	£0 (£0)
Costs of emergency and secondary care	£567 (£156)	£582 (£143)
Costs of primary and community care	£520 (£75)	£404 (£75)
<i>Total costs at baseline</i>	<i>£1096 (£184)</i>	<i>£988 (£162)</i>
Trial period	Mean (SE)	
Costs of EC/UCs	£92 (£0)	£50 (–)
Cost of smoking cessation advice	£13 (£3)	£25 (£5)
Costs of NRT prescription	£5 (£2)	£12 (£4)
Costs of emergency and secondary care	£1898 (£385)	£1173 (£324)
Costs of primary and community care	£1851 (£194)	£1456 (£185)
<i>Total costs</i>	<i>£3859 (£441)</i>	<i>£2716 (£386)</i>
EQ-5D-5L utility	Mean (SE)	
Baseline	0.621 (0.020)	0.603 (0.022)
Week 4	0.648 (0.023)	0.623 (0.025)
Week 12	0.656 (0.024)	0.640 (0.031)
Week 24	0.677 (0.023)	0.662 (0.030)
QALYs	0.303 (0.008)	0.295 (0.010)
Adjusted incremental difference	Mean (95% CI)	
Incremental costs	£1267 (£219 to £2347)	
Incremental QALYs	0.007 (–0.016 to 0.033)	
ICER	£181,000 (uncertainty see Figure 2)	

TABLE 33 Sensitivity analysis: CCA results

	EC (n = 106)	UC (n = 77)
Baseline	Mean (SE)	
Cost of smoking cessation advice	£2 (£1)	£0 (£0)
Costs of NRT prescription	£2 (£1)	£1 (£1)
Costs of emergency and secondary care	£344 (£116)	£714 (£354)
Costs of primary and community care	£513 (£120)	£325 (£64)
<i>Total costs</i>	<i>£861 (£177)</i>	<i>£1040 (£359)</i>
Trial period	Mean (SE)	
Costs of EC/UCs	£92 (£0)	£50 (-)
Cost of smoking cessation advice	£16 (£6)	£25 (£10)
Costs of NRT prescription	£2 (£1)	£12 (£8)
Costs of emergency and secondary care	£1463 (£362)	£1722 (£884)
Costs of primary and community care	£1624 (£257)	£996 (£166)
<i>Total costs</i>	<i>£3197 (£464)</i>	<i>£2805 (£897)</i>
EQ-5D-5L utility	Mean (SE)	
Baseline	0.603 (0.032)	0.645 (0.038)
Week 4	0.635 (0.032)	0.661 (0.036)
Week 12	0.655 (0.033)	0.675 (0.038)
Week 24	0.684 (0.031)	0.683 (0.037)
QALYs	0.301 (0.013)	0.310 (0.015)
Adjusted incremental estimates	Mean (95% CI)	
Incremental costs	£1023 (-£100 to £1823)	
Incremental QALYs	0.010 (-0.021 to 0.035)	
ICER	£102,300 (uncertainty see Figure 3)	

[Figure 8](#) illustrates the upwards trend of the changes of EQ-5D-5L utility values of both groups in primary analysis and CCA. In the complete cases, the mean utility started lower in the EC group but managed to reach the similar level as in the UC group week 24. The difference in utilities between primary analysis and CCA was more prominent in

the UC group than in the EC group. However, it should be noted that [Figure 8](#) adopted a Y-axis range of 0.58–0.70 only to demonstrate more clearly on the difference. In a full range of 0–1, the changes from baseline to week 24 were not as significant as shown in [Figure 8](#).

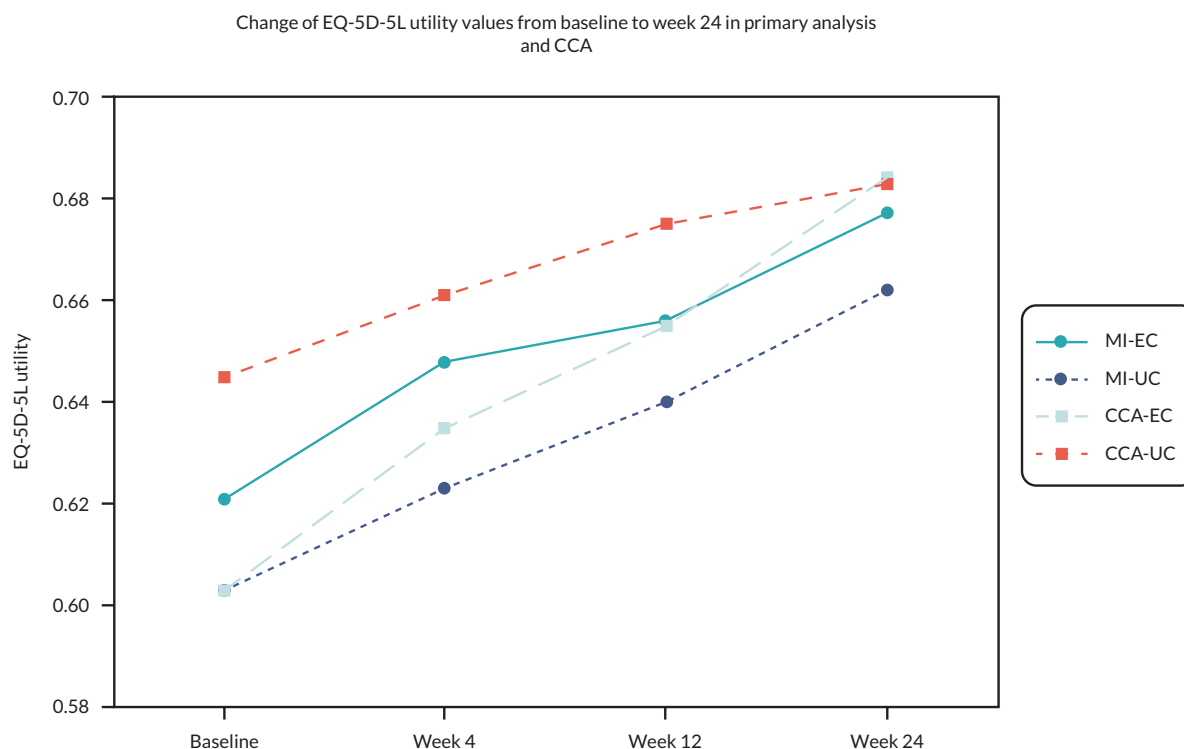


FIGURE 8 Comparison of changes of EQ-5D-5L utility values from baseline to week 24.

Appendix 9

Detailed results of secondary analyses

Costs per quitter

The 7-day point prevalence of quit was 8.37% (SE 1.79%) at week 4, 4.60% (SE 1.36%) at week 12, and 6.28% (SE 1.57%) at week 24 in the EC group, while it was 2.54% (SE 1.03%) at week 4 and week 12, and 2.12% (SE 0.94%) at week 24 in the UC group. The accumulated costs of smoking cessation were £98 (SE £3) at week 4 and £105 (SE £4) at week 12 in the EC group, while it was £56 (SE £2) at week 4 and £65 (SE £5) at week 12 in the UC group. The costs per quitter were £1172 (SE £247) in the EC group and £2207 (SE £888) in the UC group at week 4,

£2275 (SE £661) in the EC group and £2566 (SE £987) in the UC group at week 12, and ££1753 (SE £427) in the EC group and £4124 (SE £1755) in the UC group at week 24.

Incremental cost-effectiveness analysis from societal perspective

The mean spending on NRT products and travelling to receive care was low across the trial period, with the highest of £4.27 (SE £2.34) per participant at week 24 in the UC group (Table 34). Accounting for the different recall periods, the mean spending on tobacco dropped from over £100 per week before baseline to below £100 per week in the first 4 weeks of the trial, then went back to over £100 per week from week 4 to week 12, and continued increasing to over £200 per week between week 12 and week 24.

TABLE 34 Mean participants' spending on NRT, tobacco and travelling to receive care at all time points by group

Participants' spending	EC (n = 239)	UC (n = 236)
	Mean (SE)	Mean (SE)
On NRT products		
Week 4–baseline	£0.86 (£0.55)	£0.15 (£0.11)
Baseline–week 4	£0.47 (£0.47)	£0.50 (£0.24)
Week 4–week 12	£0.29 (£0.29)	£0.43 (£0.25)
Week 12–week 24	£0.56 (£0.28)	£0.35 (£0.24)

TABLE 34 Mean participants' spending on NRT, tobacco and travelling to receive care at all time points by group (*continued*)

Participants' spending	EC (n = 239)	UC (n = 236)
	Mean (SE)	Mean (SE)
On tobacco-related products		
Week 4–baseline	£428.81 (£30.94)	£411.12 (£28.52)
Baseline–week 4	£268.76 (£19.00)	£289.26 (£24.06)
Week 4–week 12	£1008.96 (£86.47)	£1204.55 (£92.81)
Week 12–week 24	£2429.03 (£185.39)	£2693.07 (£201.07)
On travelling to receive care		
Week 4–baseline	£0.80 (£0.23)	£1.77 (£0.48)
Baseline–week 4	£0.94 (£0.39)	£1.01 (£0.34)
Week 4–week 12	£1.45 (£0.56)	£1.36 (£0.44)
Week 12–week 24	£1.04 (£0.42)	£4.27 (£2.34)

Long-term cost-effectiveness extrapolation

TABLE 35 Model input parameters from the trial results

	EC	UC
Mean age	42.1	45.3
Male (n, %)	193/239 (81%)	202/236 (86%)
Over 24 weeks		
Total costs	£3833 (448)	£2722 (388)
QALYs	0.302 (0.009)	0.293 (0.010)
CO-validated sustained abstinence	0.021 (0.009)	0.008 (0.006)

