

# Evaluating Long-term Outcomes of NHS Stop Smoking Services (ELONS): a prospective cohort study

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# Abstract

## Evaluating Long-term Outcomes of NHS Stop Smoking Services (ELONS): a prospective cohort study

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**Background:** NHS Stop Smoking Services (SSSs) provide free at the point of use treatment for smokers who would like to stop. Since their inception in 1999 they have evolved to offer a variety of support options. Given the changes that have happened in the provision of services and the ongoing need for evidence on effectiveness, the Evaluating Long-term Outcomes for NHS Stop Smoking Services (ELONS) study was commissioned.

**Objectives:** The main aim of the study was to explore the factors that determine longer-term abstinence from smoking following intervention by SSSs. There were also a number of additional objectives.

**Design:** The ELONS study was an observational study with two main stages: secondary analysis of routine data collected by SSSs and a prospective cohort study of service clients. The prospective study had additional elements on client satisfaction, well-being and longer-term nicotine replacement therapy (NRT) use.

**Setting:** The setting for the study was SSSs in England. For the secondary analysis, routine data from 49 services were obtained. For the prospective study and its added elements, nine services were involved. The target population was clients of these services.

**Participants:** There were 202,804 cases included in secondary analysis and 3075 in the prospective study.

**Interventions:** A combination of behavioural support and stop smoking medication delivered by SSS practitioners.

**Main outcome measures:** Abstinence from smoking at 4 and 52 weeks after setting a quit date, validated by a carbon monoxide (CO) breath test.

**Results:** Just over 4 in 10 smokers (41%) recruited to the prospective study were biochemically validated as abstinent from smoking at 4 weeks (which was broadly comparable with findings from the secondary analysis of routine service data, where self-reported 4-week quit rates were 48%, falling to 34% when biochemical validation had occurred). At the 1-year follow-up, 8% of prospective study clients were CO validated as abstinent from smoking. Clients who received specialist one-to-one behavioural support were twice as likely to have remained abstinent than those who were seen by a general practitioner (GP) practice and pharmacy providers [odds ratio (OR) 2.3, 95% confidence interval (CI) 1.2 to 4.6]. Clients who received group behavioural support (either closed or rolling groups) were three times more likely to stop smoking than those who were seen by a GP practice or pharmacy providers (OR 3.4, 95% CI 1.7 to 6.7). Satisfaction with services was high and well-being at baseline was found to be a predictor of abstinence from smoking at longer-term follow-up. Continued use of NRT at 1 year was rare, but no evidence of harm from longer-term use was identified from the data collected.

**Conclusions:** Stop Smoking Services in England are effective in helping smokers to move away from tobacco use. Using the 52-week CO-validated quit rate of 8% found in this study, we estimate that in the year 2012–13 the services supported 36,249 clients to become non-smokers for the remainder of their lives. This is a substantial figure and provides one indicator of the ongoing value of the treatment that the services provide. The study raises a number of issues for future research including (1) examining the role of electronic cigarettes (e-cigarettes) in smoking cessation for service clients [this study did not look at e-cigarette use (except briefly in the longer-term NRT study) but this is a priority for future studies]; (2) more detailed comparisons of rolling groups with other forms of behavioural support; (3) further exploration of the role of practitioner knowledge, skills and use of effective behaviour change techniques in supporting service clients to stop smoking; (4) surveillance of the impact of structural and funding changes on the future development and sustainability of SSSs; and (5) more detailed analysis of well-being over time between those who successfully stop smoking and those who relapse. Further research on longer-term use of non-combustible nicotine products that measures a wider array of biomarkers of smoking-related harm such as lung function tests or carcinogen metabolites.

**Funding:** The National Institute for Health Research Health Technology Assessment programme. The UK Centre for Tobacco and Alcohol Studies provided funding for the longer-term NRT study.



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**BOX 1** The WHO-5 Well-being Index

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# Glossary

**Adjusted odds ratio** Odds ratio from a logistic regression model where other variables have been taken into account.

**Level 2 practitioner** Practitioner who is employed by an organisation other than the Stop Smoking Service (usually a general practitioner practice or pharmacy), but is trained in assisting with quit attempts as one of a number of job roles (e.g. practice nurses, pharmacy assistants). They are sometimes called 'community practitioners' or 'local enhanced service practitioners.'

**Service provider** An organisation commissioned to provide smoking cessation interventions, specifically behavioural support and access to medication.

**Specialist practitioner** Practitioner who is employed directly by the Stop Smoking Service management and assisting with quit attempts is the sole or main part of their role.

**Stop Smoking Services** These are government-funded smoking cessation services. At the time of the data collection they were administered through the NHS but are now administered through local authorities.



# List of abbreviations

aOR	adjusted odds ratio	NRT	nicotine replacement therapy
CI	confidence interval	NSSEC	National Statistics Socio-Economic Classification
CO	carbon monoxide	OR	odds ratio
CSS	client satisfaction survey	PCRN	Primary Care Research Network
DH	Department of Health	PCT	primary care trust
e-cigarette	electronic cigarette	p.p.m.	parts per million
ELONS	Evaluating Long-term Outcomes of NHS Stop Smoking Services study	R&D	research and development
FCTC	Framework Convention on Tobacco Control	SES	socioeconomic status
GP	general practitioner	SSS	Stop Smoking Service
HTA	Health Technology Assessment	TNS BMRB	Taylor Nelson Sofres, British Market Research Bureau
IMD	Index of Multiple Deprivation	UKCTAS	UK Centre for Tobacco and Alcohol Studies
NCSCT	National Centre for Smoking Cessation and Training	vif	variance inflation factor
NICE	National Institute for Health and Care Excellence	WHO	World Health Organization
NIHR	National Institute for Health Research		





# Plain English summary

## What was the problem/question?

The UK Stop Smoking Services (SSSs) have provided free treatment for smokers who would like to stop since 1999. The last major evaluation of English services took place from 2000–4 and since that time the services have undergone many changes. Thus, a new evaluation was appropriate.

## What did we do?

This study involved routine data from 49 of 150 English SSSs and a study of long-term outcomes of service clients in nine areas of England.

## What did we find?

Routinely collected 4-week follow-up data revealed that 34% clients reported that they had quit and had a consistent breath test result. Services were reaching up to 10% of smokers in their area.

At 1 year, 8% of the 3057 clients who took part in the long-term study stated that they had remained quit and had a supporting breath test. Clients who received specialist one-to-one support were twice as likely to quit and those who attended groups were three times more likely to stop than those seen by general practitioner practice and pharmacy staff. Of the 996 clients who responded to a satisfaction survey, 87% were satisfied or very satisfied.

## What does this mean?

If the 1-year quit rates from this study are applied to all of England, we estimate that in the year 2012–13 the services supported 36,249 clients to become non-smokers for the rest of their lives. Thus, SSSs make a valuable and valued contribution to tobacco control.



# Scientific summary

## Background

NHS Stop Smoking Services (SSSs) provide free at the point of use treatment for smokers who would like to stop. They were piloted in 1999 and rolled out across the UK from 2000. Since their inception they have evolved to offer a variety of support options. In particular, the services have moved away from offering support in groups, to providing a range of one-to-one support options in different settings. There are now also a wider variety of types of practitioner offering stop smoking support, with a particular growth in pharmacy-based provision. Significant differences have been identified between the quit rates 'achieved' by services in different locations, which may be partly because of the quality of behavioural support delivered by the practitioner who offers it. Members of our team conducted a previous national evaluation of SSSs in England between 2000 and 2004. This included a longer-term follow-up element, carried out 1 year after participating smokers had set a quit date. Given the changes that have happened in the provision of services over this decade, and the ongoing need for evidence on effectiveness, the Evaluating Long-term Outcomes for NHS Stop Smoking Services (ELONS) study was commissioned. This report sets out the findings.

## Aim and objectives

The principal aim of the study was to explore the factors that determine longer-term abstinence from smoking following intervention by SSSs.

The study objectives were to:

1. examine the effectiveness of SSSs by primary care trust (PCT) and intervention type using routine data
2. explore the reach of services by identifying what proportion of the local population set a quit date with services using routine data
3. describe the factors that determine longer-term abstinence from smoking or relapse to smoking among clients who set a quit date with services in a sample of PCTs in England
4. examine the relationship between client characteristics [in particular socioeconomic status (SES), age, gender, disability and ethnicity], adherence to treatment, intervention type received and longer-term abstinence
5. create an evidence base to guide delivery of interventions by SSSs so that these interventions will have maximal effect on smoking cessation and population health.

## Method

The ELONS study was an observational study with two main stages:

1. secondary analysis of routine data collected by SSSs
2. a prospective cohort study of SSS clients with three additional elements:
  - i. a client satisfaction survey (CSS)
  - ii. a well-being survey
  - iii. a study of longer-term nicotine replacement therapy (NRT) use.

The setting for the study was SSSs in England. For the secondary analysis, routine data from 49 services were obtained. For the prospective study and its added elements, nine services were involved. The target population was service clients.

## Results

### *Secondary analysis of routine data collected by Stop Smoking Services*

QuitManager (North 51, Nottingham, UK), an online database for recording information on SSS clients, provided the data for analysis. A total of 202,804 clients records were extracted for analysis over two separate time periods: July–December 2010 and January–June 2011.

Key findings from this element were:

- The estimated number of clients treated by SSS from mid-2010 to mid-2011 was 5–10% of their smoking population.
- The self-reported and carbon monoxide (CO)-validated quit rates were 48% and 34% respectively at 4 weeks post quit date. Highest quit rates were found among older people, men and clients with higher SES. January was the month with the highest number of quit dates set and successful quitters.
- Affluent smokers were more likely to be abstinent from smoking at 4 weeks than disadvantaged smokers.
- Varenicline (Champix®, Pfizer) and combination NRT were both used frequently and increased the chances of quitting compared with a single NRT product.
- The majority (79%) of clients received one-to-one behavioural support. This type of support was significantly less successful than open rolling groups [adjusted odds ratio for open groups 1.28, 95% confidence interval (CI) 1.15 to 1.41 compared with one to one].
- Clients who saw specialist practitioners had higher quit rates than those who saw other types of practitioners.
- As a result of SSS treatment, the estimated number of ex-smokers per 100,000 population was 184 from mid-2010– mid-2011.

## Prospective study

The secondary analysis phase of the ELONS study (phase 1) identified SSSs (based on various criteria, e.g. type of behavioural support offered) to be invited to take part in the prospective study. Nine agreed to recruit clients into the prospective study, which required practitioners to consent clients to the study and collect additional client and treatment data. This recruitment approach presented several challenges and the final sample achieved was 3075. Weights were created to correct for non-response as only a small proportion of all eligible clients in each study area were recruited. Key findings include:

- In terms of smoking cessation in the short term, the CO-validated quit rate at 4 weeks was 44.1%. With weighting this reduced marginally to 41.2%.
- For smoking cessation in the longer term, the CO-validated quit rate at 1 year was 9.3% but after weighting this reduced to 7.7%.
- Predictors of abstinence at 52 weeks included:
  - attending group behavioural support or receiving one-to-one support from a specialist practitioner
  - taking varenicline
  - attending in the New Year
  - being older
  - being more affluent
  - having a lower dependence on tobacco

- having a higher well-being score
  - having support from a spouse or partner
  - having a social network not populated with smokers.
- Taking stop smoking medication and attending support sessions (described here as 'adherence') was significantly associated with smoking cessation – more so at 4 weeks than at 1 year.
  - Limited comparisons with previous evaluations of SSSs are possible. Quit rates for 4 and 52 weeks from the ELONS prospective study were lower than those identified in the previous national evaluation in England, but higher than a more recent study in Glasgow that examined closed group and pharmacy-based services.

## Client satisfaction

All clients who participated in the prospective study (regardless of the outcome of their quit attempt) were sent a client satisfaction survey to give feedback on the service they received. There were 1006 questionnaires received and the final data set had 996 cases. Key findings were:

- A consistent pattern emerged that suggested that smokers who accessed SSSs in the study areas and responded to the survey had a positive experience. This was the case for both quitters and non-quitters. The vast majority who replied to the questionnaire indicated that they would recommend the service to others and return should the need arise.
- Additional comments highlighted the importance of practitioner/client rapport and previous research suggests that this is an important factor in a successful quit attempt.
- Despite survey findings suggesting that stop smoking medication was easy to acquire, additional comments pointed to a more complex picture where the process of obtaining this medication was over complicated and time-consuming for some respondents.
- Suggested improvements included evening appointment times, having a choice of group or one-to-one support, and a longer period of behavioural support.

## Well-being study

Well-being can improve after smoking cessation, but smokers often have concerns about stopping because they believe smoking itself brings benefits such as reduced stress levels. As part of the baseline monitoring data collection for the prospective study, clients were asked additional questions about their health and well-being. In addition, all clients, regardless of whether or not they had quit smoking, were sent postal questionnaires at 4 and 52 weeks post quit date, which included questions on well-being. Key findings include:

- Smokers who had higher levels of well-being when they first started attending were more likely to be non-smokers at 4 weeks and 1 year later.
- The most consistent baseline factors associated with well-being at baseline, 4 weeks and 52 weeks were having a diagnosed mental health condition, being dependent on tobacco, and young or older age.
- Clients aged 45–54 years had lower well-being scores than younger and older clients at all three time points, although differences were not always significant.
- Clients who had higher levels of well-being were consistently more likely to agree that they enjoyed a challenge, were doing well in life and felt more in control than other clients. A mediator of the association between dependence on tobacco and well-being appeared to be not being able to cope with stress.

## Longer-term nicotine replacement study

Additional funding was obtained to add an element that focused on longer-term NRT use. This involved collecting saliva samples from participants at baseline and at 1 year and using these to test for relevant biomarkers. Just over one-third of prospective study participants provided information on longer-term NRT use ( $n = 1047$ ) and were included. There were 258 participants (8.5% of the whole ELONS study sample) who provided baseline and follow-up saliva samples that were analysed for biomarkers. Key findings were:

- Of clients followed up at 12 months, 61.5% reported that they had used NRT during their quit attempt. However, this is likely to include over-the-counter use, as this number is substantially higher than the number of participants recorded as using NRT by the services (34.4%).
- Most clients who started on NRT used it for at least 8 weeks and more than one in five (21.5%) used it for longer than the standard 3 months.
- Long-term use was relatively rare with fewer than 1 in 10 participants still using non-combustible nicotine products at the 12-month follow-up (8.4%).
- Within this category of non-combustible nicotine products were electronic cigarettes (e-cigarettes). Few participants reported their use at 1 year (2.9%), although these data include smokers and non-smokers and most people had relapsed by 1 year post quit date. However, e-cigarettes were the most popular single product at 1 year.
- Long-term ex-smokers had much higher odds of still using non-combustible nicotine products at the 12-month follow-up than those who relapsed. Concurrent use among relapsers was 3.7% compared with 14.0% of continuous abstainers. This difference remained significant even after removing those who used e-cigarettes only.
- In terms of the biomarker analysis, 258 participants (8.5% of the whole ELONS study sample) provided baseline and follow-up saliva samples and were included. Greater levels of cotinine were associated with greater self-reported dependence. As expected, within-group analysis showed that smokers who had stopped had significantly lower cotinine levels at follow-up than those who had relapsed to smoking at follow-up. However, this was the case only for ex-smokers who did not use NRT. Cotinine levels for smokers who had stopped at follow-up but who used NRT long term had not changed from baseline to follow-up and neither did cotinine levels for those who had relapsed to smoking (irrespective of NRT use). There were no differences as a function of NRT use and smoking status at follow-up in baseline levels of alpha-amylase, a biomarker of stress.

## Conclusions

In terms of smoking cessation in the short term, findings are broadly comparable with those from routinely collected data from services. From our prospective study of just over 3000 smokers attending SSSs in nine areas of England, we found that just over 4 in 10 (41.2%) were biochemically validated as abstinent from smoking at 4 weeks post quit date. Our secondary analysis of routine data from 49 of 150 services in England found 4-week quit rates of 48% when self-reported data were included, falling to 34% when biochemical validation had occurred. This same analysis found that services were reaching up to 10% of smokers in their area in the year from July 2010. National Institute for Health and Clinical Excellence guidance previously recommended that services aim to reach at least 5% of their smoking population in 1 year. These results provide a useful indicator that (a) routine data provide a helpful and not inaccurate indicator of short-term smoking cessation outcomes and (b) services are continuing to effectively reach smokers and support them to stop.

No routine data exist for longer-term cessation outcomes at 1 year and it is some time since a study in England has looked at this issue. We found that just fewer than 8% of smokers were still abstinent from smoking 1 year after setting a quit date. If these results are applied to all of England, then we estimate that in the year 2012–13 the services supported 36,249 clients to become non-smokers for the remainder of their lives.

A range of factors, including many linked to the characteristics of clients and also SSS characteristics, influenced outcomes. For example, smokers supported to quit with the specialist service were more likely to stop smoking in the longer term. In addition, the ELONS study has shown that longer-term outcomes are influenced by the type of behavioural support a smoker receives; open groups resulted in better outcomes than other forms of behavioural support.

Three additional elements were added to the ELONS study that were more exploratory in nature and have a number of limitations. These focused on client satisfaction, well-being and longer-term NRT use. Overall, we found that those who responded to the satisfaction survey were positive about the support that they received and would recommend SSSs to others. We found that assessment of well-being could be included in routine monitoring and that positive well-being at baseline was a significant predictor of smoking abstinence at 1-year follow-up. Fewer than 1 in 10 clients who had stopped smoking at 1 year were still using non-combustible nicotine products, suggesting that long-term use is not that prevalent. However, among those who did continue to use these products we found no evidence of harm from longer-term use in the data we collected.

The study raises a number of issues for future research including:

- examining the role of e-cigarettes in smoking cessation for service clients. This study did not look at e-cigarette use (except briefly in the longer-term NRT study) but this is a priority for future studies
- more detailed comparisons of rolling groups with other forms of behavioural support
- further exploration of the role of practitioner knowledge, skills and use of effective behaviour change techniques in supporting service clients to stop smoking
- surveillance of the impact of structural and funding changes on the future development and sustainability of SSSs
- more detailed analysis of well-being over time between those who successfully stop smoking and those who relapse
- further research on longer-term use of non-combustible nicotine products that measures a wider array of biomarkers of smoking-related harm such as lung function tests or carcinogen metabolites.

## Funding

The National Institute for Health Research Health Technology Assessment programme. The UK Centre for Tobacco and Alcohol Studies provided funding the longer-term NRT study.





# Chapter 1 Introduction

Tobacco use is one of the leading causes of preventable death in the world. Each year an estimated 5.1 million people die from smoking and another 600,000 die from second-hand smoke exposure.<sup>1,2</sup> As nearly 80% of these deaths occur in low- and middle-income countries,<sup>3</sup> tobacco causes over 90,000 deaths in the UK each year, reflecting decades of high smoking prevalence. Although smoking rates have reduced from 51% of men and 41% women in 1974 to 19% today (21.1% of men and 16.5% of women)<sup>4</sup> they still remain high in the UK compared with countries such as Australia, Canada and Sweden. In addition, smoking rates in Britain are strongly socially patterned, with 29% of adults in routine and manual occupations smoking compared with 13% in managerial and professional groups.<sup>4</sup>

Countries such as the UK have made concerted efforts to reduce smoking rates over several decades. Many of the policies and interventions that have been put in place form part of the Framework Convention on Tobacco Control (FCTC), the world's first global public health treaty that was adopted by the World Health Assembly under the auspices of the World Health Organization (WHO). There are now 178 countries parties to the convention, including the UK.<sup>5</sup> The treaty seeks to reduce the burden of tobacco use through key supply and demand measures, which are laid out in its articles. Demand measures are highlighted in WHO's 'MPOWER' report including 'Monitoring tobacco use and prevention policies', 'Protecting people from tobacco smoke', 'Offering help to quit tobacco use', 'Warning about the dangers of tobacco', 'Enforcing bans on tobacco advertising, promotion, and sponsorship', and 'Raising taxes on tobacco'.<sup>6</sup> Guidance on 'offering help to quit', including the provision of services to support smokers to stop, offering counselling and effective smoking cessation medications, is contained in article 14 of the FCTC.<sup>5</sup> This is an important element of efforts to reduce smoking rates, as the success of unaided quit attempts is generally extremely low (around 5%). The chances of successfully stopping can be significantly raised if effective aids to quitting are made available.<sup>7</sup>

The UK has played a significant role in developing the evidence to underpin effective interventions for smoking cessation as set out in article 14 of the FCTC.<sup>5</sup> This has its origins in early studies on smoking and health, to research on nicotine replacement therapy (NRT) and behavioural support, through to real-world evidence on how a national treatment service for smoking can be developed and established. To introduce this study, we set out some of this historical background here, before outlining how the current study helps to bring this evidence base up to date and should inform the design of future services.

## Early research on smoking cessation in the UK

The first evidence of clear links between tobacco smoking and ill-health emerged in the 1950s when Doll and Hill published the first paper showing that smoking caused lung cancer.<sup>8</sup> This, and other evidence, led to the production of two important reports – one in the UK and one in the USA – on smoking and health. In the UK the Royal College of Physicians report of 1962 outlined the need for a comprehensive approach to reduce smoking rates.<sup>9</sup> This described a series of needed policy measures including tobacco taxes, restricting advertising and availability, education on the risks of smoking and, importantly, support for smokers wanting to quit. In the end, it would take almost 50 years for all the recommendations in *Smoking and Health* to be implemented, but in the meantime a range of important studies were conducted that provided better evidence on smoking as an addiction, rather than a 'habit', and consequently how it should be treated.<sup>10</sup> A number of early studies on nicotine and NRT were conducted by Professor Michael Russell and colleagues at the Addiction Research Unit at the University of London. These contributed to the licensing of the first pharmacological treatment for smoking cessation in 1981 – nicotine gum. From that period onwards a number of important research and policy developments on smoking cessation took place in the UK. Members of our team summarised these in an earlier study and we reproduce these here, outlined in *Table 1*.<sup>10</sup>

**TABLE 1** Key events and tobacco control initiatives 1950–2000 in the UK

Year	Event
<b>The 1950s</b>	
1950	Doll and Hill paper published in the BMJ <sup>8</sup>
1951	British doctors' study commences
1959	First smoking dependence treatment clinic opens in Salford, Greater Manchester, UK
<b>The 1960s</b>	
1962	First RCP report, <i>Smoking and Health</i> <sup>9</sup>
1962	Tobacco Practitioners Council (representing the tobacco industry) agreed to implement a code of advertising practice for cigarettes
1965	Television cigarette advertising ban
1967	Creation of Health Education Council
<b>The 1970s</b>	
1970	Mike Russell starts building a smoking research team at the Addiction Research Unit
1971	Second RCP report, <i>Smoking and Health Now</i> <sup>11</sup>
1971	Voluntary agreements on advertising began
1971	Creation of ASH
	Voluntary agreements on health warnings
1977	Third RCP report, <i>Smoking or Health</i> <sup>12</sup>
1977	Government health circular expressed need for smoking policies on all health premises
<b>The 1980s</b>	
1981	NRTs 'blacklisted'
1983	Fourth RCP report, <i>Health or Smoking?</i> <sup>13</sup>
	Voluntary agreements on product modification
	Excise duties on tobacco begin to rise significantly
1986	British Medical Association join campaign against tobacco industry
<b>The 1990s and 2000s</b>	
1991	Illegal sales law strengthened
1992	Fifth RCP report, <i>Smoking and the Young</i> <sup>14</sup>
1993	Government commits to 3% above inflation tax increase on cigarettes
1993	Ban on oral snuff throughout European Union
1997	Government commits to 5% above inflation tax increase on cigarettes
1998	White Paper, <i>Smoking Kills</i> <sup>15</sup>
1998	First English evidence-based guidelines on smoking cessation <sup>16</sup>
1999	First smoking cessation treatment services established in the English NHS
2000	NHS smoking cessation treatment services established nationally
2013	SSSs transferred from NHS to local authorities
ASH, Action on Smoking and Health; BMJ, <i>British Medical Journal</i> ; RCP, Royal College of Physicians; SSSs Stop Smoking Services.	

## NHS Stop Smoking Services

The NHS Stop Smoking Services (SSSs) were established following the publication of the 1998 White Paper, *Smoking Kills*.<sup>15</sup> Initially piloted in deprived areas of England in 1999, they were rolled-out across the UK from 2000. The services were developed on the basis of national guidance issued by the Department of Health (DH) that built on a review of the evidence of the effectiveness of smoking cessation interventions published in the journal *Thorax*.<sup>16</sup> This evidence emphasised the efficacy of intensive behavioural support (in groups or one to one) plus pharmacotherapy for smoking cessation. Services were established by primary care trusts (PCTs) and operated primarily in primary care settings delivering behavioural support and providing access to NRT and bupropion (Zyban®, GlaxoSmithKline). From 2000–4, a national evaluation of the services in England was conducted by members of our team. The evaluation found that the services were effective in supporting smokers to quit in the short term (at 4 weeks)<sup>17</sup> and the longer term (at 1 year),<sup>18</sup> and were reaching smokers from more deprived groups.<sup>19</sup> A subsequent analysis by our team also found that they were making a contribution to reducing inequalities in health caused by smoking.<sup>20</sup> However, since these studies were conducted, NHS SSSs have continued to evolve, attempted to adapt to meet local needs and encountered various financial and structural challenges. National developments, including the National Institute for Health and Care Excellence (NICE)'s guidance on services (published in 2008),<sup>21</sup> have influenced what is available and smoking cessation medications have also diversified, with new NRT products and the medication varenicline (Champix®, Pfizer) providing additional options for smokers trying to stop.

One element that has changed in the past decade is the type and variety of behavioural support options available to smokers using the services. In particular, a heavier reliance on one-to-one support options in a far wider range of settings. The existing evidence base from systematic reviews of trials would suggest that there is no significant difference in outcomes for smokers receiving group or one-to-one behavioural support. In a review of 50 randomised controlled trials<sup>22</sup> and another review of 23 studies since January 2000,<sup>23</sup> a group format for a behavioural intervention was not found to be significantly different from an individual format; yet real-world evidence may be different from trials in this respect. Findings from our earlier studies with NHS SSSs suggest that group interventions may be more effective in practice<sup>24</sup> but that smokers, given a choice, will choose one-to-one support. Issues of perceived preference may have led to the dominance of one-to-one support in today's services although new forms of group counselling (such as 'rolling groups' where clients can join without having to wait for a new group to start) have emerged.

Another element that has evolved is who provides support to stop smoking. Before the services existed, this was primarily doctors and nurses in primary care or hospitals with a few examples of specialist clinics. Today, a wider variety of professionals are involved in delivering support. In some cases this is described as different 'levels' of support. We describe these levels here.

- Level 1 practitioners are typically primary care professionals who deliver 'brief interventions', which usually involves opportunistic advice, discussion, awareness raising and/or referral to SSSs.
- Level 2 practitioners (known elsewhere as community practitioners) do not work exclusively as stop smoking specialists but instead work in other health and social care roles and deliver stop smoking support as one of a number of job tasks. The majority of level 2 service provision takes place in general practitioner (GP) practices (usually delivered by nurses and health-care assistants) and pharmacies (delivered by practitioners with a variety of posts from pharmacists to pharmacy assistants). Generally one-to-one support is offered.
- Level 3 practitioners' sole remit is to deliver smoking cessation working as smoking cessation 'specialists'. They offer a wider variety of behavioural support which can include: open and closed groups, one to ones, drop-in services, text and telephone support,<sup>25</sup> and work in various locations such as community centres, GP practices and workplaces.

For clarity, throughout this report we will differentiate between level 2 and level 3 service providers by using the terms 'level 2' and 'specialist' practitioners. Data on level 1 support are not collected by the SSS and is not part of the study.

A growing proportion of clients now receive support from level 2 practitioners. Large differences have now been identified between the quit rates achieved by services in different locations, which may be partly because of the quality of behavioural support delivered by the practitioner who offers it.<sup>26-28</sup>

The organisational context within which SSSs operate has also changed since our earlier studies. Some of these changes preceded the Evaluating Long-term Outcomes of NHS Stop Smoking Services (ELONS) study (e.g. reorganisation of PCTs in England) but possibly the most significant change occurred in April 2013, just after the fieldwork was completed, when commissioning of local SSSs moved from NHS to local authority control. This resulted in change to the funding and delivery structure of local SSSs, with some areas either reducing funding for the specialist service in favour of a greater reliance on level 2 providers or tendering out previously in-house services which has sometimes led to SSSs being run by private and voluntary sector companies. This structural change poses challenges for the services and preparation for the move also, to some extent, affected study recruitment, which is discussed further in *Chapter 4*.

As a result of all these changes, current research is needed to examine the longer-term efficacy of the different methods employed by NHS SSSs to deliver support to smokers trying to stop. Current evidence is also required to explore the effectiveness of services with different groups of smokers, particularly those from more disadvantaged groups. This report sets out findings from a study designed to examine these issues.

## Structure of this report

This is a detailed report of a complex study with a number of different elements. *Chapter 2* presents an overview of the research including aims and objectives, study design and settings. It also describes the ethical approval and local research permissions process.

*Chapters 3 and 4* present the methods and main findings of the secondary analysis element of the ELONS study respectively. *Chapters 5 and 6* describe the methods and analysis (see *Chapter 5*) and the results and key findings (see *Chapter 6*) for the second (and main) part of our study. This was a prospective cohort study of smokers using the services who were followed up in the short (4 weeks post quit date) and longer term (at 1 year).

The subsequent three chapters present findings from elements that were added to the ELONS prospective study. For ease and clarity, they are presented as standalone chapters including the methods and results for each. The focus of *Chapter 7* is an exploration of client satisfaction with the support received from their local SSS. *Chapter 8* examines the relationship between well-being and smoking status of ELONS study participants. *Chapter 9* outlines findings from a study of longer-term NRT use that was made possible by additional funding from the UK Centre for Tobacco Control Studies [now the UK Centre for Tobacco and Alcohol Studies (UKCTAS) – [www.ukctas.ac.uk](http://www.ukctas.ac.uk)]. The remaining two chapters include the discussion (see *Chapter 10*) with conclusions presented in *Chapter 11*.

## Chapter 2 Evaluating Long-term Outcomes of NHS Stop Smoking Services overview

This purpose of this chapter is to present an overview of the ELONS study including aims and objectives, study design, setting and the rationale for the methods used. It also describes the ethical approval and the local research permissions process.

### Aim and objectives

The principal aim of the study was to explore the factors that determine longer-term abstinence from smoking following intervention by SSSs in England.

The study objectives were to:

- examine the effectiveness of SSSs by PCT and intervention type using routine data
- explore the reach of services by identifying what proportion of the local population set a quit date with services using routine data
- describe the factors that determine longer-term abstinence from smoking or relapse to smoking among clients who set a quit date with services in a sample of PCTs in England
- examine the relationship between client characteristics [in particular socioeconomic status (SES), age, gender, disability and ethnicity], adherence to treatment, intervention type received and longer-term abstinence
- create an evidence base to guide delivery of interventions by SSSs so that these interventions will have maximal effect on smoking cessation and population health.

### Overview of study design

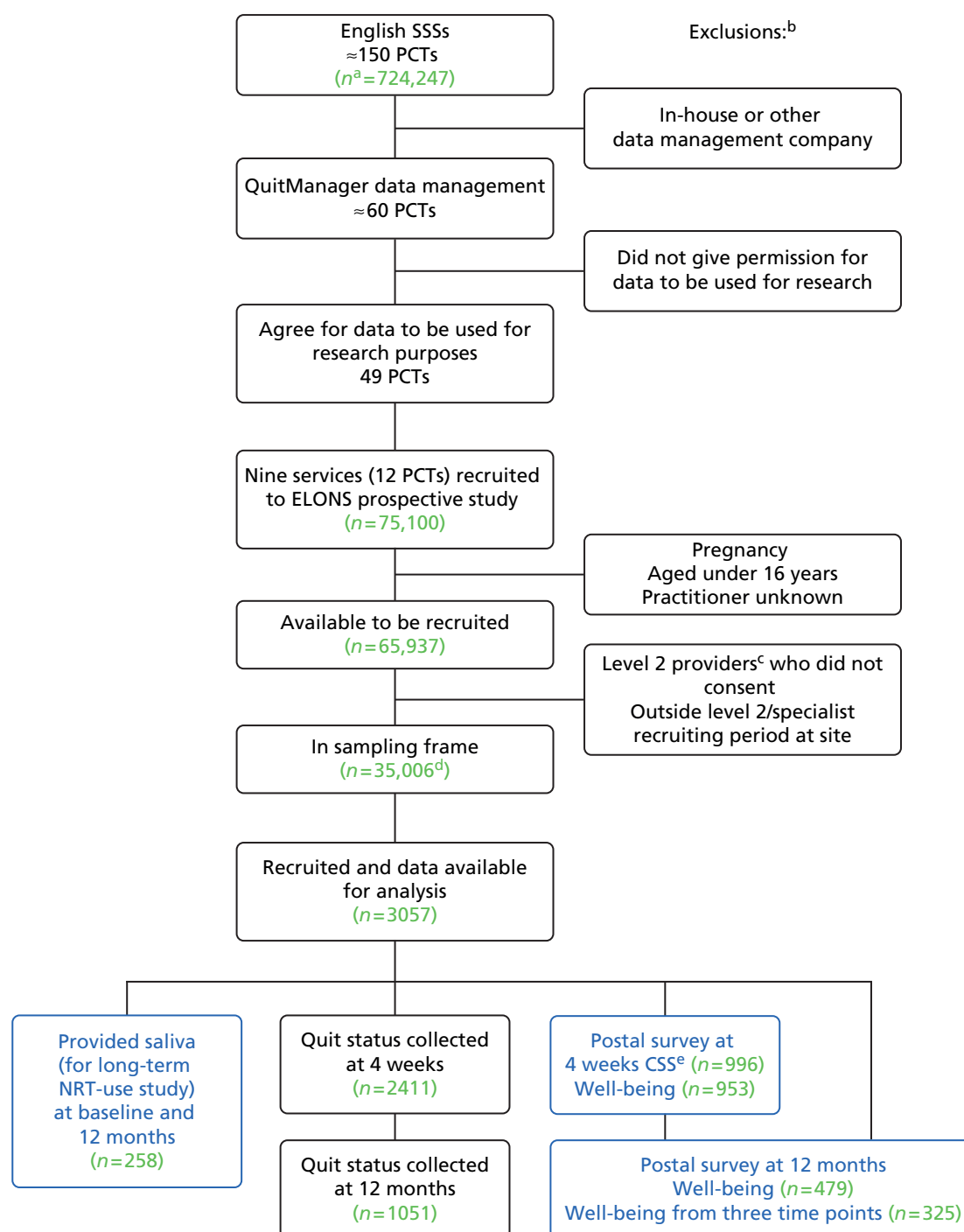
The ELONS study was an observational study with two main stages:

- secondary analysis of routine data collected by SSSs
- a prospective cohort study of SSS clients with three additional elements (which are presented as standalone chapters on the report):
  - a client satisfaction survey (CSS)
  - a well-being survey
  - a study of longer-term NRT use.

The overall aim of the prospective element of the ELONS study was to collect long-term follow-up data at 52 weeks. A subsidiary aim was to collect detailed information about clients and the treatment they received in a consistent manner. Data were collected at three key stages: baseline (i.e. when a client registered with the SSS), 4-week follow-up and 52 weeks post quit date. The 52-week follow-up data were collected by a research company, TNS BMRB (Taylor Nelson Sofres, British Market Research Bureau), that had worked with the academic team on a previous study.<sup>29</sup> Table 2 describes the data collected at each time point and also summarises the data collected for the three additional elements (client satisfaction, well-being and long-term NRT). Further detail of the data collected at each stage and data collection tools can be found in Appendix 1. A flow chart depicting sample sizes and sampling frames is also available (Figure 1).

TABLE 2 Prospective study design

Collection time point	Normal SSS practice	Prospective study	Client satisfaction	Well-being evaluation	Long-term NRT evaluation
Baseline (client registers with service)	<ul style="list-style-type: none"> <li>Monitoring data collected by SSS practitioners either on paper or input directly to QuitManager (North 51, Nottingham, UK)</li> <li>Client asked to set quit date</li> </ul>	<ul style="list-style-type: none"> <li>Consent for participation in the ELONS study</li> <li>Enhanced monitoring data: more SES measurements and medical conditions collected more consistently, smoking behaviour and quit attempt-related information collected by practitioners (except for Northants and Rotherham where data were collected by PCRN)</li> </ul>		WHO-5 Well-being Index scale added to enhanced monitoring data	Clients asked by practitioner to provide two saliva samples
4 weeks post quit date	<ul style="list-style-type: none"> <li>Practitioner follows up clients and if they self-report quit and consent performs CO validation</li> </ul>		Client satisfaction and well-being postal survey to all clients administered by research team		
Period that client is in contact with the services	<ul style="list-style-type: none"> <li>Practitioner records sessions and medication taken</li> </ul>	<ul style="list-style-type: none"> <li>Research team receives the ELONS study client data extracts from QuitManager fortnightly (and paper forms from Northants and Rotherham). Anomalies queried with sites</li> </ul>			
When client leaves	<ul style="list-style-type: none"> <li>Paper monitoring forms input to QuitManager</li> </ul>				
12 months post quit date		<p>TNS BMRB collect:</p> <ul style="list-style-type: none"> <li>Self-report quit via telephone for participants who were quit at 4 weeks</li> <li>CO-validation of self-report quitters collected by home visit</li> </ul>		<p>Well-being postal survey to all clients administered by research team</p> <ul style="list-style-type: none"> <li>TNS BMRB collect saliva samples at home visit</li> <li>Saliva samples collected from sample of non-quitters by post by NRT long-term evaluation team</li> </ul>	
CO, carbon monoxide; PCRN, Primary Care Research Network.					



**FIGURE 1** Flow diagram for the ELONS prospective study. a, *n* refers to quit attempts at the SSS from March/April 2012 to March 2013; b, more detail is available in *Chapters 5 and 6*; c, providers' employees provide smoking cessation support rather than specialists employed directly by SSSs; d, this is an overestimate because level 2 providers who did recruit did not usually recruit for the level 2 recruitment period at each site; and e, CSS.



## Definitions of smoking cessation

Smoking cessation, or 'quitting', was defined in the following ways for this study.

### *Short-term (4 weeks after quite date) self-reported quitting*

In normal SSS treatment, 4 weeks after their quit date, advisors ask their clients (either in person at a session or, if they have stopped attending treatment, by telephone) whether or not they have smoked a cigarette in the last 2 weeks. Clients who indicate that they have not smoked in this period are classified as a 'self-report' quitter at 4 weeks.

### *Short-term (4 weeks after quite date) carbon monoxide-validated quitting*

During treatment sessions clients are asked to breathe into a carbon monoxide (CO) monitor, which records the CO parts per million (p.p.m.). If clients reduce the number of cigarettes smoked their CO level falls. This can be motivating as it provides a visual representation of how stopping smoking reduces exposure to CO, which is a harmful chemical. If a client has not been smoking for the past 24 hours then the level usually falls below 10 p.p.m.<sup>30</sup> Thus, at 4 weeks if a client has self-reported that they have stopped smoking and their CO level is < 10 p.p.m. then they are said to be a CO-validated quitter at 4 weeks. In this report, we refer to CO-validated quitting and in places also as 'biochemically validated' quitting or abstinence. Where we state biochemical validation, we mean CO validation.

If the client refuses to take a CO test then they are classified as a self-report quitter only. In a minority of cases, clients may self-report that they have stopped smoking but their CO level will be  $\geq 10$  p.p.m. In this case they are said to be a 'self-reported quitter who has been refuted by CO validation'. For this study, this small minority were classified as non-quitters in quit rate and regression analysis.

### *Longer-term (52 weeks after quite date) self-reported quitting*

The research team (in this case TNS BMRB) contacted clients who self-reported quitting at 4 weeks by telephone 12 months after their quit date and asked if they had smoked within the last 7 days. Those that had not smoked in this period were then asked if they had smoked since their quit date. If they had smoked up to but not more than five cigarettes they were classified as achieving 'self-reported continuous abstinence', as consistent with the Russell standard<sup>30</sup> (the recognised standard for smoking cessation studies and also validating cessation in clinical practice). If they had smoked more cigarettes they were classified as achieving 'self-reported point prevalence abstinence'. For the analysis outlined here, only those achieving continuous abstinence and whose self-report was not refuted by the CO breath test were classified as 52-weeks self-report quitters.

### *Longer-term (52 weeks after quite date) carbon monoxide-validated quitting*

All clients who had achieved point prevalence self-report abstinence were asked if a researcher could make a home visit and carry out a CO breath test. For the analysis reported here clients with a CO level of < 10 p.p.m. and who had also self-reported that they were continuously abstinent since their quit date were classified as 52 week CO-validated quitters. Biochemically (CO-validated) abstinence from smoking at 52 weeks was the primary outcome for this study.



## Setting

The setting for the study was SSSs in England. For the secondary analysis, routine data from 49 services were obtained. For the prospective study, nine services were involved. These were Bristol, County Durham and Darlington, Hull and East Riding, Leicestershire County and Rutland, North and North East Lincolnshire, Northamptonshire, Oldham, Rotherham, and South East Essex. The target population was clients of these services. The health technologies that the ELONS study assessed were the treatment provided by SSSs – a combination of behavioural support and medication intended to increase the chance of a successful quit attempt. A key focus was to evaluate outcomes for smokers who received one of the five main forms of behavioural support (also called intervention types) provided by the services:

- closed groups (scheduled group sessions of around 1–2 hours dependent on the number of clients, normally delivered once per week and facilitated by a specialist practitioner)
- open/rolling groups (drop-in groups run at a variety of times of day and in a variety of locations where clients can attend without an appointment and for as many weeks as they wish)
- one-to-one drop-in (a clinic hosted at a regular time where clients can attend without an appointment for one-to-one support)
- one-to-one sessions with a specialist practitioner (scheduled one-to-one sessions with a practitioner whose main role it is to help people stop smoking)
- one-to-one sessions with a level 2 practitioner.

## Ethics and local permissions

Ethical approval for the ELONS study was obtained from NHS Lothian (South East Scotland Research Ethics Committee) in June 2011. During the recruitment phase of the prospective study a total of four substantial amendments were made for alternations to the study protocol and consent process. In addition to ethical approval, we also obtained local research and development (R&D) approval for each SSS. For three SSSs, single R&D office approvals were required but for the remainder two sets of approvals were required owing to the location of the SSSs and the NHS trusts involved. All the necessary local approvals were obtained before data collection began. It was also a requirement that the research team obtain NHS research passports and, for one site, it was necessary to obtain Caldicott Guardian approval.

## Public involvement

Members of the public were involved in the ELONS study in a number of ways. Within the prospective study, the public were research participants and the study was designed to provide feedback on an important public service for the benefit of future users. However, more direct forms of involvement were also included in the research.

First, the study principal investigator, Professor Bauld, serves as the public engagement lead for UKCTAS, a UK Clinical Research Collaboration Centre for Public Health Excellence that covers 13 universities (the co-investigators for the study are also UKCTAS members). In this role she convenes a panel of continuing smokers and recent quitters who meet in Bath. The original design for the ELONS study was discussed with the panel at meetings in 2010 and again in 2011, and feedback sought. Initial results were also circulated to panel members at a meeting in 2013. One of the panel members, Robert Graham, was asked to join the study steering group as a lay adviser and did so. Although he was not able to attend all steering group meetings, he maintained contact with Professor Bauld and, having used NHS SSSs himself in the past, provided very useful input.

In addition to panel contributions and Mr Graham's involvement, we had the participant information leaflets and consent forms for the study reviewed by a patient representative. This was organised through the Primary Care Research Network (PCRN) Patient and Public Involvement Manager, and we are grateful to them for facilitating this process.

We also prepared the ELONS study newsletters for all the participating services in the prospective study. There were three of these during the study. These were intended to be available to service clients as well as staff and we sent these to each site for distribution.

Finally, tailored feedback from the study was prepared for each study site and for one site an event was held that involved a varied audience and presentations on study findings. Dissemination at a number of academic and practitioner conferences is currently under way.

## Chapter 3 Secondary analysis of routine data: methods and analysis

This chapter outlines the rational, sample and analytical approach for the secondary analysis element of the ELONS study, with results presented in *Chapter 4*.

### Rationale for secondary analysis

All SSSs in England are required to submit routine monitoring data to the Health and Social Care Information Centre.<sup>31</sup> These data include basic information on client characteristics and the types of treatment received. They also include self-reported smoking status at 4 weeks post quit date. These monitoring data are supplied as aggregated summary returns and so cannot be used to analyse which factors are associated with individual-level smoking cessation outcomes.

Increasingly, however, SSS outsource management of these data to private companies. The most commonly used is QuitManager (North 51, Nottingham, UK).<sup>7,27</sup> QuitManager provides a framework for SSSs to collect the minimum data set required by the DH, plus any additional client and service information thought to be useful locally. The research team includes the Director of the National Centre for Smoking Cessation and Training (NCSCT), who has good links with North 51 and has been able to access their data for previous research and training activities. We were therefore able to obtain QuitManager data for the ELONS study in an anonymised form. This was important as by having access to these data made it possible to examine individual-level information not available from the Health and Social Care Information Centre returns. Data were available from 49 services in England. These data were analysed to fulfil objectives 1 and 2, to examine the effectiveness and reach of services. Results from this first stage also informed the selection of SSSs for the prospective cohort study.

The secondary analysis had two aims:

- to explore the reach of services by identifying the proportion of the local population who set a quit date with services using routine data
- to examine the effectiveness of NHS SSSs by PCT and intervention type using routine data.

### Sample

QuitManager<sup>32</sup> is an online database for recording information on NHS SSS clients, including sociodemographic and treatment characteristics, in accordance with the DH's standard SSS monitoring requirements. Collection of data starts at baseline (first contact with the SSS) and should be updated at each contact point. The data are collected by the stop smoking practitioner and entered onto QuitManager in 'real time' (via the computer software) or recorded on a paper form and entered at a later date. PCTs may elect not to ask clients questions, and clients themselves may not answer every question, leading to missing data. Within PCTs clients whose data are collected on paper forms may answer a slightly different set of questions to those whose data are entered electronically.

At 4 weeks post quit date clients are asked whether or not they have quit smoking for the past 14 days (self-report quit) and clients may also perform a CO breath test. Clients who have self-reported as quit and have CO readings of < 10 p.p.m. are said to be CO-validated as quit. The DH guidelines suggest 85% of clients should be CO validated.<sup>33</sup>

More than 60 out of the  $\approx 150$  English PCTs use QuitManager and 49 of these gave permission to the NCSCST for their data to be used for research purposes. Thus data from these 49 PCTs were included in the analysis.

Data on clients who set quit dates from July to December 2010 were downloaded from QuitManager in January 2012 and data on clients with quit dates between January and June 2011 were downloaded in July 2011. In total there were 202,804 client records included in the database. Each record is a 'treatment episode' where the client sets a quit date and receives treatment. It is possible for clients who relapse to have more than one treatment episode in a year.<sup>33</sup>

## Measures

### Outcomes

#### Efficacy of services: quit rates and carbon monoxide-validation rate

There were three dependent variables explored: self-report quit, CO-validated quit and CO validation. CO validation is the proportion of self-report quit who were also CO validated. We included CO-validated quit because some clients may state they have quit when they have not quit. We included self-report quit because some CO-validation rates vary so by using both of these outcomes, the results are rendered more robust.

The DH considers clients to be quitters only if self-report data are collected between 25 and 42 days after the quit date.<sup>33</sup> Inspection of the QuitManager database suggested that this narrow range may be underestimating the number of quitters, so all clients who self-reported as quit were included in the analysis.

As outlined above, we adhered to the Russell Standard for smoking cessation analysis by taking an intention-to-treat approach where clients with missing quit data were categorised as not quit.<sup>30</sup> Clients setting quit dates in December 2010 and June 2011 were therefore excluded from the analysis as they would not have reached 4 weeks post quit date (when self-report quit and CO-validation occurs) when the data were downloaded. Thus, the months included were July–November 2010 and January–May 2011 ( $n = 19,481$ ). Cases were also excluded from the main analysis if they were missing age ( $n = 201$ ) and gender ( $n = 43$ ) because too few were missing to include as a separate category. Additionally, cases were excluded if the practitioner who provided behavioural support was missing ( $n = 5573$ ) because of the multilevel structure of the data. Thus, the number of cases used in the bi-variable and multilevel multivariable analysis of the efficacy of the services was 177,291.

#### Uptake: distribution of client groups and reach of services

In order to assess uptake we looked first at whether or not clients from all sociodemographic groups were accessing the services and which service options clients were accessing.

To understand the reach of services it is necessary to know the target population: the number of smokers in the PCT. Smoking is not asked in the UK census thus estimates have to be made from smoking rates collected by government surveys and populations that have been updated from 2001 census data. The most recent estimation of adult ( $\geq 16$  years) smoking rates for PCTs was for 2003–5.<sup>34</sup> These were based on the Health Survey for England. Between 2004 and 2009 the smoking rate for Great Britain fell from 25% to 21%, thus PCT smoking rate estimates were reduced by 4% to estimate more recent smoking rates. Mid-year adult ( $\geq 16$  years) population estimates of PCTs were available for 2010. The population multiplied by the smoking rate gave an estimate of the number of smokers in the PCT. These numbers were compared with the number of QuitManager clients aged  $\geq 16$  years between July 2010 and June 2011.

There were some PCTs where this formula was not suitable. First, a few PCTs started using QuitManager or gave permission for their data to be used after July 2010 so these PCTs were included only in the second data download in July 2011. For these PCTs the number of clients was doubled to provide an estimate of the annual number of clients. Second, one PCT had to a large extent merged with another and a population estimate was available only for the overall area and a smoking rate estimate for the overall estimate was calculated by taking the average of the two constituent PCTs. Third, a PCT was known to include only clients who saw practitioners through the specialist service in QuitManager. Thus it was not possible to provide an estimate of reach for this PCT. It is possible that other PCTs may not include all their clients on QuitManager. So far, however, none of the other PCTs contacted regarding the prospective study have raised this as an issue.

### Predictors

The data have a multilevel structure: clients received behavioural support interventions from practitioners and practitioners are employed through SSSs. Originally each PCT had its own SSS although now some PCTs have a joint SSS so a few practitioners worked for more than one PCT, usually where both PCTs had a joint SSS.

The independent variables used cover client characteristics: age (divided into quartiles); gender (not pregnant women, pregnant woman, men); ethnicity (white, black, Asian, other, unknown); SES (eligibility for free prescriptions exempt, pays, unknown); National Statistics Socio-Economic Classification (NSSEC)<sup>35</sup> (routine and manual occupation, intermediate occupation, managerial or professional occupation, retired or caring for the home, sick or disabled and unable to work, never worked or long-term unemployed, in prison, other); Index of Multiple Deprivation (IMD)<sup>36</sup> (at PCT level) divided into quintiles of all English PCTs and quit attempt related characteristics [month set quit date, treatment episode number (first, second, third, fourth or more)]; medication (NRT alone, combination NRT, bupropion, varenicline, mixed medications, and other or no medication); intervention type (one to one, drop-in, open/rolling group, closed group, other); and practitioner type (specialist SSS practitioner employed by SSSs, practitioner who does cessation advice work as part of their role divided into GP, nurse, health-care practitioner, pharmacy employee, and other and unknown).

### Impact: throughput and quitters per 100,000 population

Colleagues from University College London and the UK NCSCT have developed the methodology for measuring impact. Impact is calculated as 'throughput' (number of treated smokers per 100,000 adult population)  $\times$  [percentage successfully quit at 4 weeks – 25 (if CO-verified quit or – 35 if self-report quit)]/100. The number of quitters is expressed per 100,000 of the population, not per 100,000 of the smoking population. The reason for CO-verified quit minus 25 being used in the calculation is that 25% of smokers trying to quit are estimated to be CO-verified quit at 4 weeks unaided or by use of medication alone without behavioural support. For self-reported quits minus 35 is used because of average differences between SSS self-report and CO-validated quit rates.

Owing to first to marked differences between CO-validation rates of PCTs and second to different services having a negative impact depending on whether or not the CO-validated or the self-report quit rate was used in the calculation, for this report an overall impact score was calculated. The overall impact score was the average of the CO-validated impact score and the self-report impact score.

To estimate impact on the population, unique clients were used rather than client records. The client records were aggregated so that for clients who had more than one record their age and quit status at their most recent episode at the SSS was used.

It was not possible to calculate impact for some PCTs and for others there were caveats, generally this was where there were issues in calculating uptake. Additionally, the unique patient identifier was of poor quality for four PCTs. For a further three PCTs, clients were included only in the second data download so to estimate impact the number of client records was doubled. This may be an overestimate of client records and it would be expected that some clients from the first 6 months would have revisited the

services in the second 6 months so it may also be an overestimate of unique clients. Thus, these three PCTs were excluded from statistical summaries of impact data although impact data was calculated for them.

## Analytic approach

The analyses were carried out using SPSS [SPSS version 19.0 (SPSS Inc., Armonk, NY, USA) and PASW version 18.0.3 (SPSS Inc., Chicago, IL, USA)]; Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA, USA); Stata (StataCorp LP, College Station, TX, USA) and MLwiN version (MLwiN, Centre for Multilevel Modelling, Bristol, UK) as follows.

See *Table 3* for overall quit rates and validation rates for all clients and then for clients where their age, gender and practitioner were identified. Uptake (distribution), quit rates and CO-validation rates for subgroups of these clients with various client and quit attempt-related characteristics are presented. Chi-squared was used to assess significance.

Second, a descriptive table (see *Table 4*) provides further information about the PCTs. Each row represents a different PCT. It includes the number of practitioners within each PCT, the number of clients per PCT (throughout the year) and the average number of clients per practitioner (clients/practitioner) in addition to estimates of the smoking rate, population, clients aged over 16 years and reach of services of each PCT.

The analysis included a large number of predictors and three measures of SES, so in order to assess potential multicollinearity in multivariable models, the variance inflation factor (vif) and corresponding tolerance were calculated from a logistic regression using interaction expansion (part of the Stata xi suite). In this xi suite analysis, PCT was entered as a cluster variable and practitioner was entered as an explanatory variable as only one cluster variable is allowed.

Multilevel modelling (see *Tables 5* and *6*) allows PCT and practitioner to be treated as separate levels in the analysis – otherwise known as random effects. Thus there were three levels in the models: client (level 1), practitioner (level 2) and PCT (level 3). Other independent variables were entered as fixed effects. Practitioner types were entered as a level 2 fixed effects, IMD quintiles of the PCT entered as level 3 fixed effects and all other fixed effects were at client level. MLwiN second order penalised quasi-likelihood iterative generalised least squares estimation was used for the analysis.

Odds ratios (ORs) are reported for self-report quit, CO-validated quit and CO validation. Some changes were made to the predictors for the multilevel analysis. So that practitioner should completely nest within a PCT, PCTs that shared practitioners were merged. There were 63 practitioners who worked in more than one PCT. The IMD score was then recoded for the new merged PCTs so that it was the average of both PCTs taking into account the number of clients contributed by each PCT.

In preliminary analysis (not shown) MLwiN IGLS multilevel models were compared with Stata Survey Suite models. Anomalous results were explored further using SPSS crosstabulations, Stata xt and MLwiN Markov Chain Monte Carlo. Full models did not converge in either Stata xt or MLwiN Markov Chain Monte Carlo. However, the results that were produced tended to support IGLS results; thus only MLwiN IGLS models are presented here.

Ideally we would look at how much variance of the higher levels was explained by the fixed variables; however, when a binary outcome is modelled and there is more than one higher level, it is not possible to do because the level 1 variance is always constrained to be 3.29.<sup>37</sup> Thus the impact observed on the higher-level variances from adding a fixed-effect variable to the model may be because of the overall variance changing to allow for the addition of the variable since the level 1 variance cannot change, rather than because the new variable in the model has explained the higher-level variance.<sup>38,39</sup> It is not currently possible to accurately estimate how much of the change is caused by real changes in variance and how much is caused by the constrained level 1 variance (Yang M, University of Nottingham, 2012, personal communication).

The higher-level variance is shown later in the report (see *Table 7*). The first and second columns show higher-level variance in the CO-validated modelling. The first column displays PCT-level variance and the second column displays practitioner-level variance. The next two columns show variance for the self-report modelling and the other columns show higher-level variance for the CO-validation modelling with or without exclusions of extreme PCTs (see *Table 4*). The first row displays variance in null models with no fixed effects entered. The subsequent rows display variance when fixed effects are entered one at a time so there is only one fixed effect in a model. The final row displays variance for the multivariable model when all fixed effects are entered.

Residuals for the PCTs were calculated and graphed using caterpillar plots.

For measures of impact by PCT, see *Table 8*. Each row represents a different PCT. Throughput (numbers setting a quit date per 100,000 population), CO-validated and self-report quit rates for all unique clients age 16 years or over, impact (numbers of 4-week quitters per 100,000 population) calculated using CO-validated quits only, all self-report quits and overall (average of previous two impacts) are shown and the results are also presented in a graphical format. Summary measures of unique patients, quit rates, throughput and impact, and correlations between them are provided (see *Table 9*).





## Chapter 4 Secondary analysis of routine data: findings

As described in *Chapter 3*, the first part of the ELONS study involved secondary analysis of data from clients who had used SSSs in 49 of 150 PCTs in England. These PCTs' SSSs used the QuitManager database to record and report on their routine data.

The results are ordered by topic: uptake, quitting and CO validation. Under uptake we consider client distribution of client characteristics and estimates of the percentage of each PCT's smoking population that were using the service. Under quitting we discuss self-report quit and CO-validated quit in bivariable and multivariable multilevel models, and finally we explore the proportion of self-reported quit who were CO validated (CO validation) in bivariable and multivariable multilevel models. Please note that in addition, we have already published a paper based on this work,<sup>26</sup> which had a particular focus on the relationship between SES and the types of behavioural support offered by the services.

### Uptake

Table 3 shows which groups of clients were more or less common among service users and the service options that they were more or less likely to use.

**TABLE 3** Distribution of client characteristics (uptake) and 4-week self-report and CO-validated quit rates, and CO-validation rate

Client characteristics	4-week quit rates				CO-validation rate	
	<i>n</i>	%	Self-report quit, <i>p</i> -value	CO-validated quit, % ( <i>p</i> -value)	Self-report quit, <i>n</i>	Self-reports CO-validated, % ( <i>p</i> -value)
Total: intention-to-treat quit available (December and June starts excluded)	182,603	100.0	44.1	30.7	89,085	73.9
Total: intention-to-treat quit and age, gender, practitioner identified <sup>a</sup>	177,291	100.0	48.8	34.1	86,512	74.3
Age quartiles (years)						
< 30	44,968	25.4	39.2	24.9	17,647	68.2
31–42	47,719	26.9	49.6	34.4	23,651	73.6
45–53	40,410	22.8	50.7	36.2	20,485	75.8
≥ 54	44,194	24.9	56.0	41.4	24,729	78.1
<i>p</i> -value	–	–	< 0.001	< 0.001	–	< 0.001

continued

**TABLE 3** Distribution of client characteristics (uptake) and 4-week self-report and CO-validated quit rates, and CO-validation rate (*continued*)

Client characteristics	4-week quit rates				CO-validation rate	
	<i>n</i>	%	Self-report quit, <i>p</i> -value	CO-validated quit, % ( <i>p</i> -value)	Self-report quit, <i>n</i>	Self-reports CO-validated, % ( <i>p</i> -value)
Gender						
Female (not pregnant)	88,246	49.8	48.1	33.9	42,451	74.9
Female (pregnant)	5650	3.2	45.8	26.5	2585	62.0
Male	83,395	47.0	49.7	34.9	41,476	74.5
<i>p</i> -value	–	–	< 0.001	< 0.001	–	< 0.001
Ethnic origin						
White	158,377	89.3	49.3	34.6	5237	74.0
Black, Asian, mixed, other	12,165	6.9	43.1	30.9	78,149	74.6
Unknown	6749	3.8	46.3	28.4	3126	67.1
<i>p</i> -value	–	–	< 0.001	< 0.001	–	< 0.001
Occupation						
Routine and manual	43,741	24.7	51.7	36.1	22,621	74.0
Intermediate	13,376	7.5	54.2	36.6	7251	70.7
Managerial and professional	23,661	13.4	56.6	39.6	13,400	75.0
Retired or home care	32,388	18.3	54.4	39.7	17,627	77.5
Sick or disabled and unable to work	11,852	6.7	41.7	28.5	4943	73.2
Never worked or long-term unemployed	24,512	13.8	38.8	27.0	9520	73.6
In prison	2223	1.3	48.0	42.4	1066	90.0
Other	25,538	14.4	39.5	26.0	10,084	70.6
<i>p</i> -value	–	–	< 0.001	< 0.001	86,512	< 0.001
Prescription charges						
Exempt	104,304	58.8	46.2	33.0	48,194	75.8
Pays	56,903	32.1	54.2	38.1	30,843	74.5
Unknown	16,084	9.1	46.5	27.2	7475	63.8
<i>p</i> -value	–	–	< 0.001	< 0.001	–	< 0.001
Average IMD 2010 score (PCT)						
≤ 30	49,101	27.7	44.3	30.1	21,757	72.7
31–60	25,695	14.5	48.5	37.0	12,457	80.7
61–90	22,123	12.5	49.9	35.8	11,031	72.8
91–120	40,793	23.0	50.4	36.9	20,539	76.8
≥ 121	39,579	22.3	52.4	33.5	20,728	70.5
<i>p</i> -value	–	–	< 0.001	< 0.001	–	< 0.001

**TABLE 3** Distribution of client characteristics (uptake) and 4-week self-report and CO-validated quit rates, and CO-validation rate (*continued*)

Client characteristics	4-week quit rates				CO-validation rate	
	<i>n</i>	%	Self-report quit, <i>p</i> -value	CO-validated quit, % ( <i>p</i> -value)	Self-report quit, <i>n</i>	Self-reports CO-validated, % ( <i>p</i> -value)
Month set quit date						
July 2010	15,244	8.6	46.4	31.4	7066	72.9
August 2010	13,892	7.8	48.0	32.8	6670	73.7
September 2010	14,765	8.3	49.5	33.8	7314	73.6
October 2010	15,535	8.8	49.3	33.7	7654	74.1
November 2010	13,901	7.8	48.2	30.3	6694	69.8
January 2011	26,924	15.2	52.9	38.8	14,242	76.4
February 2011	22,565	12.7	51.4	36.9	11,595	75.0
March 2011	22,490	12.7	47.8	33.7	10,740	73.8
April 2011	17,221	9.7	47.4	33.6	8161	75.6
May 2011	14,754	8.3	43.2	31.2	6376	75.5
<i>p</i> -value	–	–	< 0.001	< 0.001	–	< 0.001
Treatment episode						
Episode 1	114,369	64.5	48.5	34.3	55,420	75.0
Episode 2	36,154	20.4	49.1	33.5	17,748	72.7
Episode 3	14,391	8.1	49.6	33.9	7134	73.6
Episode 4 or more	12,377	7.0	50.2	34.9	6210	74.0
<i>p</i> -value	–	–	< 0.001	0.0	–	= 0.003
Medication used						
Single NRT	40,607	22.9	37.5	25.4	15,222	74.0
Combination NRT	67,703	38.2	49.7	37.0	33,646	78.1
Bupropion only	1129	0.6	52.1	32.9	588	69.7
Varenicline only	45,149	25.5	60.2	43.0	27,167	75.8
Mixed NRT/bupropion/ varenicline	4479	2.5	46.6	34.3	2085	76.6
No medication or missing	18,224	10.3	42.8	21.0	7804	52.9
<i>p</i> -value	–	–	< 0.001	< 0.001	–	< 0.001
Intervention type						
One to one	140,119	79.0	47.6	33.8	66,621	74.5
Drop-in clinic	24,736	14.0	50.7	33.3	12,550	74.8
Open (rolling) group	4780	2.7	65.5	52.1	3130	85.3
Closed group	2512	1.4	63.5	50.1	1595	80.9
Other or missing	5144	2.9	50.9	23.3	2616	49.8
<i>p</i> -value	–	–	< 0.001	< 0.001	–	< 0.001

continued

**TABLE 3** Distribution of client characteristics (uptake) and 4-week self-report and CO-validated quit rates, and CO-validation rate (*continued*)

Client characteristics	4-week quit rates				CO-validation rate	
	<i>n</i>	%	Self-report quit, <i>p</i> -value	CO-validated quit, % ( <i>p</i> -value)	Self-report quit, <i>n</i>	Self-reports CO-validated, % ( <i>p</i> -value)
Practitioner type						
Specialist	55,603	31.4	55.6	37.7	30,902	74.6
GP	3535	2.0	45.1	34.9	1593	78.7
Nurse	18,091	10.2	42.3	28.3	7660	69.5
Health-care assistant	7070	4.0	45.4	35.2	3206	80.4
Pharmacy	18,890	10.7	40.6	29.7	7670	76.5
Other or unknown	74,102	41.8	47.9	33.9	35,481	73.9
<i>p</i> -value	–	–	< 0.001	< 0.001	–	< 0.001
Total	177,291	100.0	< 0.001	< 0.001	86,512	< 0.001

a 'Intention to treat' refers to missing cases included as not quit. 'Age, gender, practitioner identified' indicates that cases missing one or more of these characteristics were excluded from analysis.

Source: QuitManager (completed treatment episodes between 1 January 2011 and 30 June 2011, excluding quit dates set in December 2010 and June 2011).

### Client characteristics

There were slightly more women setting quit dates than men, with 3.2% of clients pregnant at the time of data entry. Seven per cent of clients were from ethnic minorities, although 4% of client ethnicities are unknown. One-quarter of the clients were under 30 years and one-quarter were aged  $\geq 54$  years. A large proportion was exempt from paying prescription charges (58.8%), and for 9% this information was unavailable. The largest category of occupation in the sample was routine and manual (24.4%), with the second largest being retired or home carer (18.1%). There were over 2000 prisoners who set quit dates.

### Service type characteristics

Between 13,000 and 27,000 clients set quit dates each month. The highest numbers of clients set quit dates in January to March and the lowest numbers were in August and November. The PCTs providing client data were fairly evenly divided by disadvantage. The majority of clients (64.5%) had not used the SSS previously (treatment episode 1). Combination NRT (more than one type of NRT) was the most commonly used medication (38.2%). Less than 1% used bupropion alone. Among intervention types, one-to-one behavioural support was by far the most common (79%) whereas only 14% took part in drop-ins, 2.7% took part in open/rolling groups and 1.4% were members of closed groups. Practitioner type had a large proportion of missing values (41.8%), so it was not possible to assess how accurately the proportions of the other categories reflect the distribution of practitioner types, however, the largest category displayed was specialist practitioner at 31.4%.

Each row in *Table 4* displays information about a different PCT. For each of these, the first column displays information on the number of practitioners within each PCT (ranging from 14–334). The subsequent column shows the number of clients seen in each PCT with practitioner identified and this is followed by an average of clients per practitioners for each PCT (ranging from 8–310). There was variation in the number of practitioners recorded by the PCTs (from 20–300). In some PCTs it appeared that practitioners saw over 250 clients on average whereas in others practitioners saw fewer than 10 clients each.

**TABLE 4** Primary care trusts characteristics (each row is a different PCT)

Number of practitioners in QuitManager database	Clients with practitioner identified, July 2010–June 2011	Mean clients per practitioner	Estimated PCT smoking rate (%) in 2003–5 aged ≥ 16 years (95% CI) <sup>a</sup>	Estimated population 2010 aged ≥ 16 years <sup>b</sup>	SSS clients aged ≥ 16 years, July 2010–June 2011 <sup>c</sup>	Estimate of PCT smokers reached (%) <sup>d</sup>
77	2876	37.4	32.1 (28.0 to 36.5)	135,000	2849	7.5
106	2673	25.2	27.8 (24.1 to 31.9)	182,100	2659	6.1
15	4398	293.2	24.9 (22.1 to 28.0)	315,500	6132	9.3
22	5441	247.3	24.9 (22.1 to 28.0)	278,200	5400	9.3
137	6635	48.4	30.3 (27.4 to 33.4)	114,300	6597	21.9
74	4000	54.1	20.1 (18.6 to 21.7)	259,300	4000	9.6
256	5887	23.0	24.8 (22.0 to 27.7)	368,300	5868	7.7
121	2546	21.0	21.9 (19.0 to 25.2)	251,200	2584	5.7
95	6236	65.6	19.6 (18.5 to 20.8)	373,100	6164	10.6
302	10,038	33.2	25.0 (23.6 to 26.5)	422,400	10,083	11.3
58	1662	28.7	27.9 (24.7 to 31.5)	81,400	1683	8.6
128	4573	35.7	26.8 (24.3 to 29.5)	255,200	4576	7.9
276	3804	13.8	25.0 (22.4 to 27.8)	199,700	3769	9.0
44	7229	164.3	23.5 (22.4 to 24.5)	599,500	7097	6.1
177	3113	17.6	18.6 (16.5 to 20.9)	256,600	3125	8.3
83	2862	34.5	21.2 (19.1 to 23.6)	282,000	2834	5.8
87	1936	22.3	14.5 (11.9 to 17.5)	185,400	1965	10.1
102	3573	35.0	24.9 (22.1 to 28.0)	215,500	3718	8.2
332 <sup>e</sup>	8203	24.7	22.9 (21.8 to 24.1)	–	–	–
334 <sup>e</sup>	6293	18.8	19.8 (18.7 to 21.0)	–	–	–
– <sup>e</sup>	–	–	21.4 (20.3 to 22.6)	886,500	14,512	8.8
188	3689	19.6	28.2 (25.8 to 30.7)	161,600	3626	9.3
95	3861	40.6	22.0 (19.4 to 24.9)	190,100	3942	11.5
73	4878	66.8	40.9 (36.4 to 45.5)	217,100	4824	6.0
131	3432	26.2	27.5 (22.9 to 32.6)	163,100	3708	9.7
81	1154	14.2	18.8 (14.4 to 24.2)	141,800	1963	9.4
79	637	8.1	21.7 (18.7 to 24.9)	138,400	619	2.5
142	4993	35.2	30.1 (26.1 to 34.4)	243,300	4921	7.8
228	7400	32.5	21.9 (20.8 to 22.9)	564,000	7286	7.2
100	2996	30.0	26.8 (24.1 to 29.7)	212,600	2985	6.1
280	10,778	38.5	23.3 (22.2 to 24.5)	583,300	10,634	9.4
43	1493	34.7	24.6 (22.0 to 27.3)	128,100	1487	5.6
123	3111	25.3	18.4 (16.4 to 20.6)	173,900	3115	12.4

continued

**TABLE 4** Primary care trusts characteristics (each row is a different PCT) (*continued*)

Number of practitioners in QuitManager database	Clients with practitioner identified, July 2010–June 2011	Mean clients per practitioner	Estimated PCT smoking rate (%) in 2003–5 aged ≥ 16 years (95% CI) <sup>a</sup>	Estimated population 2010 aged ≥ 16 years <sup>b</sup>	SSS clients aged ≥ 16 years, July 2010–June 2011 <sup>c</sup>	Estimate of PCT smokers reached (%) <sup>d</sup>
21	6518	310.4	25.9 (24.6 to 27.1)	550,800	12,920 <sup>f</sup>	10.7
36	2215	61.5	33.5 (29.7 to 37.4)	128,400	2207	5.8
62	5060	81.6	36.2 (32.1 to 40.6)	256,600	4994	6.0
27	5268	195.1	29.0 (26.4 to 31.8)	171,100	5203	12.1
89	1273	14.3	17.6 (15.1 to 20.3)	211,600	1532	5.3
63	582	9.2	19.3 (16.1 to 23.0)	152,900	573	2.4
130	5105	39.3	25.3 (22.6 to 28.1)	205,800	5013	11.5
14	459	32.8	29.0 (26.1 to 32.0)	230,900	1754	3.0
113	4224	37.4	21.3 (20.2 to 22.5)	241,500	4163	10.0
21	603	28.7	21.1 (20.0 to 22.2)	429,700	1356 <sup>f</sup>	NA
268	4155	15.5	24.5 (22.9 to 26.2)	275,500	8254 <sup>f</sup>	14.6
90	1774	19.7	27.7 (24.2 to 31.5)	236,500	1772	3.2
75	3562	47.5	25.2 (22.7 to 27.9)	129,500	3501	12.7
113	2100	18.6	25.8 (23.4 to 28.4)	203,200	4140 <sup>f</sup>	9.3
293	3937	13.4	21.3 (20.2 to 22.5)	438,000	7798 <sup>f</sup>	10.3
93	4099	44.1	21.7 (20.3 to 23.1)	193,000	4061	11.9
<b>6040</b>	<b>196,511</b>	<b>32.5 (average)</b>	–	–	–	–

CI, confidence interval; NA, not available.

a Estimated smoking rates based on the Health Survey for England.<sup>34</sup>

b Estimated mid-year PCT population estimate 2010.<sup>40</sup>

c From QuitManager.

d Derived from (population estimate in 2010/100) × [% smoking estimate – 4% (because of the decline in smoking since 2003–5<sup>41</sup>)].

e Population data were available only for a county, whereas SSS data were available for constituent PCTs.

f PCT contributed to only second data download so clients for whole year estimated by doubling client numbers achieved in January–June 2011.

## Reach of services by primary care trust

Estimated smoking rates varied from 15% to 41%. PCT populations varied from 80,000 to nearly 900,000. Most services saw between 5% and 10% of their population of smokers between July 2010 and June 2011. Note that smoking estimates were accompanied by confidence intervals (CIs) of approximately 6% thus these should be treated with caution.

## Cessation

### Bivariable results

The overall quit rates of the entire database (see *Table 3*) without exclusions for missing data in the gender, age or practitioner type variables were 44.1% (self-report) and 30.7% (CO validated). The quit rates of the sample used in the analysis were 48.8% (self-report) and 34.1% (CO validated).

The SSSs target is at least 35% for self-report and CO-validated quit.<sup>33</sup> Overall, the self-report quit rate comfortably passed this level and the CO-validated quit rate almost reached this level. Three PCTs did not reach the 35% target for self-report quitting. Some subgroups met this target for CO-validated quitting, they were: clients who were working or who were retired or caring for the home, prisoners, clients who paid for prescriptions, clients in PCTs who were not particularly disadvantaged or affluent, clients who set quit dates in January or February, clients who took combination NRT or just varenicline, clients who attended groups and clients whose practitioner was a specialist or a health-care assistant. Of the 49 PCTs, 28 met this target for CO-validated quitting.

### Multivariable results

Multivariable modelling in Stata indicated the extent of multicollinearity. All vifs were below 2.54 for self-reported and CO-validated models so there was no significant multicollinearity in the data (concerns are raised if a vif is  $\geq 10$ ). Multilevel multivariable ORs for client variables are presented in *Table 5* and ORs of quit attempt-related variables are presented in *Table 6*.

**TABLE 5** Multilevel multivariable ORs (95% CI) of CO-validated quit, self-report quit and CO validation: client characteristic fixed effects

Outcome	Self-report quit, OR (95% CI) (n = 177,291)	CO-verified quit, OR (95% CI) (n = 177,291)	CO validation, OR (95% CI) (n = 86,512)	CO validation, OR (95% CI) (n = 80,002)
Exclusions	–	–	–	Extreme PCTs <sup>a</sup>
Null model (constant)	0.34 (0.27 to 0.43)	0.13 (0.09 to 0.19)	1.58 (0.77 to 3.25)	1.69 (0.98 to 2.90)
Age (years) at quit date quartiles				
10–30	1	1	1	1
31–42	1.44 (1.40 to 1.48)	1.53 (1.48 to 1.58)	1.29 (1.22 to 1.35)	1.34 (1.27 to 1.41)
43–53	1.54 (1.49 to 1.59)	1.73 (1.67 to 1.79)	1.48 (1.40 to 1.57)	1.60 (1.51 to 1.69)
54–100	2.02 (1.96 to 2.09)	2.28 (2.20 to 2.37)	1.69 (1.60 to 1.80)	1.87 (1.76 to 1.99)

continued

**TABLE 5** Multilevel multivariable ORs (95% CI) of CO-validated quit, self-report quit and CO validation: client characteristic fixed effects (*continued*)

Outcome	Self-report quit, OR (95% CI) ( <i>n</i> = 177,291)	CO-verified quit, OR (95% CI) ( <i>n</i> = 177,291)	CO validation, OR (95% CI) ( <i>n</i> = 86,512)	CO validation, OR (95% CI) ( <i>n</i> = 80,002)
Gender				
Female (not pregnant)	1	1	1	1
Female (pregnant)	1.29 (1.20 to 1.38)	1.16 (1.07 to 1.26)	0.93 (0.82 to 1.05)	0.87 (0.77 to 1.00)
Male	1.07 (1.04 to 1.09)	1.04 (1.02 to 1.07)	0.97 (0.94 to 1.01)	0.97 (0.93 to 1.00)
Ethnicity				
Black, Asian, mixed, other	1	1	1	1
White	1.02 (0.98 to 1.07)	1.04 (0.99 to 1.09)	1.05 (0.97 to 1.13)	1.05 (0.97 to 1.14)
Unknown	1.02 (0.95 to 1.09)	0.96 (0.89 to 1.03)	0.90 (0.80 to 1.02)	0.89 (0.79 to 1.01)
NSSEC				
Routine and manual	1	1	1	1
Intermediate	1.14 (1.10 to 1.19)	1.09 (1.04 to 1.14)	0.96 (0.89 to 1.03)	0.96 (0.89 to 1.03)
Managerial and professional	1.19 (1.15 to 1.24)	1.14 (1.10 to 1.18)	1.02 (0.97 to 1.08)	1.02 (0.96 to 1.09)
Retired or home carer	1.07 (1.03 to 1.11)	1.06 (1.02 to 1.11)	1.02 (0.96 to 1.09)	1.02 (0.96 to 1.09)
Sick or disabled and unable to work	0.70 (0.67 to 0.73)	0.70 (0.67 to 0.74)	0.85 (0.78 to 0.93)	0.83 (0.76 to 0.90)
Always/long-term unemployed	0.75 (0.72 to 0.78)	0.76 (0.73 to 0.79)	0.96 (0.90 to 1.02)	0.94 (0.88 to 1.01)
In prison	1.15 (1.00 to 1.32)	1.98 (1.71 to 2.29)	3.82 (2.92 to 4.98)	4.84 (3.61 to 6.47)
Other	0.84 (0.81 to 0.87)	0.82 (0.78 to 0.85)	0.91 (0.85 to 0.97)	0.89 (0.83 to 0.96)
Prescription payment				
Exempt	1	1	1	1
Pays	1.24 (1.21 to 1.27)	1.18 (1.14 to 1.21)	0.98 (0.93 to 1.02)	0.97 (0.93 to 1.02)
Unknown	1.08 (1.03 to 1.13)	0.92 (0.88 to 0.97)	0.84 (0.78 to 0.90)	0.80 (0.74 to 0.86)
Average IMD score 2010 (PCT)				
Ranked 1–30 (disadvantaged)	1	1	1	1
Ranked 31–60	1.20 (0.85 to 1.69)	1.58 (0.91 to 2.77)	3.61 (1.14 to 11.47)	1.67 (0.72 to 3.86)
Ranked 61–90	1.29 (0.88 to 1.89)	1.34 (0.72 to 2.51)	0.61 (0.17 to 2.19)	0.60 (0.25 to 1.45)
Ranked 91–120	1.25 (0.92 to 1.70)	1.43 (0.88 to 2.35)	1.34 (0.49 to 3.67)	1.19 (0.59 to 2.42)
Ranked ≥ 121 (affluent)	1.36 (0.96 to 1.91)	1.61 (0.92 to 2.81)	1.06 (0.34 to 3.33)	1.01 (0.45 to 2.22)

a Three PCTs with particularly high or low CO-validation rates were excluded.



**TABLE 6** Multilevel multivariable ORs (95% CI) of CO-validated quit, self-report quit and CO validation: quit attempt-related fixed effects

Outcome	Self-report quit, OR (95% CI) (n = 177,291)	CO-verified quit, OR (95% CI) (n = 177,291)	CO validation, OR (95% CI) (n = 86,512)	CO validation, OR (95% CI) (n = 80,002)
Exclusions	–	–	–	Extreme PCTs <sup>a</sup>
Quit date month				
July 2010	1	1	1	1
August 2010	1.04 (0.99 to 1.09)	1.04 (0.99 to 1.10)	1.05 (0.96 to 1.15)	1.05 (0.96 to 1.15)
September 2010	1.14 (1.08 to 1.20)	1.11 (1.05 to 1.17)	1.02 (0.93 to 1.11)	1.02 (0.93 to 1.11)
October 2010	1.10 (1.05 to 1.16)	1.08 (1.02 to 1.14)	1.01 (0.92 to 1.09)	1.00 (0.91 to 1.09)
November 2010	1.02 (0.97 to 1.07)	0.88 (0.84 to 0.93)	0.82 (0.75 to 0.89)	0.77 (0.71 to 0.85)
January 2011	1.33 (1.27 to 1.39)	1.34 (1.28 to 1.41)	1.11 (1.02 to 1.19)	1.11 (1.03 to 1.21)
February 2011	1.17 (1.12 to 1.22)	1.19 (1.14 to 1.25)	1.06 (0.98 to 1.15)	1.06 (0.97 to 1.15)
March 2011	1.02 (0.98 to 1.07)	1.04 (0.99 to 1.09)	0.98 (0.90 to 1.06)	0.96 (0.88 to 1.05)
April 2011	0.96 (0.91 to 1.01)	1.02 (0.97 to 1.08)	1.08 (0.99 to 1.17)	1.08 (0.99 to 1.18)
May 2011	0.85 (0.81 to 0.89)	0.97 (0.91 to 1.02)	1.08 (0.99 to 1.19)	1.10 (1.00 to 1.21)
Episode				
Episode 1	1	1	1	1
Episode 2	0.97 (0.94 to 0.99)	0.97 (0.94 to 0.99)	1.00 (0.96 to 1.05)	1.00 (0.95 to 1.05)
Episode 3	1.00 (0.96 to 1.04)	0.98 (0.94 to 1.03)	1.00 (0.94 to 1.07)	0.99 (0.93 to 1.07)
Episode 4 or more	1.04 (1.00 to 1.08)	1.04 (1.00 to 1.09)	1.05 (0.98 to 1.13)	1.04 (0.96 to 1.13)
Medication				
Single NRT	1	1	1	1
Combination NRT	1.88 (1.83 to 1.94)	2.06 (2.00 to 2.13)	1.55 (1.47 to 1.65)	1.66 (1.56 to 1.76)
Bupropion only	1.79 (1.58 to 2.03)	1.48 (1.29 to 1.69)	0.97 (0.79 to 1.20)	0.96 (0.77 to 1.18)
Varenicline only	2.57 (2.49 to 2.65)	2.31 (2.24 to 2.40)	1.31 (1.23 to 1.39)	1.37 (1.29 to 1.45)
Mixed NRT/bupropion/ varenicline	1.46 (1.37 to 1.57)	1.64 (1.53 to 1.76)	1.46 (1.30 to 1.65)	1.55 (1.37 to 1.76)
No medication or missing	1.13 (1.08 to 1.18)	0.80 (0.76 to 0.84)	0.74 (0.68 to 0.80)	0.68 (0.63 to 0.74)
Intervention type				
One to one	1	1	1	1
Drop-in clinic	0.96 (0.91 to 1.01)	1.02 (0.96 to 1.07)	1.01 (0.93 to 1.10)	0.97 (0.89 to 1.06)
Open (rolling) group	1.15 (1.04 to 1.27)	1.28 (1.15 to 1.41)	1.39 (1.18 to 1.64)	1.45 (1.23 to 1.73)
Closed group	1.12 (1.00 to 1.26)	1.11 (0.99 to 1.24)	1.15 (0.96 to 1.37)	1.16 (0.96 to 1.39)
Other or missing	1.12 (1.03 to 1.21)	0.62 (0.57 to 0.68)	0.46 (0.40 to 0.51)	0.41 (0.36 to 0.46)
SSS practitioner				
Specialist	1	1	1	1
GP	0.46 (0.38 to 0.55)	0.53 (0.42 to 0.66)	1.15 (0.83 to 1.61)	1.43 (0.97 to 2.10)
Nurse	0.58 (0.52 to 0.64)	0.70 (0.62 to 0.78)	1.11 (0.95 to 1.29)	1.19 (0.99 to 1.43)
Health-care assistant	0.69 (0.60 to 0.78)	0.86 (0.74 to 0.99)	1.29 (1.05 to 1.58)	1.42 (1.11 to 1.80)
Pharmacy	0.67 (0.61 to 0.73)	0.91 (0.82 to 1.02)	1.80 (1.55 to 2.10)	2.20 (1.84 to 2.64)
Other or unknown	0.78 (0.72 to 0.84)	0.88 (0.80 to 0.97)	1.25 (1.10 to 1.41)	1.34 (1.16 to 1.55)

a Three PCTs with particularly high or low CO-validation rates were excluded.

The results for CO-validated quit and self-report quit are mostly similar so they are discussed simultaneously with differences alluded to. Generally unknown and other classifications were associated with less chance of quitting than reference groups.

### Demography

The relationship between client-related characteristics and CO-validated or self-report quits were mostly similar. As age increased so did the chances of quitting. Clients aged over 53 years were twice as likely to quit as those age 30 years or under. Men and pregnant women were more likely to quit than non-pregnant women. In the bivariable results pregnant women had the lowest quit rate. Further exploration (not shown) suggested that the change in the multivariable results was attributed to pregnant women being less likely to take medication. Ethnicity was not significantly related to quitting.

### Socioeconomic status

Compared with clients with routine and manual occupations, clients with intermediate, managerial and professional occupations, the retired, home carers and prisoners were more likely to quit. Those who paid for prescriptions were more likely to quit than those who were exempt. PCT deprivation was not significantly related to quitting.

### Stop Smoking Service related

September, January and February appeared to be particularly successful months for setting a quit date with a SSS. Lower chances of quitting in May and November might partly be because of late quit information not being included in the database owing to cut off points at the end of December and June. However, differences between these months and the other months were not always significant, suggesting this had a minimal effect. Clients who had used the service once before were less likely to quit than those who had never used the service before and those who had used the service four or more times were more likely to quit. Taking any medication other than single NRT increased the chances of quitting. The highest ORs were for clients who took varenicline alone. These people were more than twice as likely to self-report and CO validate as quit.

For intervention type, the highest chances of quitting were among clients who took part in open/rolling groups. Closed-group clients were significantly more likely to self-report as quit than those who undertook one-to-one counselling but the difference did not quite reach significance for CO validation. Further analysis (not shown) suggested this was caused by a number of factors such as the practitioner, SES and medication.

Among the practitioner types, clients of specialist advisers were more likely to quit than clients of other (and unspecified) practitioner types. This difference was significant for all categories except for CO validation among practitioners who held pharmacy posts. ORs were surprisingly low for GPs given bivariable results. Further analysis (not shown) suggested this was because the majority of GPs worked in one PCT (Warwickshire) where quit rates were similar to other practitioner types, but in most other PCTs, with more than 20 clients seen by GPs, GPs were achieving fewer CO-validated quits than other practitioner types.

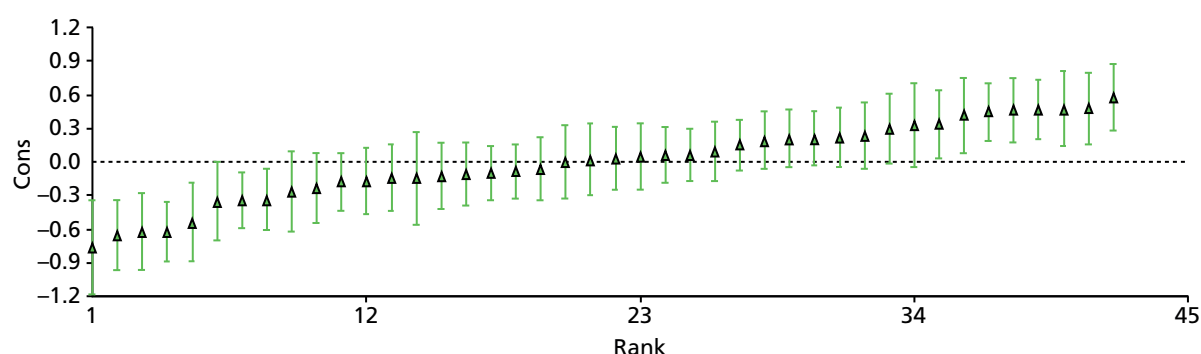
### Primary care trust and practitioner

Figure 2 is a caterpillar plot of PCT residuals for the multilevel multivariable model of self-report quit. PCT CIs that do not overlap 0.0 represent significant departures from the average. The lowest chances of self-reported quitting were found in the PCT ranked 1.

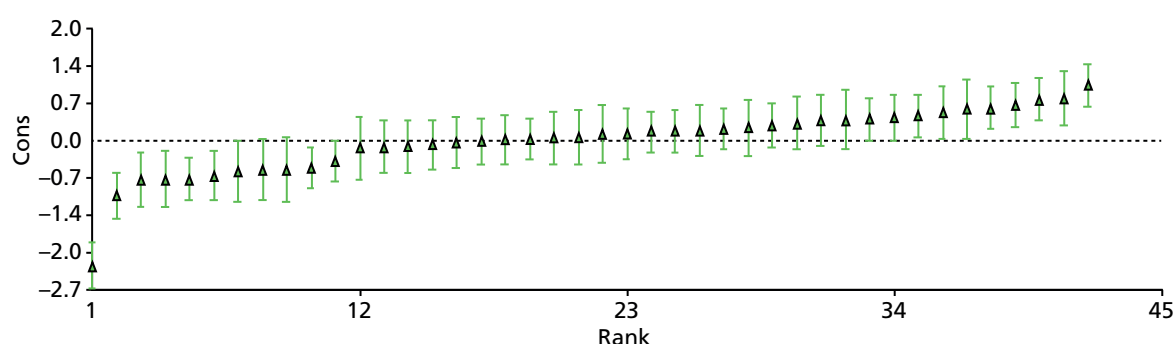
Figure 3 is a caterpillar plot of PCT residuals for CO-validated quit. PCT CIs that do not overlap 0.0 represent significant departures from the average. Further exploration (not shown) suggested that excluding clients from the lowest ranked PCT made little difference to the results.

There is little that can be said with certainty about the higher-level variance (Table 7), as it is not possible to tell how much of the change in variance between models is owing to fixed effects in the model and how much is the result of level one variance being constrained to 3.29, leading to inflated or deflated higher level variance.

We can safely say that there was significant variance between practitioners and between PCTs even after all fixed effects had been included for both self-report and CO-validated quit. It is probably also safe to say that there was less variance between PCTs and between practitioners for self-report quits than CO-validated quits.



**FIGURE 2** Residual caterpillar plot of PCTs for multivariable multilevel model of self-report quits.



**FIGURE 3** Residual caterpillar plot of PCTs for multivariable multilevel model of CO-validated quits.

**TABLE 7** Primary care trust-level and practitioner-level variance for models with no fixed effects, one fixed effect and all fixed effects

Models	CO validated		Self-report		CO validation	
	PCT variance (95% CI)	Practitioner variance (95% CI)	PCT variance (95% CI)	Practitioner variance (95% CI)	PCT variance (95% CI)	Practitioner variance (95% CI)
<b>No fixed effect</b>						
Null model (constant)	0.36 (0.20 to 0.53)	0.54 (0.51 to 0.58)	0.14 (0.07 to 0.20)	0.41 (0.38 to 0.43)	1.83 (1.03 to 2.63)	1.32 (1.23 to 1.42)
<b>One fixed effect</b>						
Quit date month	0.36 (0.20 to 0.52)	0.54 (0.51 to 0.58)	0.14 (0.07 to 0.20)	0.41 (0.38 to 0.43)	1.83 (1.02 to 2.64)	1.33 (1.23 to 1.42)
Age (years) at quit date quartiles	0.38 (0.21 to 0.55)	0.55 (0.51 to 0.58)	0.14 (0.08 to 0.21)	0.40 (0.38 to 0.43)	1.84 (1.03 to 2.65)	1.35 (1.25 to 1.44)
Gender	0.36 (0.20 to 0.53)	0.54 (0.51 to 0.57)	0.14 (0.07 to 0.20)	0.41 (0.38 to 0.43)	1.82 (1.01 to 2.63)	1.32 (1.23 to 1.41)
Ethnicity	0.37 (0.20 to 0.53)	0.54 (0.51 to 0.57)	0.13 (0.07 to 0.20)	0.40 (0.38 to 0.43)	1.83 (1.02 to 2.64)	1.32 (1.23 to 1.42)
NSSEC	0.36 (0.20 to 0.51)	0.52 (0.49 to 0.56)	0.12 (0.07 to 0.18)	0.39 (0.36 to 0.41)	1.83 (1.03 to 2.63)	1.31 (1.22 to 1.40)
Prescription payment	0.36 (0.20 to 0.52)	0.53 (0.50 to 0.57)	0.13 (0.07 to 0.20)	0.40 (0.37 to 0.43)	1.82 (1.02 to 2.63)	1.30 (1.21 to 1.39)
IMD 2010 (PCT)	0.30 (0.17 to 0.44)	0.53 (0.49 to 0.56)	0.11 (0.06 to 0.16)	0.40 (0.38 to 0.43)	1.40 (0.78 to 2.02)	0.74 (0.68 to 0.80)
Episode	0.37 (0.20 to 0.53)	0.54 (0.51 to 0.58)	0.14 (0.07 to 0.20)	0.40 (0.38 to 0.43)	1.83 (1.02 to 2.63)	1.32 (1.23 to 1.42)
Medication	0.38 (0.21 to 0.55)	0.53 (0.50 to 0.57)	0.15 (0.08 to 0.23)	0.40 (0.37 to 0.43)	1.84 (1.02 to 2.65)	1.29 (1.19 to 1.38)
Intervention type	0.35 (0.20 to 0.51)	0.53 (0.50 to 0.56)	0.13 (0.07 to 0.19)	0.40 (0.37 to 0.42)	1.80 (1.00 to 2.60)	1.29 (1.20 to 1.38)
SSS practitioner	0.37 (0.20 to 0.53)	0.53 (0.50 to 0.57)	0.13 (0.07 to 0.19)	0.38 (0.35 to 0.40)	1.91 (1.07 to 2.75)	1.29 (1.20 to 1.38)
<b>All fixed effects</b>						
Multivariable model	0.34 (0.19 to 0.50)	0.49 (0.46 to 0.52)	0.13 (0.07 to 0.18)	0.36 (0.33 to 0.38)	1.47 (0.82 to 2.11)	0.71 (0.65 to 0.76)
Multivariable MCMC model	0.43 (0.22 to 0.65)	0.53 (0.49 to 0.57)	–	–	–	–
Multivariable model without extreme PCTs	–	–	–	–	0.64 (0.34 to 0.94)	1.02 (0.94 to 1.10)
MCMC, Markov chain Monte Carlo.						

## Carbon monoxide validation

The CO-validation rate (self-reports that were CO validated) of the database was 73.9% and was 74.3% among clients with gender, age and practitioner identified (see *Table 3*). The DH has recommended that SSSs should aim to CO validate 85% of clients.<sup>33</sup> Client groups where CO validation of 85% was achieved were prisoners and clients enrolled in open groups. Of the 49 PCTs, 13 achieved CO-validation rates of 85% or more.

### Multivariable results

Odds ratios for IMD at PCT level and multilevel variance changes suggested that some PCTs were having a disproportionate effect on the results, as an intermediate quintile was most associated with quitting (see *Table 4*) and including this variable in the model was associated with a major reduction in PCT-level variance (see *Table 7*). Two PCTs, with very high CO validation rates and one PCT with a particularly low validation rate were consequently excluded. Both models are shown (see *Table 6*). Multivariable modelling in Stata provided vifs and tols. All were below 3.20, so there was no significant multicollinearity in the data.

### Demography

As age increased, CO validation was more likely. Non-pregnant women were more likely to be CO validated than men and pregnant women. Ethnicity had no effect on CO-validation rates.

### Socioeconomic status

Prisoners were much more likely to be CO validated than other groups, approximately four times more likely than routine and manual workers. Eligibility for paying for prescriptions and PCT deprivation (once extreme PCTs were excluded) did not significantly affect CO-validation rates.

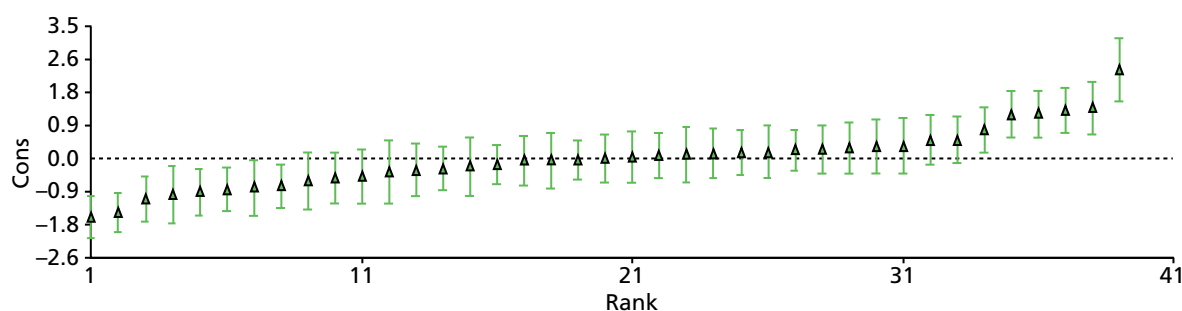
### Stop Smoking Service related

Self-report quitters who set quit dates in January were most likely to be CO validated and November quitters were least likely. Clients who took varenicline, combination NRT or a mixture of medications were more likely to be CO validated than those who took single NRT. Self-report quitters who enrolled in open groups were more likely to be CO validated. CO-validation rates were lowest among specialist practitioners. Health-care assistants, pharmacy employees and unclassified practitioners were significantly more likely to CO validate clients than specialist practitioners (see *Table 6*).

### Primary care trust and practitioner

Residuals suggest (*Figure 4*) that, after taking other demographic- and service-related factors into account, there was significant variation in PCT validation rates.

There is little that can be said with certainty about the higher-level variance, as it is not possible to tell how much of the change in variance between models (see *Table 7*) is owing to fixed effects in the model and how much is the result of level one variance being constrained to 3.29 in binary outcome models.



**FIGURE 4** Caterpillar plot of residuals for multivariable multilevel model predicting CO validation (model excluding extreme PCTs).

The variance between PCTs appeared to halve when PCT deprivation was entered into the model. The fixed effects suggested that PCTs that were fairly, but not the most, disadvantaged were three times more likely to be CO validated. This suggested that idiosyncrasies were responsible rather than an effect of deprivation. When extreme PCTs were excluded the variance between PCTs halved and there was no longer significant variation between practitioners.

## Impact

In general, the services had a positive impact over and above what would be expected from quitting spontaneously or with medication only. When the impact was calculated using all self-report quitters, two services were estimated to have a negative impact as did six services when only CO-validated quitters were included. However, only one service was judged to have a negative impact when both CO-validated quitting and all self-report quitting were taken into account. At the other end of the scale, two PCTs were estimated to have independently added over 400 ex-smokers per 100,000 population between mid-2010 and mid-2011 (*Table 8*).

**TABLE 8** Unique clients number and quit rates, throughput and impact per 100,000 population by PCT (each row is a different PCT)

Unique clients age ≥ 16 years				Clients per 100,000 PCT population <sup>a</sup>			
				Throughput	Impact (4-week quitters) calculated		
<i>n</i>	Client records unique clients (%)	CO-validated quit (%) <sup>b</sup>	Self-report quit (%) <sup>b</sup>		From CO-validated quit	From self-report quit	Overall (average self-report and CO validated)
2658	93.3	39.5	47.9	1969	285	254	270
2496	93.9	49.6	53.2	1371	337	249	293
5565	90.8	38.8	46.2	1764	243	198	220
4776	88.4	31.7	42.0	1717	115	120	118
5718	86.7	5.8	36.3	5003	–	–	–
3556	88.9	23.1	49.6	1371	–26	200	87
5429	92.5	35.3	46.4	1474	152	168	160
2463	95.3	36.8	44.6	980	116	94	105
5555	90.1	25.3	47.0	1489	4	179	92
9618	95.4	42.9	53.1	2277	408	412	410
1611	95.7	41.3	50.5	1979	323	307	315
4010	87.6	38.1	48.9	1571	206	218	212
3453	91.6	40.8	61.4	1729	273	456	365
6748	95.1	45.7	57.3	1126	233	251	242
2657	85.0	36.7	55.1	1035	121	208	165
2655	93.7	45.3	64.8	941	191	281	236
2991	95.2	31.3	37.5	1667	105	42	73
1822	92.7	35.4	42.1	983	102	70	86
3433	92.3	40.0	45.5	1593	239	167	203
7197	87.8	27.2	55.7	–	–	–	–

**TABLE 8** Unique clients number and quit rates, throughput and impact per 100,000 population by PCT (each row is a different PCT) (*continued*)

Unique clients age ≥ 16 years				Clients per 100,000 PCT population <sup>a</sup>			
				Impact (4-week quitters) calculated			
<i>n</i>	Client records unique clients (%)	CO-validated quit (%) <sup>b</sup>	Self-report quit (%) <sup>b</sup>	Throughput	From CO-validated quit	From self-report quit	Overall (average self-report and CO validated)
5620	89.1	28.1	55.1	–	–	–	–
12,817	88.3	27.7	55.4	1446	38	295	167
3324	91.7	20.1	45.6	2057	–101	218	59
3374	85.6	23.9	45.7	1775	–20	190	85
4409	91.4	41.5	60.8	2031	335	524	430
3395	91.6	24.3	39.5	2082	–15	94	40
1892	96.4	15.2	52.3	1334	–131	231	50
580	93.7	53.3	64.9	419	119	125	122
4403	89.5	37.0	44.2	1810	217	166	192
6842	93.9	44.8	61.7	1213	240	324	282
2828	94.7	34.7	41.8	1330	129	90	110
9679	91.0	41.4	55.6	1659	272	342	307
1407	94.6	52.1	60.8	1098	298	283	291
2826	90.7	35.2	48.3	1625	166	216	191
2071	93.8	56.9	64.1	1613	515	469	492
4533	90.8	28.4	53.1	1767	60	320	190
4626	88.9	26.8	41.1	2704	49	165	107
1487	97.1	34.6	54.4	703	67	136	102
549	95.8	45.3	58.9	359	73	86	79
4474	89.2	40.2	56.1	2174	330	459	395
1422	81.1	31.0	33.2	616	37	–11	13
1296 <sup>c</sup>	95.6	47.3	65.8	–	–	–	–
7880 <sup>c</sup>	95.5	28.2	46.7	2860	92	335	213
1683 <sup>c</sup>	95.0	18.0	26.4	712	–50	–61	–56
3974 <sup>c</sup>	96.0	38.7	45.4	1956	268	203	236
7646 <sup>c</sup>	98.1	39.6	49.9	1746	255	260	257
3676	90.5	26.3	41.1	1905	25	116	70

a Estimated mid-year PCT population estimate 2010. Impact calculations could not take place for some PCTs for the following reasons: first, poor-quality unique client identifiers; second, a markedly low CO-validation rate; third, population data being available only for a county whereas SSS data were available for constituent PCTs; and fourth, only specialist service clients included in QuitManager.

b Quit rates for unique clients are calculated using all QuitManager clients aged ≥ 16 years. For returning clients, their quit status at their last visit was used. Note that it was not possible to calculate quit rates for clients who set quit dates in December and June.

c Client records from four PCTs were included only in the second data download thus client records were doubled to estimate 1-year downloads. This is likely to have resulted in an overestimate of client records and also unique clients.

To represent quit rates, throughput and impact on the same graph (*Figure 5*), different scales were used. Thus, a point of 100 on the y-axis represents 100 extra ex-smokers per 100,000 population (impact), 1000 clients setting quit dates per 100,000 population (throughput) or a quit rate of 10%. The graph suggests that impact is more strongly related to quit rates than throughput. Two London PCTs displayed high quit rates but low throughput whereas three others displayed particularly high throughput but low CO-validated quit rates.

Summary statistics for unique clients (as opposed to client records) and impact in general were also calculated. There were 171,830 unique clients (note that unique clients could not be identified for three PCTs) and 157,479 clients where quit rates could be calculated (i.e. did not quit in December or June). The CO-validated quit rate of unique clients was 34.4%, the self-report quit rate was 49.8% and the CO-validation rate for clients who self-reported as quit was 73.3%. There were 169,909 unique clients aged  $\geq 16$  years altogether. The CO-validated quit rate for these clients was 34.5% and the self-report quit rate was 50.0%.

Impact rate summaries and correlations between impact rates throughput and quit rates were calculated for 40 PCTs for adults aged  $\geq 16$  years. The distribution of client records and unique clients among the PCTs were skewed, and quit rates and impact measures were normally distributed.

The median number of client records per PCT was 3713 (interquartile range 2101–5136) and the median number of unique clients was 3385 (interquartile range 2169–4603). There were 92.0% (interquartile range 89.7–94.7) of client records that referred to unique clients.

The mean quit rates for unique clients aged  $\geq 16$  years in the PCTs used for calculations were 36% (CO validated) and 50% (self-report) (*Table 9*). On average 1487 unique clients set a quit date per 100,000 population and 184 ex smokers per 100,000 population were added. If only CO-validated quits were taken into account there were 152 extra ex-smokers and if all self-report quits were included there were 216 extra ex-smokers.

Overall, impact was significantly positively associated with CO-validated quitting, self-report quitting and impact, taking into account either only CO-validated quits or taking into account all self-report quits. Throughput was not significantly associated with quitting or impact, taking into account CO-validated quits but it was significantly associated with impact taking into account all self-reported quits and overall impact. Thus, PCTs with a better throughput did have a higher increase in the number of self-reported smokers in the population but such PCTs were not CO validating sufficiently to be sure that the number of ex-smokers is increasing with a higher number of clients.

### **Impact and quitting**

Two PCTs with particularly low CO-validated quit rates were reaching the highest proportion of smokers in their local area. It is therefore possible that these PCTs were focusing on reach at the expense of achieving quits. This was corroborated by the impact analysis.

The PCTs with the highest impact were generally those with high quit-rates and vice versa.



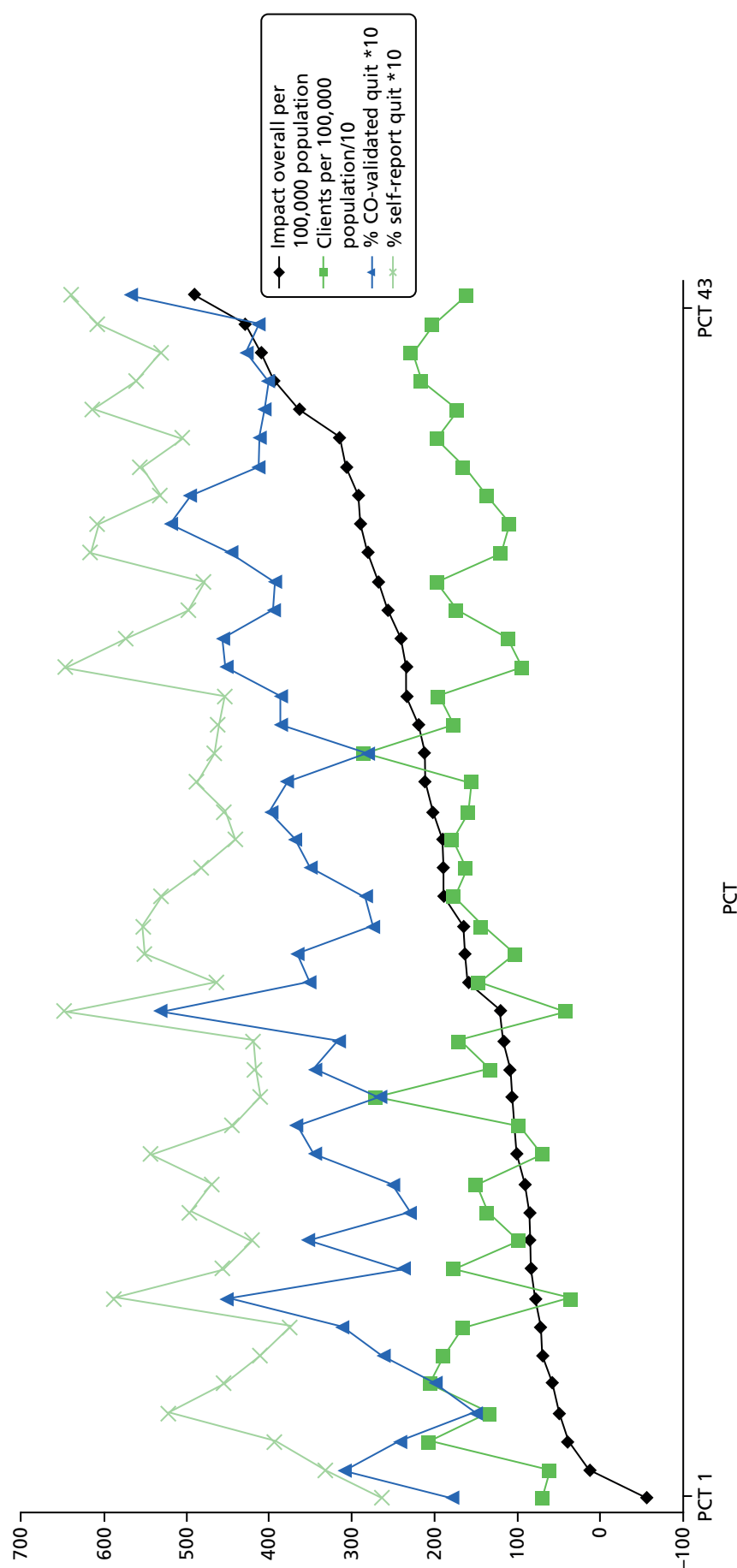


FIGURE 5 Impact, throughput and quit rates by PCT.

**TABLE 9** Summary of average impact and throughput per 100,000 population, quit rates for 40 PCTs and correlations for unique clients aged 16 years and over

Measure	Mean (SD)	Correlation with throughput		Correlation with CO-validated impact		Correlation with self-report impact		Correlation with overall impact	
		<i>r</i>	<i>p</i> -value	<i>r</i>	<i>p</i> -value	<i>r</i>	<i>p</i> -value	<i>r</i>	<i>p</i> -value
CO-validated quit	35.9% (9.7%)	-0.204	0.207	0.845	< 0.001	0.439	0.005	0.716	< 0.001
Self-report quit	50.0% (8.9%)	-0.133	0.414	0.505	0.001	0.735	< 0.001	0.675	< 0.001
Throughput	1487 (521)	–		–		–		–	
Impact (CO validated)	152 (144)	0.218	0.177	1	–	0.657	< 0.001	0.919	< 0.001
Impact (self-report)	216 (131)	0.450	0.004	–	–	1	–	0.901	< 0.001
Impact overall	184 (125)	0.361	0.022	–	–	–	–	1	–

SD, standard deviation.

## Socioeconomic status

Results presented in the published multivariable analysis<sup>26</sup> showed that affluent smokers were more likely to be abstinent from smoking at 4 weeks post quit date than disadvantaged smokers as measured by either eligibility for free prescriptions or by occupational group (as measured by the NSSEC), for example adjusted odds ratio (aOR) 1.38 (95% CI 1.35 to 1.42) for clients who paid for prescriptions compared with those eligible for free prescriptions. In total, almost 80% of the service clients received one-to-one counselling but open group forms of behavioural therapy were more successful [main effect aOR 1.26 (95% CI 1.12 to 1.41)] except among some of the most disadvantaged clients (prisons and long-term unemployed). Closed groups were little deployed and they were not significantly more successful than one-to-one behavioural therapy after controls. Practitioner type did make a difference for some clients, with all but the most affluent less likely to be successful if they had been treated by a nurse compared with other types of practitioners, including smoking cessation specialists [main effect aOR 0.73 (95% CI 0.65 to 0.83)]. More details are found in the published paper.<sup>26</sup>

## Summary of key points

- The estimated number of clients treated by SSSs from mid-2010 to mid-2011 was 5–10% of their smoking population.
- The self-reported and CO-validated quit rates were 49% and 34% respectively at 4 weeks post quit date.
- Smokers attempting to stop with NRT and minimal behavioural support have previously been estimated to have quit rates of 25% (for CO-validated quits) and 35% (for self-reported quits) at 4 weeks, so SSS interventions need to show rates higher than these and they should aim for rates of at least 50% for self-report and at least 35% for CO validated.<sup>33,42</sup>
- The lower CO-validation rate was likely to be the result of the CO-validation rate of self-report quits being below recommended levels (74% compared with the recommended 85%).<sup>33</sup> This was, however, slightly better than that reported for all PCTs in 2009/10 (69%).<sup>33</sup>

- The self-reported quit rate for all English SSSs from April 2010 to March 2011 was also 49%, with 70% of these CO validated<sup>43</sup> compared with 74% in the current sample. Overall, 787,527 people set a quit date<sup>43</sup> compared with the 202,084 client records in the QuitManager database used here. Thus, the North 51 PCTs that allowed their data for research purposes comprised roughly one-quarter of the total and have similar self-report quit and CO-validation rates. It must be noted that the self-report quit rate used was not as narrow as the DH quit rate regarding time of data collection but was more stringent in that it was an intention-to-treat analysis.
- Highest quit rates were found among older people, men and clients with higher SES. January was the month with the highest number of quit dates set and the most successful quitters.
- Affluent smokers were more likely to be abstinent from smoking at 4 weeks post quit date than disadvantaged smokers.
- Varenicline and combination NRT were both used frequently and increased the chances of quitting compared with a single NRT product.
- The majority (79%) of clients received one-to-one behavioural support. This type of support was significantly less successful than open rolling groups [aOR open groups 1.28 (95% CI 1.15 to 1.41) compared with one to one].
- Clients who saw specialist practitioners had higher quit rates than those who saw other types of practitioners.
- As a result of SSS treatment, the estimated number of ex-smokers per 100,000 population was 184 from mid-2010 to mid-2011.



## Chapter 5 Prospective study: methods and analysis

This chapter describes the methods used in the prospective study element of the ELONS study, including the rationale, recruitment, sample and approach to data analysis. A particular focus of this chapter is recruitment challenges faced during this part of the research and strategies implemented by the research team to address these.

### Rationale for the second element: prospective cohort study

Stop Smoking Services in England are not required to routinely collect data on longer-term cessation outcomes. Only outcomes 4 weeks after a client's quit date are collected and reported. Furthermore, the routine data collected by SSSs are limited in scope, and the quality and quantity of data collected varies between service providers. Consequently, there was a need for a prospective cohort study to collect long-term (12-month) follow-up data and more detailed and consistent information on client and service characteristics. Data from the prospective study were used to fulfil study objectives 3, 4 and 5 of the ELONS study, to explore the relationship between client characteristics, treatment characteristics and longer-term abstinence from smoking.

### Recruitment

Stop Smoking Service clients were eligible to be recruited to the ELONS study if they were aged 16 years or over and were not pregnant. In order to compare behavioural support types, initial power calculations suggested that we needed data from quit attempts made by 5000 individuals, with at least 370 quit attempts within each behavioural support type with 90% power and an average quit rate of 15%. This quit rate was based on the previous evaluation of long-term outcomes of the English services.<sup>18</sup>

Recruitment to the ELONS study was a multistage process:

- Secondary analysis of QuitManager data was conducted (see *Chapter 3* and *4*). The PCTs became the sampling frame of services. To achieve statistical power we initially approached services on the basis that they offered clients a range of behavioural support types. In order for our PCTs to be representative we also approached services with a range of short-term (4 week) quit rates and geographies (urban and rural areas, affluent and disadvantaged areas, and include areas from most regions of England).
- Once services were identified within this sampling frame, a member of the research team made contact with the service commissioner and service manager to invite them to take part in the study.
- After the service manager had agreed to participate, the research team obtained permission from the local PCT R&D department, and service support costs used to reimburse SSSs for staff time spent on the ELONS study were negotiated.
- While this process was under way, the team liaised with services to decide whether to include only specialists or additionally include level 2 providers.
- If it was decided that level 2 providers could be included, they needed to be approached individually (as each is a separate contractor, i.e. a pharmacy) to determine if they would take part.
- Once participation of a service (and if relevant its linked level 2 practitioners) was confirmed, a study briefing was delivered to smoking cessation practitioners to enable them to recruit clients to the ELONS study.
- After these elements were in place, stop smoking advisors recruited clients to the study. Inclusion criteria were all clients who were over 16 years old, were not pregnant and had set a quit date.

The recruitment process was aided considerably by the involvement of the PCRN staff, who helped us make initial contact with SSS managers and colleagues in R&D, promoted the study to level 2 providers, finalised service support costs and delivered study briefings. Two service managers (Northamptonshire and Rotherham) did not want their practitioners to be burdened with recruitment to the ELONS study or collecting the extra monitoring data. In these sites, PCRN-funded staff recruited clients, and collected client and treatment characteristics on paper forms. However, as PCRN are organised by area and each have their own budget, the level of support available did vary across the nine ELONS study sites.

## Recruitment challenges

Recruitment was a particular challenge for the prospective study. The initial hurdle was that the data collected in QuitManager did not consistently differentiate between behavioural support types. The main ambiguity was between one-to-one specialist practitioner support and level 2 support and, to a lesser extent, between one to one and drop-in. To overcome this, to some extent, the likely behavioural support range was checked with site managers when they were first contacted.

The second hurdle was securing the participation of SSSs as study sites. If services agreed to take part, this would involve SSS practitioners consenting clients to the study and collecting additional client and treatment data. This could be perceived as onerous in the context of limited appointment times and with local targets to meet. In addition, when we approached SSSs they were preparing for their busiest time of the year (post Christmas/New Year and No Smoking Day on 14 March). Moreover, local service funding was contracting in the face of NHS reforms and the move of public health from the NHS to Local Authorities in England (see *Chapter 1*). This led to some staff being made redundant or having their employment grade changed. Despite this, only three PCTs that the research team approached declined to participate in the study. The main reasons for declining were that they perceived available service support costs to be inadequate, it was an onerous consent process and there were factors related to service reorganisation.

Eight services were initially recruited to the study. From the numbers of clients attending these services recorded in the data set used for secondary analysis, it was thought that the target of 5000 participants (as set out in the original study proposal) would be achievable. However, the process of site recruitment took longer than expected (it was common for this process to take months rather than weeks): site managers needed to engage with colleagues and senior staff to explain what participation would involve before they could agree to take part; R&D permissions, liaison with local PCRN and service support cost calculation also were needed before a site could be confirmed as taking part and start recruitment. As a result of this, client recruitment started later than planned, after the busy New Year period had ended. In addition, the recruitment start date was staggered by site.

The third recruitment challenge was engaging with level 2 providers. As discussed previously, SSSs are delivered via specialist providers (their remit is purely smoking cessation) and level 2 providers such as GP practices, pharmacies and dentists (also called community providers) whose staff deliver smoking cessation in conjunction with their other responsibilities. Level 2 provision has grown over the past decade<sup>44</sup> and thus it was important to involve these providers as well as specialists. Level 2 providers have different management arrangements to the specialist service, so each level 2 provider needed to be contacted separately. We therefore had to implement a recruitment strategy, which is summarised below (note there was some deviation between sites depending on the extent of SSS management commitment to the study, PCRN involvement and service support costs):

1. we identified which sites had level 2 service provision
2. we agreed with SSS managers whether or not we could approach their level 2 providers
3. where permission was granted, we publicised the study and letters were sent to all level 2 providers (via the SSS) to describe the evaluation and invite them to opt in by completing an 'expression of interest form' and returning in a reply paid envelope

4. to increase the number of providers, telephone calls were made by the research team and PCRN staff to practice managers and pharmacy managers/pharmacists from GP practices and pharmacies who had been active in the previous 6 months
5. a news article was added to the newsfeed page of QuitManager for each site, with instructions on how to register interest as a recruitment site
6. the research team and PCRN staff briefed the level 2 providers through lunchtime and early evening briefing events (with refreshment and buffet to encourage attendance) or individual face-to-face and telephone briefings for those who were unable to attend events.

Six sites recruited level 2 service providers. The number of individual providers recruited varied between 4 and 23.

The fourth challenge was obtaining informed consent. In order to secure PCRN help and to be able to reimburse SSSs for their time using service support costs, we asked the NHS Ethics Committee to classify the ELONS study as a research study rather than an audit or evaluation. This classification differed from that taken in ethical review processes for our previous national study of SSSs, conducted between 2001 and 2004.<sup>18</sup> In the earlier study, the National Institute for Health Research (NIHR) and PCRN, etc., did not exist, there were no service support costs available and ethical requirements were arguably not as onerous. At that time we were permitted to merely add consent to take part in the research as a single question on existing service data collection sheets, but not for this study. For the ELONS study, the Research Ethics Committee required a consent form for each client with a section relating to each element of the study. Clients were asked to consent to each part. This procedure and the length of the consent form was undoubtedly a barrier to participation and SSSs reported that it resulted in serious time implications, which was the fifth recruitment barrier.

One of our study sites served as a within-study pilot and we tried out our recruitment methods there. This was Country Durham and Darlington, where we were able to estimate that the process of recruiting a client, seeking informed consent, asking the additional monitoring questions and collecting saliva samples added an additional 10–15 minutes to the appointment. This meant that the ELONS study added additional time to each consultation, which affected the number of people that the service could see. From a service manager perspective, this was of concern because they had local targets to meet (in terms of the number of clients they see and successful 'quits' at 4-week follow-up) with ongoing funding dependent on these targets being met. Some sites found this easier to manage than others, depending on how they delivered their service. Situations where there were particular problems included:

- Groups where the consent process and collection of baseline data had to be done for all group members. With limited staff, this could take up the majority of a session.
- One-to-one sessions where slots were doubled/triple booked because of a high did-not-attend rate in order to keep service busy. This meant the additional time required to recruit clients to the ELONS study was limited.

A sixth recruitment challenge was 'buy-in' from both the SSS practitioner and clients. The ELONS study mostly relied on practitioners to recruit clients and some were more confident and committed to this than others. This is an issue in any research study that recruits in routine practice. Some practitioners were genuinely interested in, and could see the value of, research and so made extra efforts to encourage their clients to consent to participate. Others were not so enthusiastic, or had more limited time. Client 'buy-in' was also an important issue for recruitment. Some practitioners, particularly pharmacy employees, reported that clients simply did not want to take part. Practitioner feedback suggests that the main reasons were that clients did not have time to go through the recruitment process (particularly for working people who scheduled appointments) or did not want to be contacted for follow-up (often older people).

A further challenge was failure to set quit dates. In the previous English longer-term evaluation,<sup>18</sup> clients were included in a study only if they 'set a quit date' (i.e. gave the SSS a particular day when they were

going to attempt to stop smoking). In some of the services, clients were recruited to the study when they registered with the SSS, which was sometimes before they set a quit date. Some of these clients never did set a quit date. Comparing the QuitManager prospective study extracts with the saliva samples database for the long-term NRT use study revealed further clients who had been initially recruited to the ELONS study (as they had provided saliva samples) but had been dropped from QuitManager owing to lack of progress with their quit attempt.

The last challenge was footfall. Several sites reported a general decrease in the number of people using their service during the study period. Analysis of the number of quit dates set over the recruitment period for the ELONS study (March 2012–March 2013) suggests that this was a reality. The number of quit dates set in SSSs in England for 2011/12 was 816,444 and in 2012/13 this has decreased by 11% to 724,247.<sup>31</sup> The decline continued after recruitment was completed, and much or at least some of this has been attributed to more smokers using electronic cigarettes (e-cigarettes) for cutting down or quitting rather than more established methods.

## Strategies to address recruitment challenges

By late July 2012 it became clear that the client recruitment rate was considerably below the level that was expected from the previous English long-term evaluation, where up to 80% of clients in the two study areas had been recruited.<sup>18</sup> Various strategies were implemented to improve recruitment:

- We negotiated further assistance from the PCRN/Clinical Research Unit and we were able to boost the number of level 2 providers.
- A substantial amendment was submitted to ethics to simplify the consent form from six points to initial to three tick boxes, which was approved (we initially asked for a move away from written to verbal consent which was rejected).
- In order to support and motivate sites, we encouraged practitioners who were recruiting well to share their approach with their peers who were performing less well. We also supplied fortnightly updates to site leads with a breakdown of recruits by practitioner name so that they could monitor performance and discuss with staff when appropriate. Practitioners were sent a newsletter and either a mug or a pen with the ELONS study logo to both thank them and act as a reminder to keep recruiting.
- A further two sites were approached to take part in the ELONS study. One of these, Hull and East Riding, agreed to take part.
- Clients who had agreed to be recruited to the ELONS study but where there was no record of quit date set were included in the analysis.
- We postponed the end of recruitment from the end of November 2013 to the end of January 2014 where sites were willing.

## Sample

Despite efforts to boost recruitment, the challenges described above meant that our initial target baseline sample of 5000 (as set out in our original research proposal) was too ambitious. Therefore, in consultation with the chairperson of the NIHR Health Technology Assessment (HTA) Board and statistical practitioner we revised our sample size calculation to a more realistic target sample of 3000, which allowed us to maintain a sufficient level of power to detect meaningful effect sizes between the intervention groups (90% to 80% power).

The NIHR HTA agreed the revised sample size of 3000 and the study was also granted a 7-month extension to allow us to successfully recruit this number of participants.

The measures taken and the timing of measures are presented in *Chapter 2* and *Table 2*.



## Prospective study analysis

For the prospective study, six stages of analysis were undertaken. These were:

- preliminary analysis of short-term quit rates using unweighted data
- comparison with the 'all cases' data set to develop weights
- short- and longer-term unweighted and weighted quit rates
- multivariable and multilevel logistic regression modelling of CO-validated abstinence at 4 weeks
- multivariable logistic regression modelling of CO-validated abstinence at 52 weeks
- adherence to treatment
- comparison of longer-term quit rates with those in other evaluations.

### *Preliminary analysis of short-term quit rates using unweighted data*

We present tables of 4-week quit rates for variables grouped into 10 key themes: location; demography; SES; health and well-being; smoking behaviour; support; behavioural support type; medication; introduction to the service; and finally, data collection variables. We also created crosstabulations of relationships between each variable and location, behavioural support type and sociodemographic characteristics, and results from these are referred to where relevant. These figures are not tabulated in this report, as they are very detailed, but are available on request.

Unless it is stated otherwise 'quitting' refers to CO-validated abstinence at 4 weeks. We have taken a finding to be significant at the traditional  $p < 0.05$  level. Sometimes the chi-squared test result was invalid owing to low numbers of expected cases in cells, in which case significance was recorded as  $p = \text{not available}$ . For contingency ( $2 \times 2$ ) tables we could have used Fisher's exact test but in practice most variables we used generated tables greater than  $2 \times 2$ .

### *Weighting*

As the requirements for detailed consent (along with the other pressures on services outlined above) meant that it was not possible to recruit a high proportion of clients, weighting was undertaken to correct for non-response so that the quit rates would take into account any differences in important variables such as demographics between the ELONS study sample and the population. In order to create the weights, the ELONS study research team requested a QuitManager extract of all quit attempts (with quit dates) that took place at the nine study sites from March 2012 to March 2013 (the months where any ELONS study client set a quit date). All nine SSS managers gave permission for the data from their service to be made available. The database included the majority of the routine data that was collected by the sites but without identifying information. This database is referred to as 'all cases' in the remainder of the report.

The 'all cases' database was used to develop weights in order to calculate quit rates generalisable to the nine services that took part in the ELONS study. The weights were trimmed rim weights, which were provided by TNS BMRB. Rim weights are created using an iterative algorithm to ensure that the weight is the best fit to the proportions of various characteristics in the population. Trimming reduces the size of overly large weights so that they cannot go above a particular value. The weights were created using these variables: behavioural support type, age, gender and SES (measured by NSSEC). Note that the 'other/unclear' group of behavioural support in the ELONS study was too small for weighting so quit attempts in this group were redistributed to either the nearest group or the group of which they were most likely to be a member (three quit attempts to GP practice service and the remainder to one-to-one specialist). We also intended to weight for location (study site) but there were large differences in proportions recruited by location, which led to instability in the weighting and so the decision was made to exclude this, with behavioural support used to explain some of the differences by location. As an alternative, quit rates were calculated taking into account clustering by location.

**Short- and longer-term weighted quit rates: variable definitions**

Short- (4 week) and longer-term (52 week) raw and weighted CO-validated quit rates are presented for the variables that were significant predictors of 4-week quitting. Clients lost to follow-up were coded as still smoking, consistent with conducting an intention-to-treat analysis as set out in the Russell Standard.<sup>30</sup> The same rim weights were used for the 12-month quit rates as the 4-week quit rates to allow our estimates to be generalisable to the nine services that took part in the ELONS study.

Data were collected from all nine study sites. The behavioural support types used in the analysis were specialist closed groups, open groups, drop-ins and one-to-one sessions; GP practice, pharmacy service and other/unknown. Seasonality effects were analysed through the time of year that a quit attempt started. Quit attempts that started during the main summer holiday period, the post-summer holiday 'back to school' period and the New Year were differentiated from those starting at other times of year.

Demographic variables included age, gender and ethnicity. Age at first contact was included in the analysis as data were available for all respondents. Ethnicity was categorised as white British, other white, Asian (including mixed white and Asian) and other.

Socioeconomic status was measured through a count of the number of indicators of disadvantage. The indicators of disadvantage were routine and manual occupation/unemployed/permanently sick; no educational qualifications or highest qualification is General Certificate of Secondary Education or equivalent; eligible for free prescriptions; housing is rented and single parent (see *Table 11*) for details of these indicators. The variable was dichotomised into 0 to 1 indicators compared with two or more indicators.

Medication was operationalised by whether or not clients had taken varenicline at week 1. Combination NRT (using more than one NRT product concurrently) was not included because it was not associated with quitting in preliminary analysis. This is further discussed in *Chapter 6, Adherence to treatment*. This may be because one of the more successful sites and the only user of open groups used very little combination NRT. We could not explore this further because of multicollinearity between site and medication. Varenicline at week 1 was measured because abstinence from smoking was strongly associated with higher numbers of records of smoking medication and clients who had more records had more opportunity to change medication (see *Chapter 6, Adherence to treatment*).

For the element assessing well-being, following standard practice the WHO-5 Well-being Index<sup>45</sup> items were converted to a percentage. Thus, a score of 0 indicates the lowest well-being and a score of 100 represents the highest well-being.

Initial analysis of dependence showed that high daily consumption of cigarettes and smoking within 5 minutes of waking were associated with low quit rates. However, the highest quit rates were associated with quitting between 6 and 60 minutes after waking (47–49% in preliminary analysis); quit rates of clients who smoked over 60 minutes after waking had quit rates similar to clients who smoked within 5 minutes of waking (42% and 41% respectively). Furthermore there was not a linear relationship between cigarettes smoked per day and quitting. Thus the Heaviness of Smoking Index was of only borderline significance in preliminary analysis and had a non-linear relationship with quitting. Thus concerns arose that the true importance of being dependent might be missed if the Heaviness of Smoking Index was used to represent dependence in the analysis, so instead a dichotomous variable was used: clients who smoked > 30 cigarettes per day or who smoked within 5 minutes of waking were coded as dependent and contrasted with all other clients.

Clients who were very or extremely determined to quit were differentiated from other clients. Clients who stated that their spouse or partner was supporting them during their quit attempt were also differentiated from other clients, as were clients who indicated that a half, a few or none of their friends and family smoked.

### Multivariable predictors of quitting at 4 weeks in the prospective study

Multilevel logistic regression was conducted using MLwiN version 2.29. The dependent variable was CO-validated abstinence at 4 weeks. Weighting is not recommended in multilevel modelling, including variables where differential recruitment has occurred is preferred.<sup>46</sup> Thus all final models using prospective study data needed to include behavioural support types and locations.

#### Fixed effects

The fixed-effects variables are described in *Short- and longer-term weighted quit rates: variable definitions*.

Four other fixed effects were tested because preliminary bivariable analysis (see *Chapter 6*) suggested they might be of importance but were excluded from the final model:

- Marital status (non-significant in multivariable analysis).
- Practitioner had the ELONS study clients who did not set a quit date (non-significant in multivariable analysis).
- Saliva collected (non-significant in multivariable analysis).
- Serious previous quit attempt with or without quitting aids (clients who had made a quit attempt in the last 12 months but had not used aids were less likely to quit than both those who had not made a quit attempt and those who had made a quit attempt with quitting aids. Owing to the non-intuitive results and the desire for simplicity, this variable was excluded).

#### Random effects

There were potentially five levels:

- client quit attempt
- client: only 22 clients were recruited to the ELONS study twice, so the client level was not included
- practitioner
- service provider: the models failed to run because of conflicts with practitioner and location
- location: there was no significant level 2 variance as there were only nine locations, so location was included as a fixed effect.

Thus in the final models two levels were included: the first level was client quit attempt and the second level was practitioner. There were 234 practitioners in the prospective study and the median number of clients recruited was four.

#### Modelling

Modelling occurred in three stages. First, all fixed effects were entered into the model individually, second, all fixed effects were entered into the model simultaneously, and third, all fixed effects were entered into the model.

The model was then tested for multicollinearity by comparing the size of the CI when each variable was added individually with the CI when each variable was added simultaneously.<sup>46</sup> If the standard error increased by 50% or more multicollinearity was deemed to be present.<sup>46</sup> This did not occur.

### Multivariable logistic regression modelling of carbon monoxide-validated cessation at 52 weeks

Initial multilevel modelling revealed that there was consistently no evidence of variance between practitioners (i.e. the practitioner made no difference to the chances of long-term quitting), so single level logistic regression modelling was undertaken using SPSS. All significant fixed effects at 4 weeks (analysis 2) were entered into the model and a backwards-stepwise method was used to eliminate non-significant variables. However, the a priori variables, behavioural support, location, time of year and sociodemographic variables, (with the exception of ethnicity) were kept in the model irrespective of statistical significance. Variables that did not reach statistical significance in the 4-week multivariate analyses (marital status,

medical conditions, how introduced to the service) were then added to the model; however, none of these reached statistical significance in the multivariable model. Multicollinearity was tested by comparing the standard error in models with each variable added individually and simultaneously. If the standard error increased by 50% or more multicollinearity was present. This did not occur.

### ***Adherence to treatment***

Adherence – or continuing to attend SSSs – could not be included in multilevel modelling. This was owing to issues with direction of causality: it is not clear whether failure to adhere reduces the chances of quitting or whether clients relapse and then stop attending sessions and taking medication.

There were two measures of adherence collected in the prospective study: number of behavioural support sessions attended and number of occasions that medication was recorded. Sample distributions and weighted quit rates at 4 and 52 weeks were calculated for adherence, adherence and medication, and medication taken on any occasion and on the first occasion. Medication types included 'single NRT' (one form of NRT recorded), 'combination NRT' and varenicline. The other/mixed medication category included bupropion or clients who had taken more than one of the aforementioned medication types.

In an attempt to overcome issues with direction of causality we have followed work by Shiffman and colleagues<sup>47,48</sup> and we have considered adherence prior to a person being abstinent. Thus we have analysed whether or not adherence was associated with 52-week quitting only in those who attained 4 weeks abstinence; we have assessed their attendance prior to 4 weeks using weighted means.

### ***Comparing longer-term outcomes with those in other evaluations***

Quit rates and follow-up rates in the ELONS study were compared with previous evaluations of SSSs in the UK. This type of comparison is not normally attempted or appropriate for observational studies, but was included here as the studies in question were conducted by the same research team and employed an almost identical research design. The previous studies were of two English services in 2002 (the 'national evaluation' in England described in the introduction to this report)<sup>17–19</sup> and of pharmacy and group-based services in Glasgow in 2007. Raw data rather than weighted data are presented. This is because none of the three data sets include data from all SSSs in England – all collected data from a small number of locations. In addition, weights for the final percentage (CO-validated quit rate of those successfully followed-up) could not be calculated because not all clients were included in the denominator. Thus the only meaningful comparison is between the raw data from all three studies.

## Chapter 6 Prospective study findings

This chapter presents findings from the prospective cohort study. Findings from the additional elements of the prospective cohort study (CSS, well-being and longer-term NRT) are presented in *Chapters 7–9*.

Sections of this chapter describe findings from the different stages of analysis conducted in the prospective study including:

- analysis of short-term outcomes using unweighted data
- comparing the ELONS study and the 'all cases' data sets
- short- and longer-term quit rates
- adjusted ORs from logistic regression of quitting in the short and long term
- adherence with treatment
- comparison of longer-term quit rates with those in other evaluations.

### Analysis of short-term outcomes using unweighted data

This section describes the characteristics of the ELONS study clients, the types of support they received from services and how these were associated with stopping smoking in the short term (4 weeks after their quit date). Note: this material represents an early stage of work, using unweighted data, in order to inform further refining of the variables and multivariable analysis. Thus, these are not the main findings of our study.

Data were available from 3075 clients; there were, however, six participants that were excluded from this preliminary analysis because they were pregnant, leaving 3069 cases. Overall, at 4 weeks post quit date just over a half of study participants reported that they had quit smoking (56.6%). Most of these clients had their report of abstinence confirmed by CO validation – the 4-week CO-validated quit rate was 44%.

Note that chi-squared tests test only the significance of the greatest difference between categories: they cannot differentiate intermediate categories. For several variables, particularly those that were collected only for the ELONS study clients, it was the other/unknown category that was the least likely to quit. This was because clients who did not complete the ELONS study monitoring form often were those also who failed to engage properly with the service and many did not set a quit date. For these variables we therefore do not know whether or not the categories of interest differ significantly at this stage but we can assess if quit rates are in the expected direction.

### Demographic characteristics

As *Table 10* shows, short-term quit rates varied between clients with different characteristics.

#### Age

Smokers recruited in the study were from all age groups, but primarily 25–54 years (68%). The older a client, the more likely they were to stop smoking at 4 weeks (69% of 65–85-years-old compared with 41% of 16- to 24-year-olds,  $p < 0.001$ ). In addition, more of the older clients had their self-report of abstinence validated by CO breath test. For example, 41% of 16- to 24-year-olds reported that they had quit but only 25% were validated with a CO test, a gap of 16%. In contrast, the gap between self-report and CO-validated quits at 4 weeks was just 8% for clients aged 65–85 years (69% and 61% respectively).

#### Gender

Around a half of both males and females self-reported as quit at 4 weeks (58% and 55% respectively,  $p = 0.06$ ) but there was no significant gender difference at 52 weeks.

**TABLE 10** Demographic variables: distribution and quit rates

Demographic variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>Age (years)</b>				
16–24	330	10.8	41.2	24.9
25–34	676	22.0	53.4	38.2
35–44	760	24.8	55.5	41.8
45–54	631	20.6	59.0	47.5
55–64	458	14.9	65.3	57.2
65–85	214	7.0	69.2	60.8
<i>p</i> -value	–	–	< 0.001	< 0.001
<b>Gender</b>				
Male	1355	44.2	58.5	44.9
Female	1714	55.9	55.1	43.3
<i>p</i> -value	–	–	= 0.60	= 0.408
<b>Ethnicity</b>				
White British	2877	93.7	56.7	44.1
Other white	70	2.3	61.4	48.6
Asian (including mixed white and Asian)	64	2.1	46.9	26.6
Black (including mixed white and black)	24	0.8	54.2	41.7
Other/unknown	34	1.1	64.7	58.8
<i>p</i> -value	–	–	= 0.393	< 0.001
<b>Marital status</b>				
Separated/divorced	369	12.0	57.5	46.1
Single (including widowed)	684	22.3	50.4	36.8
Married/living with partner	1443	47.0	61.5	48.1
Other/unknown	573	18.7	51.3	40.8
<i>p</i> -value	–	–	< 0.001	< 0.001

### Ethnicity

Most (94%) of the recruited population were white British, 2% were 'other white' ethnicities or Asian (including mixed Asian and white). About 1% were either black (or mixed black and white) or 'other/unknown'. Clients in this final category were significantly more likely to quit than Asians (59% compared with 27%,  $p < 0.001$ ) although the numbers are very small. There was no difference in self-reported quit rates possibly because of the gap between self-report and CO-validated quit rates for Asians. The majority of Asian clients (80%) were men.

### Marital status

Clients who reported that they were married were more likely to have stopped smoking at 4 weeks ( $p < 0.001$ ).

### Socioeconomic status

Baseline data collection included a range of questions about SES, these are described below and presented in Table 11.

**TABLE 11** Socioeconomic status: distribution and quit rate

SES	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>NSSEC</b>				
Routine and manual	941	30.7	59.4	46.3
Intermediate	284	9.3	58.5	44.0
Managerial/professional	434	14.1	65.4	51.2
Retired	344	11.2	69.2	59.0
Home carer	197	6.4	46.2	35.5
Sick/disabled and unable to work	220	7.2	50.0	36.8
Never worked/long-term unemployed	443	14.4	46.5	35.2
Full-time student	102	3.3	41.2	23.5
Other/unknown	104	3.4	40.4	31.7
<i>p</i> -value	–	–	<0.001	<0.001
<b>NSSEC (four category)</b>				
Routine and manual	941	30.7	59.4	46.3
Managerial/professional and intermediate	718	23.4	62.7	48.3
Sick/disabled and never worked/long term	663	21.6	47.7	35.8
Other/unknown	747	24.3	55.3	44.2
<i>p</i> -value	–	–	<0.001	<0.001
<b>Education</b>				
None	602	19.6	56.6	46.2
GCSE or equivalent	855	27.9	56.8	44.2
Apprenticeship/vocational	148	4.8	60.8	48.0
A-level or equivalent	316	10.3	60.8	44.6
Degree or equivalent	290	9.5	62.8	46.2
Other/unknown	858	28.0	52.1	40.6
<i>p</i> -value	–	–	=0.011	=0.231
<b>Eligibility for free prescriptions</b>				
Eligible for free prescriptions	1437	46.8	48.6	37.2
Pays	1081	35.2	63.6	48.0
Outside 19–59 years age group/unknown	551	18.0	63.9	53.9
<i>p</i> -value	–	–	<0.001	<0.001
<b>Housing tenure</b>				
Private renting	742	24.2	51.8	37.3
Social/council renting	753	24.5	49.1	39.0
Buying on a mortgage	789	25.7	65.3	51.7
Own outright	468	15.3	69.9	57.9
Other/unknown	317	10.3	44.8	31.6
<i>p</i> -value	–	–	<0.001	<0.001

continued



**TABLE 11** Socioeconomic status: distribution and quit rate (*continued*)

SES	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>Household type</b>				
Lone parent <sup>a</sup>	232	7.6	48.3	38.4
≥ 2 adults and children	912	29.7	57.6	41.7
No children in household	1839	59.9	58.2	46.7
Other/unknown	86	2.8	36.0	26.7
<i>p</i> -value	–	–	< 0.001	< 0.001
A-level, advanced level; GCSE, General Certificate of Secondary Education.				
a Given the age distribution a minority may be lone grandparents, etc.				

## Occupation

Around one-third of clients (31%) reported working in routine and manual occupations, with other types of occupational group fairly evenly distributed. The best 4-week outcomes were found in the managerial/professional and retired groups (65% and 69% self-report compared with 51% and 59% CO validated, respectively). There was a significant difference between retired and other/unknown SES. Outcomes for full-time students were among the poorest and also had the largest gap between self-report and CO-validated quits (41% compared with 23%). This is not surprising considering that the majority of students will be under 24 years and similar outcomes were found when looking at 4-week outcome by age; 16- to 24-year-olds had the poorest outcomes. Only 20% of clients with professional, managerial and intermediate occupations reported having degrees, which seems low. In the general population, 30% women and 20% men have a degree.<sup>49</sup>

## Education

Highest educational qualification was an extra question added for the ELONS study, not required in routine monitoring. It was particularly poorly answered by most sites, with 28% missing overall. From the data available, there was no relationship between reported education and CO-validated quitting, although there was a relationship in the expected direction for self-report [i.e. better outcomes for clients with a degree than those with no qualifications (63% compared with 57%)] ( $p = 0.011$ ).

## Eligibility for free prescriptions

Clients who reported paying for prescriptions were more likely to have better 4-week outcomes than those who did not (64% compared with 49% self-report outcomes) but those whose eligibility was unknown or were outside the 19–59 age range where eligibility reflects SES were most likely to quit ( $p < 0.001$ ).

## Housing tenure

Short-term quit rates were higher among homeowners compared with those reporting living in rented accommodation. Those buying outright were most likely to quit, which is likely to reflect age and those whose tenure was unknown were least likely, which is likely to reflect lack of engagement with the services ( $p < 0.001$ ).

## Lone parents

Of the sample, 80% stated that they were lone parents. Overall, lone parents had very low quit rates (36%). Of these lone parents, 16% were men ( $p < 0.001$ ).

## Health and well-being

A number of medical conditions can affect which stop smoking medications are appropriate for clients and, probably for this reason, data on health issues were well recorded by practitioners who completed monitoring forms with clients. Some key results are described here and presented in *Table 12*.



**TABLE 12** Distribution and quit rates of the health and well-being variables

Health and well-being variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b><i>Any medical condition</i></b>				
Has one or more medical condition(s)	1725	56.2	57.3	45.3
Has no medical condition	1344	43.8	55.8	42.3
<i>p</i> -value	–	–	= 0.414	= 0.089
<b><i>Mental health condition(s)<sup>a</sup></i></b>				
Has mental health condition	486	15.8	50.8	38.9
Does not have mental health condition	2583	84.2	57.7	45.0
<i>p</i> -value	–	–	= 0.005	= 0.014
<b><i>Heart/blood/circulation condition</i></b>				
Has heart/blood/circulation condition(s)	532	17.3	61.3	51.1
Does not have heart/blood/circulation condition(s)	2537	82.7	55.7	42.5
<i>p</i> -value	–	–	= 0.017	< 0.001
<b><i>All lung and respiratory illness<sup>b</sup></i></b>				
Has lung and respiratory illness	648	21.1	53.7	43.1
Does not have any lung and respiratory illness	2421	78.9	57.4	44.2
<i>p</i> -value	–	–	= 0.090	= 0.590
<b><i>Other condition<sup>c</sup></i></b>				
Has other condition	354	11.5	60.2	47.2
Does not have any other condition	2715	88.5	56.2	43.7
<i>p</i> -value	–	–	= 0.153	= 0.199
<b><i>Medical conditions limiting</i></b>				
Severely limiting	202	6.6	57.9	43.6
Moderately limiting	562	18.3	56.9	47.3
No limiting effects	961	31.3	57.3	44.5
No medical condition	1344	43.8	55.8	42.3
<i>p</i> -value	–	–	= 0.867	= 0.230
<b><i>Self-assessment of health</i></b>				
Not good	658	21.4	51.1	38.8
Fairly good	1325	43.2	56.5	44.6
Good	1003	32.7	61.9	47.4
Unknown	83	2.7	39.8	35.0
<i>p</i> -value	–	–	< 0.001	= 0.002

continued

**TABLE 12** Distribution and quit rates of the health and well-being variables (*continued*)

Health and well-being variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>WHO-5 Well-being Index</b>				
Concerning level of well-being	1646	53.6	55.1	41.9
Good level of well-being	1325	43.2	59.9	47.3
Missing	98	3.2	37.8	34.7
<i>p</i> -value	–	–	< 0.001	= 0.002
a Including addiction and degenerative.				
b Including chronic obstructive pulmonary disorder, emphysema, asthma and other respiratory conditions.				
c Not mental health, heart, blood, circulation or respiratory.				

### Medical conditions

Having a medical condition was not related to abstinence at 4 weeks and neither was having a more severe medical condition. This may be because the type of medical condition was important: clients who had a mental health condition were less likely to quit compared with those without (39% compared with 45%,  $p = 0.014$ ) whereas clients with a heart, blood or circulation condition were more likely to quit compared with those without (51% compared with 43%,  $p < 0.001$ ). There was no relationship for respiratory conditions or other medical conditions. Heart, blood and circulation conditions were 25 times more prevalent in the oldest age group than the youngest age group (49% compared with 2%,  $p < 0.001$ ). Mental health conditions were about twice as common among clients claiming sickness or unemployment benefits than overall (29% compared with 15%,  $p < 0.001$ ). Mental health conditions were about twice as prevalent in the 45–54 years age group compared with the youngest and oldest age group (20% compared with 10% and 12% respectively,  $p = 0.003$ ).

### Self-assessed health and well-being

The ELONS study participants were also asked about their own perceptions of health and well-being. Interestingly, clients who chose not answer these questions had the lowest chances of stopping smoking. Thus we cannot tell from the chi-squared tests whether or not there were significant differences in quitting by self-assessed health or well-being.

Around two-fifths of people aged 45 years and younger assessed their health as good before age 45 years compared with one-quarter of people aged 46 years and above ( $p < 0.001$ ).

Over a half of the sample (54%) had a concerning level of well-being. A concerning level of well-being was more common in people who had a mental health condition (71% vs. 53%;  $p < 0.001$ ). Clients receiving group-based treatment were more likely to have good levels of well-being than those receiving one-to-one treatment (51–55% vs. 41–44%;  $p < 0.001$ ). Highest levels of well-being (about a half reporting good well-being) were found in the two youngest age groups. Lowest levels of good well-being (35%) were found in the 45–54 years age groups who were also more likely than other age groups to have a mental health condition ( $p < 0.001$ ). Well-being was similar among clients with professional/managerial/intermediate occupations and clients with routine and manual occupations (49% to 50%) but poorer among clients claiming sickness or unemployment benefits (35%;  $p < 0.001$ ).

### Smoking behaviour

Questions on smoking behaviour were centred on assessing nicotine dependence and motivation to stop smoking. The pattern of responses is shown in *Table 13*.

**TABLE 13** Smoking behaviour variables: distribution and quit rate

Smoking behaviour variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b><i>HSI tobacco dependence score</i></b>				
0 – little or no dependence	144	4.7	67.4	49.3
1 – lower dependence	194	6.3	60.8	43.3
2	363	11.8	60.3	44.6
3	834	27.2	61.4	48.
4	839	27.3	53.3	41.8
5	487	15.9	51.3	42.7
6 – higher dependence	179	5.8	46.4	36.9
Missing	29	0.9	–	–
<i>p</i> -value	–	–	< 0.001	= 0.049
<b><i>Smoking after waking</i></b>				
≤ 5 minutes	1334	43.5	52.0	41.0
6–30 minutes	1158	37.7	59.8	47.1
31–60 minutes	290	9.4	62.4	48.6
> 60 minutes	268	8.7	60.8	42.2
Missing	19	0.6	–	–
<i>p</i> -value	–	–	< 0.001	= 0.007
<b><i>Cigarettes smoked per day</i></b>				
≤ 10	498	16.2	65.3	48.0
11–20	1634	53.2	56.6	43.4
21–30	695	22.7	54.7	45.5
≥ 31	230	7.5	44.8	35.7
Other/unknown	12	0.4	41.7	33.3
<i>p</i> -value	–	–	< 0.001	= 0.025
<b><i>Number of years smoked</i></b>				
< 10	472	15.4	49.4	35.4
11–20	873	28.5	52.6	38.8
21–30	699	22.8	57.7	45.1
31–40	566	18.4	61.3	50.5
> 40	438	14.3	66.9	58.0
Missing	21	0.7	14.3	14.3
<i>p</i> -value	–	–	< 0.001	< 0.001

continued

**TABLE 13** Smoking behaviour variables: distribution and quit rate (*continued*)

Smoking behaviour variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>How determined to quit<sup>a</sup></b>				
Not at all or quite determined	263	8.6	43.4	30.0
Very determined	1183	38.6	54.5	42.4
Extremely determined	1557	50.7	61.7	48.6
Unknown	66	2.2	27.3	19.7
<i>p</i> -value	–	–	<0.001	<0.001

HSI, Heaviness of Smoking Index.

a Forty-seven study site 2 clients were asked this question on a 6-point scale ranging from 5 'I know I should' to 10 'desperate'. These were incorporated into the above variable as follows: 5–7 coded as 'not at all/quite', 8–9 coded as 'very' and 10 as 'extremely'.

### Smoking dependence

Of those who smoked  $\leq 10$  cigarettes per day, 65% reported that they were abstinent at 4 weeks in comparison with just 45% of those who smoked  $\geq 31$  cigarettes per day. There was not a linear relationship for the intermediate categories. Clients who smoked within 5 minutes of waking were least likely to quit by 4 weeks (41% compared with 42–49%;  $p < 0.001$ ). However, the relationship was not linear. There were better outcomes for those who smoked the longest; 67% of those smoked for  $\geq 40$  years had quit, in comparison to just 49% of those who smoked for  $\leq 10$  years ( $p < 0.001$ ). This variable is, however, strongly correlated with age and older people are more likely to be successful in stopping smoking. The sick/unemployed ( $p < 0.001$ ), males ( $p = 0.002$ ) and middle-age groups ( $p < 0.001$ ) reported higher nicotine dependency than other groups.

### Motivation

Over a half (51%) of clients were extremely determined to quit and they had the highest quit rates, with 62% self-reported abstinence at 4 weeks. There were no SES or gender differences in determination to quit. As outlined above, clients in midlife were most dependent on tobacco (4–9% had the highest dependency score compared with 3% in the oldest and youngest age groups;  $p < 0.001$ ) but were also the most determined to quit (50–54% compared with 44–47%;  $p =$  not available).

### Support for the quit attempt

Participants were also asked about sources of support to stop smoking other than SSS staff, and previous experience of smoking cessation. This included support from friends and family, work colleagues, number of previous quit attempts and previous use of pharmacotherapy. Results are summarised here and further detail is available in *Table 14*.

### Social support

The best outcomes were found in clients who were not surrounded by smokers: 30% of clients who reported that all their friends and family were CO validated as quit at 4 weeks compared with 53% who reported that none of their friends or family members smoked ( $p < 0.001$ ).

There was very little difference in quit rates between the 87% who had sources of support to stop and the 11% who did not. Clients who did not provide information about this type of support were less likely to quit – 27% compared with 43–45% ( $p = 0.007$ ). Quit rates were slightly higher for clients who had a spouse/partner or work colleagues supporting their quit attempt and slightly lower for clients who had family or friends supporting their quit attempt. It was not possible to tell whether or not these differences were significant because those who did not provide any information about support were much less likely to quit.

**TABLE 14** Distribution and quit rates of the support variables

Support variables	n (N = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>Smokers in the home</b>				
Other smokers at home	1266	41.3	55.1	42.5
No one else smokes at home	1619	52.8	58.5	45.4
Missing	184	6.0	50.5	41.9
p-value	–	–	= 0.045	= 0.247
<b>Friends and family smokers</b>				
All smoke	104	3.4	45.2	29.8
Most smoke	577	18.8	50.8	36.4
About half smoke	611	19.9	54.3	42.6
A few smoke	1424	46.4	60.9	48.0
None smoke	259	8.4	64.9	52.5
Not applicable or missing	94	3.1	33.0	30.9
p-value	–	–	< 0.001	< 0.001
<b>Work or study smokers</b>				
All smoke	60	2.0	46.7	25.0
Most smoke	300	9.8	55.0	42.7
About half smoke	396	12.9	60.4	45.2
A few smoke	926	30.2	60.0	45.9
None smoke	324	10.6	62.0	48.8
Not applicable or missing	1063	34.6	51.7	41.9
p-value	–	–	< 0.001	= 0.008
<b>Access to support</b>				
Supporter available	2669	87.0	54.7	44.6
No one supporting	322	10.5	58.5	42.9
Missing	78	2.5	34.6	26.9
p-value	–	–	< 0.001	= 0.007
<b>Family support</b>				
Family supporting attempt	1185	38.6	55.4	41.9
No family support	1806	58.9	58.4	46.1
Missing	78	2.5	34.6	26.9
p-value	–	–	< 0.001	< 0.001
<b>Friend support</b>				
Friend supporting attempt	561	18.3	54.9	41.5
No friend support	2430	79.2	57.7	45.1
Missing	78	2.5	34.6	26.9
p-value	–	–	(< 0.001)	(= 0.003)

continued

**TABLE 14** Distribution and quit rates of the support variables (*continued*)

Support variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>Spouse support</b>				
Spouse supporting attempt	1556	50.7	61.1	48.3
No spousal support	1435	46.8	53.0	40.3
Missing	78	2.5	34.6	26.9
<i>p</i> -value	–	–	< 0.001	< 0.001
<b>Colleague support</b>				
Work colleague support attempt	200	6.5	60.5	46.0
No work support	2791	90.9	57.0	44.3
Missing	78	2.5	34.6	26.9
<i>p</i> -value	–	–	< 0.001	= 0.008
<b>Number of previous attempts</b>				
Serious previous quit attempt in the last year	1253	40.8	57.2	44.0
No serious quit attempt in last year	1755	57.2	57.3	44.7
Unknown	61	2.0	24.6	24.6
<i>p</i> -value	–	–	< 0.001	= 0.008
<b>SSS attendance</b>				
Attended SSS in LPA	394	12.8	56.9	44.4
Did not attend SSS in LPA	859	28.0	57.4	43.8
Missing	1816	59.2	56.2	44.0
<i>p</i> -value	–	–	= 0.846	= 0.977
<b>Varenicline use</b>				
Used varenicline in LPA	347	11.3	62.5	48.1
Did not use varenicline	906	29.5	55.2	42.4
Missing	1816	59.2	56.2	44.0
<i>p</i> -value	–	–	= 0.55	= 0.187
<b>Previous use of over-the-counter NRT</b>				
Used NRT over the counter in LPA	281	9.2	59.8	44.8
Did not use NRT bought over the counter	972	31.7	56.5	43.7
Missing	1816	59.2	56.2	44.0
<i>p</i> -value	–	–	= 0.53	= 0.946
<b>Previous use of prescribed NRT</b>				
Used NRT prescribed by GP in LPA	232	7.6	57.8	46.1
Did not use NRT prescribed by GP	1021	33.3	57.1	43.5
Missing	1816	59.2	56.2	44.0
<i>p</i> -value	–	–	= 0.846	= 0.766

**TABLE 14** Distribution and quit rates of the support variables (*continued*)

Support variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b><i>Bupropion use</i></b>				
Used bupropion in LPA	17	0.6	64.7	58.8
Did not use bupropion	1236	40.3	57.1	43.8
Missing	1816	59.2	56.2	44.0
<i>p</i> -value	–	–	= 0.706	= 0.462
<b><i>Use of smoking helpline</i></b>				
Used smoking helpline in LPA	11	0.4	72.7	54.6
Did not use smoking helpline	1242	40.5	57.1	43.9
Missing	1816	59.2	56.2	44.0
<i>p</i> -value	–	–	= 0.500	= 0.777
<b><i>Use of support</i></b>				
Used nothing in LPA	208	6.8	45.2	33.2
Used some form of support	1045	34.1	59.6	46.1
Missing	1816	59.2	56.2	44.0
<i>p</i> -value	–	–	= 0.001	= 0.003
LPA, latest previous attempt.				

Female participants were more likely than male participants to have other smokers in the home (43% vs. 39%;  $p = 0.007$ ) and not to have support from a spouse/partner (53% vs. 41%;  $p < 0.001$ ).

### Previous serious quit attempt in the last year

Clients who did not answer questions about their previous quit attempt were less likely to quit (25%) but there was little difference between clients who had and had not made a quit attempt (44–45%). Those who had used some sort of support in their previous quit attempt (e.g. varenicline or the SSS) were significantly more likely to quit than those who had not (33% vs. 46%;  $p = 0.003$ ).

### Behavioural support

Behavioural support describes the format of counselling that participants received from the SSS (e.g. closed groups, open groups, drop-in and one to one) (*Table 15*).

At the basic level, using the unweighted data, key findings (see *Table 15*) included:

- more than 40% of clients who received three of the four 'specialist' type of behavioural support (closed group, open group, and one to one) were CO validated as quit
- fewer than 40% of clients who received behavioural support in a GP practice or pharmacy setting, or who attended a specialist drop-in were CO validated as quit
- open-group clients were the most likely to be CO validated as quit (53%;  $p < 0.001$ ) but the self-report quit rates of one-to-one clients and open-group clients were similar (approximately 60%).

**TABLE 15** Behavioural support type variables: distribution and quit

Behavioural support type variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>Practitioner level</b>				
Level 2	379	12.4	48.0	38.7
Specialist	2679	87.3	58.0	45.2
Missing	11	0.4	–	–
<i>p</i> -value	–	–	< 0.001	= 0.001
<b>Support type</b>				
Closed-group specialist	102	3.3	52.9	43.1
Open-group specialist	550	17.9	61.6	53.0
Drop-in specialist	887	28.9	52.1	39.4
One-to-one specialist	1131	36.9	61.4	46.3
GP practice service	270	8.8	48.9	35.9
Pharmacy service	97	3.2	45.4	38.1
Other or unclear	32	1.0	40.6	21.9
<i>p</i> -value	–	–	< 0.001	< 0.001
<b>Intervention type</b>				
Closed group	102	3.3	52.9	43.1
Open (rolling) group	550	17.9	61.6	53.1
Drop-in clinic	887	28.9	52.1	39.4
One-to-one support (any provider)	1517	49.4	57.8	43.6
Other	10	0.3	50.0	20.0
Missing	3	0.1	–	–
<i>p</i> -value	–	–	= 0.009	< 0.001
<b>Practitioner type</b>				
Specialist	2679	87.3	58.0	45.2
Health-care assistant <sup>a</sup>	134	4.4	57.5	38.8
Practice nurse	120	3.9	40.0	32.5
Assistant (pharmacy)	35	1.1	40.0	28.6
Dispenser/technician	37	1.2	37.8	35.1
Pharmacist/manager	25	0.8	64.0	56.0
Other	27	0.9	48.2	40.7
Missing	12	0.4	–	–
<i>p</i> -value	–	–	< 0.001	= 0.0003



**TABLE 15** Behavioural support type variables: distribution and quit (*continued*)

Behavioural support type variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>Intervention setting</b>				
Pharmacy	121	3.9	45.5	37.2
GP practice <sup>b</sup>	1592	51.9	57.7	43.8
Community-oriented building	634	20.7	59.0	47.2
Well-being centre (e.g. healthy living centre)	67	2.2	50.8	37.3
Workplace or education	161	5.3	59.6	49.1
Children's centre	92	3.0	60.9	51.1
Sports and leisure	88	2.9	59.1	48.9
Dedicated SSS shop or stall	110	3.6	42.7	27.3
Other	204	6.7	52.0	41.7
<i>p</i> -value	–	–	= 0.007	= 0.003
<b>Sessions</b>				
One session	449	14.6	19.8	14.7
Two sessions	331	10.8	15.7	4.5
Three sessions	348	11.3	25.3	15.8
Four sessions	336	11.0	47.3	28.9
Five sessions	374	12.2	70.3	55.4
Six sessions	360	11.7	83.6	65.3
Seven or eight sessions	467	15.2	88.9	76.0
Nine or more sessions	374	12.2	97.3	84.5
Unknown	30	1.0	23.3	13.3
<i>p</i> -value	–	–	< 0.001	< 0.001
a Includes a few phlebotomists. b Includes a few clients who were seen at polyclinics.				

What might explain these patterns? There are a number of potential confounders:

- Pharmacy clients were less likely to be prescribed varenicline (20% of pharmacy clients were prescribed varenicline compared with  $\geq 40\%$  for the other behavioural support types;  $p < 0.001$ ).
- Older clients were more likely to attend GP practices than other clients (12% of 65- to 85-year-olds received GP practice services compared with 6% of 16- to 17-year-olds), whereas younger clients were more likely to attend pharmacy services (5% of 16- to 17-year-olds received pharmacy services compared with 2% of 65- to 85-year-olds;  $p = 0.026$ ).
- Drop-in clients were likely to have a lower SES. Drop-in groups had the highest percentage of sick/unemployed clients (25% of drop-in clients were sick/unemployed compared with  $\leq 24\%$  of clients participating in other behavioural support types), clients eligible for free prescriptions (54% drop-in clients were eligible compared with  $\leq 52\%$  of clients in other behavioural support types;  $p < 0.001$ ) and social rent (28% of drop-in clients were social renters compared with  $\leq 25\%$  of clients in other behavioural support types;  $p < 0.001$ ).
- Medication was more likely to be recorded on three or more occasions by specialists (46% of clients who received specialist support has medication recorded compared with 36% of clients who received GP or pharmacy services;  $p < 0.001$ ).

- Group clients had higher levels of well-being (51–55% of group clients had higher well-being scores compared with 41–45% of clients who received other behavioural support types;  $p < 0.001$ ).
- Clients of level 2 providers were less determined to quit (43% of clients who attended level 2 providers were extremely determined compared with 52% of specialist clients;  $p = 0.003$ ) and were less likely to have a heart/blood/circulation condition (2% of level 2 clients compared with 8% of specialist clients;  $p = 0.002$ ).

However, specialists were more likely to see clients with some characteristics associated with lower quit rates:

- mental health condition (16% of specialist clients compared with 12% of level 2 clients;  $p = 0.041$ )
- permanently sick/unemployed (23% of specialist clients compared with 14% of level 2 clients;  $p < 0.001$ )
- high dependency on tobacco (6% of specialist clients compared with 5% of level 2 clients scored highest on dependence and 5% of specialist clients compared with 6% of level 2 clients scored lowest on the dependence scale ( $p = 0.007$ ))
- higher proportion of smokers among friends and family (23% compared with 16% all or most of friends and family smoke;  $p = 0.031$ ).

### Practitioner type

Clients were supported to stop by a range of types of practitioner working in for a number of different service providers (see *Table 15*).

- Most clients (87%) were seen by a specialist practitioner.
- About 8% of clients were seen by practice nurses and health-care assistants based in GP practices. Only two-thirds of people seen in practice by a health-care practitioner who claimed to be quit were actually validated to be so.
- About 3% of clients were seen by pharmacy practitioners.
  - Pharmacy practitioners had the most extreme quit rates (i.e. the highest and lowest), but altogether pharmacy practitioners recruited only 97 clients so subgroups are very small.
  - Clients who saw pharmacy assistants were least likely to be CO validated as quit, and clients who saw pharmacy managers or pharmacists were most likely to have a CO-validated quit compared with all other practitioner types ( $p = 0.0003$ ).
- One per cent of clients were seen by other types of practitioners. Most of these were GP practice staff who worked in roles such as administration and receptionists and/or those who worked in a general well-being improvement field such as health trainers and people working in healthy living centres. There were a few clients who were seen by dental practice staff.

### Intervention setting

Clients were treated in a wide range of venues (see *Table 15*). Over a half of the ELONS study participants were seen in GP practices (52%) and one-fifth (21%) in a community-oriented building such as a community centre. Clients who attended sessions in a children's centre were most likely quit (51%) and those who attended a dedicated SSS shop or stall were least likely to quit (27%;  $p = 0.003$ ). However, this might reflect who was recruited from these settings:

- Sick/unemployed people made up a higher proportion of clients seen at a dedicated SSS shop/stall (33% of a dedicated SSS shop/stall clients were sick/unemployed compared with  $\leq 28\%$  at other locations;  $p < 0.001$ ).
- A higher proportion of dedicated SSS shop/stall clients were in the youngest age group than was true for all other settings except for well-being centres (18% dedicated SSS shop/stall clients and 19% well-being centre clients compared with  $\leq 11\%$  at other locations;  $p < 0.001$ ).

### Session attendance

The more sessions a client attended, the better the 4-week outcome (97% of clients who attended at least nine sessions reported a quit at 4 weeks compared with just 16% of clients who attended two sessions;  $p < 0.001$ ) (see *Table 15*). However, it should be noted that 11 of the 23 level 2 providers in site 1 used paper forms and these had to be returned to the specialist service after the 4-week quit outcome was recorded, which meant that not all sessions may have been recorded. In contrast, practitioners who entered data electronically at source could record up to 12 sessions. However, these paper-based providers recruited only 87 clients.

### Medication

Practitioners recorded which smoking cessation medication their clients were taking to help them quit – this would normally happen during their behavioural support session. The derived variables from this information focused on frequency and type (*Table 16*).

### Frequency

There was a lot of variation in number of days between sessions; bearing this in mind the following key points emerged from the data:

- the more occasions that medication was recorded as being taken, the more likely clients were to quit [68% who had medication recorded on three or more occasions quit compared with 26% who took medication on one or two occasions and 17% where medication was not recorded ( $p < 0.001$ )]
- younger people took medication on fewer occasions. Only 30% took medication on three or more occasions compared with 44% or more in the other age groups ( $p < 0.001$ ).

**TABLE 16** Medication variables: distribution and quit rates

Medication variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>Medication (frequency of recording)</b>				
No occasions	93	3.0	24.7	17.2
1 occasion	998	32.5	32.9	21.8
2 occasions	616	20.1	46.8	32.1
3 occasions	540	17.6	70.0	56.5
4 occasions	471	15.4	88.5	74.5
5–10 occasions	338	11.0	89.9	77.5
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	< 0.001
<b>Medication (frequency truncated)</b>				
No occasions	93	3.0	24.7	17.2
1 or 2 occasions	1614	52.6	38.2	25.8
3–10 occasions	1349	44.0	81.5	68.1
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	< 0.001

continued

**TABLE 16** Medication variables: distribution and quit rates (*continued*)

Medication variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>Medication and occasions</b>				
Single NRT only 1–2 occasions	407	13.3	37.6	26.8
Single NRT only 3 or more occasions	189	6.2	81.5	73.5
Combination NRT only 1–2 occasions	448	14.6	30.1	15.9
Combination NRT only 3 or more occasions	125	4.0	79.2	67.2
Varenicline only 1–2 occasions	614	20.0	42.8	31.9
Varenicline only 3 or more occasions	699	22.8	85.3	69.4
Other/mixed medication 1–2 occasions	145	4.7	44.8	27.6
Other/mixed medication 3 or more occasions	336	11.0	74.4	62.5
No medication recorded	93	3.0	24.7	17.2
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	< 0.001
<b>Medication (type only)</b>				
Single NRT only	596	19.4	51.5	41.6
Combination NRT only	573	18.7	40.8	27.1
Varenicline only	1313	42.8	65.4	51.9
Other/mixed medication	481	15.7	65.5	52.0
No medication recorded	93	3.0	24.7	17.2
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	< 0.001
<b>Varenicline use</b>				
Took varenicline	1445	47.1	64.3	50.7
Did not take varenicline	1611	52.5	50.2	38.3
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	< 0.001
<b>Bupropion use</b>				
Took bupropion	32	1.0	53.1	31.3
Did not take bupropion	3024	98.5	56.9	44.3
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	= 0.002
<b>NRT combination use</b>				
NRT combination	962	31.4	52.1	38.8
Did not take NRT combination	2092	68.2	59.1	46.7
Missing	15	0.5	–	–
<i>p</i> -value	–	–	< 0.001	< 0.001

**TABLE 16** Medication variables: distribution and quit rates (*continued*)

Medication variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b><i>NRT single use</i></b>				
NRT single	1003	32.7	58.7	47.2
Did not take NRT single	2051	66.8	56.0	42.8
Missing	15	32.7	–	–
<i>p</i> -value	–	–	< 0.168	< 0.024
<b><i>NRT patch use</i></b>				
Used NRT patch	1321	43.0	52.7	41.2
Did not use NRT patch	1735	56.5	60.1	46.5
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	< 0.001
<b><i>Lozenge use</i></b>				
Took lozenge	390	12.7	55.4	40.3
Did not take Lozenge	2666	86.9	57.1	44.8
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	< 0.001
<b><i>Gum use</i></b>				
Took gum	222	7.2	59.0	43.7
Did not use gum	2834	92.3	56.7	44.1
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	= 0.006
<b><i>Inhaler use</i></b>				
Used inhaler	545	17.8	48.4	36.9
Did not use an inhalator	2511	81.8	58.7	45.8
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	< 0.001
<b><i>Spray use</i></b>				
Used spray	303	9.9	50.5	35.3
Did not use mouth/nasal spray	2753	89.7	57.6	45.2
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	< 0.001
<b><i>Minitab</i></b>				
Used Minitab	30	1.0	53.3	40.0
Did not use Minitab	3026	98.6	56.9	44.2
Missing	13	0.4	–	–
<i>p</i> -value	–	–	< 0.001	= 0.005

## Medication type

People who used combination NRT (taking two or more forms of NRT in the same week and never single NRT) were no more likely to quit than those using a single form of NRT. In fact, a much lower proportion were likely to achieve abstinence at 4 weeks (27% quit compared with 42% of people who took single NRT). Combination NRT varied between 66% and 3% between study sites ( $p < 0.001$ ).

Varenicline was the most common type of medication (43% used at least once). Varenicline use also varied by study site ( $p < 0.001$ ) and by NSSEC (33% sick/unemployed clients compared with 53% clients with routine and manual occupations and 51% clients with professional, managerial and intermediate occupations;  $p < 0.001$ ). Only 1% took bupropion.

## Type and frequency

Single NRT and combination NRT tended to be recorded on one or two occasions. Varenicline and other/mixed medication were more likely to be recorded on three or more occasions. Quit rates were approximately 32% or below if medications were recorded only on one or two occasions but were over 60% if they were noted on three or more occasions ( $p < 0.001$ ). There were marked variations in medication type and frequency by study site.

## Accessing services

At baseline, participants were asked questions about how they had accessed the service (Table 17).

Over half already knew of their SSS because they had made a previous quit attempt (53%). Only 5% of clients had heard about the service through marketing.

Men were more likely to be introduced by referral from a GP practice (21% compared with 17% of women;  $p < 0.001$ ). The youngest age groups were most likely to be introduced through friends and family (22% compared with 11% or below for the other age groups;  $p < 0.001$ ). 'Stoptober' (a government-supported campaign to encourage smokers to quit for at least the month of October) was mentioned as a route into the service for 81 clients.

The quit rates were similar regardless of the route by which people got to the service.

**TABLE 17** Accessing services: distribution and quit rates

Accessing services	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>Introduction to the SSS</b>				
Marketing	154	5.0	52.6	42.9
Friends and family	317	10.3	53.6	38.9
GP practice	568	18.5	58.8	45.8
Other organisations	211	6.9	47.9	38.9
Unknown	202	6.6	54.5	42.1
Previous quit attempt with services	1617	52.7	58.3	45.4
<i>p</i> -value	–	–	= 0.035	= 0.150
<b>Mention of Stoptober</b>				
Mentioned Stoptober	81	2.6	48.2	44.4
No mention of Stoptober	2988	97.4	56.9	44.0
<i>p</i> -value	–	–	< 0.001	= 0.933

### Some data collection issues to consider

The way in which data are collected has the potential to influence the smoking cessation outcomes reported. Here we highlight this so that the prospective study results can be better understood. Four methodological issues are described: first, the time of year that the client set their quit date; second, clients not setting a quit date; third, the numbers of clients who were recruited to the ELONS study who had more than one quit attempt with the SSS; and fourth, whether or not clients provided a saliva sample at baseline (for analysis of long-term NRT use).

Clients in the ELONS study set quit dates between March 2012 and March 2013, as shown in *Table 18*. These were clustered, however, with most being set between July and November 2012. This reflects the staggered start and end of data collection for each site. There were 150 clients who did not set a quit date from only three of the nine sites. These locations collected monitoring information before clients were required to set a quit date and so needed to ask for consent to the ELONS study before they knew whether or not clients were going to get as far as actually setting a quit date. These clients were not excluded in the analysis – they form part of the prospective study data set.

**TABLE 18** Distribution and quit rates of the data collection variables

Data collection variables	<i>n</i> ( <i>N</i> = 3069)	%	Self-report quit (%)	CO-validated quit (%)
<b>Month quit date set</b>				
March 2012	2	0.1	0.0	0.0
April 2012	24	0.8	70.8	62.5
May 2012	53	1.7	43.4	30.2
June 2012	137	4.5	57.7	47.5
July 2012	429	14.0	54.8	44.8
August 2012	505	16.5	53.5	42.0
September 2012	497	16.2	61.4	48.1
October 2012	589	19.2	63.8	50.1
November 2012	343	11.2	60.6	43.2
December 2012	152	5.0	63.2	44.1
January 2013	144	4.7	66.0	53.5
February 2013	41	1.3	80.5	58.5
March 2013	3	0.1	33.3	0.0
Missing quit date	150	4.9	0.00	0.0
<i>p</i> -value	–	–	< 0.001	< 0.001
<b>Saliva collection</b>				
Saliva collected	1874	61.1	54.5	41.5
Saliva not collected	1195	38.9	60.0	48.0
<i>p</i> -value	–	–	= 0.003	< 0.001

There were 22 clients, from five of the nine sites, who were recruited twice to the ELONS study. This means they had more than one quit attempt with the service during the study period – they were ‘repeat’ attenders (this is not shown in *Table 18*).

Two-thirds of clients gave a saliva sample, as *Table 18* illustrates. These clients were significantly less likely to quit at 4 weeks. Younger clients were more likely to give a saliva sample (68% compared with 55% and 57% for the two oldest age groups).

## Comparing the ELONS study and ‘all cases’ data sets

The final ELONS study sample consisted of 3057 SSS clients, once pregnant clients and clients whose advisor was unclear had been excluded. For the reasons described in *Chapter 5*, these participants represented a small proportion of those who accessed SSSs in the study areas during the recruitment period. The sample is therefore not representative of all service clients in those areas. This is important as the ELONS study was designed to try and draw some overall conclusions about the longer-term effectiveness of the support to stop smoking offered by services in England. As a first stage in the analysis, therefore, we conducted comparisons between the ELONS study data and that available for all service clients, drawn from the routine (QuitManager) data available for each site.

The ‘all cases’ database contained quit attempts with quit dates that took place at the nine study sites from March 2012 to March 2013 (the months where any ELONS study client set a quit date;  $n = 71,800$ ). Quit attempts where the client was pregnant, under the age of 16 years or were a prisoner who attended the specialist service were excluded because these clients were not recruited to the ELONS study ( $n = 65,972$ ). Additionally, to be consistent with the final ELONS study sample, quit attempts where the practitioner was unknown were also excluded ( $n = 65,937$ ). Thus, 5% of qualifying quit attempts that were made in the nine study sites were included in the ELONS study. However, because the recruitment period for each site was variable, if we just look at periods when the specialists and level 2 providers were actually recruiting, 9% of quit attempts were included in the ELONS study. Recruitment rates were higher for the specialist service (14%) than the level 2 providers (2%) at least partly because not all level 2 providers took part and those that did recruited for different periods.

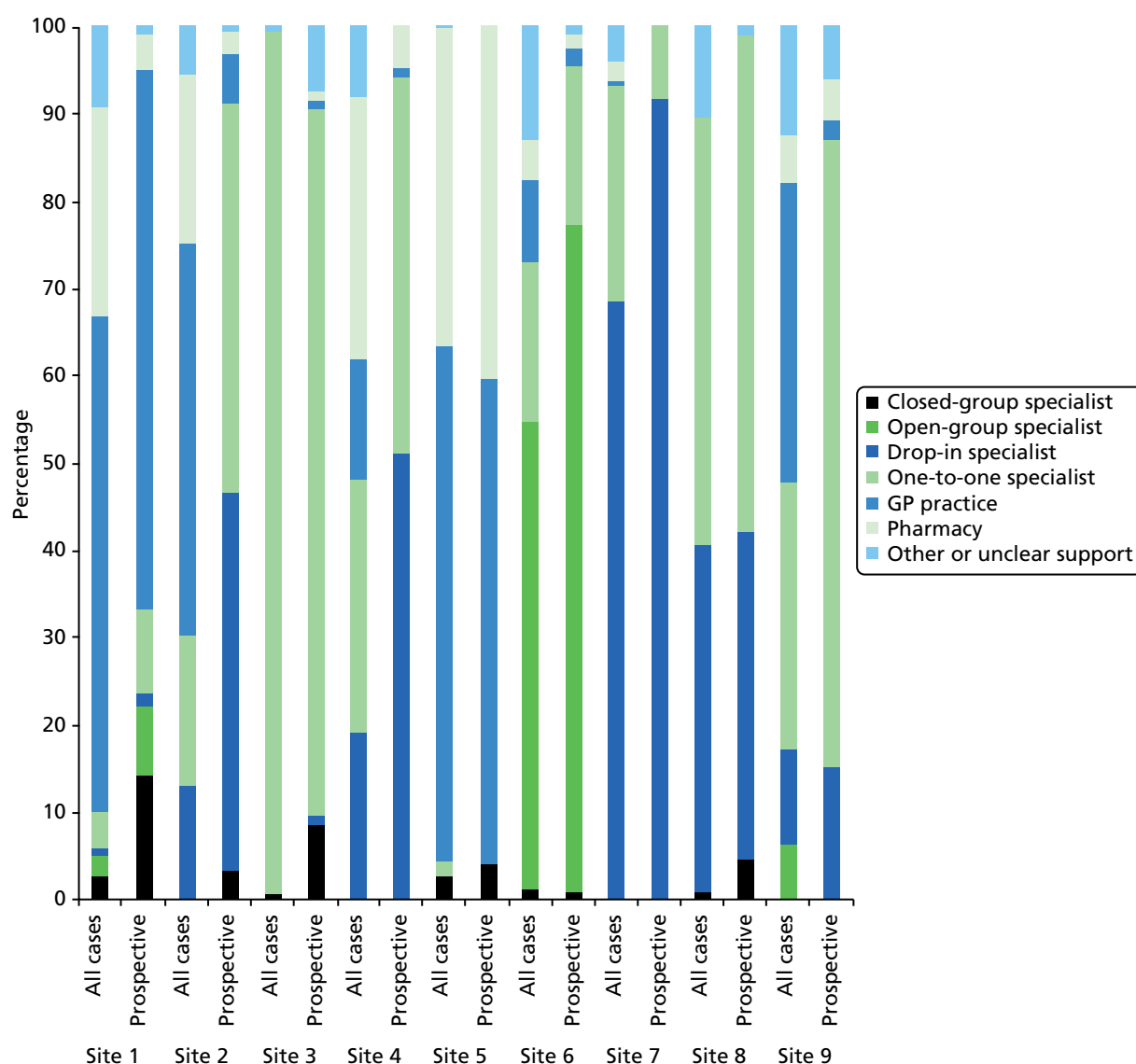
The ‘all cases’ database was used to develop weights in order to calculate quit rates generalisable to the nine services that took part in the ELONS prospective study. The frequencies of the variables included and response rates are provided in *Table 19*. The response rate was the number of ELONS study clients divided by the number of all cases clients multiplied by 100.

Clustering by service also had to be taken into account when producing final quit rates. This was because different locations offered different behavioural support types and some sites we were not able to recruit clients accessing some behavioural support types. The overall profiles of the ELONS study clients behavioural support types, however, strongly reflected ‘all cases’ behavioural support types. This is illustrated in *Figure 6*, which compares the behavioural support in each site the ‘all cases’ data set with the behavioural support types of clients recruited to the ELONS prospective study.



**TABLE 19** Distribution of variables used for weighting in the 'all cases' and the ELONS study data sets

Variables	'All cases', <i>n</i>	ELONS, <i>n</i>	Response rate (%)
Behavioural support			
Closed-group specialist	541	102	18.9
Open-group specialist	2159	550	25.5
Drop-in specialist	11,308	887	7.8
One-to-one specialist	21,796	1131	5.2
Level 2 GP practice	16,412	269	1.6
Level 2 pharmacy	9821	97	1.0
Other or unclear	3900	21	0.5
Gender			
Female	34,955	1710	4.9
Male	30,982	1347	4.3
Age group (years)			
16–24	7120	327	4.6
25–34	13,226	673	5.1
35–44	15,338	758	4.9
45–54	13,851	629	4.5
55–64	9933	456	4.6
≥ 65	6469	214	3.3
NSSEC			
Routine and manual occupations	18,201	939	5.2
Managerial/professional and intermediate occupations	14,098	716	5.1
Sick/disabled and never worked/long-term unemployed	14,932	660	4.4
Other/unknown	18,706	742	4.0
Total	65,937	3057	4.6



**FIGURE 6** Distribution of behavioural support by location in the routine monitoring data and clients recruited to the prospective study.

## Short- and longer-term quit rates

The main results for the ELONS study are the short- and longer-term cessation rates achieved by participants in the prospective study. The CO-validated raw quit rate at 4 weeks was 44.1% but after weighting this reduced marginally to 41.2% (95% CI 34.9% to 47.9%). The raw quit rate in the longer term, at 1 year, was 9.3% but after weighting this reduced marginally to 7.7% (95% CI 6.6% to 9.0%). The weighted results are shown in *Table 20*. These also include the proportion of people who had relapsed to smoking at 4 and 52 weeks post quit date, and also those lost to follow-up. Participants who were lost to follow-up (22.6% at 4 weeks and 45.2% at 52 weeks) were assumed to be smoking, consistent with an intention-to-treat analysis.

We also examined differences in short- and longer-term cessation outcomes by key variables of interest, including client and service characteristics (*Table 21*). Quit rates in the short and longer term did vary between groups of clients with particular characteristics, and the type of support provided by the SSSs.

**TABLE 20** Short- and longer-term weighted quit status

Short- and longer-term weighted quit status	Weighted (%) (95% CI)
<b>Short-term quit status (4 weeks)</b>	
CO validated	41.3 (34.9 to 48.0)
Self-report not CO validated	12.2 (8.3 to 17.5)
Relapsed (including quit refuted by CO validation)	23.9 (15.8 to 34.5)
Lost to follow-up	22.6 (15.1 to 32.4)
<b>Longer-term quit status (52 weeks)</b>	
CO validated	7.7 (6.6 to 9.0)
Self-report not CO validated	5.6 (5.1 to 6.1)
Relapsed at 4 or 52 weeks (including quit refuted by CO validation)	41.6 (31.0 to 53.0)
Lost to follow-up at 4 or 52 weeks	45.2 (34.6 to 56.2)

**TABLE 21** Weighted CO-validated quit rates (per cents and weighted 95% CI), weighted mean age and well-being (and weighted 95% CI) by key variables for the ELONS study at 4 and 52 weeks

Key variables	n	%	4 weeks (95% CI)	52 weeks (95% CI)
Behavioural support				
Closed-group specialist	102	3.3	42.9 (28.6 to 58.6)	13.8 (8.7 to 21.3)
Open-group specialist	550	18.0	53.1 (36.4 to 69.1)	11.6 (6.5 to 20.1)
Drop-in specialist	887	29.0	39.6 (24.3 to 57.2)	7.6 (5.1 to 11.0)
One-to-one specialist	1131	37.0	46.1 (39.5 to 52.8)	10.2 (7.6 to 13.7)
GP practice service	269	8.8	36.1 (26.2 to 47.3)	5.1 (2.9 to 8.8)
Pharmacy service	97	3.2	38.2 (18.7 to 62.5)	5.2 (1.5 to 15.8)
Other or unclear	21	0.7	NA	NA
Behavioural support (truncated)				
Group specialist	652	21.3	–	12.1 (10.5 to 13.8)
Drop-in specialist	887	29.0	–	7.6 (5.1 to 11.0)
One-to-one specialist	1131	37.0	–	10.2 (7.6 to 13.7)
GP practice or pharmacy service	366	12.0	–	5.1 (2.8 to 9.3)
Other or unknown	21	0.7	–	NA
Time of year of quit attempt				
Other months	767	25.1	39.4 (33.6 to 45.5)	7.0 (5.2 to 9.4)
Summer – July and August	970	31.7	38.0 (31.4 to 45.0)	6.3 (4.4 to 8.9)
Back to school – September and October	1128	36.9	46.2 (37.8 to 54.8)	8.7 (6.4 to 11.7)
New Year – January and February	192	6.3	37.8 (24.5 to 53.3)	13.1 (5.1 to 29.6)

continued

**TABLE 21** Weighted CO-validated quit rates (per cents and weighted 95% CI), weighted mean age and well-being (and weighted 95% CI) by key variables for the ELONS study at 4 and 52 weeks (*continued*)

Key variables	<i>n</i>	%	4 weeks (95% CI)	52 weeks (95% CI)
Age (years) <sup>a</sup>				
Not quit mean	–	–	41.1 (40.1 to 42.0)	43.3 (42.5 to 44.1)
Quit mean	–	–	47.2 (46.0 to 48.3)	46.8 (44.4 to 49.2)
Gender				
Female	1710	55.9	40.1 (35.3 to 45.1)	7.2 (6.0 to 8.5)
Male	1347	44.1	42.5 (33.4 to 52.2)	8.4 (6.8 to 10.2)
Ethnicity				
White British	2866	93.8	41.6 (35.7 to 47.8)	7.4 (6.1 to 9.0)
Other white	69	2.3	39.9 (18.2 to 66.3)	11.5 (4.5 to 26.0)
Asian (including mixed white and Asian)	64	2.1	25.1 (13.9 to 41.0)	3.6 (1.3 to 9.5)
Other and unknown	58	1.9	40.3 (17.5 to 68.3)	21.6 (7.0 to 50.1)
SES				
0–1 indicators of low SES	1123	36.7	48.4 (38.5 to 58.4)	10.3 (8.4 to 12.7)
2–5 indicators of low SES	1934	63.3	37.1 (30.2 to 44.6)	6.2 (5.0 to 7.7)
WHO-5 Well-being Index (weighted mean) <sup>a</sup>				
Not quit mean	–	–	51.6 (50.0 to 53.2)	52.7 (51.4 to 53.9)
Quit mean	–	–	55.5 (53.8 to 57.1)	59.3 (56.5 to 62.1)
Medication in week 1				
Varenicline not recorded	1661	54.3	37.0 (31.7 to 42.7)	6.2 (4.9 to 7.7)
Took varenicline	1396	45.7	47.4 (39.1 to 55.8)	10.0 (7.2 to 13.8)
Dependence				
Other	1681	55.0	45.4 (40.3 to 50.6)	9.8 (7.7 to 12.4)
Highly dependent	1376	45.0	35.7 (26.1 to 46.6)	4.9 (2.9 to 8.2)
Determination to quit				
Other	328	10.7	26.6 (20.9 to 33.2)	5.9 (4.3 to 8.0)
Very/extremely determined	2729	89.3	43.0 (36.0 to 50.4)	8.0 (6.7 to 9.5)
Support from spouse partner				
Other	1507	49.3	38.5 (32.3 to 45.1)	6.2 (4.5 to 8.5)
Support from spouse/partner	1550	50.7	43.9 (37.0 to 51.0)	9.2 (7.4 to 11.3)
Friends and family				
Other	771	25.2	33.3 (27.5 to 39.7)	3.4 (2.6 to 4.4)
Half or fewer smoke	2286	74.8	43.7 (36.9 to 50.8)	9.1 (7.5 to 10.9)
Total	3057	100.0	41.2 (34.9 to 47.9)	7.7 (6.6 to 9.0)

NA, not available.

a There is some evidence of skew in the continuous variables, however, as a rule of thumb, skew and kurtosis can be ignored below 0.8. Age raw data: mean, 42.52; median, 42.00; skew, 0.250; standard error skew, 0.044; kurtosis, –0.715; standard error kurtosis –0.089. WHO-5 raw data: mean, 53.78; median, 56.00; skew, –0.333; standard error skew, 0.044; kurtosis, –0.479; standard error kurtosis, –0.089.

### Client characteristics and abstinence

In the short term, at 4 weeks, quit rates were higher among older people and clients with higher levels of well-being. There were no significant gender, socioeconomic or ethnic differences. Differences in medication, dependence on tobacco, social network and support from a spouse or partner did not reach significance for short-term quit rates. However, quit rates were higher among those who were more determined to quit.

In the longer term, at 52 weeks, quit rates were higher among older people [mean age of quitters 46.8 years (95% CI 44.4 to 49.2 years) compared with a mean age of 43.3 years (95% CI 42.5 to 44.1 years) for non-quitters]. Less-disadvantaged people had a quit rate of 10.3% (95% CI 8.4% to 12.7%) compared with a quit rate of 6.2% (95% CI 5.0% to 7.7%) among more-disadvantaged people. Clients with higher levels of well-being when they began their quit attempt were more likely to quit than those with lower well-being [mean well-being score was 59.3 out of 100 (95% CI 56.5 to 62.1) compared with 52.7 out of 100 (95% CI 51.4 to 53.9) for non-quitters]. There were no significant gender or ethnic differences. Likewise, at 52 weeks, differences in medication, dependence on tobacco, determination to quit and support from a spouse or partner did not quite reach significance. Quit rates were higher among those whose social network was less populated with smokers, 9.1% (95% CI 7.5% to 10.9%) compared with 3.4% (95% CI 2.6% to 4.4%).

### Service characteristics, timing and abstinence

In the initial analysis, we differentiated six forms of behavioural support offered by services. These were closed and open specialist groups, specialist drop-ins, one-to-one specialist and behavioural support provided by GP practice employees and pharmacy employees. CIs overlapped for all forms of support but there were only about 100 clients who received closed group support or pharmacy service support leading to very wide CIs. Initially, the sample design was powered so that the smallest group size was 100 and the next group size was 500. Furthermore, the power calculations were based on a quit rate of 15% rather than 8%. Thus, CI overlap could be because of lack of power because both closed groups and pharmacies consisted only of about 100 clients. As *Table 21* shows, quit rates for both forms of group support were similar and were higher than other forms of support, and quit rates for non-specialist services were similar and lower than other forms of support groups. Thus some behavioural support groups were merged for the 52-week analysis. Clients who received group support had significantly higher quit rates, 12.1% (95% CI 10.5% to 13.8%) compared with clients who received support from a GP practice or pharmacy service, 5.1% (95% CI 2.8% to 9.3%). Clients who received one-to-one or drop-in specialist support quit rates were intermediate, 10.2% (95% CI 7.6% to 13.7%) and 7.6% (95% CI 5.1% to 11.0%), respectively. At 52 weeks, there were no significant seasonality effects.

### Multivariable predictors of abstinence in the short term

Multivariable logistic regression was undertaken in order to better understand which characteristics of clients and services were most closely related to abstinence from smoking after taking other factors into account at 4 and 52 weeks. These results are shown in *Table 22*.

Looking first at the 4-week predictors, shown in *Table 22*, clients who attended open groups had the highest ORs of quitting in the short term, at 4 weeks, aOR 1.5 (95% CI 1.0 to 2.2). Clients who attended open groups were significantly more likely to quit than clients who attended specialist one-to-one sessions. Cessation at 4 weeks was associated with: attending services in the New Year, aOR 1.5 (95% CI 1.1 to 2.2); older age, aOR 1.032 (95% CI 1.026 to 1.039); affluence, aOR 1.3 (95% CI 1.1 to 1.6); white (non-British) compared with Asian, aOR 2.5 (95% CI 1.1 to 5.5); lower dependence on tobacco, aOR 1.3 (95% CI 1.1 to 1.5); determination to quit, aOR 2.3 (95% CI 1.7 to 3.0); taking varenicline, aOR 1.6 (95% CI 1.4 to 1.9); higher levels of well-being, aOR 1.004 (95% CI 1.000 to 1.007); support from a spouse or partner, aOR 1.3 (95% CI 1.1 to 1.5); or low levels of smoking among friends and family, aOR 1.2 (95% CI 1.0 to 1.5). The difference between men and women was not significant.

**TABLE 22** Adjusted ORs (and 95% CI) by key variables in ELONs at 4 and 52 weeks

Key variables	<i>n</i> ( <i>N</i> = 3057)	%	4 weeks (95% CI)	52 weeks (95% CI)
Behavioural support				
Closed-group specialist	102	3.3	0.9 (0.6 to 1.5)	N/A
Open-group specialist	550	18.0	1.5 (1.0 to 2.2)	N/A
Drop-in specialist	887	29.0	0.7 (0.6 to 0.9)	N/A
One-to-one specialist	1131	37.0	1	N/A
GP practice service	269	8.8	0.8 (0.5 to 1.3)	N/A
Pharmacy service	97	3.2	0.9 (0.6 to 1.6)	N/A
Other or unclear	21	0.7	0.6 (0.2 to 1.7)	N/A
Behavioural support (truncated)				
Group specialist	652	21.3	N/A	3.4 (1.7 to 6.7)
Drop-in specialist	887	29.0	N/A	1.7 (0.9 to 3.5)
One-to-one specialist	1131	37.0	N/A	2.3 (1.2 to 4.6)
GP practice or pharmacy service	366	12.0	N/A	1
Other or unknown	21	0.7	N/A	2.3 (0.5 to 11.6)
Time of year of quit attempt				
Other months	767	25.1	1	1.2 (0.8 to 1.7)
Summer – July and August	970	31.7	1.2 (1.0 to 1.5)	1
Back to school – September and October	1128	36.9	1.4 (1.1 to 1.7)	1.2 (0.9 to 1.6)
New Year – January and February	192	6.3	1.5 (1.1 to 2.2)	1.7 (1.0 to 2.9)
Age (in years)	–	–	1.032 (1.026 to 1.039)	1.011 (1.002 to 1.020)
Gender				
Female	1710	55.9	1	1
Male	1347	44.1	1.1 (0.9 to 1.3)	1.2 (0.9 to 1.5)
Ethnicity				
White British	2866	93.8	1.3 (0.7 to 2.4)	Did not enter
Other white	69	2.3	2.5 (1.1 to 5.5)	Did not enter
Asian (including mixed white and Asian)	64	2.1	1	Did not enter
Other and unknown	58	1.9	2.4 (1.1 to 5.6)	Did not enter
SES				
0–1 indicators of low SES	1123	36.7	1.3 (1.1 to 1.6)	1.4 (1.1 to 1.9)
2–5 indicators of low SES	1934	63.3	1	1
WHO-5 Well-being Index (weighted mean)	–	–	1.004 (1.000 to 1.007)	1.007 (1.001 to 1.013)
Medication in week 1				
Varenicline not recorded	1661	54.3	1	1
Took varenicline	1396	45.7	1.6 (1.4 to 1.9)	1.7 (1.3 to 2.3)

**TABLE 22** Adjusted ORs (and 95% CI) by key variables in ELONs at 4 and 52 weeks (*continued*)

Key variables	<i>n</i> ( <i>N</i> = 3057)	%	4 weeks (95% CI)	52 weeks (95% CI)
Dependence				
Other	1681	55.0	1.3 (1.1 to 1.5)	1.5 (1.1 to 1.9)
Highly dependent	1376	45.0	1	1
Determination to quit				
Other	328	10.7	1	Did not enter
Very/extremely determined	2729	89.3	2.3 (1.7 to 3.0)	Did not enter
Support from spouse partner				
Other	1507	49.3	1	1.0
Support from spouse/partner	1550	50.7	1.3 (1.1 to 1.5)	1.4 (1.0 to 1.8)
Friends and family				
Other	771	25.2	1	1.0
Half or fewer smoke	2286	74.8	1.2 (1.0 to 1.5)	2.0 (1.4 to 2.9)
Practitioner	–	–	Variance = 0.140 (SE = 0.049)	No variance identified
N/A, not applicable; SE, standard error.				

### **Multivariable predictors of abstinence in the longer term**

A number of factors contributed to whether or not SSS clients maintained abstinence from smoking in the longer term. Compared with clients who received support from either a GP practice or pharmacy service, the odds of quitting were three times higher for those who received group support, aOR 3.4 (95% CI 1.7 to 6.7) and the odds of quitting were twice as high for clients who received support on a one-to-one basis from a specialist adviser, aOR 2.3 (95% CI 1.2 to 4.6).

For every year of age, clients were more likely to quit, aOR 1.011 (95% CI 1.002 to 1.020). There was no evidence that men were more likely to maintain abstinence than women. Clients whose quit attempt began in the New Year were more likely to quit than those who started during the summer holiday period, aOR 1.7 (95% CI 1.0 to 2.9). More-affluent clients were more likely to have stopped smoking at 1 year, aOR 1.4 (95% CI 1.1 to 1.9) than less-affluent clients.

Clients who had higher levels of well-being were more likely to be abstinent from smoking at 1 year. Thus for every increase of 1 on the well-being scale (range 0–100), clients were more likely to be non-smokers, aOR 1.007 (95% CI 1.0003 to 1.013). Clients who were less dependent on tobacco were significantly more likely to quit, aOR 1.5 (95% CI 1.1 to 1.9). Clients whose quit attempt was supported by a spouse or partner were significantly more likely to be abstinent at 1 year, aOR 1.4 (95% CI 1.0 to 1.8). Clients whose social network included fewer smokers were more likely to quit, aOR 2.0 (95% CI 1.4 to 2.9). Starting a quit attempt taking varenicline was also associated with abstinence in the longer term, aOR 1.7 (95% CI 1.3 to 2.3). Ethnicity and determination to quit were eliminated from the model by the backwards-stepwise procedure.

## Adherence to treatment

It is likely that an important determinant of successful quit attempts is the extent to which service clients continue to attend sessions and also use stop smoking medication. One general term we can apply to describe these two issues (attendance and medication use) is 'adherence'. Owing to concerns about reverse causality we could not include adherence in multilevel modelling. Instead, we tried to examine this issue in some depth. The two measures of adherence collected were number of sessions of behavioural support and number of occasions that medication was recorded.

As Table 23 shows, drop-off among the ELONS study clients from attending sessions was steady: a little over 10% of the sample did not return following each session. In addition, about half the sample were recorded as only taking medication on one occasion.

Adherence was much more strongly associated with cessation at 4 weeks than 52 weeks. This provides some evidence that reverse causality does exist: clients who had not quit at 4 weeks did not continue to attend sessions after 4 weeks. At 52 weeks differences were smaller but still significant for both number of sessions and medication taken.

**TABLE 23** Adherence distributions and weighted quit rates

Adherence measures	<i>n</i> ( <i>N</i> = 3057)	%	Weighted quit at 4 weeks (%) (95% CI)	Weighted quit at 52 weeks (%) (95% CI)
<b>Number of sessions</b>				
1	447	14.6	9.2 (2.3 to 30.0)	3.4 (0.8 to 13.3)
2	331	10.8	5.4 (1.5 to 17.4)	1.9 (0.8 to 4.2)
3	348	11.4	21.8 (12.8 to 34.6)	5.7 (2.8 to 11.4)
4	336	11.0	42.2 (26.6 to 59.4)	7.2 (3.6 to 13.6)
5	374	12.2	58.0 (47.3 to 67.9)	9.2 (4.7 to 17.0)
6	360	11.8	68.1 (53.3 to 80.0)	10.6 (6.4 to 17.0)
7 or 8	467	15.3	78.3 (69.4 to 85.2)	13.1 (8.5 to 19.7)
9 or more	374	12.2	84.0 (74.7 to 90.3)	16.1 (10.8 to 23.3)
Unknown	20	0.7	15.8 (1.3 to 72.7)	0.0 (0.0 to 0.0)
<b>Occasions medication recorded (full)</b>				
No occasions or none recorded	101	3.3	11.1 (4.5 to 24.9)	5.0 (0.7 to 26.9)
1 occasion	991	32.4	13.2 (7.7 to 21.8)	4.6 (3.0 to 7.2)
2 occasions	616	22.0	30.1 (22.0 to 39.6)	7.3 (5.2 to 10.2)
3 occasions	540	17.7	57.4 (49.5 to 64.9)	8.9 (4.9 to 15.6)
4 occasions	471	15.4	76.7 (66.3 to 84.7)	9.4 (5.9 to 14.8)
5–10 occasions	338	11.1	80.7 (66.9 to 89.7)	14.1 (9.4 to 20.7)
<b>Occasions medication recorded (short)</b>				
No occasions or none recorded	101	3.3	11.1 (4.5 to 24.9)	5.0 (0.7 to 26.9)
1 or 2 occasions	1607	52.6	20.0 (14.5 to 26.9)	5.7 (4.2 to 7.7)
3 or more occasions	1349	44.1	70.0 (63.9 to 75.5)	10.4 (8.3 to 12.9)



Adherence to medication was explored further by taking into consideration the type of medication taken (Table 24). The majority of clients who took either only single NRT or only combination NRT were recorded only taking medication on one or two occasions. Similar proportions were recorded taking varenicline on one or two occasions and three or more occasions. Thus those who took varenicline were more likely to adhere to taking their medication.

The 4-week quit rates of clients who took all types of medication for three or more occasions were significantly higher than those who took medication on one or two occasions. Differences are marked: fewer than one-quarter of clients quit if medication was recorded only once or twice, whereas approximately two-thirds or more of clients quit if they took medication three or more times (irrespective of medication type).

Number of occasions on which NRT was recorded did not have a significant impact on quit rates but clients who took varenicline on three or more occasions were significantly more likely to quit than clients who took varenicline on one or two occasions. Quit rates of clients who took varenicline on three or more occasions were also significantly higher than the quit rates of clients who took combination NRT on one to two occasions or clients who took single NRT on three or more occasions.

If we consider what type of medication clients took at any point (Table 25), two-fifths of clients took varenicline and one-fifth took either only single or combination NRT. Clients who at any point took more than one form of NRT on one occasion (thus combination NRT) were significantly less likely to quit at 4 weeks. This is not consistent with evidence on the effectiveness of combination NRT and raises some questions about the recording of combination therapy use in the study. There were no significant differences at 52 weeks.

**TABLE 24** Medication and adherence

Medication and adherence	<i>n</i> ( <i>N</i> = 3057)	%	Weighted quit at 4 weeks (%) (95% CI)	Weighted quit at 52 weeks (%) (95% CI)
Single NRT only one or two occasions	407	13.3	23.4 (14.3 to 35.9)	7.5 (4.6 to 11.7)
Single NRT only three or more occasions	189	6.2	84.3 (67.4 to 93.3)	4.0 (2.0 to 7.9)
Combination NRT only one or two occasions	444	14.5	13.0 (8.6 to 19.3)	4.8 (2.8 to 7.9)
Combination NRT only three or more occasions	125	4.1	64.6 (52.5 to 75.0)	9.0 (3.6 to 20.7)
Varenicline only one or two occasions	611	20.0	22.6 (13.1 to 36.3)	5.4 (2.7 to 10.5)
Varenicline only three or more occasions	699	22.9	70.3 (65.6 to 74.6)	14.1 (10.9 to 18.1)
Other/mixed medication only one or two occasions	145	4.7	23.9 (15.5 to 34.9)	5.4 (3.0 to 9.4)
Other/mixed medication only three or more occasions	336	11.0	63.1 (57.4 to 68.4)	8.1 (5.0 to 12.6)
No medication recorded	101	3.3	11.1 (4.5 to 24.9)	5.0 (0.7 to 26.9)

**TABLE 25** Stop smoking medication taken at any point

Medication and time point	<i>n</i> ( <i>N</i> = 3057)	%	Weighed quit at 4 weeks (%) (95% CI)	Weighed quit at 52 weeks (%) (95% CI)
<b><i>Medication at any point</i></b>				
Single NRT only	596	19.5	43.8 (38.0 to 49.8)	6.3 (4.2 to 9.4)
Combination NRT only	569	18.6	25.1 (20.3 to 30.6)	5.8 (3.8 to 8.6)
Varenicline only	1310	42.9	48.1 (40.0 to 56.4)	10.1 (7.2 to 14.0)
Other/mixed medication	481	15.7	49.7 (40.8 to 58.7)	7.1 (5.1 to 10.0)
No medication recorded	101	3.3	11.1 (4.5 to 24.9)	5.0 (0.7 to 26.9)
<b><i>Medication at week 1</i></b>				
Single NRT only	652	21.3	44.6 (39.0 to 50.3)	5.9 (4.1 to 8.4)
Combination NRT only	864	28.3	34.7 (27.3 to 42.8)	6.5 (4.8 to 8.7)
Varenicline only	1396	45.7	47.5 (39.1 to 56.0)	10.0 (7.2 to 13.8)
Other/mixed/none recorded	145	4.7	17.8 (10.8 to 28.1)	5.2 (1.5 to 16.2)

Clients who adhered to medication protocols (i.e. took medication for several weeks) have more chances to change medication. Thus, we also looked at medication recorded in week 1 because then there was no chance of dropping out through failure to quit. There were no significant differences in quitting detected at 4 or 52 weeks.

#### ***Adherence among clients who were carbon monoxide-validated as quit at 4 weeks***

In further analysis we investigated whether or not the number of sessions that clients who quit at 4 weeks attended was associated with cessation at 52 weeks. Given that SSS clients normally attend and have medication recorded once a week, we looked at whether or not clients attended up to four sessions or had medication recorded up to four times. These results are shown in *Table 26*.

These results suggest that adherence has no discernible effect on quitting as CIs overlap. Note that the vast majority of clients who quit at 4 weeks did attend for four sessions.

**TABLE 26** Adherence among clients who were CO validated as quit at 4 weeks only

Adherence measures	<i>n</i>	Weighted CO-validated 52-week quit (%) (95% CI)
Sessions attended		
One	65	21.0 (13.1 to 32.0)
Two	15	19.9 (10.8 to 33.8)
Three	55	16.3 (9.6 to 26.3)
Four or more	1210	15.4 (12.4 to 18.9)
Sessions unknown or not 4-week CO-validated quit	1712	2.1 (1.4 to 3.2)
Total	3057	–
Occasions medication recorded		
No occasions	16	44.5 (6.2 to 90.6)
One occasion	217	22.3 (14.6 to 32.6)
Two occasions	198	20.5 (11.9 to 32.8)
Three occasions	305	13.6 (7.6 to 23.1)
Four or more occasions	613	13.3 (10.0 to 17.5)
Not 4-week CO-validated quit	1708	2.1 (1.4 to 3.2)
Total	3057	–
Single NRT only		
One occasion	55	27.3 (7.9 to 62.0)
Two occasions	54	25.1 (9.6 to 51.4)
Three occasions	46	6.2 (1.3 to 25.3)
Four or more occasions	93	4.3 (1.4 to 12.5)
Total	248	–
Combination NRT only		
One occasion	39	20.2 (9.7 to 37.3)
Two occasions	31	33.3 (17.7 to 53.8)
Three occasions	42	12.0 (2.1 to 46.6)
Four or more occasions	42	15.9 (4.5 to 43.2)
Total	154	–
Varenicline only		
One occasion	120	20.6 (13.5 to 30.2)
Two occasions	76	14.6 (5.5 to 33.6)
Three occasions	150	19.5 (9.6 to 35.4)
Four or more occasions	335	17.0 (12.6 to 22.5)
Total	681	–
Total	3057	7.7 (6.6 to 9.0)

## Comparisons between the ELONS study and other studies

How do the short- and longer-term results from the ELONS study compare with previous studies? Some limited comparisons can be made, although these come with a range of caveats (discussed further in *Chapter 10*) owing to the observational nature of the data. There are two previous pieces of research conducted by members of our team that employed very similar approaches. The first of these was the previous 'national evaluation' of SSSs in England that was conducted between 2001 and 2004,<sup>17,18</sup> already mentioned in *Chapter 1*. This involved two areas of England – Nottingham and North Cumbria. The second study was conducted in Glasgow between 2005 and 2007 and compared a pharmacy-based SSS with another service providing closed-group behavioural support.<sup>28</sup> Both reported abstinence rates at 1 year.

As *Table 27* shows, the previous English evaluation in Nottingham and North Cumbria had a higher CO-validated quit rate at 52 weeks (14.6%) than the ELONS study and a lower lost to follow-up rate (37.5%). The difference in lost to follow-up occurred at all stages (4-week follow-up, 52-week telephone and 52-week validation) but was highest for the 52-week telephone interview. The Glasgow evaluation had a lower CO-validated quit rate. This was primarily because of a much higher loss to follow-up at 4 weeks. These comparisons are discussed in more detail in *Chapter 10*.

**TABLE 27** Quit rates and follow-up rates comparing the ELONS study with two other long-term evaluations of the UK SSSs

Quit rates and follow-up rates	Nottingham/North Cumbria 2002, n (%) (N = 2069)	Glasgow 2007, n (%) (N = 1785)	ELONS <sup>a</sup> 2012/13, n (%) (N = 3057)
4-week follow-up			
1. CO-validated quit	1129 (54.6)	401 (22.5)	1349 (44.1)
2. Self-report not CO validated	139 (6.7)	151 (8.5)	380 (12.4)
3. Self-report refuted by CO validation	4 (0.2)	16 (0.9)	6 (0.2)
4. Non-quitters	388 (18.8)	259 (14.5)	676 (22.1)
5. Lost to follow-up	409 (19.8)	958 <sup>b</sup> (53.7)	646 (21.1)
Total 4-week self-report (excluding refuted by CO test)	1268 (61.3)	552 (70.3)	1729 (56.5)
52-weeks follow-up (Russell Standard):			
1. CO-validated quit (0–5 cigarettes since quit date)	303 (14.6)	64 (3.6)	285 (9.3)
2. Self-report not CO validated	65 (3.1)	63 (3.5)	165 (5.4)
3. Self-report refuted by CO validation	8 (0.4)	1 (0.1)	18 (0.6)
4. Non-quitters at 52 weeks	525 (25.4)	264 (14.8)	583 (19.1)
5. Non-quitters at 4 weeks	392 (18.9)	259 (14.5)	676 (22.1)
6. Lost to follow-up at 52 weeks	367 (17.7)	179 (10.0)	684 (22.4)
7. Lost to follow-up at 4 weeks	409 (19.8)	955 (53.5)	646 (21.1)
Total 52-week self-report (excluding refuted by CO test)	368 (17.7)	127 (7.1)	450 (14.7)
Alternative self-report quit rates at 52 weeks <sup>c</sup>			
Point prevalence <sup>d</sup>	NA	131 (7.3)	558 (18.3)
Continuous abstinence (not a puff <sup>e</sup> )	377 (18.2)	108 (6.1)	390 (12.8)
Alternative CO-validated quit rates at 52 weeks			
Point prevalence <sup>d</sup>	NA	NA	348 (11.4)
Continuous abstinence (not a puff <sup>e</sup> )	303 (14.6)	62 (3.5)	260 (8.5)
Total eligible for follow-up at 52 weeks (all 4-week self-report)	1272 (61.5)	568 (31.8)	1735 (56.7)
Total successfully followed up at 52 weeks	901 (43.5)	392 (22.0)	1051 (34.4)
Total eligible for CO validation at Russell Standard	376 (18.2)	128 (7.2)	475 (15.5)
Total given CO test	311 (15.0)	65 (3.6)	310 (10.1)
CO-validated quit rate of those successfully followed up	34.5%	16.1%	27.1%

NA, not available.

a Unweighted results for the ELONS study are reported here.

b Three cases reported as lost to follow-up at 4 weeks appear to have been followed up at 12 months.

c These include all self-report (includes refutes).

d Whether or not the client had smoked within the previous 7 days in the ELONS study and the previous 2 weeks in the Glasgow study.

e Measured since the quit date in the ELONS study and since 4-week follow-up in the Glasgow and Nottingham/North Cumbria studies.

## Summary of key points

- The prospective study collected data from over 3000 SSS clients at 4 and 52 weeks after their quit date. Only a small proportion (9%) of all service clients in the nine study areas were recruited. To correct for this, weights were applied, drawing on an 'all cases' database created from routine data in the study areas.
- Recruitment rates were higher for the specialist service (14%) than the level 2 providers (2%) at least partly because not all level 2 providers took part and those that did recruited for different periods.
- In terms of smoking cessation in the short term, the raw quit rate at 4 weeks was 44.1%. With weighting this reduced marginally to 41.2%. In comparison, the quit rate for England from April 2012 to March 2013 was 37%.<sup>31</sup>
- For smoking cessation in the longer term, the raw quit rate at 1 year was 9.3% but after weighting this reduced to 7.7%.
- Predictors of smoking abstinence at 4 weeks were:
  - attending an open group
  - attending SSS in the New Year
  - being older
  - being more affluent
  - having a lower dependence on tobacco
  - being determined to quit
  - having a higher well-being score
  - having support from a spouse or partner
  - having a social network not populated with smokers.
- Predictors of abstinence at 52 weeks were largely similar and included:
  - attending group behavioural support or receiving one-to-one support from a specialist practitioner
  - taking varenicline
  - attending SSS in the New Year
  - being older
  - being more affluent
  - having a lower dependence on tobacco
  - having a higher well-being score
  - having support from a spouse or partner
  - having a social network not populated with smokers.
- Taking stop smoking medication and attending support sessions (described here as 'adherence') was significantly associated with smoking cessation – more so at 4 weeks than at 1 year.
- Limited comparisons with previous evaluations of SSSs in England are possible. Quit rates for 4 and 52 weeks from the ELONS prospective study were lower than those identified in the previous national evaluation in England, but higher than a recent study in Glasgow that examined closed-group and pharmacy-based services.

## Chapter 7 Client satisfaction survey

All clients who participated in the prospective cohort (regardless of the outcome of their quit attempt) were sent a CSS to give feedback on the service they received. This chapter presents the rationale for adding the CSS to the prospective studies, the recruitment approach, sample analysis and results. Results are presented in two sections. Section one groups findings under six headings: client characteristics; thoughts of the SSS overall; making initial contact with SSS; appointment times and venues; service received; and medication. In order to assess whether or not levels of satisfaction have an influence on abstinence from smoking, section two compares CSS findings with three key variables from the ELONS prospective study data set: CO-validated quitting, location and behavioural support type.

### Rationale

A questionnaire to measure client satisfaction with SSSs was developed by members of the research team in 2008 as part of the DH's 'gold standard' monitoring and evaluation guidance for SSSs.<sup>50</sup> The questions were designed to assess the overall level of client satisfaction with SSSs, with additional questions to look at specific elements of the service, for example, appointment times, convenience of venue, type of support received, willingness to recommend the service to others and smoking status. A copy of the questionnaire is appended (see *Appendix 1*).

Stop Smoking Services are under no obligation to use a CSS, which means that there was no consistency of use among the nine ELONS study sites. Some administered the survey but had no resource to analyse or make use of the findings to improve their service; others asked some questions but not all. Thus, despite not being directly relevant to research objectives, the research team thought that by offering to administer, analyse and write up the CSS and feed findings back to sites, this might encourage sign-up from the selected SSSs. This, in turn, would boost the study sample and contribute to answering the research objectives. In addition, the CSS generated useful data, highlighting the value of the service provided to smokers trying to quit.

### Recruitment, sample and analysis

The research team posted a self-complete questionnaire to all clients 4-weeks after their quit date was set (regardless of the outcome of their quit attempt). To encourage response, two reminder mailings were sent and a prize draw of £200 of high street vouchers was offered.

There were 1006 questionnaires received and the final data set had 996 cases (one was removed because of missing data and nine discarded because they had been completed twice). This means that one-third (33%) of the ELONS study participants completed this survey. Questionnaire data were entered into Excel and then transferred to SPSS (version 19.0) for analysis. Respondents were also given the opportunity to write additional comments about the service they received. These have been analysed thematically and placed in the relevant sections, with quotes to illustrate where relevant. As a result of missing data, the number of clients responding to each question will vary.

### Findings

#### *Client characteristics*

Table 28 presents sample characteristics of clients who completed a CSS in comparison with the main ELONS study sample. Of the respondents who completed a CSS, 71% were CO validated as abstinent from smoking 4 weeks after their quit date. In the overall ELONS study sample, the proportion of clients who had a CO-validated quit was a lot lower (44%). Clients who were successful in their quit attempt were more likely to complete the survey and this should be remembered when reviewing the findings.

**TABLE 28** Client satisfaction survey sample characteristics

CSS sample characteristics	Recruited to ELONS		Responded to CSS	
	<i>n</i> ( <i>N</i> = 3069)	%	<i>n</i> ( <i>N</i> = 996)	%
<b>Smoking status</b>				
CO-validated quit	1350	44.0	711	71.4
Self-report quit	1737	56.6	831	83.4
Smoking	1332	43.4	165	16.6
<b>Gender</b>				
Male	1355	44.2	558	56.0
Female	1714	55.8	438	44.0
<b>Age groups (years)</b>				
16–24	330	10.8	66	6.6
25–34	676	22.0	149	15.0
35–44	760	24.8	198	19.9
45–54	631	20.6	236	23.7
55–64	458	14.9	221	22.2
65–85	214	7.0	126	12.7
<b>Ethnicity</b>				
White British	2877	93.7	937	94.1
Other white	70	2.3	22	2.2
Asian (including mixed white and Asian)	64	2.1	9	0.9
Black (including mixed white and black)	24	0.8	11	1.1
Other/unknown	34	1.1	17	1.7
<b>SES</b>				
Professional managerial	718	23.4	243	24.4
Routine and manual	941	30.7	258	25.9
Unemployed/permanently sick	663	21.6	194	19.5
Other	747	24.3	301	30.2
<b>Behavioural support type</b>				
Closed group	102	3.3	32	3.2
Open group	550	17.9	207	20.8
Drop-in	887	28.9	255	25.6
One-to-one specialist	1131	36.9	389	39.1
GP practice	270	8.8	79	7.9
Pharmacy	97	3.2	25	2.5
Other or unclear	32	1.0	9	0.9



## Overall opinions

Clients were asked for their overall opinion of the SSS, with 87% saying they were either very satisfied or satisfied.

In open-ended responses, clients described the service they had attended as: 'supportive'; 'encouraging'; 'very good'; 'excellent'; 'friendly'; 'welcoming'; 'reassuring'; 'good advice'; 'well-informed'; 'enthusiastic'; 'helpful'; and 'understanding'.

Satisfaction with the support received was also high; 87% of respondents were either very satisfied or satisfied with the support they received. In addition, nearly all respondents (96%) said that they would recommend the SSS to other smokers who want to stop smoking. As one respondent wrote:

*I would have struggled to stop smoking without the help of the service. I would definitely recommend anyone wishing to stop smoking to use this service.*

A further 94% would return to a SSS should they start smoking again and 86% felt that they would be welcomed back:

*I hope to never use the service again but would not hesitate to if the requirement came about again.*

Perhaps not surprisingly, positive feedback was more likely among 'quitters' (i.e. respondents who had a successful quit attempt at 4 weeks) than 'non-quitters'. This is examined further in this chapter.

## Making initial contact with Stop Smoking Service

Respondent feedback on making initial contact and arranging an appointment with the SSS was also extremely positive (Table 29). The majority of respondents (94%) said it was easy to contact the SSS and the majority (88%) were given an appointment date or told how long they would need to wait to receive one. Three-fifths (60%) waited 5 or fewer days for their first appointment (22% were seen straight or away or within 24 hours) and the majority (92.5%) felt the time they waited was acceptable. One-third (31%) were contacted by the SSS before their first appointment to encourage and motivate them to attend (it should be noted that in some service clients are seen straight away so this question was not relevant to some participants).

**TABLE 29** Making initial contact with SSSs

Initial contact with SSSs	Responded to CSS	
	<i>n</i> ( <i>N</i> = 940–988)	%
<b>Easy to contact SSS</b>		
Yes	926	93.7
No	29	2.9
Unsure	33	3.3
<b>Given appointment date</b>		
Yes	852	87.6
No	95	9.8
Unsure	26	2.7
<b>How long for appointment date (days)</b>		
0–5	568	60.4
6–10	281	29.9
≥ 10	91	9.7
<b>Length of time acceptable</b>		
Yes	902	92.5
No	31	3.2
Unsure	42	4.3
<b>Contact from SSS before appointment</b>		
Yes	303	31.2
No	553	56.9
Unsure	116	11.9

### Appointment times and venue

Appointment times and venues were rated very highly with 95% of respondents reporting that appointment times were convenient, and a further 97% stating that the venue was also convenient (Table 30). Child care costs were irrelevant for 83% of the sample. Three respondents said that they were offered support with child care costs. Two-fifths (41.5%) were given the choice of whether they would like an individual or group appointment.

Similar findings were evident from the open-ended comments, with an appreciation of the flexible consultation approach and the different type of behavioural support on offer:

*As working full time was unable to attend weekly appointments – staff arranged telephone consultations which was great otherwise would most probably have stopped going.*

*I liked the idea of walk in centre, every Wednesday, just for smokers and the one to one appointments which I had every week with the same person. To me it was better than a group session.*

**TABLE 30** Appointment times and venues

Appointment times and venues	Responded to CSS	
	<i>n</i> ( <i>N</i> = 972–996)	%
<b>Time convenient</b>		
Yes	936	95.2
No	23	2.3
Unsure	24	2.4
<b>Place convenient</b>		
Yes	955	97.0
No	18	1.8
Unsure	12	1.2
<b>Child care support</b>		
Yes	3	0.3
No	157	15.8
Unsure	7	0.7
Not applicable/did not answer	829	83.2
<b>Able to choose group or one to one</b>		
Yes	403	41.5
No	460	47.3
Unsure	109	11.2

However, there were suggestions for improvement, which mainly centred on having more flexible appointment times, a wider choice of behavioural support, a longer treatment period, more telephone contact to maintain morale and introducing a diet class to address potential weight gain after smoking cessation.

*There are no evening appointments at my local clinic, which makes things difficult for those who work full time.*

*I would have preferred individual appointments to group therapy.*

*I feel that instead of having to attend for just 4 weeks it should be rolled out to at least 8. From past experience I feel 4 weeks is too quick.*

*Maybe a text or phone call between appointment time, i.e. 2 weeks is a long time to leave someone without encouragement. I liked the way my smoking service only encourages a full quit.*

*Maybe introduce a dieting class, i.e. dieting support. I think many people especially woman don't want, or find it hard to quit smoking because they put on too much weight.*

### Service received

Respondents were either satisfied or very satisfied with support from SSS staff (89%). Nine out of 10 (90%) rated the information and advice they received as very helpful or helpful and a further 82% found the written advice helpful/very helpful. Finally, 86% found having their CO checked at every visit helpful or very helpful. This was also the view from the open-ended comments; however, there were some important comments about practitioners. As we have already seen, in the main, practitioners were highly praised and appreciated but there were some comments that suggested that practitioner/client rapport was inadequate in some way. The same applied to continuity of practitioners, that is, not seeing the same practitioner at each visit and being able to make contact. Both the ELONS study secondary analysis and prospective data sets revealed that the individual practitioner had a significant influence, at least on short-term quit rates.

*A couple of us had not fully stopped smoking, whereas most had. The attitude displayed by one nurse seemed patronising and dismissive. It needed to be more constructive. It put me off going back and without the support which was otherwise good I failed to stop.*

*[Name of practitioner] was the best person for the job, she was dead easy to talk to about anything but the woman who took over from her made me feel really unsettled in a telephone consultation therefore never went back!!!*

*It would be helpful to see the same person every week. Sometimes I saw different people and had to keep introducing myself and explaining how long I'd given up etc.*

### Medication

Respondents indicated that the information given about different types of stop smoking medication was helpful (94%) and 92% reported that it was easy to obtain their medication of choice [with a half (49.8%) via GP prescription] (Table 31).

**TABLE 31** Medication

Medication	Responded to CSS	
	<i>n</i> ( <i>N</i> = 974–993)	%
<b>Medication information helpful</b>		
Yes	929	93.9
No	20	2.0
Unsure	40	4.0
<b>Source of medication<sup>a</sup></b>		
GP prescription	485	49.8
Chemist (bought myself)	27	2.8
Chemist (with a voucher)	132	13.6
Chemist (with service letter or prescription)	174	17.9
SSS	198	20.3
<b>Ease of accessing medication</b>		
Yes	897	91.8
No	54	5.5
Unsure	26	2.7
<sup>a</sup> Percentage more than 100% as a few respondents indicated more than one option, so each one was analysed separately.		

However, analysis of open-ended comments highlighted two areas for consideration: a lack of information on the side effects of medication and difficulty obtaining medication.

*Side effects of varenicline need to be highlighted – include info on all possible side effects.*

*Explain more about how stopping smoking will affect your immunity to illness. I have never had so many colds/flu infections/virus infections as this in my life since I stopped smoking.*

*Chemist don't carry enough stock! Most weeks I have to wait for some. Normally next day + costs of travel again.*

*It would be better if stop smoking staff could give out medication as I had to make three trips with letters, prescriptions etc. to finally get medication 5 days later.*

## Client satisfaction survey findings and the ELONS prospective study data set

Satisfaction levels by three key variables from the ELONS study data set (CO-validated quitting, location and behavioural support type) are explored in this section. CO-validated abstinence from smoking (in the short term) was chosen in order to explore whether or not any of the satisfaction variables might point to facilitators for cessation. Location was chosen because some issues with satisfaction may be study site specific and so may be relevant for only some sites. Finally, behavioural support was chosen as one of the aims of the ELONS study in order to assess the effectiveness of various forms of behavioural support and establish whether or not the support that clients receive affects their satisfaction.

Some sites and behavioural support categories did not support analysis owing to insufficient respondent numbers and were merged into 'other' categories. Note that different sites offered different forms of behavioural support and recruitment was higher for some support types than others. The percentage of respondents from each location for each support type is tabulated (Table 32). Nearly two-thirds (63%) of GP practice respondents were from site 1 and 96% of open-group respondents were from site 6.

**TABLE 32** Percentage of clients from each site for each behavioural support type

Behavioural support group	Site 1, % (n = 94)	Site 2, % (n = 245)	Site 4, % (n = 136)	Site 6, % (n = 245)	Site 8, % (n = 156)	Other sites, % (n = 117)	Total, %	Total, n (N = 996)
Open group	3.9	–	–	96.1	–	–	100.0	207
Drop-in	–	39.6	22.0	–	22.0	16.5	100.0	255
One-to-one specialist	3.6	33.7	18.5	9.3	24.2	10.8	100.0	389
GP practice	63.3	15.2	2.5	5.1	–	13.9	100.0	79
Other support <sup>a</sup>	33.3	1.5	9.1	9.1	13.6	33.3	100.0	66
Percentage of clients from each site	9.4	24.6	13.7	24.6	16.0	11.7	100.0	–

<sup>a</sup> Other support included closed groups (n = 32), pharmacy (n = 25), other level 2 (n = 8) and other/unclear (n = 1).

Response categories for the 5-point Likert scales were merged to enable analysis. Chi-squared tests were conducted between CO-validated quitting and all the satisfaction variables. If there was a significant difference between quitters and non-quitters ( $p < 0.05$ ) then chi-squared tests were conducted for location and behavioural support types. Results are presented where  $p < 0.05$ .

### **Overall satisfaction and supportiveness of staff**

Those who were CO validated as having stopped smoking were slightly more likely to be very satisfied with the services overall (64% vs. 51%) and less likely to state they were satisfied or unsure, unsatisfied and very unsatisfied (Table 33). A similar pattern emerged for satisfaction with staff supportiveness. Of the quitters, 68% were very satisfied with staff supportiveness versus 54% of non-quitters. The highest level of satisfaction with supportiveness was among respondents who attended open groups (70% very satisfied).

### **Returning to the services**

The majority of respondents (those who were abstinent from smoking and those who had not stopped or relapsed by 4 weeks) said they would return to the SSS if they needed help with another quit attempt (Table 34). There was a small but significant difference: 96% of quitters said they would return compared with 89% of non-quitters.

Although the majority of respondent's thought they would be welcomed back, quitters were slightly more likely to say they would be welcomed (88% vs. 79%). This may reflect differences in behavioural support as it was only among respondents who had attended open groups where over 90% believed they would be welcomed back.

**TABLE 33** Comparing satisfaction with service between quitters and non-quitters, study sites and behavioural support

Behavioural support type	Very satisfied (%)	Satisfied (%)	Unsure, unsatisfied, very unsatisfied (%)
<b>Quitting (<math>p = 0.001</math>)</b>			
Not CO validated as quit	51.1	33.3	15.6
Quit (CO validated)	64.4	23.8	11.8
Total	60.6	26.5	12.9
<b>Quitting (<math>p &lt; 0.001</math>)</b>			
Not CO validated as quit	54.1	31.4	14.5
Quit (CO validated)	67.5	23.0	9.5
Total	63.7	25.4	10.9
<b>Behavioural support (<math>p = 0.014</math>)</b>			
Open group	70.0	24.2	5.8
Drop-in	62.5	29.2	8.3
One-to-one specialist	64.0	22.0	14.0
GP practice	58.2	27.8	13.9
Other support	53.0	31.8	15.2
Total	63.7	25.4	10.9

**TABLE 34** Client views on key aspects of service provision

Client views	Yes (%)	No or unsure (%)
<b>Return to SSS</b>		
<i>Quitting (p &lt; 0.001)</i>		
Not CO validated as quit	89.3	10.7
Quit (CO validated)	96.3	3.7
Total	94.3	5.7
<b>Welcomed back to SSS</b>		
<i>Quitting (p &lt; 0.001)</i>		
Not CO validated as quit	79.2	20.8
Quit (CO validated)	88.2	11.8
Total	85.6	14.4
<i>Behavioural support (p = 0.011)</i>		
Open group	92.2	7.8
Drop-in	87.3	12.7
One-to-one specialist	82.9	17.1
GP practice	81.0	19.0
Other support	80.3	19.7
Total	85.6	14.4
<b>Whether or not given written information</b>		
<i>Quitting (p = 0.017)</i>		
Not CO validated as quit	89.8	10.2
Quit (CO validated)	94.3	5.7
Total	93.0	7.0
<i>Location (p &lt; 0.001)</i>		
Site1	90.3	9.7
Site 2	92.1	7.9
Site 4	87.2	12.8
Site 6	99.2	0.8
Site 8	91.1	8.9
Other sites	93.2	6.8
Total	93.0	7.0
<b>Medication information helpful</b>		
<i>Quitting (p &lt; 0.001)</i>		
Not CO validated as quit	88.7	11.3
Quit (CO validated)	96.0	4.0
Total	93.9	6.1
<i>Location (p &lt; 0.001)</i>		
Site1	83.9	16.1
Site 2	94.3	5.7
continued		

**TABLE 34** Client views on key aspects of service provision (*continued*)

Client views	Yes (%)	No or unsure (%)
Site 4	92.5	7.5
Site 6	96.3	3.7
Site 8	93.7	6.3
Other sites	98.3	1.7
Total	93.9	6.1
<b>Whether or not given CO test each session (<math>p=0.011</math>)</b>		
Not CO validated as quit	90.8	9.2
Quit (CO validated)	95.3	4.7
Total	94.0	6.0

**Information provided**

The majority of respondents were given written information, however, those who had stopped smoking by 4 weeks were slightly more likely to report that they had been given written information (94% vs. 90%). There was a significant difference between locations but even the site with the lowest provision achieved 87% clients being given written information.

Of those who had stopped smoking, 96% found information about medication helpful compared with 89% of those who had not. Helpfulness of information about medication was lower in site 1 (84%) than other sites (or site groups) analysed where over 90% agreed that information about medication was helpful. Comments about medication from site 1, which came from respondents who attended a variety of behavioural support types, included reports that side effect issues were not covered, they were encouraged to take medication when they did not want it and that their choice of medication was not easily available:

*I'd like to see that mild smokers are taken just as seriously as heavy smokers, in the sense that the whole course of patches should be offered not only an inhaler, I did manage to get some but only with protest.*

**Carbon monoxide validation at each session**

Carbon monoxide-validated quitters were slightly more likely to state that they had a CO-validation test at each session than those quit but not CO validated (95% vs. 91%). Among those who had taken a CO-validated test at each session (see *Table 34*), quitters were more likely to say it was very helpful than non-quitters (73% vs. 63%). There was a significant difference between location, with respondents from site 6 reporting highest levels of helpfulness (81%) and site 1 respondents were least likely to say that the CO-validation test was very helpful (57%). This may reflect the behavioural support type: 87% of open-group clients said that a CO test during each session was very helpful, compared with 59% of GP practice clients. Site 8 was chosen for the study because of its low CO-validation rate. Clients in site 8 were most likely to say that they were unsure about CO validation or they found it unhelpful or very unhelpful (13% compared with an average of 9% in all other sites).



## Summary of key points

- A consistent pattern emerged that suggests that smokers who accessed SSSs, in the ELONS study areas and responded to the survey, had a very positive experience, for both quitters and non-quitters. The vast majority who replied to the questionnaire indicated that they would recommend the service to others and return should the need arise.
- There were several examples of good practice, when SSSs offered more than they are required to do by the DH (e.g. contacting clients before their first appointment to encourage them to attend and offering child care and a choice of behavioural support options).
- Additional comments highlighted the importance of practitioner/client rapport, and multilevel modelling of the ELONS study secondary analysis and prospective study data sets suggests that this is an important factor in a successful quit attempt, at least in the short term.
- Despite quantitative findings suggesting that medication was easy to acquire, additional comments pointed to a more complex picture where the process of obtaining medication was overcomplicated and time-consuming for some respondents.
- Suggested improvements centred on evening appointment times, having a choice of group or one-to-one support and a longer period of support.
- Analysis of client satisfaction between quitters and non-quitters, SSS location and behavioural support types revealed some small but significant differences:
  - Quitters were more likely to be satisfied with staff supportiveness and happier to return to the services if needed, with the information provided and CO validation.
  - Open-group clients were happier about staff supportiveness, returning to the service and CO testing. GP practice clients were least comfortable with CO testing. It must be noted that open-group clients were mostly recruited from a single site.
- Finally, despite an encouraging response rate (response to self-completion postal surveys are generally low, even with repeated reminders) clients who were motivated to complete the survey were also more likely to have had a successful quit attempt. This means the views of those who did not quit are under-represented.



## Chapter 8 Well-being study

Well-being can improve after smoking cessation, but smokers often have concerns about stopping because they believe smoking itself brings benefits, such as reduced stress levels.<sup>51</sup> The ELONS study provided an opportunity to examine changes in well-being before and after stopping smoking to add to our understanding of this issue.

### Rationale

Additional information on the health and well-being of the ELONS prospective study participants was collected for a number of reasons. First, it has been argued that the ultimate aim of health care is to improve quality of life.<sup>52</sup> It would, therefore, be expected that a health intervention, such as a smoking cessation programme, would improve well-being,<sup>53–55</sup> but previous research has highlighted some unintended consequences.<sup>52,56</sup> In addition, as well as being a desired outcome of a health interventions, well-being may also be a predictor of successful smoking cessation.<sup>55–59</sup> No studies that we could identify had examined changes in well-being among clients of NHS SSSs and thus we decided to include a focus on this in the current study.

### Recruitment

As part of the baseline monitoring data collection for the prospective study, clients were asked additional questions about their health and well-being. In addition, all clients, regardless of their smoking status, were sent postal questionnaires at 4 and 52 weeks post quit date, which included questions on well-being (see *Appendix 1*).

### Measures

#### Medical conditions variables

Health was operationalised as the presence or absence of medical conditions. Practitioners collected detailed information on medical conditions for two reasons. First, SSSs provide medication to support smoking cessation and other medications need to be understood to make sure the medication is appropriate. Second, we wished to consider medical conditions because there is an association between many medical conditions and smoking. For the ELONS study, each service was required to ask about a list of medical conditions for consistency. Medical conditions reported by clients were amalgamated into the following for analysis: any medical condition; heart, blood and circulatory conditions; lung and respiratory conditions; mental health conditions; client had a condition but none of the above conditions were present; and a limiting medical condition (in conjunction with the limiting illness variable).

#### Well-being variables

Well-being data were chiefly collected through the WHO-5 Well-being Index.<sup>45</sup> (*Box 1*). The WHO-5 Well-being Index has been used in studies on diabetes, suicide, substance abuse, obesity and depression. In a sample of over 3000 clients who received health trainer services in the West Midlands,<sup>60</sup> the WHO-5 Well-being Index score improved by 37.5% (from a score of 44.1 to a score of 60.7) after receiving the service.

**BOX 1** The WHO-5 Well-being Index**Over the last 2 weeks**

I have felt cheerful and in good spirits.

I have felt calm and relaxed.

I have felt active and vigorous.

I woke up feeling fresh and rested.

My daily life has been filled with things that interest me.

**Response scale**

All of the time = 5.

Most of the time = 4.

More than half the time = 3.

Less than half the time = 2.

Some of the time = 1.

At no time = 0.

The five items that make up this scale were asked at three time points: baseline, as an extension to the client satisfaction postal survey, at 4 weeks and a further postal survey sent to all the ELONS study participants at 52 weeks.

A score for the WHO-5 Well-being Index is derived by summing the responses to the five constituent items and multiplying by four, which provides a continuous variable with a potential range of 0 to 100. The range and skew were calculated. A dichotomised variable can also be derived: a concerning level (as opposed to a good level) of well-being occurs where the overall well-being score is under 13 or any individual item score is 0 or 1.

Additional questions on well-being were asked in the 4-week and 52-week postal surveys, including a 'components of well-being' scale modified from the validated psychosocial benefits from home scale<sup>61-63</sup> to apply to smoking cessation clients. The components, measuring protection, control, prestige and response to change, are theoretically related to ontological security but also implicitly assume that well-being is affected by outside, and therefore modifiable, sources rather than fixed personality traits. Thus the ten items are intended to measure psychosocial feelings, which may connect well-being to external factors (*Table 35*). These items were included in both postal surveys.

**TABLE 35** Ontological security items (all answered on a 5-point Likert scale with responses ranging from strongly agree to strongly disagree)

Concept	Items
Protection	I can deal with stress; I feel safe
Control	I feel in control; I can do what I want, when I want
Prestige	Most people would like a life like mine; I feel I'm doing well in life
Response to change	My life has a sense of routine; I worry about things going wrong (reversed); I enjoy a challenge; I'm frightened of change (reversed)

### Socioeconomic status

An alternative measure of SES was used in the analysis described here because of possible contamination between the prospective study measure of SES, and health and well-being with the inclusion of permanently sick and eligibility for free prescriptions. Here, a three-category variable was used: low SES [(unemployed or basic education or social renting) and no high SES conditions,  $n = 1179$ ] mid SES (mixed or no indicators of low or high SES,  $n = 1480$ ) and high SES (owns home and either has a professional/managerial occupation or has tertiary education and no low SES conditions,  $n = 300$ ).

### Analysis

The analysis for this element of the ELONS study was intended to be exploratory. The following questions were examined:

- What was the level of response to the well-being questions?  
This analysis was undertaken in order to see whether or not the WHO-5 Well-being Index scale was acceptable to respondents and whether or not the samples of respondents who answered the well-being questions were adequate for analysis.
- Did health and well-being at baseline predict quitting at 4 weeks and 52 weeks?  
This analysis was undertaken in order to consider first, whether or not well-being and smoking cessation were significantly associated, and second, which health and well-being variables should be included in the final model of factors predicting quitting reported on elsewhere in this report.
- How did well-being change over time among quitters and non-quitters?  
This analysis was undertaken in order to explore whether or not findings of a systematic review<sup>50</sup> (that well-being improves after cessation) were replicated among the ELONS study clients or whether or not attending the smoking cessation services had unintended adverse consequences for well-being.
- Which clients had the highest well-being at baseline, 4 weeks and 52 weeks?  
This analysis was undertaken to explore first, the stability of the concept of well-being over time (for instance, if the same factors constantly associated with well-being), second, which factors are associated with well-being, and third, which psychosocial factors may link external factors to well-being.

### What was the level of response to the well-being questions?

The number of clients who responded to the well-being questions at baseline and in the 4- and 52-week surveys were as follows: 2959 clients responded at baseline only, 953 responded at 4 weeks only, 939 at baseline and 4 weeks, 479 at 52 weeks only, 471 at baseline and 52 weeks, 325 at all three points and 77 had no well-being score at any point (see *Table 45* for more details about the responses). Response rates were low at 4 and 52 weeks, as was expected from a postal survey, but were adequate to proceed with analysis given that there was good representation from all demographic groups (see *Table 46*) and convergence was achieved in multivariable modelling.

### ***Did health and well-being at baseline predict quitting?***

The aim of this analysis was to establish whether or not clients' levels of well-being at the start of their quit attempt was related to quitting or if more traditional measures of medical conditions were preferable.

Outcomes of logistic regression analyses were 4-week and 52-week CO-validated quitting. For 4-week quitting, practitioner was added as a level two variable. For 52-week quitting, there was no evidence of variance between practitioners consistently, so single-level modelling was used. Each medical condition and well-being variable was analysed separately. Other fixed-effect variables included in the models were location, behavioural support type, month quit attempt started, age, gender, ethnicity, SES, whether or not they had taken varenicline, dependence on tobacco and determination to quit (4 weeks only), supportive spouse or partner, and friends and family smoking status.

### ***How did well-being change over time among quitters and non-quitters?***

The aim of this analysis was to explore whether or not quitting smoking was associated with changes in well-being.

Initially the distribution of the continuous well-being score was examined in order to establish whether parametric or non-parametric statistics should be used in this analysis.

### **Mean well-being of quitters and non-quitters**

Weighted means were calculated, using the same weights as the prospective study analysis, overall and by 4- and 52-week CO-validated quitting. Means were calculated for clients who had data at different combinations of time points (e.g. baseline and 4 weeks or baseline and 52 weeks). The sample size was kept constant by adding dummy data (e.g. the mean) to clients who did not have a well-being score at 4 weeks or 52 weeks, and an indicator variable was created to distinguish between clients with real data (as they had answered the questions) and clients with dummy data. The weighted means (excluding clients with dummy data) were tabulated and drawn on a line graph (see *Figure 7* and *Table 37*).

### ***Which clients had the highest well-being at baseline, 4 and 52 weeks?***

In this analysis the aim was to explore associations with well-being in order to understand how high levels of well-being may be achieved. This may be helpful because clients with higher well-being are more likely to be able to successfully quit smoking long term.

There was no evidence of variance between practitioners at baseline, so single-level models were used for modelling well-being at baseline; however, practitioner was included a random effect at the second level for 4 weeks and 52 weeks. Modelling occurred in two stages. In the first stage, variables that had been used in the prospective study analysis were included in addition to well-being. Non-significant variables (with the exception of a priori variables: location, behavioural support, quit attempt start date, age, gender and SES) were excluded from the model. For modelling of well-being collected in the 4-week and 52-week postal surveys there was then a second stage where ontological security variables were added as continuous variables. Non-significant optional variables were removed and multicollinearity was checked.

### **Which ontological security variables explained why other variables were associated with quitting?**

Each ontological security variable that was significant in the final model was added individually to the stage one model and the changes in coefficients of other independent variables were noted. This final analysis was undertaken only for well-being measured at 4 weeks because of the smaller response to the postal survey at 52 weeks.

## Findings

### *Did health and well-being at baseline predict quitting?*

The analysis presented below suggests that well-being at baseline was a predictor of abstinence from smoking in the short and longer term, but medical conditions were not.

Logistic regression modelling was used to examine whether or not health and well-being at baseline predicted quitting at 4 weeks and 52 weeks once other factors had been taken into account (*Table 36*). This analysis suggested that none of the medical conditions variables predicted either short- or long-term quitting. Well-being analysed as a continuous variable did predict abstinence but not as a dichotomous variable.

### *How did well-being change over time among quitters and non-quitters?*

Well-being at baseline approximately followed a normal distribution. Skew was below  $\pm 0.8$  and could be disregarded so parametric statistics could be used. The range of well-being scores was between 0 and 100 and so could be viewed as a percentage.

**TABLE 36** Odds ratios (95% CI) of quitting at 4 and 52 weeks in final models<sup>a</sup> when each medical condition or well-being measure is added separately

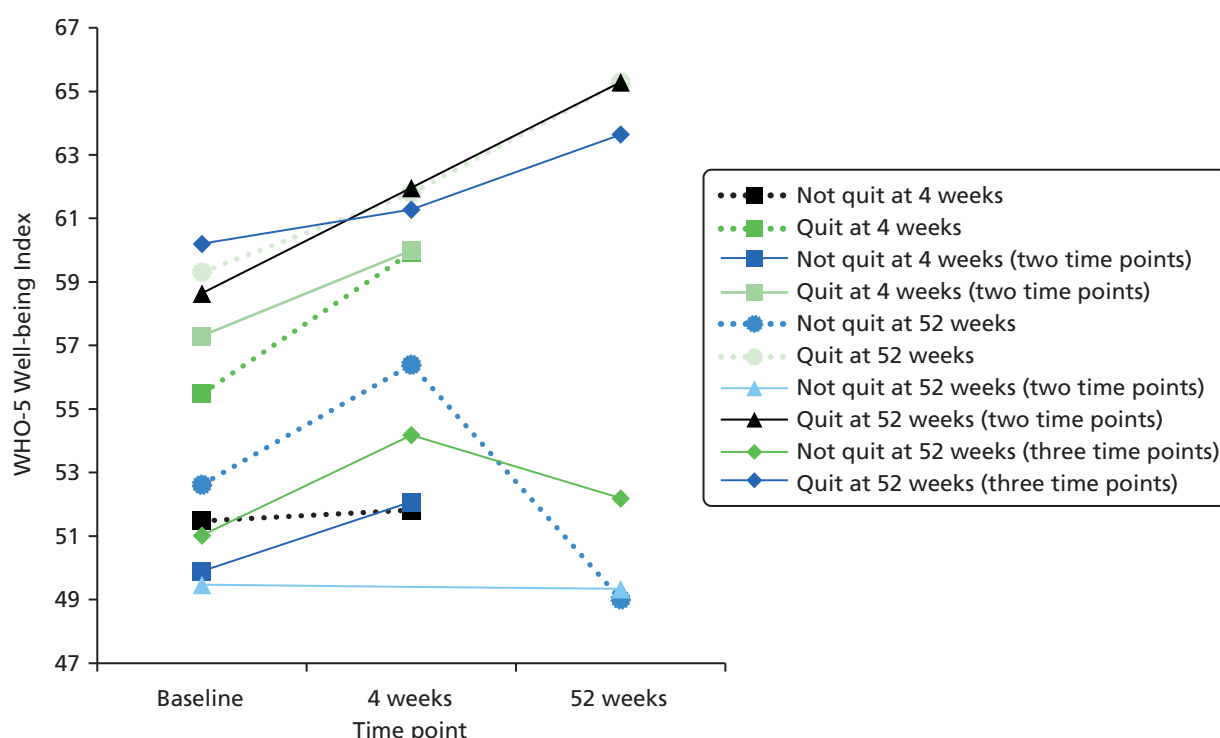
Health or well-being scale	CO-validated quit at 4 weeks (95% CI)	CO-validated quit at 52 weeks (95% CI)
<b>Medical conditions</b>		
Any	0.92 (0.78 to 1.08)	0.85 (0.65 to 1.12)
Heart, blood, circulation	1.01 (0.81 to 1.26)	0.81 (0.56 to 1.16)
Respiratory	0.88 (0.72 to 1.07)	0.86 (0.62 to 1.19)
Mental health	0.91 (0.73 to 1.13)	0.75 (0.50 to 1.12)
Other condition but none of above	0.97 (0.76 to 1.24)	1.12 (0.77 to 1.63)
Severely limiting (vs. no condition)	0.77 (0.55 to 1.09)	0.59 (0.32 to 1.11)
<b>WHO-5 Well-being Index</b>		
Continuous: 1% increase in well-being	1.004 (1.00004 to 1.007)	1.007 (1.0013 to 1.014)
Dichotomy: good vs. concerning level of well-being	1.11 (0.94 to 1.31)	1.10 (0.85 to 1.43)
<sup>a</sup> Models control for location, behavioural support type, time of year of quit attempt, age, gender, ethnicity, SES, whether or not they have taken varenicline, dependence on tobacco and determination to quit, supportive spouse or partner, and friends and family smoking status.		

The weighted well-being mean of the sample was 53.15 (95% CI 51.96 to 54.34) (Table 37). Clients who did not manage to quit for 4 weeks had lower well-being at baseline than those who quit (Figure 7). In addition, the mean well-being at baseline of 52-week quitters was higher than those who did not manage to quit for 52 weeks. CIs did not overlap for 4-week quitters and non-quitters, and CIs of clients who did manage to quit for 52 weeks did not overlap with those who did not manage to quit for 52 weeks, 4 weeks and the sample overall. This indicates that there were significant differences between these client groups.

**TABLE 37** Mean well-being (95% CI) at baseline, 4 weeks and 52 weeks, overall and by CO-validated quit status at 4 and 52 weeks for groups of clients who answered (and did not answer) well-being questions at various time points

Follow-up and quit status	Baseline (95% CI)	4 weeks (95% CI)	52 weeks (95% CI)
<b>4 weeks</b>			
Total	53.15 (51.96 to 54.34)	57.29 (55.25 to 59.32)	–
Not quit	51.48 (49.83 to 53.13)	51.82 (47.98 to 55.66)	–
Quit	55.48 (53.80 to 57.16)	59.93 (57.60 to 62.26)	–
<b>Responded to WHO-5 scale questions at 4 weeks if answered baseline and 4 weeks</b>			
Total	54.90 (52.96 to 56.84)	57.43 (55.39 to 59.48)	–
Not quit	49.90 (46.41 to 53.40)	52.08 (48.22 to 55.94)	–
Quit	57.30 (55.01 to 59.58)	59.99 (57.65 to 62.34)	–
<b>52 weeks</b>			
Total	53.15 (51.96 to 54.34)	57.29 (55.25 to 59.32)	52.76 (49.91 to 55.62)
Not quit	52.62 (51.36 to 53.88)	56.40 (54.11 to 58.69)	49.01 (45.72 to 52.31)
Quit	59.31 (56.47 to 62.14)	61.80 (57.82 to 65.77)	65.29 (61.29 to 69.28)
<b>Responded to WHO-5 scale questions at 52 weeks if answered baseline and 52 weeks</b>			
Total	51.63 (48.96 to 54.31)	–	53.10 (50.26 to 55.93)
Not quit	49.47 (46.24 to 52.70)	–	49.34 (46.05 to 52.63)
Quit	58.64 (54.64 to 62.64)	–	65.29 (61.29 to 69.28)
<b>Responded to WHO-5 scale questions at 52 weeks if answered all three points</b>			
Total	53.60 (50.54 to 56.67)	57.43 (55.39 to 59.48)	55.42 (52.31 to 58.52)
Not quit	51.02 (47.13 to 54.90)	54.18 (50.41 to 57.96)	52.19 (48.48 to 55.90)
Quit	60.20 (56.12 to 64.27)	61.28 (57.33 to 65.24)	63.64 (58.81 to 68.47)
Shaded cells indicate overlapping CIs between quitters and non-quitters.			





**FIGURE 7** Well-being over time by smoking status.

Confidence intervals for weighted means of well-being for non-quitters over the three time points overlapped when clients provided data at three time points. CIs for non-quitters also overlapped for both time points if the clients provided data at any two time points. The well-being scores of quitters consistently increased over time but CIs of the first time points overlapped with those of later time points. However, CIs for quitters and non-quitters at each time point did not overlap. This is an indication that quitters had significantly higher well-being than non-quitters.

### **Which clients had the highest well-being at baseline, 4 and 52 weeks?**

A summary of variables that were associated with well-being at each time point is presented in *Table 38*. Full models with all coefficients are presented in *Appendix 2* (see *Tables 46* and *47*).

### **Factors associated with higher well-being at baseline**

At baseline, multivariable modelling suggested that the factor with the strongest association with well-being was absence of a mental health condition. Thus, clients without a mental health condition had well-being scores nearly 10 points higher than those with a condition (see *Tables 38* and *46* for more details). Other factors with significant associations with well-being at baseline were high SES, with the most affluent clients having well-being scores that were 4 points higher than the most disadvantaged clients. Support from spouse or partner, determination to quit, lower dependence on tobacco, taking varenicline and the absence of a physical medical condition (such as not having heart, blood or circulatory problems) were all significantly associated with well-being at baseline. Age had a U-shaped relationship with well-being, where well-being was poorest in those aged 45–54 years compared with clients aged 16–24 years and 65–85 years. Asian clients had significantly higher well-being than non-British white clients, although numbers of these clients were very small.

**TABLE 38** Variables significantly associated with well-being at baseline, 4 weeks and 52 weeks

Variables	Baseline	4 weeks		52 weeks	
	Model 1	Model 1 <sup>a</sup> (OS excluded)	Model 2 <sup>b</sup> (OS included)	Model 1 <sup>a</sup> (OS excluded)	Model 2 <sup>b</sup> (OS included)
Quit smoking	–	Quit at 4 weeks	Quit at 4 weeks	Quit at 52 weeks	Quit at 52 weeks
Age	Age (U-shaped)	Age (U-shaped)	Age 25–34 years	Age (U-shaped)	–
Ethnicity	Ethnicity (Asian)	Ethnicity (Asian)	Ethnicity (Asian)	–	–
Dependence	Low dependence	Low dependence	–	Low dependence	–
Mental health	No mental health problems	No mental health problems	–	No mental health problems	–
Heart, blood, circulation or respiratory conditions	No heart, blood or circulation condition, no respiratory, no other condition	–	No heart, blood or circulation conditions	No respiratory conditions	–
Support	Spouse/partner support	Spouse/partner support	–	–	–
Determination	More determined to quit	–	–	–	–
Medication	Taking varenicline	–	–	–	–
OS answers	–	–	I enjoy a challenge; I feel I'm doing well in life; I feel in control; I can deal with stress; Most people would like a life like mine	–	I enjoy a challenge; I feel I'm doing well in life; I feel in control; I can do what I want, when I want; I feel safe; I worry about things going wrong (reversed); My life has a sense of routine

OS, ontological security.

a Model 1: a priori independent variables were: behavioural support; age; location; time of year; gender; and SES. Independent variables, which were removed if they were non-significant through a backwards-stepwise procedure, were: ethnicity (baseline and 4 weeks only); smoking dependence; determination to quit; support from spouse/partner; smoking in social network; took varenicline in week 1; mental health condition; respiratory condition; heart, blood or circulation condition; other condition.

b Model 2: independent variables were the same as model 1 with the addition of the OS variables: I can deal with stress; I feel safe; I feel in control; I can do what I want, when I want; Most people would like a life like mine; I feel I'm doing well in life; My life has a sense of routine; I worry about things going wrong (reversed) I enjoy a challenge; I'm frightened of change (reversed).

### Factors associated with higher well-being at 4 weeks

Well-being scores at 4 weeks were associated with: successful cessation; age; Asian ethnicity (compared with non-British whites); absence of heart, blood and circulatory diseases; and five ontological security items (I enjoy a challenge; I feel I'm doing well in life; I feel in control; I can deal with stress; and most people would like a life like mine) (see *Tables 38 and 47* for more details). If ontological security items were not entered, then dependence on tobacco (low dependence), no mental health issues, and spouse and partner support were significantly associated with well-being (see *Appendix 2, Table 47*).

As the inclusion of the ontological security items caused attrition in the coefficients of other variables, this was explored further by adding each ontological security variable separately (*Tables 39 and 40*). Attrition in the well-being coefficients of the youngest and oldest clients, the highest SES groups and those who had a spouse/partner supporting their quit attempt was particularly marked when the item 'I'm doing well in life' was added to the model. Attrition in the well-being scores of clients with an absence of mental health conditions was particularly marked when the item 'I feel in control' was added to the model. Feeling in control partly attenuated the relationship between well-being and quitting but the association still remained significant.

### Factors associated with higher well-being at 52 weeks

At 1 year after the quit date, only the ontological security items [I enjoy a challenge, I can do what I want when I want, I feel in control, I feel safe, I worry about things going wrong (reversed), I feel I'm doing well in life, My life has a sense of routine] and being abstinent from smoking at 52 weeks were associated with well-being (see *Tables 38 and 47*). However, if the ontological security items were not entered into the model, well-being was associated with cessation at 52 weeks and also the following variables collected at baseline: age, low dependence and not having either a lung/respiratory or a mental health condition (see *Table 47*).

## Summary of key points

- The WHO-5 Well-being Index was integrated successfully into routine questions asked of service clients at baseline. This suggests services could ask about well-being if useful for monitoring purposes.
- Clients who arrived at the SSS and who had higher levels of well-being at the start of their quit attempt were significantly more likely to be non-smokers at 4 weeks and 52 weeks.
- In addition, well-being among those who stopped smoking remained higher than that of continuing smokers at all measurement points. There was a linear rise in the levels of well-being among quitters, however, the CIs of quitters' well-being at baseline, 4 weeks and 52 weeks overlapped.
- The most consistent factors associated with well-being at baseline, 4 weeks and 52 weeks were: not having a diagnosed mental health condition; low dependence on tobacco; and young or older age.
- Clients aged 45 to 54 years had lower well-being scores than younger and older clients at all three time points, although differences were not always significant.
- Clients who had higher levels of well-being were consistently more likely to agree that they enjoyed a challenge, were doing well in life and felt more in control than other clients. A mediator of the association between dependence on tobacco and well-being appeared to be not being able to cope with stress.

**TABLE 39** Change in well-being coefficient [Beta (95% CI)] of sociodemographic variables when different ontological security variables are added to the stage one model

Variable	Model 1	Add OS1 <sup>a</sup>	Add OS2 <sup>b</sup>	Add OS5 <sup>c</sup>	Add OS6 <sup>d</sup>	Add OS9 <sup>e</sup>
Age group (years)						
16–24 (95% CI)	9.05 (3.28 to 14.82)	6.58 (1.07 to 12.09)	8.77 (3.54 to 14.00)	7.16 (1.77 to 12.55)	6.24 (1.23 to 11.25)	5.73 (0.75 to 10.71)
25–34 (95% CI)	6.66 (2.34 to 10.97)	4.40 (0.27 to 8.53)	6.98 (3.07 to 10.89)	6.23 (2.21 to 10.24)	4.11 (0.35 to 7.86)	5.10 (1.38 to 8.82)
35–44 (95% CI)	3.48 (–0.50 to 7.46)	2.98 (–0.81 to 6.77)	1.82 (–1.80 to 5.44)	4.14 (0.43 to 7.86)	2.08 (–1.38 to 5.53)	3.47 (0.03 to 6.90)
45–54	0	0	0	0	0	0
55–64 (95% CI)	2.27 (–1.61 to 6.15)	2.54 (–1.15 to 6.22)	1.72 (–1.79 to 5.24)	0.93 (–2.69 to 4.55)	1.37 (–2.00 to 4.73)	1.25 (–2.09 to 4.59)
65–85 (95% CI)	5.44 (0.66 to 10.23)	6.95 (2.39 to 11.51)	4.36 (0.02 to 8.69)	3.31 (–1.16 to 7.79)	3.49 (–0.67 to 7.64)	3.06 (–1.07 to 7.19)
Gender						
Male (95% CI)	0.58 (–2.16 to 3.32)	–0.36 (–2.98 to 2.25)	–0.74 (–3.23 to 1.75)	0.84 (–1.71 to 3.39)	–0.34 (–2.72 to 2.04)	1.74 (–0.63 to 4.10)
Female	0	0	0	0	0	0
SES						
Low SES	0	0	0	0	0	0
Mid SES (95% CI)	1.39 (–1.63 to 4.41)	0.74 (–2.13 to 3.62)	–0.39 (–3.14 to 2.36)	–0.72 (–3.55 to 2.12)	–0.21 (–2.84 to 2.41)	–1.85 (–4.47 to 0.78)
High SES (95% CI)	4.04 (–0.50 to 8.58)	2.62 (–1.71 to 6.94)	1.12 (–3.01 to 5.25)	0.26 (–4.01 to 4.54)	2.11 (–1.83 to 6.05)	–1.40 (–5.35 to 2.55)
Practitioner variance (standard error)	0.9 (4.4)	0.8 (3.9)	2.7 (4.2)	2.2 (4.3)	0.0 (0.0)	1.8 (3.6)
Client-level unexplained error (standard error)	415.6 (19.5)	376 (17.6)	339.7 (16.0)	359.8 (16.9)	313.4 (14.4)	307.3 (14.4)
–2log likelihood	8453.0	8357.4	8265.4	8319.0	8181.9	8168.5
OS, ontological survey.						
a I enjoy a challenge.						
b I can deal with stress.						
c Most people would like a life like mine.						
d I feel in control.						
e I feel I'm doing well in life.						

**TABLE 40** Change in well-being coefficient [Beta (95% CI)] of smoking and health-related variables when different ontological security variables added to the stage one model

Variable	Model 1	Add OS1 <sup>a</sup>	Add OS2 <sup>b</sup>	Add OS5 <sup>c</sup>	Add OS6 <sup>d</sup>	Add OS9 <sup>e</sup>
Smoking dependence						
Not recorded as dependent (95% CI)	3.31 (0.55 to 6.07)	2.54 (−0.09 to 5.17)	<b>0.66 (−1.86 to 3.19)</b>	2.96 (0.39 to 5.54)	1.50 (−0.90 to 3.91)	1.30 (−1.08 to 3.69)
Dependent	0	0	0	0	0	0
Quit attempt supported by spouse/partner						
Supported (95% CI)	4.83 (2.14 to 7.53)	4.24 (1.67 to 6.80)	3.92 (1.48 to 6.37)	2.24 (−0.31 to 4.79)	3.59 (1.25 to 5.93)	<b>1.34 (−1.02 to 3.69)</b>
Other	0	0	0	0	0	0
Mental health condition						
Yes	0	0	0	0	0	0
Not recorded (95% CI)	10.77 (7.05 to 14.49)	8.56 (5.00 to 12.12)	5.05 (1.59 to 8.51)	7.79 (4.29 to 11.29)	<b>4.85 (1.56 to 8.14)</b>	6.71 (3.48 to 9.95)
CO-validated quit rate						
Quit at 4 weeks (95% CI)	6.11 (3.05 to 9.17)	5.87 (2.96 to 8.77)	4.78 (2.00 to 7.56)	5.26 (2.40 to 8.11)	<b>3.25 (0.58 to 5.92)</b>	3.62 (0.97 to 6.27)
Not quit at 4 weeks	0	0	0	0	0	0
OS, ontological survey. a I enjoy a challenge. b I can deal with stress c Most people would like a life like mine. d I feel in control. e I feel I'm doing well in life. Bold text indicates which ontological security variable produced the greatest change in the well-being coefficient of each independent variable when it was added to the model.						



## Chapter 9 Longer-term nicotine replacement therapy study

This chapter presents findings from the additional research on longer-term NRT use that was added to the ELONS study after the prospective study had commenced. This work was made possible by additional funding from the UK Centre for Tobacco Control Studies to Lion Shahab at University College London, who collaborated with the ELONS study team and drew on additional advice from Professor Ann McNeill of King's College London.

Like previous chapters it begins by describing the value that this adds to the ELONS study. Next is a description of the method, sample and analytical approach, followed by the findings and a summary of key points.

### Rationale and study aims

There is good evidence from both population studies and clinical trials that the provision of NRT to smokers who cut down their cigarette consumption results in more sustained decreases in cigarette consumption and improves their chances of stopping smoking completely.<sup>64,65</sup> Cutting down with NRT is associated with both increased motivation to stop and improved quit rates<sup>64,66</sup> and does not increase overall nicotine intake.<sup>67</sup> Trials have also shown that extended use of NRT by ex-smokers may result in better long-term abstinence rates.<sup>68,69</sup> For this reason, NRT in the UK is licensed for smoking reduction, that is, dual use, and available to smokers who cannot or are unwilling to stop smoking completely, as a long-term harm reduction measure<sup>70</sup> NRT licensing is also being changed to allow its use for harm reduction purposes among ex-smokers.<sup>71</sup>

Harm reduction refers to the reduced psychological or physiological harm from substance use without complete cessation.<sup>66</sup> In the case of tobacco use, harm reduction may refer to the partial substitution of cigarettes with non-combustible forms such as NRT to reduce cigarette consumption or for temporary abstinence. However, harm reduction may also constitute the complete and permanent substitution of cigarettes with less harmful products, switching smokers from combustible to non-combustible nicotine delivery devices, including NRT.<sup>72</sup>

The reason for focusing on NRT is that the burning of tobacco causes the most harm and not nicotine per se.<sup>73</sup> Nonetheless, there is considerable worry among potential users<sup>74</sup> and SSS staff<sup>75</sup> regarding the safety of long-term NRT use.

There is little research in this topic, and the studies that have looked at this issue suggest that long-term NRT use is safe and any associated health risks are small,<sup>76</sup> certainly compared with continued smoking.<sup>77,78</sup> Yet, surprisingly few data exist on the impact of long-term NRT use in terms of health outcomes in the general population. Most data come from clinical trials, which have samples that tend to differ in important ways from general population samples<sup>79</sup> and in which NRT is provided free together with behavioural support, which may affect normal usage patterns. By contrast, most NRT in the UK is used without advice and bought over the counter,<sup>80</sup> and in many other countries (unlike in the UK) it is rarely provided for free on prescription.<sup>81</sup> Consequently, there is a need for further research in the area of harm reduction (as recently indicated by NICE)<sup>82</sup> as investigating this issue will allow more precise quantification of the likely benefits or harms of substituting cigarettes with NRT among current and ex-smokers.

To help add to research to this topic, this addition to the ELONS study aimed to:

- examine the prevalence of long-term NRT use among current smokers and ex-smokers
- explore the impact of long-term NRT use on biomarkers of nicotine exposure and stress among current smokers and ex-smokers.

## Methods and sample

All clients recruited to the ELONS study were asked by practitioners to provide two saliva samples at baseline and (if they received a home visit and had provided samples at baseline) an additional two saliva samples at 52 week follow up. The saliva samples were collected to measure two biomarkers of interest: cotinine, the primary metabolite of nicotine as a biomarker of exposure; and alpha-amylase, a digestive enzyme and indicator of autonomic nervous system activation that correlates with acute and chronic stress as a biomarker of risk/potential harm.<sup>83</sup>

In order to maximise recruitment to the main ELONS study, clients were able to consent to participate even if they did not want to provide saliva samples. In addition, saliva sample collection at baseline was not conducted with some community practitioners (level 2 practitioners) who were not willing or able to conduct this element. For these two reasons, not all the ELONS study participants took part in the additional research on long-term NRT use. This addition to the prospective study also included a randomly selected sample of clients who were not abstinent at the 4-week follow-up who were also sent a saliva kit through the post at 12-months follow-up and asked to return samples in a reply paid envelope. This was done in order to obtain a comparable sample of smokers. The saliva kit contained two Salivettes®, a letter from the project lead asking for help and detailed instructions on how to collect their own sample as well as a £10 Marks and Spencer voucher.

This request to provide a saliva sample resulted in 1875 useable saliva samples for analysis (which represents 61% of the ELONS study participants). At 12-month follow-up, saliva samples were obtained from 169 of a potential 320 participants (i.e. those who took part in the follow-up telephone interview, were abstinent from smoking and had given a saliva sample at baseline). In addition a random sample ( $n = 392$ ) of participants who had given a saliva sample at baseline and were known to have relapsed at 4-week follow-up were contacted at 12-month follow-up and asked to provide a saliva sample. This resulted in saliva samples from 89 participations.

## Analysis

Data were analysed with IBM SPSS Statistics 20.0.0. Comparisons were made between those who did and did not respond to the follow-up phone call and questionnaire, and between those who did and did not provide a saliva sample at baseline and at follow-up. Differences were assessed with chi-squared tests and independent *t*-tests for categorical and continuous variables, respectively.

Owing to the typically positively skewed distribution of cotinine and alpha-amylase values, and a relatively small sample size, non-parametric Kruskal–Wallis tests were used to compare differences between smokers and quitters with and without NRT use. As we were concerned about the potential of confounders, we conducted a sensitivity analysis to assess the impact of these on the results. We used a generalised linear model, which enabled adjustment for potential confounders with a gamma distribution and a log link (all 0 values were replaced with 0.001) to account for the non-normal distribution.



Given the longitudinal study design, where participants were essentially their own control, we conducted an analysis to see how levels of biomarkers changed over time as this would tell us about the influence of using NRT or stopping smoking on these health indices. For the mixed-design analysis (looking at change across time), generalised linear models with a normal distribution and identity link were run using the change score in biomarkers to determine the impact of NRT use and smoking status on these biomarkers over time. Statistical significance was set at the standard level ( $p < 0.05$ ), and the Bonferroni correction was applied in post-hoc analyses. Prevalence estimates are weighted where indicated (see *Chapter 5, Weighting* for further information) but, unless otherwise stated, all data are unweighted.

Please note that given the complexity of study design, respondents were treated in the analysis according to their last status, that is, relapsers at 4 weeks who had stopped smoking by the 12-month follow-up were counted as quitters, and self-reported quitters at 12-months who failed CO assessment were counted as relapsers and analysed accordingly.

## Findings

Findings are divided into two sections:

- prevalence of longer-term NRT use
- impact of longer-term NRT use.

### *Prevalence of longer-term nicotine replacement therapy use among current smokers and ex-smokers*

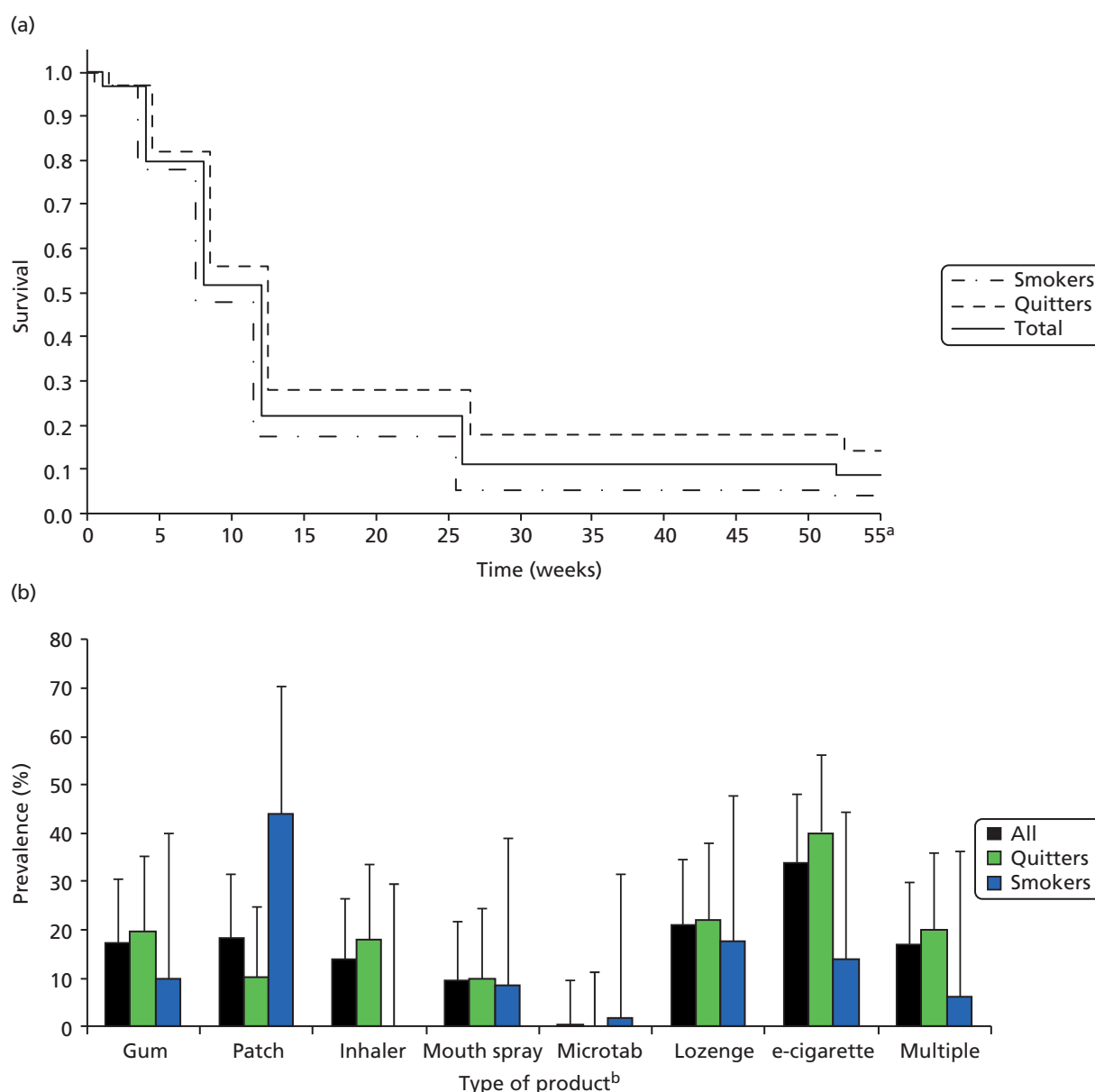
A total of 1047 participants (34.4% of the whole sample) provided information on long-term NRT use and therefore form the analytic sample for the prevalence analysis. As shown in *Table 41*, those who were lost at follow-up were younger, had smoked for a shorter period of time, were less likely to have a medical condition and were less likely to be white or cohabiting.

Of clients followed up, 61.5% (95% CI 58.4% to 64.6%,  $n = 583$ ) claimed that they had used NRT during their initial quit attempt. (Note: all prevalence estimates in this section are weighted but  $n$  numbers are unweighted.) However, this estimate is likely to include over-the-counter use, as this number is substantially higher than the number of participants recorded as using NRT by the services as shown in *Table 41* (34.4%, 95% CI 31.4% to 37.4%;  $n = 310$ ). *Figure 8* provides a breakdown of clients' length of use of NRT as a function of smoking status at follow-up and type of NRT used long term. As can be seen, most clients who started on NRT used it for at least 8 weeks and more than one in five (21.5%, 95% CI 18.3% to 25.0%,  $n = 137$ ) used it for longer than the standard 3 months. However, long-term use was relatively rare with fewer than 1 in 10 participants still using non-combustible nicotine products at 12-months follow-up (8.4%, 95% CI 6.4% to 11.0%;  $n = 50$ ). Prevalence of NRT use was even lower when excluding participants who used e-cigarettes only (6.0%, 4.3% to 8.3%;  $n = 35$ ) and use of e-cigarettes was also relatively uncommon (2.9%, 1.8% to 4.7%;  $n = 18$ ). However, it should be noted that these data include smokers and non-smokers, and most people had relapsed.

Generally, there were few differences between those clients who had relapsed between the 4-week and 12-month follow-up and those who had remained abstinent in terms of their NRT use (see *Figure 8a*). However, long-term ex-smokers were much more likely still be using non-combustible nicotine products at 12-month follow-up than relapsers (OR 4.25, 95% CI 2.15 to 8.40); concurrent use among relapsers stood at 3.7% (95% CI 2.0% to 6.5%,  $n = 12$ ) compared with 14.0% (95% CI 10.3% to 18.7%,  $n = 38$ ) among continuous abstainers. The difference between ex- and current smokers was attenuated but remained significant when excluding those who used e-cigarettes only (OR 2.91, 95% CI 1.38 to 6.11) with 3.5% (95% CI 1.9% to 6.3%,  $n = 10$ ) of relapsers and 9.5% (95% CI 6.4% to 13.8%,  $n = 25$ ) of abstainers still using NRT.

**TABLE 41** Baseline characteristics as a function of availability of follow-up questionnaire data

Baseline characteristics	Follow-up at 12 months	
	Responded ( <i>N</i> = 1047)	Did not respond ( <i>N</i> = 681)
<b><i>Sociodemographic/health characteristics</i></b>		
Age (years), mean (SD)	46.4 (14.0)	41.1 (13.7)***
Female, % ( <i>n</i> )	55.0 (576)	53.6 (365)
White, % ( <i>n</i> )	97.2 (1018)	94.7 (645)**
Cohabiting, % ( <i>n</i> )	53.4 (559)	47.3 (322)*
Routine/manual occupation, % ( <i>n</i> )	30.9 (323)	34.5 (235)
Degree or equivalent, % ( <i>n</i> )	10.6 (111)	10.4 (71)
Medical condition, % ( <i>n</i> )	59.5 (622)	52.9 (360)**
<b><i>Smoking characteristics</i></b>		
HSI, mean (SD)	3.28 (1.45)	3.22 (1.46)
Smoking length < 10 years, % ( <i>n</i> )	10.9 (114)	17.4 (118)***
Quit attempt last 12 months, % ( <i>n</i> )	41.7 (434)	41.0 (275)
<b><i>SSS treatment characteristics</i></b>		
<i>Intervention type, % (<i>n</i>)</i>		
Closed group	3.2 (34)	2.9 (20)
Open (rolling) group	20.8 (218)	17.6 (120)
Drop-in clinic	26.5 (277)	27.2 (185)
One-to-one support	49.2 (515)	51.9 (353)
Other	0.3 (3)	0.3 (2)
<i>Medication, % (<i>n</i>)</i>		
Single NRT	17.4 (182)	17.9 (122)
Combination NRT	12.2 (128)	15.1 (103)
Varenicline	50.2 (526)	48.5 (330)
Other	19.0 (199)	17.0 (116)
None	1.1 (12)	1.5 (10)
*, <i>p</i> = 0.05; **, <i>p</i> = 0.01; ***, <i>p</i> = 0.001; HSI, Heaviness of Smoking Index; SD, standard deviation.		



**FIGURE 8** Prevalence of (a) length of NRT use following quit date and (b) product type used long term. a, Continuing users at follow-up (this includes e-cigarettes and provides base for *Figure 8b*). b, No use of nicotine nasal spray.

*Figure 8b* provides a breakdown of the prevalence of products used as well as the incidence of multiple use. Overall, e-cigarettes were the most popular product followed by the nicotine lozenge, patch and gum. Microtab (Nicorette®, McNeil) and nasal spray were the least popular products. Around 20% of clients were using multiple products. Owing to the small numbers involved (only 50 clients used products long term), there was insufficient power to detect meaningful differences between those who had remained abstinent and those who had relapsed. However, the use of the nicotine patch appeared particularly prevalent among current smokers, while the use of e-cigarettes, gum and the inhaler was more common among ex-smokers.

### Impact of longer-term nicotine replacement therapy use on biomarkers of nicotine exposure and stress among current smokers and ex-smokers

A total of 258 participants (8.5% of the whole sample) provide baseline and follow-up saliva samples and therefore formed the analytic sample for the biomarker analysis. Table 42 shows the characteristics of those who did or did not provide saliva samples at baseline or follow-up. As can be seen, those providing samples at baseline were younger, more likely to be male and non-white, and slightly less likely to be cohabiting. There were also some differences in the treatment sought (they were less likely to have used varenicline or gone to a drop-in clinic) but there were few differences in terms of smoking characteristics.

**TABLE 42** Baseline characteristics as a function of baseline and follow-up sample availability

Baseline characteristics	Baseline		Follow-up at 12 months	
	Sample available (n = 1875)	No sample available (n = 1170)	Sample available (n = 258)	No sample available (n = 454)
<b>Sociodemographic/health characteristics</b>				
Age, mean (SD)	41.7 (14.1)	43.7 (14.1)***	45.7 (13.4)	42.2 (14.6)**
Female, % (n)	52.7 (989)	60.9 (713)***	51.6 (133)	48.7 (221)
White, % (n)	95.0 (1782)	97.5 (1141)***	96.5 (249)	93.8 (426)
Cohabiting, % (n)	45.4 (852)	49.5 (579)*	53.9 (139)	44.9 (204)*
Routine/manual occupation, % (n)	30.6 (573)	31.1 (364)	25.2 (65)	30.6 (139)
Degree or equivalent, % (n)	8.9 (167)	10.5 (123)	10.5 (27)	9.3 (42)
Medical condition, % (n)	55.5 (1041)	57.3 (670)	57.4 (148)	58.4 (265)
<b>Smoking characteristics</b>				
HSI, mean (SD)	3.39 (1.46)	3.37 (1.43)	3.19 (1.54)	3.51 (1.41)**
Smoking length < 10 years, % (n)	16.6 (308)	13.6 (159)*	9.3 (24)	14.3 (65)
Quit attempt last 12 months, % (n)	41.3 (752)	41.6 (485)	38.1 (98)	38.4 (172)
<b>SSS treatment characteristics</b>				
Intervention type, % (n)	–	***	–	*
Closed group	4.5 (84)	1.5 (18)	6.6 (17)	4.6 (21)
Open (rolling) group	19.0 (357)	16.2 (189)	21.3 (55)	13.9 (63)
Drop-in clinic	25.4 (476)	35.2 (411)	24.4 (63)	30.4 (138)
One-to-one support	50.8 (952)	46.8 (547)	47.7 (123)	50.7 (230)
Other	0.3 (6)	0.3 (4)	0 (0)	0.4 (2)
Medication, % (n)	–	***	–	**
Single NRT	17.3 (323)	23.0 (269)	17.4 (45)	15.2 (69)
Combination NRT	21.4 (400)	14.2 (166)	16.3 (42)	27.3 (124)
Varenicline	41.4 (774)	45.7 (534)	48.4 (125)	37.4 (170)
Other	16.9 (316)	14.4 (165)	16.3 (42)	19.2 (87)
None	2.9 (55)	3.0 (35)	1.6 (4)	0.9 (4)
*, $p = 0.05$ ; **, $p = 0.01$ ; ***, $p = 0.001$ ; HSI, Heaviness of Smoking Index; SD, standard deviation.				

At follow-up, those who provided a saliva sample were older and more likely to be cohabiting. Again, there were some treatment differences (they were less likely to have used a drop-in clinic but more likely to have used varenicline). Clients for whom a follow-up sample was available had lower baseline levels of dependence (likely reflecting the lower response rate among those who smoked at 4 weeks compared with those who had stopped at 4 weeks).

Table 43 provides an overview of available viable cotinine and alpha-amylase saliva samples as function of smoking status and NRT use. Unfortunately, some samples provided insufficient saliva or were contaminated and, therefore, cotinine and/or alpha-amylase levels could not be determined (5.7%). In addition, a number of participants (18.1%) provided only one rather than two saliva samples at either baseline or follow-up, which meant not all analytes could be assessed. However, in each of the relevant subgroups at least 50% of the analytic sample had a complete set of data on all analytes, and at least 67% and 58% had both baseline and follow-up data on cotinine and alpha-amylase, respectively.

**TABLE 43** Biomarker results availability by follow-up NRT use and smoking status

Biomarker results availability	Smokers		Quitters	
	NRT use (n = 18)	No NRT use (n = 73)	NRT use (n = 12) <sup>a</sup>	No NRT use (n = 153)
Baseline assessment				
Cotinine sample, % (n)	94.4 (17)	93.2 (68)	91.7 (11)	95.4 (146)
Alpha-amylase sample, % (n)	66.7 (12)	61.6 (45)	75.0 (9)	71.2 (109)
Follow-up assessment				
Cotinine samples, % (n)	88.9 (16)	94.5 (69)	75.0 (9)	97.4 (149)
Alpha-amylase samples, % (n)	72.2 (13)	58.9 (43)	75.0 (9)	72.5 (111)
All assessments				
Cotinine samples, % (n)	83.3 (15)	89.0 (65)	66.7 (8)	92.8 (142)
Alpha-amylase samples, % (n)	61.1 (11)	57.5 (42)	75.0 (9)	67.3 (103)
All samples, % (n)	61.1 (11)	53.4 (39)	58.3 (7)	66.0 (101)
<sup>a</sup> Original sample (n = 14) included two e-cigarette only users who have been removed.				

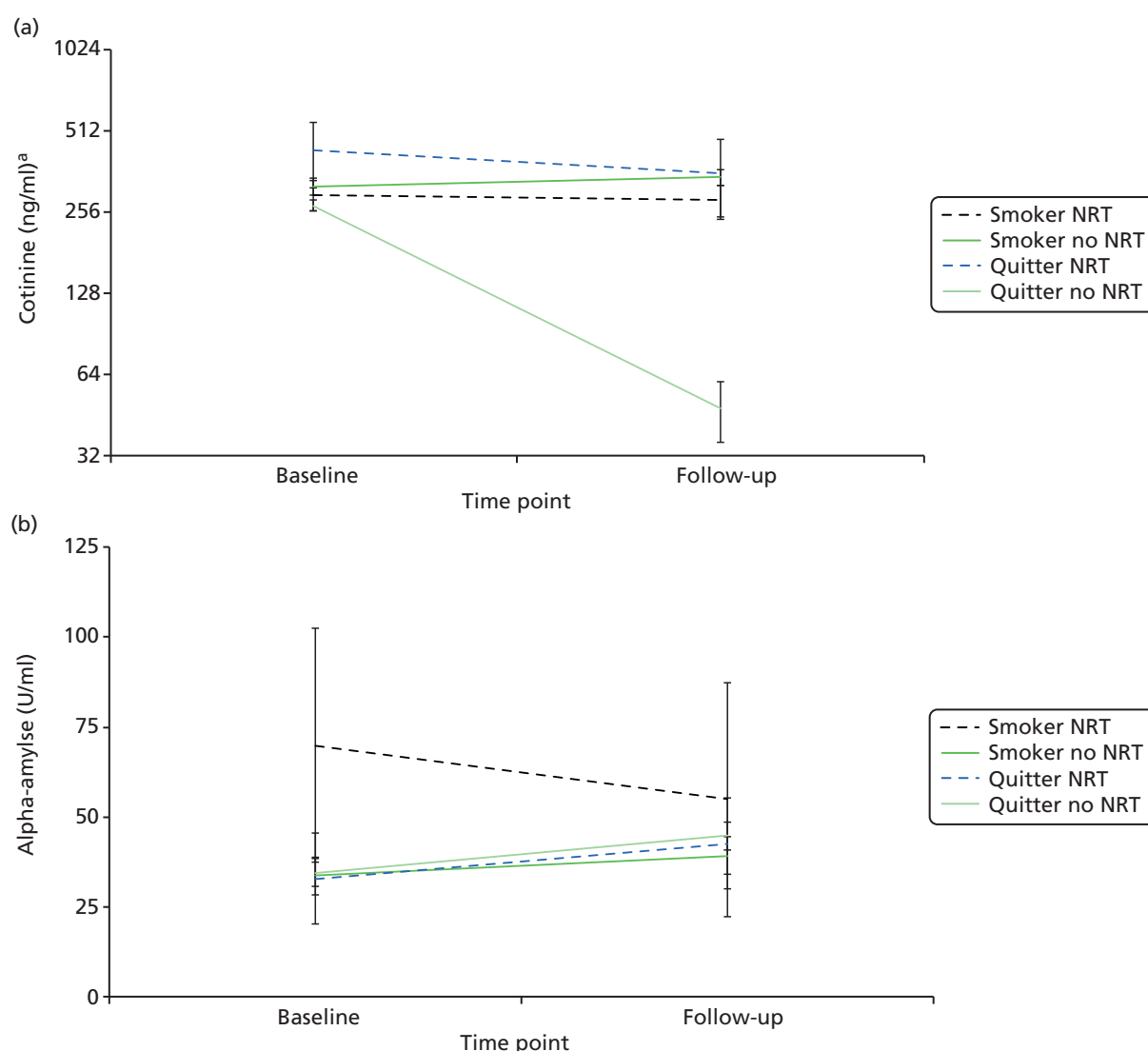
As can be seen in *Table 44*, there were some differences in baseline cotinine levels between groups ( $p = 0.025$ ). Those who had stopped smoking at follow-up and were still using NRT had higher levels than other groups. However, these overall differences in baseline cotinine became barely significant when adjusting for potential confounders (age, gender, ethnicity, occupation, any medical condition and nicotine dependence;  $p = 0.245$ ) and after taking into account multiple comparisons, quitters who used NRT at follow-up, did not differ from any other group. In addition to older age ( $p = 0.011$ ), dependence as measured by the Heaviness of Smoking Index was the only other significant predictor ( $p < 0.001$ ). There were no differences as a function of NRT use and smoking status at follow-up in baseline levels of alpha-amylase ( $p = 0.956$ ). This was confirmed in adjusted analysis ( $p = 0.185$ ), which showed that older age ( $p = 0.001$ ), being non-white ( $p = 0.021$ ) and having any medical condition ( $p = 0.002$ ) were associated with higher alpha-amylase activity at baseline.

There was a clear difference between groups in follow-up cotinine levels ( $p < 0.001$ ), confirmed in adjusted analysis ( $p < 0.001$ ). Non-NRT users who were abstinent had significantly lower cotinine values than smokers with ( $p = 0.017$ ) or without concurrent NRT use ( $p < 0.001$ ) but not compared with quitters who used NRT ( $p = 0.232$ ). Baseline nicotine dependence was the only other significant predictor ( $p < 0.001$ ). Yet, even among CO-validated non-smokers at follow-up who indicated that they did not use NRT, over one in five had cotinine values above the usual cut-off level, suggesting either a high rate of deception in this group or undeclared use of other nicotine-containing products. No differences were apparent in alpha-amylase levels at follow-up ( $p = 0.684$ ), confirmed in adjusted analysis ( $p = 0.734$ ). Only lower dependence at baseline had an association with greater follow-up alpha-amylase activity ( $p = 0.004$ ) but none of the other covariates or factors were associated.

**TABLE 44** Biomarker results by follow-up NRT use and smoking status

Biomarker results	Smokers		Quitters	
	NRT use ( $n = 18$ )	No NRT use ( $n = 73$ )	NRT use ( $n = 12$ )	No NRT use ( $n = 153$ )
<b>Baseline assessment</b>				
Cotinine (ng/ml), mean (SEM)	280.2 (36.7)	320.1 (22.0)	414.3 (90.4)	270.1 (13.7)
Alpha-amylase (U/ml), mean (SEM)	75.6 (41.2)	32.6 (4.4)	32.8 (7.4)	34.9 (3.2)
<b>Follow-up assessment</b>				
Cotinine (ng/ml), mean (SEM)	280.6 (36.6) <sup>a</sup>	333.1 (22.3) <sup>a</sup>	324.4 (102.5) <sup>a</sup>	45.8 (9.7) <sup>b,c</sup>
Alpha-amylase (U/ml), mean (SEM)	48.3 (17.7)	39.4 (5.7)	42.6 (17.7)	43.7 (4.2)
SEM, standard error of the mean.				
a Statistically significantly different ( $p = 0.05$ ) with quitters using no NRT.				
b Statistically significantly different ( $p = 0.05$ ) with quitters using NRT.				
c Of the sample of CO-verified quitters with no self-reported NRT use ( $n = 141$ ), this means that 31 (22.2%) had values above the usual cut-off level of 15 ng/ml to identify smokers.				
d Statistically significantly different ( $p = 0.05$ ) with smokers using no NRT.				

Changes in biomarkers from baseline to follow-up were analysed in those with complete data (Figure 9). For cotinine values, greater dependence at baseline was associated with an increase in cotinine levels ( $p = 0.047$ ). In addition, over and above an expected main effect of smoking status ( $p < 0.001$ ), there was a significant NRT use by smoking status interaction ( $p = 0.021$ ). This can be seen clearly in Figure 9a. Compared with current smokers, there was a significant reduction in cotinine values only among quitters who did not use NRT or put differently, smoking status did not have an impact on cotinine values among those who used NRT but did among those who did not. By contrast, there was no discernible impact of either smoking status or NRT use on alpha-amylase activity (see Figure 9b). However, there was a marginal effect of dependence ( $p = 0.062$ ) and ethnicity ( $p = 0.052$ ) on changes in alpha-amylase activity. Both lower baseline nicotine dependence and non-white ethnicity were associated with an increase in alpha-amylase activity across time.



**FIGURE 9** Change in (a) cotinine levels and (b) alpha-amylase activity from baseline to follow-up as a function of NRT use and smoking status at follow-up. a, Plotted on log-2 scale.

## Summary of key points

- Just over one-third of the ELONS prospective study participants provided information on longer-term NRT use ( $n = 1047$ ) and were included in this addition to the main ELONS study.
- Of clients followed up at 12 months, 61.5% reported that they had used NRT during their initial quit attempt. However, this is likely to include over-the-counter use, as this number is substantially higher than the number of participants recorded as using NRT by the services (34.4%).
- Most clients who started on NRT used it for at least 8 weeks and more than one in five (21.5%) used it for longer than the standard 3 months.
- Long-term use was relatively rare with fewer than 1 in 10 participants still using non-combustible nicotine products at 12-months follow-up (8.4%).
- Within this category of non-combustible nicotine products were e-cigarettes. Few participants reported their use at 1 year, just 2.9%, although these data include smokers and non-smokers and most people had relapsed by 1 year post quit date. However, e-cigarettes were the most popular single product at 1 year (used more commonly than the gum, lozenge or patch).
- Long-term ex-smokers had much higher odds of still using non-combustible nicotine products at 12-month follow-up than those who relapsed. Concurrent use among relapsers was 3.7%, compared with 14.0% of continuous abstainers. This difference remained significant even after removing those who used e-cigarettes only.
- In terms of the biomarker analysis, 258 participants (8.5% of the whole ELONS study sample) provided baseline and follow-up saliva samples and were included. Greater levels of cotinine (a metabolite of nicotine) were associated with greater self-reported dependence. As expected, within-group analysis showed that smokers who had stopped had significantly lower cotinine levels at follow-up than those who had relapsed to smoking at follow-up. However, this was the case for only ex-smokers who did not use NRT. Cotinine levels for smokers who had stopped at follow-up but who used NRT long term had not changed from baseline to follow-up and neither did cotinine levels for those who had relapsed to smoking (irrespective of NRT use). There were no differences as a function of NRT use and smoking status at follow-up in baseline levels of alpha-amylase, a biomarker of stress.



## Chapter 10 Discussion

The UK remains one of very few countries in the world that offers free at the point of use treatment services for people seeking support to stop smoking.<sup>10</sup> These services form an important part of a wider network of policies aimed to reduce smoking rates, including policies such as tobacco taxation, mass media campaigns, bans on advertising and Smokefree laws.<sup>15</sup> The ELONS study was designed to provide up-to-date evidence on the effectiveness of these SSSs, building on earlier research. As routine data collected by the services reports on only short-term outcomes and is limited in detail, this study was also intended to examine longer-term outcomes and explore the factors that influence quit rates.

The findings raise a number of issues. Here we reflect on the results, focusing on key themes:

- short- and longer-term cessation rates in context
- the influence of client characteristics
- the influence of service characteristics
- satisfaction with services
- well-being
- longer-term use of NRT
- limitations
- future research.

### Short- and longer-term cessation rates in context

This study examined smoking cessation in the short term (at 4 weeks) in two ways: through an analysis of routine data and through the prospective study. Our prospective study results were broadly comparable with those from routinely collected data from services. Among 3000 smokers attending SSSs in nine areas of England, we found that just over 4 in 10 (41.2%) were biochemically validated as abstinent from smoking at 4 weeks post quit date. Our secondary analysis of routine data from 49 of 150 services in England found 4-week quit rates of 48% when self-reported data were included, falling to 34% when biochemical validation had occurred. This same analysis found that services were reaching up to 10% of smokers in their area in the year from July 2010, with the majority coming from more-deprived areas. NICE guidance previously recommended that services aim to reach at least 5% of their smoking population in a year.<sup>21</sup> These results provide suggest that (a) routine data provide a useful and not inaccurate indicator of short-term smoking cessation outcomes and (b) services are continuing to effectively reach smokers and support them to stop.

In the longer term, we found that fewer than 8% of smokers were still abstinent from smoking 1 year after setting a quit date with their local service. Outcomes were influenced by characteristics of clients and there was also a clear link with service characteristics such as the type of behavioural support received, and the background and training of the smoking cessation practitioner.

Cessation rates identified in this study were lower at both 4 and 52 weeks than in our previous research conducted over a decade ago as part of a 'national' evaluation of the services in England shortly after they were established.<sup>17,18</sup> At face value it might be assumed that service standards had slipped in the intervening period, but our view is that this is too simplistic an explanation. Our earlier work was conducted with just two (albeit large) services that performed better than the national average based on comparisons with routine data. The ELONS study purposively selected nine services that offered different types of interventions in a range of settings, some of which reported quit rates higher than the national average while others reported lower rates. In addition, the configuration of services has changed in the last

decade and there is clearly a greater reliance on community practitioners (such as pharmacists and practice nurses) with lower short-term quit rates delivering support rather than specialist smoking cessation staff. Others have argued that the smoking population itself may have changed<sup>84,85</sup> and that remaining smokers are more nicotine dependent and find it harder to stop. Research design differences between the studies may also explain some of the difference.

Despite rates of abstinence from smoking being lower in the ELONS study than in some previous studies with service clients, they remain significantly higher than in untreated populations. Previous research with 'self-quitters' not participating in a smoking treatment programme has estimated abstinence rates at 25% at 4 weeks,<sup>42</sup> which is considerably lower than the overall 4-week quit rate (41%) and the lowest 95% CI boundary (36%). At 1 year, abstinence rates with self-quitters are approximately 3%,<sup>86</sup> considerably lower than the 8% found here. Thus the behavioural support and stop smoking medication provided by the services makes a significant difference and improves outcomes for individual smokers. The ELONS study is consistent with previous studies in demonstrating this.<sup>7,17</sup>

The ELONS study only assessed smoking status up to 1 year after an initial quit attempt, yet it is possible to extrapolate our results to estimate the number of life-long non-smokers achieved.

The study took place during the financial year 2012–13. In that year, routine data returns from all SSSs in England showed that 724,247 quit dates were set.<sup>87</sup> Applying the ELONS study results (8% quit at 1 year), 55,767 would have been CO validated as abstinent at 1 year. The best estimates of the relapse rate to smoking after 1 year are 35%.<sup>88</sup> This would leave 36,249 lifelong abstinent quitters. This is a substantial figure and is one indicator of the ongoing value of the life-saving treatment that the services provide.

## The influence of client characteristics

Consistent with other studies, we found that smoking cessation outcomes varied significantly between different groups of people who accessed SSSs. At 1 year, for example, a number of client characteristics were associated with either maintaining abstinence or having relapsed to smoking. As other studies have found, the odds of maintaining a quit attempt increased with age.<sup>89,90</sup> This may be caused by a range of factors including learning from previous quit attempts, contact with health services, personal circumstances (such as the death of loved ones owing to smoking-related disease) or for some, additional time to commit to focusing on getting the most from the support on offer. Individuals with higher levels of well-being when they began their quit attempt were more likely to be successful in the longer term, as were those who had fewer smokers in their social network – neither of these findings are surprising but being aware of these factors may be useful for practitioners treating smokers.

Although some predictors of relapse to smoking identified in previous studies did not quite reach significance here (e.g. level of dependence on smoking, lower levels of determination to quit), others did, including deprivation. More disadvantaged clients were less likely to remain abstinent from smoking at 1 year, as our previous work and that of others has shown.<sup>18,91,92</sup> Thus, although SSSs are able to reach significant numbers of smokers living in disadvantaged areas,<sup>19</sup> these smokers face additional barriers to quitting. This poses challenges for service delivery, and requires time and resources to ensure particularly effective forms of support (including medication) are delivered to those who need it most.

## The influence of service characteristics

Client characteristics cannot be easily modified, but service characteristics can, and our findings show that some interventions are more effective than others. We found that smokers supported to quit with specialist services (including group behavioural support and one-to-one support from a specialist) were more likely to have stopped smoking in the longer term. This is consistent with other studies<sup>24,44,93</sup> and

reflects the training and expertise that specialist practitioners have, and also that they see more smokers than part-time (level 2) practitioners and are therefore more likely to maintain standards of knowledge and practice. Time and resource pressures in settings such as GP practices and pharmacies may also contribute to poorer outcomes for clients of non-specialists.<sup>94,95</sup>

Important differences in outcomes between forms of behavioural support were also identified. Clients attending open groups achieved the highest quit rates and maintained the highest ORs compared with other forms of behavioural support, even after controls. These results reflect those of our previously published paper<sup>26</sup> on the success of open groups.

In addition, we found that drop-ins (i.e. where people can simply drop-in to see a SSS practitioner without an appointment) did not result in as positive cessation outcomes as other types of support types. Potential reasons for this lower performance might include less client motivation contact (especially if demand is high) or drop-ins being selected by smokers who were less likely to quit, or that practitioners have limited capacity to plan and deliver effective behavioural support within this setting.

One of the objectives of this study was to provide guidance on interventions that will have maximal benefits. From the secondary analysis it would appear that the services that had the highest impact focused on quit rates rather than throughput. The results from the prospective study suggest that services will be particularly effective in terms of achieving long-term cessation if they provide groups or one-to-one support by specialist practitioners.

## Satisfaction with services

Feedback from patients or clients is important to inform service development. In our satisfaction survey of SSS clients, we found that those who responded had a positive experience, and this was true both for those who were successful in stopping smoking and those who were not. The vast majority of participants who replied to the questionnaire indicated that they would recommend the service to others and return should the need arise. In addition, we found several examples of good practice where SSSs have offered more than they are required to do by national service standards.<sup>96</sup> This included, for example, contacting clients before their first appointment to encourage them to attend and offering child care and a choice of behavioural support options.

Additional comments highlighted the importance of practitioner/client rapport. In addition, despite many clients finding stop smoking medication easy to acquire, additional comments pointed to a more complex picture where the process of obtaining medication was overcomplicated and time-consuming for some respondents. Suggested improvements to the SSS centred on evening appointment times, having a choice of group or one-to-one support and a longer period of support.

Analysis of client satisfaction between quitters and non-quitters, SSS location and behavioural support types revealed some small but significant differences. Those who had stopped smoking were more likely to be satisfied with staff supportiveness and happier to return to the services if needed, with the information provided and CO validation. Open-group clients were also more positive about staff supportiveness, returning to the service and CO testing. GP practice clients were least comfortable with CO testing.

Despite an encouraging response rate (response to self-completion postal surveys are generally low, even with repeated reminders) clients who were motivated to complete the survey were also more likely to have had a successful quit attempt. This means the views of those who did not quit are under-represented.

## Well-being

As outlined earlier in the report, we included a modest exploratory study of well-being and smoking cessation within the ELONS prospective study. Positive well-being at baseline significantly predicted abstinence from smoking 1 year later. Although few other studies have looked at positive well-being, research has found that psychological distress and mental health conditions can reduce the chances of successfully stopping smoking.<sup>57,97,98</sup> Smokers in these previous studies have reported experiencing more negative moods shortly after quitting that may be related to relapse.<sup>98</sup>

In our analysis we did not find that levels of well-being changed significantly over time, unlike a previous systematic review.<sup>50</sup> Those who stopped smoking did tend to have higher well-being than non-quitters at all time points. This suggests that the level of well-being at baseline is important as a predictor of who may quit smoking, and that this difference is maintained.

Clients who managed to stop smoking in the ELONS study and who completed the well-being survey were more likely to agree that they felt in control. Feelings of control have not received much attention in the context of smoking cessation, although perceived control has been found to positively influence intention to quit smoking.<sup>99</sup> In addition, having financial difficulties, which could signify feelings of a lack of control, has been associated with fewer quit attempts and less success in the quit attempts that did take place.<sup>100</sup>

Clients who were more dependent on tobacco at baseline had lower well-being at all three time measurement points. This was possibly mediated by being unable to cope with stress. Other studies have found that stress is associated with higher levels of smoking.<sup>101,102</sup> Neurologically, this may be related to higher levels of cortisol and adrenocorticotrophic hormone as a response to stress.<sup>103</sup> However, despite smokers stating that they smoke to cope with stress, higher levels of stress have been found among smokers,<sup>104</sup> which then declines with smoking cessation.<sup>105</sup> Thus, smoking tobacco (rather than stopping) appears to be associated with heightened feelings of stress. This is an important message for services to communicate to clients.

Well-being was low among many smokers approaching the SSS, and well-being is a predictor of smoking cessation success. This raises the issue of whether or not it could be helpful to train practitioners in techniques such as cognitive-behavioural therapy, or alternatively employ practitioners already qualified with cognitive-behavioural therapy, in order to address feelings of stress and insufficient control.

## Longer-term use of nicotine replacements therapy

We found that over one in five NHS SSS clients who achieved short-term abstinence reported continuing to use NRT beyond the standard treatment length of 3 months. However, complete substitution of cigarettes with non-combustible nicotine products long term was less common, at just below 10%. In our previous 'national' evaluation of SSSs in England, conducted in Nottingham and North Cumbria in 2002, self-reported longer-term NRT use at 1 year was just 5%.<sup>106</sup> This means that more people may now be using cleaner forms of nicotine longer term, with 6% of our sample reporting using NRT at 1 year and 2.9% using e-cigarettes at 1 year post quit date. Recent policy and licensing changes in favour of harm reduction<sup>70,82</sup> may have offered some reassurance in this regard, although it is worth noting that the reported rate of longer-term e-cigarette usage in the ELONS study is low compared with the estimates of one in five smokers or recent ex-smokers using e-cigarettes in the general population.<sup>107</sup>

Concurrent long-term use of NRT among SSS clients in the study who have relapsed to smoking, reflecting partial substitution, was much lower at fewer than 4%. This is in agreement with similar figures from the general population suggesting that longer-term NRT use among smokers is rare.<sup>108</sup> Indeed, concurrent NRT use among smokers, either for temporary abstinence or cutting down, has remained relatively stable since 2002<sup>109</sup> and mostly reflects short-term use.<sup>108</sup>

This study provides some rare insights in the exposure to nicotine associated with single use or long-term dual use of NRT as well as its impact on a biological indicator of stress, alpha-amylase. Clinical trials suggest that permanent replacement of cigarettes with NRT among ex-smokers can result in 40% of baseline levels of nicotine being substituted by nicotine-replacement products.<sup>110,111</sup> Although the cross-sectional analysis did not detect a significant increase in cotinine levels among ex-smokers using NRT compared with those not using NRT, the within-group analysis suggests that virtually all baseline nicotine may be replaced by NRT among long-term ex-smokers. This finding is against a background of excluding participants from analysis based on CO verification of their smoking status and concurrent use of other nicotine delivery devices, that is, e-cigarettes. Moreover, confirming previous research,<sup>67,112</sup> the concurrent use of NRT among smokers did not appear to increase their nicotine intake. These findings reflect that smokers are very adept at titrating nicotine levels, with some nicotine otherwise obtained from cigarettes being replaced by nicotine from NRT.<sup>113</sup> However, our results indicate this may also apply to ex-smokers, which is consistent with a strong genetic component in nicotine intake,<sup>114</sup> but at odds with clinical studies showing that nicotine substitution from NRT tapers off over time.<sup>110</sup> The fact that long-term use among ex-smokers did not result in a decrease in cotinine levels, however, does not mean that long-term use maintains addiction to nicotine. Although we controlled for baseline characteristics, the study design cannot exclude reverse causation, that is, the fact that particular individuals who happen to have a high sensitivity to nicotine intake, use NRT for longer.

Although it is unlikely that a substantially increased nicotine intake from NRT would be harmful,<sup>115,116</sup> it clearly is a concern for some people and a potential barrier to effective use of nicotine products.<sup>74</sup> Our results do not suggest that NRT use leads to an increased intake compared with continued smoking. Moreover, there was no evidence that use of NRT (either concurrently or among ex-smokers) was associated with an increase in a biomarker of stress response, alpha-amylase, used as a proxy here to signal potential harm. The somewhat paradoxical finding that greater activity in alpha-amylase at follow-up and an increase in alpha-amylase activity across time were both associated with lower nicotine dependence is likely because tobacco smoke has been shown to acutely inhibit alpha-amylase activity.<sup>117</sup> Given that lower nicotine dependence was associated with lower exposure to tobacco smoke, as measured by cotinine levels, and smaller increases in cotinine levels from baseline, the inhibitory action of tobacco smoke on alpha-amylase in this group of users was therefore likely to be smaller. Altogether, these findings suggest that long-term NRT use is safe and not associated with increased health risks, certainly compared with continued smoking.<sup>78</sup>

## Limitations

Each element of the ELONS study had a number of limitations. For example, in the secondary analysis our estimates of the reach of the services were based on estimates of both the number of smokers and the population in the PCT. We also assumed that smoking declined uniformly by 4% in all PCTs between 2003 and 2005, and also in 2009, when it is likely that the smoking rate declined more in PCTs with an affluent population and less in PCTs with a more disadvantaged population.<sup>118</sup> For all but the impact analysis we assumed that each client in the database was unique when we estimated that 8% of clients used the SSS more than once during the year. However, the consistency of our estimates between PCTs (the majority between 5% and 12%) and the consistency of quit rates calculated for unique clients and client records gives support to the technique used.

Other limitations pertain to the use of routine monitoring data with pre-set variables: SES was measured using NSSEC, IMD and free prescriptions. NSSEC is complicated to classify and may not reflect SES for clients who are not the chief income earner of the household. IMD was included at PCT level, which is large geographically and may explain the lack of significant results. Eligibility for free prescriptions can be for medical or age reasons in addition to low income. In the analysis all ethnic minorities were compared with white people. Ethnicity was not disaggregated further because of small numbers.

The secondary analysis includes only data from PCTs who agreed to their QuitManager data set being used for research purposes. North 51 is based in Nottingham, which may be the reason for a concentration of PCTs in central England. Nevertheless there are PCTs included in all regions of England from County Durham and Darlington in the North East to Bristol in the South West. Comparison with 2010/11 data for all English PCTs found similar rates of self-report quit and CO validation. Furthermore, the self-reported quit rate for all English SSSs from April 2010 to March 2011 was also 49%, and 70% were CO validated<sup>43</sup> compared with 74% in the secondary analysis sample suggesting that the sample were representative of the whole.

Some of the limitations of the secondary analysis were ameliorated by the prospective study. These include, for example, only short-term follow-up data collected for routine monitoring, which may be of lower quality, and inconsistently collected data on levels of tobacco dependence and social support, which could not be used in the analysis. Data on the practitioner type was also poorly collected, perhaps partly because the DH does not publish it.

However, the prospective study also had limitations, the most substantial being recruitment. Reasons for this are discussed in detail in *Chapter 5*, but were partly because of the cumbersome consent process to the study required by ethical review and the need for all aspects to be classified as research (rather than service evaluation) to be eligible to become a NIHR portfolio study and access service support costs. This type of consent process would be expected and appropriate in a trial or study of a new intervention, but it is problematic in an observational study of an existing service. Far simpler questions and a simpler process (such as those we have been permitted to use in earlier studies with NHS SSSs) could still have protected client confidentiality.

In addition, policy and service changes also affected recruitment, as described in *Chapter 5*. The result was that we recruited only a small proportion of eligible service clients in each study area. To overcome the low response rate we have used weighting and multivariable analysis. However, CIs of quit rates for many behavioural support types were wide and it may be that some non-significant differences are a consequence of the study being underpowered.

Owing to selection of the PCTs for the secondary analysis and the prospective study being limited to services that used Quit Manager software, this could raise issues of validity – specifically representativeness. If we redid, in particular the prospective study, with completely different areas, we might have obtained slightly different results. This is an important caveat. That said, we did try as much as possible to recruit areas in varying parts of the country that offered a range of types of interventions as outlined in *Chapter 5*. However, it should be remembered that the 4-week quit rate for the prospective study was 41.2%, which is remarkably similar to the quit rate for England from April 2012 to March 2013 (37%)<sup>31</sup> given the impact profile of the PCTs that enrolled in the study (see *Chapter 4*). Moreover, the ELONS prospective study sample differed little in terms of demographic characteristics to all the clients that attended the nine services. This should go some way to allay concerns about representativeness.

There are data collection issues common to both the secondary analysis and the prospective study that focus on issues of definition of interventions that were beyond our control. In brief, we were dependent on local understandings of what formed different behavioural support types for example, and different settings for delivery and practitioner categories. In the 4-week analysis in the prospective study we were also dependent on local data collection being accurate and timely, which we suspect it was not in all cases. Busy practitioners do not always collect the best data, for a variety of reasons. This may explain some of the differences between the 4-week results that go against the findings of previous studies,<sup>7,17</sup> in particular our findings around combination NRT not being as effective as other medication forms. This finding was not carried through into the 52-week results, where we saw results that were more consistent with previous research.



We treated group clients as independent, whereas the chances of a group member quitting may depend to some extent on the other group members and the culture of the group. The effect of a group is very difficult to take into account especially for open groups where members change and the number of sessions attended may vary markedly.<sup>119–121</sup>

The well-being and client satisfaction elements of the ELONS study also had limitations. At baseline, the WHO-5 items were included in routine monitoring questions administered by practitioners so almost all participants had well-being data at this stage. At follow-up the well-being questions were included in postal surveys sent to clients' home addresses, as was the satisfaction questionnaire. As with most postal surveys, the response rate was low and caution is therefore required in interpreting the results. For the well-being element in particular, it is also the case that the analysis reported was largely exploratory and any conclusions can only be tentative.

The longer-term NRT element added to the ELONS study also had a number of limitations. Despite an initial large sample size, dropout across the main study was inevitably substantial, resulting in relatively few clients with complete baseline and follow-up data on biomarkers. In addition, the baseline sample differed from the sample followed up. However, differences were relatively modest and therefore unlikely to have substantially biased findings. In addition, weighting was used in the assessment of long-term NRT use prevalence, which should account for differential dropout. Although clients self-selected into groups rather than being experimentally assigned, this reflects real-world use of NRT. Moreover, the study design allowed clients to be their own control, thus further reducing confounding. Assessment was carried out with established, ecologically valid measures and smoking status verified.

## Future research

The study raises a number of issues for future research. First, a significant gap in the research relates to the use of e-cigarettes. When the ELONS study was commissioned in 2010/11, e-cigarette use was still relatively rare, but has grown significantly since then. Although we asked about e-cigarette use in the longer-term NRT study, we did not address it elsewhere. Recent monitoring data and reports from service managers indicate that the 'rise' of e-cigarettes has coincided with a significant drop in SSS client numbers, particularly in the period since the ELONS study was conducted. Future research should examine this issue, and also look at effective ways to combine e-cigarette use with the support provided by services. Useful pilots and some ongoing research in England are already under way, but more is needed.

In addition, previous research has shown that effective behavioural support delivered by trained practitioners roughly doubles smokers' chances of successfully stopping.<sup>122,123</sup> However, there was great variety in the type and, in all likelihood, the quality of the behavioural support provided to the ELONS study participants. This study did not set out to capture factors that affect the quality of behavioural support such as the training status of practitioners (whether NCSCT certified or not), the presence, perception and use of treatment protocols, and the amount of support and supervision available to individual practitioners. This is both a limitation of the ELONS study and an issue to be explored in more detail in further research. Within that, a priority should be to explore in more detail what factors influence the success of a rolling-group model of behavioural support when compared with other options.

For the well-being element, no formal tests for differences between well-being scores over time or between quitters and non-quitters were undertaken. In further analysis, regression models or propensity scores could be used to test relationships more precisely. Alternatively a qualitative approach to well-being may yield insights. For example, interviews or a diary over the quit attempt may aid understanding of how and when well-being changes occur and their relationship to failure or success of the quit attempt. Slightly broader research may also be helpful in this area, examining issues such as insecurities in housing,<sup>124</sup> relationships<sup>125</sup> and income,<sup>100</sup> which may impact on the success of quit attempts. While these wider contributors to poorer well-being are difficult to tackle, helping to create resilience in smokers who face

multiple life challenges may help them to move away from tobacco, which will yield mental as well as physical health benefits for them in the longer term.

We began to explore longer-term use of nicotine-containing products in this study but there is a sizeable research agenda on this topic that is still to be explored. In particular, further research would benefit from measuring a wider array of biomarkers of smoking-related harm, such as lung function tests or carcinogen metabolites to confirm our preliminary results.

Although there are some obvious and clear conclusions from this evidence base (such as behavioural support type and client demographic characteristics) that can guide service delivery, there are some questions that are more difficult to answer – for example, why do some services find it easier to meet targets than others? It is likely that a process evaluation collating qualitative evidence from individual poorly performing services and services with excellent performance would provide further insights into this important area. Additionally, despite non-quitters appearing to be highly satisfied with the services, the low response rate to the CSS calls for more qualitative research among clients who drop out and relapse to understand how the service can support these groups.

Finally, there is a need for ongoing research on NHS SSSs that is useful to inform policy, including determining the factors that contribute to the ongoing development and sustainability of the services. This is useful not only in a UK context but to inform work in other countries to establish or improve the provision of services to support smokers to stop using tobacco.



## Chapter 11 Conclusions

This detailed observational study of smoking treatment services in England has yielded a number of findings that allow us to draw conclusions about the factors that influence outcomes for clients, as well as describe effectiveness in the short and longer term.

In terms of smoking cessation in the short term, the findings of the ELONS study are broadly comparable with those from routinely collected data from services. From our prospective study of just over 3000 smokers attending SSSs in nine areas of England, we found that just over 4 in 10 (41.2%) were biochemically validated as abstinent from smoking at 4 weeks post quit date. The secondary analysis of routine data from 49 of 150 services in England found 4-week quit rates of 48% when self-reported data were included, falling to 34% when biochemical validation had occurred. This same analysis found that services were reaching up to 10% of smokers in their area in the year from July 2010, with the majority coming from more deprived areas. NICE guidance previously recommended that services aim to reach at least 5% of their smoking population in a year.<sup>21</sup> These results provide a useful indicator that (a) routine data provide a helpful and not inaccurate indicator of short-term smoking cessation outcomes and (b) services are continuing to effectively reach smokers and support them to stop.

No routine data exist on longer-term cessation at 1 year and it is some time since a study in England has looked at this issue. We found that just fewer than 8% of smokers were still abstinent from smoking 1 year after setting a quit date with their local service. If these results are applied to all of England, then we estimate that in the year 2012–13 the services supported 36,249 clients to become non-smokers for the remainder of their lives, which is a significant number.

A range of factors, including many linked to the characteristics of clients, but also service characteristics, influenced smoking cessation outcomes in the prospective study. For example, smokers supported to quit with the specialist service were more likely to stop smoking in the longer term. In addition, the ELONS study builds on previous research that shows that longer-term outcomes are influenced by the type of behavioural support a smoker receives – rolling groups resulted in better outcomes than other forms of behavioural support.

Three additional elements were added to the ELONS study that were more exploratory in nature. These focused on client satisfaction, well-being and longer-term NRT use. Overall, we found that those who responded to the satisfaction survey were positive about the support they received and would recommend SSSs to others. We found that assessment of well-being using a standard set of questions could be included in routine monitoring and that smokers who had higher levels of well-being when they first started attending services were more likely to be non-smokers at 4 weeks and 1 year later. Assessing well-being may therefore help give advisers an indication of who may need more support during their quit attempt. It may also provide an opportunity to help clients make links with other local services or networks who could assist them in improving other aspects of their lives that may be responsible for lower levels of well-being.

The longer-term NRT study found that use of NRT while smoking did not appear to increase overall nicotine intake. Its long-term use among former SSS clients who remained abstinent was not uncommon compared with concurrent use among smokers. Long-term use of NRT did not appear to have a detrimental effect on the chronic stress response among smokers or ex-smokers and did not increase exposure to nicotine among smokers. In contrast, it was associated with continuing high cotinine levels among ex-smokers. This analysis provides some reassurance about longer-term nicotine use when not delivered through tobacco. It builds on earlier research indicating that long-term NRT use is not associated with increased health risks as assessed here, and is certainly safer than continued smoking.



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## Contributions of authors

**Fiona Dobbie** (Research Fellow) was the project manager responsible for delivering the study. She also drafted and edited chapters of the final report, contributed to outputs from the study and delivered presentations at national conferences and to local SSSs.

**Rosemary Hiscock** (Research Fellow) was the lead analyst for the study, selected sites for the prospective study, drafted and edited chapters of the final report, wrote first drafts of journal articles and presented findings at national conferences.

**Jo Leonardi-Bee** (Associate Professor, Faculty of Medicine and Health Sciences) was the project statistician and offered advice to the lead analyst (Rosemary Hiscock). She also assisted with the design and delivery of the study, and commented on all outputs including the final report.

**Susan Murray** (Research Fellow) was the data manager, conducted analysis for the study, and contributed to study outputs and presented findings at a national conference.

**Lion Shahab** (Lecturer in Health Psychology) lead the NRT study, and assisted with the design and delivery of the study. He drafted and edited *Chapter 9* of the final report.

**Paul Aveyard** (Professor of Behavioural Medicine), **Tim Coleman** (Professor of Primary Care), **Andy McEwen** (Executive Director, NCSCT) and **Hayden McRobbie** (Professor of Public Health Interventions) played a key role in all elements of the original design of the study. They advised on aspects of delivery as relevant to their areas of expertise and contributed to all study outputs, including providing detailed feedback on the final report and draft articles.

**Richard Purves** (Research Fellow) assisted with the organisation and analysis of the prospective study and contributed to study outputs.

**Linda Bauld** (Professor of Health Policy) was the principal investigator with overall responsibility for the design, co-ordination and delivery of the study. Along with the co-investigators, she designed the study. She drafted and edited chapters of the final report and contributed to all outputs from the study. She has also led the dissemination of results to date at national and international conferences, and to practitioner audiences.

## Publications

Hiscock R, Murray S, Brose LS, McEwen A, Bee JL, Dobbie F, *et al.* Behavioural therapy for smoking cessation: the effectiveness of different intervention types for disadvantaged and affluent smokers. *Addict Behav* 2013;**38**:2787–96.

Hiscock R, Dobbie F, Bauld L. Smoking cessation and socioeconomic status; an update of existing evidence from a national evaluation of English Stop Smoking Services. *Biomed Res Int* 2015.

## Data sharing statement

Data sharing requests should be directed to the corresponding author.

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# Appendix 1 Data collection instruments

The ELONS prospective study had three stages of data collection.

## *Screening/Baseline Assessment (at quit date):*

- At baseline, when participants set a quit date, monitoring data was collected by SSS advisers along with an optional saliva sample. This included the same routine questions that SSS were already collecting as well as extra question of relevance to ELON.

## *4 weeks post quit date:*

- Self-reported smoking status and CO measurement collected by SSS advisers.
- Advisers also recorded number of weeks of pharmacotherapy (medication) taken and the number of sessions each client attended.
- Client satisfaction and wellbeing questionnaire was posted to participants' home address.

## *52 weeks post quit date:*

- All participants who had quit at four weeks were followed up by telephone interview to identify self-reported smoking status. If they reported that they were abstinent from smoking, a home visit was arranged to record CO measurement and collect a saliva sample.

Data collection tools for each stage are included below.

## **ELONS prospective study baseline data collection**

Data confidentiality and security		
This information will be stored on a secure computer and sent in an anonymised form to a University research team who are helping us to improve our service.		
For practitioner to complete:		
Practitioner type: (primary role)		
<input type="checkbox"/> <sub>1</sub> Practice nurse	<input type="checkbox"/> <sub>6</sub> Pharmacist	<input type="checkbox"/> <sub>11</sub> Specialist smoking practitioner
<input type="checkbox"/> <sub>2</sub> GP	<input type="checkbox"/> <sub>7</sub> Dispenser	<input type="checkbox"/> <sub>12</sub> Other (please write in)
<input type="checkbox"/> <sub>3</sub> Health Care Assistant	<input type="checkbox"/> <sub>8</sub> Counter Assistant	
	<input type="checkbox"/> <sub>9</sub> Dentist	

<input type="checkbox"/> <sub>4</sub> Health trainer <input type="checkbox"/> <sub>10</sub> Dental nurse ..... <input type="checkbox"/> <sub>5</sub> Receptionist	
Setting: (where session(s) with this client take place) <input type="checkbox"/> <sub>1</sub> GP practice <input type="checkbox"/> <sub>5</sub> ..... <input type="checkbox"/> <sub>9</sub> Home visit <input type="checkbox"/> <sub>2</sub> Pharmacy    Workplace/college/school <input type="checkbox"/> <sub>10</sub> Other (please write in) <input type="checkbox"/> <sub>3</sub> Hospital <input type="checkbox"/> <sub>6</sub> Community ..... <input type="checkbox"/> <sub>4</sub> Dental    centre/church ..... practice <input type="checkbox"/> <sub>7</sub> Children's centre <input type="checkbox"/> <sub>8</sub> Prison	
Intervention type: <input type="checkbox"/> <sub>1</sub> One to one <input type="checkbox"/> <sub>3</sub> Open/rolling group <input type="checkbox"/> <sub>5</sub> Other (please write in) <input type="checkbox"/> <sub>2</sub> Drop in <input type="checkbox"/> <sub>4</sub> Closed group .....	
Medication given to this client: (tick all that apply) <input type="checkbox"/> <sub>1</sub> Single NRT <input type="checkbox"/> <sub>3</sub> Champix/Varenicline <input type="checkbox"/> <sub>5</sub> No medication <input type="checkbox"/> <sub>2</sub> Combination <input type="checkbox"/> <sub>4</sub> Zyban/Bupropion NRT	
For client to complete:	
DOB:	Gender <input type="checkbox"/> <sub>1</sub> Male <input type="checkbox"/> <sub>2</sub> Female
Title:	First name:      Surname:
Address:      Post Code:	
Home Telephone No:	Mobile:
Other Telephone No:	Email:
Who referred you to this service? <input type="checkbox"/> <sub>1</sub> Myself <input type="checkbox"/> <sub>2</sub> GP <input type="checkbox"/> <sub>3</sub> Other Health Professional <input type="checkbox"/> <sub>4</sub> Other .....	
How did you hear about this service? <input type="checkbox"/> <sub>1</sub> Friend <input type="checkbox"/> <sub>2</sub> Work <input type="checkbox"/> <sub>3</sub> Paper <input type="checkbox"/> <sub>4</sub> Radio <input type="checkbox"/> <sub>5</sub> Poster <input type="checkbox"/> <sub>6</sub> Bus	Are you in paid employment? <input type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>2</sub> No  If you answered 'yes', what is your occupation? .....  If you answered 'no', Are you:

<input type="checkbox"/> <sub>7</sub> GP <input type="checkbox"/> <sub>8</sub> Other Health Professional <input type="checkbox"/> <sub>9</sub> Pharmacy <input type="checkbox"/> <sub>10</sub> Word of mouth <input type="checkbox"/> <sub>11</sub> From a national advert <input type="checkbox"/> <sub>12</sub> Leaflet <input type="checkbox"/> <sub>13</sub> Other....(please specify) .....	<input type="checkbox"/> <sub>1</sub> Unemployed? <input type="checkbox"/> <sub>2</sub> Full-time student? <input type="checkbox"/> <sub>3</sub> Sick/disabled and unable to work? <input type="checkbox"/> <sub>4</sub> Retired? <input type="checkbox"/> <sub>5</sub> Homemaker/full time parent/carer <hr/> Do you get free prescriptions? <input type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>2</sub> No
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Which ethnic group would you describe yourself as belonging to (tick one only):  White <input type="checkbox"/> <sub>1</sub> British <input type="checkbox"/> <sub>2</sub> Irish <input type="checkbox"/> <sub>3</sub> Any other White background Dual Heritage <input type="checkbox"/> <sub>4</sub> White & Black Caribbean <input type="checkbox"/> <sub>5</sub> White & Black African <input type="checkbox"/> <sub>6</sub> White & Asian <input type="checkbox"/> <sub>7</sub> Any other Dual Heritage background Asian or Asian British <input type="checkbox"/> <sub>8</sub> Indian <input type="checkbox"/> <sub>9</sub> Pakistani <input type="checkbox"/> <sub>10</sub> Bangladeshi <input type="checkbox"/> <sub>11</sub> Any other Asian background  <input type="checkbox"/> Black or Black British <input type="checkbox"/> <sub>12</sub> Caribbean <input type="checkbox"/> <sub>13</sub> African <input type="checkbox"/> <sub>14</sub> Any other Black background  Other Ethnic Group <input type="checkbox"/> <sub>15</sub> Chinese <input type="checkbox"/> <sub>16</sub> Any other ethnic group <input type="checkbox"/> <sub>17</sub> I do not wish to disclose this		
Which best describes your highest level of educational qualification?  <input type="checkbox"/> <sub>1</sub> Still at school <input type="checkbox"/> <sub>2</sub> No formal qualification	Which best describes your housing situation? (please tick the option that best applies to you)  <input type="checkbox"/> <sub>1</sub> Own outright <input type="checkbox"/> <sub>2</sub> Own with mortgage	What is your current marital status?  <input type="checkbox"/> <sub>1</sub> Never married <input type="checkbox"/> <sub>2</sub>



<input type="checkbox"/> <sub>3</sub> GCSE/O-grade/equiv. <input type="checkbox"/> <sub>4</sub> A-level/equivalent <input type="checkbox"/> <sub>5</sub> Apprenticeship <input type="checkbox"/> <sub>6</sub> Other vocational qf <input type="checkbox"/> <sub>7</sub> Degree <input type="checkbox"/> <sub>8</sub> Higher degree	<input type="checkbox"/> <sub>3</sub> Social/Council Renting <input type="checkbox"/> <sub>4</sub> Private Renting <input type="checkbox"/> <sub>5</sub> Other, please state .....	Married/civil partnership <input type="checkbox"/> <sub>3</sub> Cohabiting  <input type="checkbox"/> <sub>4</sub> Divorced <input type="checkbox"/> <sub>5</sub> Separated <input type="checkbox"/> <sub>6</sub> Widowed
How many people (including yourself) live in your home?  Adults (aged 16 or over, include yourself)  .....  Children (aged 0-15)  .....	Thinking about your friends and family only, how many smoke?  <input type="checkbox"/> <sub>0</sub> Not applicable <input type="checkbox"/> <sub>1</sub> None smoke <input type="checkbox"/> <sub>2</sub> A few smoke <input type="checkbox"/> <sub>3</sub> About half smoke <input type="checkbox"/> <sub>4</sub> Most smoke <input type="checkbox"/> <sub>5</sub> All smoke  Now thinking about the people you work or study with, how many smoke? <input type="checkbox"/> <sub>0</sub> Not applicable <input type="checkbox"/> <sub>1</sub> None smoke <input type="checkbox"/> <sub>2</sub> A few smoke <input type="checkbox"/> <sub>3</sub> About half smoke <input type="checkbox"/> <sub>4</sub> Most smoke <input type="checkbox"/> <sub>5</sub> All smoke	Over the last twelve months would you say your health has on the whole been.....?  <input type="checkbox"/> <sub>1</sub> Good  <input type="checkbox"/> <sub>2</sub> Fairly Good  <input type="checkbox"/> <sub>3</sub> Not Good
Does anyone in your home smoke regularly?  <input type="checkbox"/> <sub>1</sub> Yes <input type="checkbox"/> <sub>2</sub> No <input type="checkbox"/> <sub>3</sub> Does not apply to me	<input type="checkbox"/> <sub>0</sub> Not applicable <input type="checkbox"/> <sub>1</sub> None smoke <input type="checkbox"/> <sub>2</sub> A few smoke <input type="checkbox"/> <sub>3</sub> About half smoke <input type="checkbox"/> <sub>4</sub> Most smoke <input type="checkbox"/> <sub>5</sub> All smoke	



<p>Have you made a serious attempt to stop smoking in the last 12 months? i.e. you decided that you would try to make sure you never smoked again?</p> <p><input type="checkbox"/><sub>1</sub> Yes <input type="checkbox"/><sub>2</sub> No</p>	<p>Which, if any, of the following did you try to help you stop smoking during the most recent serious quit attempt? (Please tick all that apply)</p> <p><input type="checkbox"/><sub>1</sub> Nicotine replacement bought over the counter <input type="checkbox"/><sub>2</sub> Nicotine replacement prescribed by GP <input type="checkbox"/><sub>3</sub> Zyban (bupropion) <input type="checkbox"/><sub>4</sub> Champix (varenicline) <input type="checkbox"/><sub>5</sub> Attended an NHS stop smoking session <input type="checkbox"/><sub>6</sub> Smoking helpline <input type="checkbox"/><sub>7</sub> None of the above</p>	<p>On average, how many cigarettes do you usually smoke per day?</p> <p><input type="checkbox"/><sub>1</sub> 10 or less <input type="checkbox"/><sub>2</sub> 11-20 <input type="checkbox"/><sub>3</sub> 21-30 <input type="checkbox"/><sub>4</sub> 31 or more</p> <hr/> <p>How many years have you been smoking? .....years</p>
<p>How soon after you wake up do you smoke your first cigarette?</p> <p><input type="checkbox"/><sub>1</sub> Within 5 minutes <input type="checkbox"/><sub>2</sub> 6-30 minutes <input type="checkbox"/><sub>3</sub> 31-60 minutes <input type="checkbox"/><sub>4</sub> After 60 minutes</p>	<p>Do you have anyone who will support you to stop smoking?</p> <p><input type="checkbox"/><sub>1</sub> Yes <input type="checkbox"/><sub>2</sub> No</p> <p>If yes, who? (please tick all that apply)</p> <p><input type="checkbox"/><sub>1</sub> Spouse/partner <input type="checkbox"/><sub>2</sub> Family member <input type="checkbox"/><sub>3</sub> Friend <input type="checkbox"/><sub>4</sub> Work Colleagues <input type="checkbox"/><sub>5</sub> Other (please specify .....)</p>	<p>How determined are you to give up smoking at this attempt?</p> <p><input type="checkbox"/><sub>1</sub> Not at all determined <input type="checkbox"/><sub>2</sub> Quite determined <input type="checkbox"/><sub>3</sub> Very determined <input type="checkbox"/><sub>4</sub> Extremely determined</p>

<p>Do you have any medical conditions? (please tick all that apply)</p> <p><input type="checkbox"/><sub>1</sub> High blood pressure</p> <p><input type="checkbox"/><sub>2</sub> Heart problems</p> <p><input type="checkbox"/><sub>3</sub> Diabetes</p> <p><input type="checkbox"/><sub>4</sub> Respiratory problems</p> <p><input type="checkbox"/><sub>5</sub> Stroke</p> <p><input type="checkbox"/><sub>6</sub> Ulcers</p> <p><input type="checkbox"/><sub>7</sub> Bad circulation</p> <p><input type="checkbox"/><sub>8</sub> Under/overactive thyroid</p> <p><input type="checkbox"/><sub>9</sub> Skin problems</p> <p><input type="checkbox"/><sub>10</sub> Mental health problems</p> <p><input type="checkbox"/><sub>11</sub> Physical disability</p> <p><input type="checkbox"/><sub>12</sub> Other.....</p> <p>...</p>	<p>Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks.</p> <p>(Please tick ONE box for EACH statement)</p> <p>Over the last two weeks:</p> <p>1. I have felt cheerful and in good spirits</p> <p><input type="checkbox"/><sub>5</sub> all of the time</p> <p><input type="checkbox"/><sub>4</sub> most of the time</p> <p><input type="checkbox"/><sub>3</sub> more than half the time</p> <p><input type="checkbox"/><sub>2</sub> less than half the time</p> <p><input type="checkbox"/><sub>1</sub> some of the time</p> <p><input type="checkbox"/><sub>0</sub> at no time</p> <p>2. I have felt calm and relaxed</p> <p><input type="checkbox"/><sub>5</sub> all of the time</p> <p><input type="checkbox"/><sub>4</sub> most of the time</p> <p><input type="checkbox"/><sub>3</sub> more than half the time</p> <p><input type="checkbox"/><sub>2</sub> less than half the time</p> <p><input type="checkbox"/><sub>1</sub> some of the time</p> <p><input type="checkbox"/><sub>0</sub> at no time</p> <p>3. I have felt active and vigorous</p> <p><input type="checkbox"/><sub>5</sub> all of the time</p> <p><input type="checkbox"/><sub>4</sub> most of the time</p> <p><input type="checkbox"/><sub>3</sub> more than half the time</p> <p><input type="checkbox"/><sub>2</sub> less than half the time</p> <p><input type="checkbox"/><sub>1</sub> some of the time</p> <p><input type="checkbox"/><sub>0</sub> at no time</p> <p>4. I woke up feeling fresh and rested</p> <p><input type="checkbox"/><sub>5</sub> all of the time</p> <p><input type="checkbox"/><sub>4</sub> most of the time</p> <p><input type="checkbox"/><sub>3</sub> more than half the time</p> <p><input type="checkbox"/><sub>2</sub> less than half the time</p> <p><input type="checkbox"/><sub>1</sub> some of the time</p> <p><input type="checkbox"/><sub>0</sub> at no time</p> <p>5. My daily life has been full of things that interest me</p> <p><input type="checkbox"/><sub>5</sub> all of the time</p> <p><input type="checkbox"/><sub>4</sub> most of the time</p> <p><input type="checkbox"/><sub>3</sub> more than half the time</p> <p><input type="checkbox"/><sub>2</sub> less than half the time</p> <p><input type="checkbox"/><sub>1</sub> some of the time</p> <p><input type="checkbox"/><sub>0</sub> at no time</p> <p>How much do your medical conditions limit you in any way from completing your everyday activities? (e.g. mobility)</p> <p><input type="checkbox"/><sub>1</sub> Severely</p> <p><input type="checkbox"/><sub>2</sub> Moderately</p> <p><input type="checkbox"/><sub>3</sub> Not at all</p>
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## 52 week telephone interview schedule

### EVALUATING LONGER TERM OUTCOMES IN NHS STOP SMOKING SERVICES (ELONS)

#### DRAFT TELEPHONE QUESTIONNAIRE: 52 WEEK FOLLOW-UP –FINAL version

#### INTRODUCTION

Please could I speak to <named participant>?

#### IF NOT THROUGH TO NAMED PERSON AND ASKED WHY CALLING:

<Named participant> is taking part in a research study evaluating NHS stop smoking services called ELONS and I'm calling about this.

#### ONCE THROUGH TO NAMED PERSON:

Good morning / afternoon/ evening about a year ago you tried to stop smoking with help from your local <stop smoking service/pharmacy/GP practice/dentist>. You also very kindly agreed to take part in a research study called ELONS to evaluate the help you received. As part of this research study I am calling to find out how you are getting on. It will only take a few minutes. My name is \_\_\_\_\_ and I am from TNS BMRB, the independent research company which is conducting follow up calls for the ELONS Research Study.

#### IF NECESSARY:

When you agreed to take part in the ELONS Research Study you gave consent to be contacted to see how you are getting on with your attempt to quit smoking.

#### SECTION A: ELONS CORE QUESTIONS

##### ASK ALL

Q1. Have you smoked in the last 7 days? [SC]

Yes

No

ASK ALL

Q2. We understand that you attended an NHS stop smoking service about a year ago. You had successfully stopped smoking when they followed you up 4 weeks after your original quit date. Have you smoked at all since then?

IF RESPONDENT IS UNSURE WHAT A QUIT DATE IS: This is the date you agreed to stop smoking.

No, not at all

Yes, between 1 and 5 cigarettes

Yes, more than 5 cigarettes

## SECTION B: UCL ADDITIONAL QUESTIONS

ASK ALL

Q3. Thinking back to your quit attempt with your local < stop smoking service/pharmacy/GP practice/dentist> a year ago, did you use any nicotine replacement therapy, e.g. nicotine gum, patch, inhaler, nasal spray, mouth spray, microtab, lozenge or any other supplementary products, e.g. electronic cigarette? [SC]

Yes – ASK Q4

No – SKIP TO Q6a

Can't remember

ASK Q4 IF Q3 = 'YES'

Q4. How long did you use this additional support for? READ OUT [SC]

Less than a day

Less than a week

More than 1 week and up to a month

More than 1 month and up to 2 months

More than 2 months and up to 3 months

More than 3 months and up to 6 months

More than 6 months and up to a year

Still using it

Can't remember [DO NOT READ OUT]

ASK Q5 IF Q4 = 8

Q5. And can you tell me which of the following forms of support you are still using?

Tick all that apply. READ OUT [MC, RANDOMISE]

1. Nicotine gum
2. Nicotine patch
3. Nicotine inhaler
4. Nicotine nasal spray
5. Nicotine mouth spray
6. Nicotine microtab
7. Nicotine Lozenge
8. Electronic cigarette
9. Other (SPECIFY)
10. Can't remember [DO NOT READ OUT]

#### SECTION C: AGREEMENT FOR FOLLOW UP VISIT

ASK Q6a or b IF Q1 = 'NO'

IF A SALIVA SAMPLE HAS BEEN GIVEN AT THE BASELINE (DEFINED FROM SAMPLE FILE)

Q6a.

As part of this research study, we would like to send one of our interviewers to visit you for a breath test\* and also to collect a saliva sample? These are common ways of looking at the effects of stopping smoking and you may remember giving them at your local stop smoking service. It will only take a few minutes and our interviewer can either come to your home or your workplace, whichever is most convenient for you?

Yes

No

#### ADDITIONAL INFORMATION ON CO BREATH TEST IF REQUIRED

\* The breath test involves blowing into a machine that measures the amount of carbon monoxide in your breath

IF A SALIVA SAMPLE HAS NOT BEEN GIVEN AT THE BASELINE (DEFINED FROM SAMPLE FILE)

Q5b. As part of this research study, we would like to send one of our interviewers to visit you for a breath test\*. This is a common way of looking at the effects of stopping smoking and you may remember giving one at your local stop smoking service. It will only take a few minutes and our interviewer can either come to your home or your workplace, whichever is most convenient for you?

Yes

No

#### ADDITIONAL INFORMATION ON CO BREATH TEST IF REQUIRED

\* The breath test involves blowing into a machine that measures the amount of carbon monoxide in your breath

IF NOT ASKED Q6a/b, THANK AND CLOSE

IF Q6a/b = 'NO', THANK AND CLOSE

IF Q6a/b = 'YES', SAY: Thank you, please can I check your address and contact telephone number and someone will be in touch over the next few days to arrange a convenient time.

READ OUT CONTACT DETAILS TO CONFIRM AND UPDATE IF NECESSARY. CHECK THIS IS THE BEST NUMBER TO CONTACT THEM ON.

OPEN TEXT BOX TO RECORD ANY ADDITIONAL INFORMATION FOR THE FACE TO FACE VISIT (TO BE PASSED ON TO THE FACE TO FACE INTERVIEWER)

THANK AND CLOSE

## Client satisfaction and well-being survey



### Evaluating long term outcomes of NHS Stop Smoking Services (ELONS)

#### CONFIDENTIAL NHS STOP SMOKING SERVICE CLIENT SATISFACTION SURVEY

It is important that NHS Stop Smoking Services know if there is anything that they could do to improve the support that they provide to smokers. Your views about this are very important to us and will be treated in the strictest confidence. The results of this survey will be used for research and service development purposes. Please answer the following questions as honestly as you can, and return in the prepaid envelope provided. Thank you.

*Please TICK the appropriate box for EACH question:*

1.	Overall, how satisfied are you with the support you have received to stop smoking?	Very satisfied <input type="checkbox"/> <sub>1</sub>	satisfied <input type="checkbox"/> <sub>2</sub>	unsure <input type="checkbox"/> <sub>3</sub>	unsatisfied <input type="checkbox"/> <sub>4</sub>	Very unsatisfied <input type="checkbox"/> <sub>5</sub>
2.	Would you recommend this service to other smokers who want to stop smoking?	No <input type="checkbox"/> <sub>0</sub>	Unsure <input type="checkbox"/> <sub>1</sub>	Yes <input type="checkbox"/> <sub>2</sub>		
3.	In the event that you started smoking again, would you go back to the service for help with stopping smoking?	No <input type="checkbox"/> <sub>0</sub>	Unsure <input type="checkbox"/> <sub>1</sub>	Yes <input type="checkbox"/> <sub>2</sub>		
4.	If you returned to the service for help with stopping smoking in the future, do you think that you would be welcomed back?	No <input type="checkbox"/> <sub>0</sub>	Unsure <input type="checkbox"/> <sub>1</sub>	Yes <input type="checkbox"/> <sub>2</sub>		

5. Have you smoked since your last appointment with the service?					
No, not a single puff	Yes, just a few puffs	Yes, 1-5 cigarettes	More than 5 cigarettes		
<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>		
6. Was it easy to contact the stop smoking service when you had decided that you wanted to stop smoking?					
No	Unsure	Yes			
<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>			
7. When you contacted the stop smoking service, were you given an appointment date or told how long you would have to wait to see someone?					
No	Unsure	Yes			
<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>			
8. How long did you have to wait before your first appointment/group (please enter number of days)? .....days					
9. Was the length of time you had to wait for your first appointment acceptable to you?					
No	Unsure	Yes			
<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>			
10. Was there contact from the stop smoking service before your appointment to encourage and motivate you to attend treatment?					
No	Unsure	Yes			
<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>			
11. Are the appointment times you were given convenient for you?					
No	Unsure	Yes			
<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>			
12. Is the place where you go for your appointments convenient for you to get to?					
No	Unsure	Yes			
<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>			
13. Have you been offered support with childcare costs?					
Not applicable	No	Unsure	Yes		
<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>		
14. Were you given a choice of an individual appointment or a group session appointment?					
No	Unsure	Yes			
<input type="checkbox"/> <sub>0</sub>	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>			
15. How satisfied are you with how supportive staff have been?					
Very satisfied	satisfied	Unsure	unsatisfied	Very unsatisfied	
<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>	
16. How helpful have the information and advice that staff have given you during your appointment been?					
Very helpful	helpful	Unsure	Unhelpful	Very unhelpful	
<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>	



17. How helpful has the written information that staff have given to you been?

None given	Very helpful	helpful	Unsure	Unhelpful	Very unhelpful
<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5

18. Do you find having your carbon monoxide (CO) reading done at every visit helpful?

CO not taken every visit	Very helpful	helpful	Unsure	Unhelpful	Very unhelpful
<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5

19. Was the information that you were given about the choice of medication helpful?

No	Unsure	Yes
<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2

20. How did you get your medication?

GP prescription	Chemist (bought myself)	Chemist (with a voucher)	Chemist (with a service letter or prescription)	The stop smoking service
<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4	<input type="checkbox"/> _5

21. Was it easy to get hold of your medication once you had chosen which medication you were going to use for your stop smoking attempt?

No	Unsure	Yes
<input type="checkbox"/> _0	<input type="checkbox"/> _1	<input type="checkbox"/> _2

If there are any changes that you would like to see to the Stop Smoking Service, or if there was anything they did particularly well, then please give details here:



UK Centre for  
**Tobacco Control Studies**  
A UKCRC Public Health Research Centre of Excellence

## Evaluating long term outcomes of NHS Stop Smoking Services (ELONS)

### CONFIDENTIAL CLIENT WELLBEING QUESTIONNAIRE

Please answer the following questions about how things are going:

Q1. On the whole how happy are you with your life in general? Look at the faces and TICK the box under the face which shows best how you feel.



<input type="checkbox"/>	<sub>1</sub>	<input type="checkbox"/>	<sub>2</sub>	<input type="checkbox"/>	<sub>3</sub>	<input type="checkbox"/>	<sub>4</sub>	<input type="checkbox"/>	<sub>5</sub>	<input type="checkbox"/>	<sub>6</sub>	<input type="checkbox"/>	<sub>7</sub>
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Q2. Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better wellbeing.

*Example: If you have felt cheerful and in good spirits more than half of the time during the last two weeks, put a tick in the box with the number 3 in the lower right corner*

*Please tick ONE box for EACH statement.*

Over the last two weeks:		all of		most	more	less	some	at no
		the	of the	than	than	of	the	time
		time	time	half	of	half	of	time
				the time	the time			
1	I have felt cheerful and in good spirits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<sub>5</sub>	<sub>4</sub>	<sub>3</sub>	<sub>2</sub>	<sub>1</sub>	<sub>0</sub>	
2	I have felt calm and relaxed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<sub>5</sub>	<sub>4</sub>	<sub>3</sub>	<sub>2</sub>	<sub>1</sub>	<sub>0</sub>	
3	I have felt active and vigorous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<sub>5</sub>	<sub>4</sub>	<sub>3</sub>	<sub>2</sub>	<sub>1</sub>	<sub>0</sub>	
4	I woke up feeling fresh and rested	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<sub>5</sub>	<sub>4</sub>	<sub>3</sub>	<sub>2</sub>	<sub>1</sub>	<sub>0</sub>	

Over the last two weeks:

	all the time	of the time	most of the time	more than half of the time	less than half of the time	some of the time	at no time
5 My daily life has been filled with things that interest me	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0	

Q3. How many of the people you know smoke?

Please tick ONE box for EACH statement.

	not applicable	none smoke	a few smoke	about half smoke	most smoke	all smoke
Friends	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
People I work with or study with	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

## Confidential Client Wellbeing Questionnaire

Q4. Below are some opinions that people might have about themselves. How strongly do you agree or disagree with each one?

Please tick ONE box for EACH statement.

	strongly agree	agree	neither agree nor disagree	disagree	disagree strongly
I enjoy a challenge	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
I can deal with stress	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
I'm frightened of change	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
I can do what I want, when I want	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Most people would like a life like mine	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
I feel in control	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1

	strongly agree	agree	neither agree nor disagree	disagree	disagree strongly
I feel safe	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
I worry about things going wrong	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
I feel I'm doing well in life	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
My life has a sense of routine	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1

Q5. If you have made any changes to your life to help you quit please write in the box:

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE. We could not do this study without your help.

*Please could you just look back to check that you haven't missed any questions*

Now please send it back to us in the prepaid envelope provided.

## Appendix 2 Supplementary tables from well-being study

The main aims of the ELONS prospective study were to determine the proportion of SSS clients who remained abstinent from smoking 12 months after setting a quit date, and which clients were most likely to have stopped. A novel aspect of the ELONS study was that data on well-being was also collected from participants, not something normally done by the services. Well-being at baseline was a predictor of both short- and long-term quitting (see *Chapters 6 and 8*). Data on well-being were also collected through postal surveys at 4 weeks and 12 months post quit date (or since first contact for the 150 clients who did not set a quit date) in order to explore whether or not well-being changed over the course of a quit attempt and which client and service characteristics were associated with well-being at different time points. The main results of this analysis are presented in *Chapter 8*. This Appendix contains three tables that provide extra information supporting the findings presented in *Chapter 8*.

*Table 45* presents information on clients' levels of response to the main measure of well-being used in the study (whether or not it was possible to calculate a score for the WHO-5 Well-being Index) in the postal surveys compared with the ELONS prospective study sample at baseline and all clients who set a quit date with the services when clients in each service were being recruited to the ELONS study.

*Tables 46 and 47* present multivariable linear regression results, presenting client and service characteristics that were associated with well-being at baseline, 4 weeks and 12 months. *Table 46* presents results of analyses of associates including the previous dependent variables and additionally 'ontological security'. Ontological security was operationalised as 10 items intended to measure feelings of being protected, in control, prestige and response to change. The analysis with well-being at 4 weeks as the outcome includes ontological security collected in the 4-week postal survey and the analysis with well-being at 12 months as the outcome includes ontological security collected in the 12-month postal survey.

**TABLE 45** Participation in the ELONS study overall, and the well-being element of the 4- and 52-week postal surveys

Variables	All cases		ELONS		4-week postal survey		52-week postal survey	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
<b>Age (years)</b>								
16–24	7120	11	327	10.7	65	6.8	28	5.8
25–34	13,226	20	673	22.0	147	15.4	47	9.8
35–44	15,338	23	758	24.8	194	20.4	97	20.3
45–54	13,851	21	629	20.6	229	24.0	109	22.8
55–64	9933	15	456	14.9	210	22.0	140	29.2
65–85	6469	10	214	7.0	108	11.3	58	12.1
Total	65,937	100.0	3057	100.0	953	100.0	479	100.0
<b>Gender</b>								
Female	34,955	53	1710	55.9	531	55.7	267	55.7
Male	30,982	47	1347	44.1	422	44.3	212	44.3
Total	65,937	100.0	3057	100.0	953	100.0	479	100.0
<b>NSSEC</b>								
Routine and manual occupations	18,201	28	939	30.7	251	26.3	112	23.4
Managerial/professional and intermediate occupations	14,098	21	716	23.4	239	25.1	133	27.8
Sick/disabled and unemployed	14,932	23	660	21.6	188	19.7	86	18.0
Other/unknown	18,706	28	742	24.3	275	28.9	148	30.9
Total	65,937	100.0	3057	100.0	953	100.0	479	100.0
<b>Behavioural support</b>								
Closed group	541	1	102	3.3	30	3.1	18	3.8
Open group	2159	3	550	18.0	202	21.2	84	17.5
Drop-in	11,308	17	887	29.0	247	25.9	130	27.1
One-to-one specialist	21,796	33	1131	37.0	374	39.2	188	39.2
GP practice	16,412	25	269	8.8	75	7.9	45	9.4
Pharmacy	9821	15	97	3.2	23	2.4	9	1.9
Other or unclear	3900	6	21	0.7	2	0.2	5	1.0
Total	65,937	100.0	3057	100.0	953	100.0	479	100.0
<b>CO-validated quit at 52 weeks</b>								
Not quit	–	–	2772	90.7	775	81.3	351	73.3
Quit	–	–	285	9.3	178	18.7	128	26.7
Total	–	–	3057	100.0	953	100.0	479	100.0

**TABLE 46** Multivariable regression modelling of well-being at baseline, 4 weeks and 52 weeks including data collected at baseline and quitting as dependent variables<sup>a</sup>

Variables	Well-being at baseline		Well-being at 4 weeks		Well-being at 52 weeks	
	<i>n</i>	Beta (95% CI)	<i>n</i>	Beta (95% CI)	<i>n</i>	Beta (95% CI)
Smoking cessation behavioural support						
Specialist group	634	2.31 (-0.81 to 5.43)	232	-0.68 (-6.19 to 4.82)	102	-5.07 (-13.24 to 3.11)
Specialist drop-in	856	-0.80 (-3.02 to 1.42)	247	-0.52 (-4.11 to 3.07)	130	3.28 (-1.95 to 8.52)
Specialist one to one	1090	0	374	0	188	0
Provided by GP practice or pharmacy	358	0.46 (-3.29 to 4.21)	98	0.10 (-5.98 to 6.18)	54	-6.43 (-15.59 to 2.73)
Other or unclear	21	9.60 (0.38 to 18.81)	2	5.11 (-24.12 to 34.33)	5	-0.34 (-20.17 to 19.50)
Time of year						
Other months	736	1.11 (-2.38 to 4.61)	227	-0.37 (-6.15 to 5.40)	135	-6.42 (-15.71 to 2.88)
Summer – July and August	933	1.75 (-1.70 to 5.21)	300	0.29 (-5.22 to 5.80)	168	-5.58 (-14.82 to 3.66)
Back to school – September and October	1100	2.24 (-1.12 to 5.60)	354	2.56 (-2.87 to 7.98)	149	-3.77 (-12.95 to 5.42)
New Year – January and February	190	0	72	0	27	0
Age group (years)						
16–24	314	5.61 (2.66 to 8.57)	65	9.05 (3.28 to 14.82)	28	13.80 (4.72 to 22.88)
25–34	651	3.46 (1.09 to 5.83)	147	6.66 (2.34 to 10.97)	47	3.77 (-3.67 to 11.21)
35–44	734	2.33 (0.06 to 4.60)	194	3.48 (-0.50 to 7.46)	97	6.32 (0.33 to 12.31)
45–54	608	0	229	0	109	0
55–64	442	1.60 (-1.00 to 4.19)	210	2.27 (-1.61 to 6.15)	140	3.96 (-1.53 to 9.44)
65–85	210	5.62 (2.23 to 9.00)	108	5.44 (0.66 to 10.23)	58	7.71 (0.71 to 14.71)
Gender						
Male	1302	1.18 (-0.37 to 2.73)	422	0.58 (-2.16 to 3.32)	267	0.34 (-3.64 to 4.33)
Female	1657	0	531	0	212	0
SES						
Low SES (unemployed/basic education/social rent)	1179	0	333	0	134	0
Mid SES	1480	3.14 (1.48 to 4.79)	503	1.39 (-1.63 to 4.41)	276	4.10 (-0.51 to 8.72)
High SES (owns home and professional manager/tertiary education)	300	3.92 (1.17 to 6.66)	117	4.04 (-0.50 to 8.58)	69	4.70 (-1.80 to 11.21)

continued

**TABLE 46** Multivariable regression modelling of well-being at baseline, 4 weeks and 52 weeks including data collected at baseline and quitting as dependent variables<sup>a</sup> (*continued*)

Variables	Well-being at baseline		Well-being at 4 weeks		Well-being at 52 weeks	
	<i>n</i>	Beta (95% CI)	<i>n</i>	Beta (95% CI)	<i>n</i>	Beta (95% CI)
Ethnicity						
White British	2776	3.49 (-1.63 to 8.61)	895	3.10 (-5.93 to 12.14)	454	–
Other white	66	0	21	0	8	–
Asian (including mixed Asian and white)	62	7.50 (0.04 to 14.96)	9	21.83 (5.60 to 38.06)	2	–
Ethnicity other or unknown	55	2.71 (-4.79 to 10.22)	28	2.79 (-8.93 to 14.51)	15	–
Smoking dependence						
Not recorded as dependent	1634	3.19 (1.62 to 4.75)	562	3.31 (0.55 to 6.07)	276	5.31 (1.19 to 9.43)
Dependent	1325	0	391	0	203	0
Determination to quit						
Determined	2688	3.43 (0.77 to 6.10)	873	–	425	–
Not recorded as determined	271	0	80	–	54	–
Quit attempt supported by spouse/partner						
Supported	1530	2.50 (0.96 to 4.04)	511	4.83 (2.14 to 7.53)	235	–
Other	1429	0	442	0	244	–
Proportion of friends and family who smoke						
Half or more do not smoke	2249	1.80 (-0.04 to 3.63)	165	–	83	–
Other	710	0	788	–	396	–
Took varenicline in first week						
Took varenicline	1356	2.48 (0.88 to 4.08)	476	–	224	–
Varenicline not recorded	1603	0	477	–	255	–
Mental health condition						
Yes	471	0	146	0	69	–
Not recorded	2488	9.95 (7.81 to 12.10)	807	10.77 (7.05 to 14.49)	410	9.94 (4.24 to 15.65)
Heart, blood or circulatory conditions						
Yes	512	–	196	–	101	–
Not recorded	2447	3.39 (1.19 to 5.59)	757	–	378	–
Respiratory or lung condition						
Yes	624	–	216	–	116	–
Not recorded	2335	6.30 (4.37 to 8.23)	737	–	363	6.60 (1.84 to 11.36)



**TABLE 46** Multivariable regression modelling of well-being at baseline, 4 weeks and 52 weeks including data collected at baseline and quitting as dependent variables<sup>a</sup> (*continued*)

Variables	Well-being at baseline		Well-being at 4 weeks		Well-being at 52 weeks	
	<i>n</i>	Beta (95% CI)	<i>n</i>	Beta (95% CI)	<i>n</i>	Beta (95% CI)
Has other condition not included above						
Yes	349	–	121	–	71	–
No condition or has one of above conditions	2610	2.79 (0.32 to 5.25)	832	–	408	–
CO-validated quit rate						
Quit at 4 weeks	1315	N/A	268	0	304	N/A
Not quit at 4 weeks	1644	–	685	6.11 (3.05 to 9.17)	175	–
CO-validated quit rate						
Quit at 52 weeks	282	N/A	178	N/A	351	–
Not quit at 52 weeks	2677	–	775	–	128	11.76 (7.23 to 16.29)
Practitioner variance	–	11.4 (4.2)	–	0.9 (4.4)	–	10.2 (12.4)
Client-level unexplained variance (standard error)	–	422.3 (11.2)	–	415.6 (19.5)	–	444.9 (30.6)
–2log likelihood	–	26338.65	–	8453.027	–	4290.095
Total ( <i>N</i> )	2959	–	953	–	479	–
N/A, not applicable.						
a Location was also included in the model but is not presented.						

**TABLE 47** Multivariable regression modeling of well-being at 4 weeks and 52 weeks including data collected at baseline, ontological security collected in the postal surveys and quitting as dependent variables<sup>a</sup>

Variables	Well-being at 4 weeks		Well-being at 52 weeks	
	<i>n</i>	Beta (95% CI)	<i>n</i>	Beta (95% CI)
Smoking cessation behavioural support				
Specialist group	232	1.69 (–1.18 to 4.57)	102	–0.89 (–6.64 to 4.85)
Specialist drop-in	247	–0.50 (–5.34 to 4.33)	130	2.81 (–0.87 to 6.49)
Specialist one to one	374	0	188	0
Provided by GP practice or pharmacy	98	4.07 (–19.04 to 27.18)	54	–0.24 (–6.68 to 6.19)
Other or unclear	2	–0.67 (–5.97 to 4.63)	5	8.42 (–5.33 to 22.17)
Time of year				
Other months	227	–1.55 (–6.12 to 3.02)	135	–2.89 (–9.32 to 3.55)
Summer – July and August	300	0.16 (–4.21 to 4.53)	168	–1.65 (–8.04 to 4.75)
Back to school – September and October	354	0.73 (–3.56 to 5.01)	149	–2.65 (–8.99 to 3.68)
New Year – January and February	72	0	27	0

continued

**TABLE 47** Multivariable regression modeling of well-being at 4 weeks and 52 weeks including data collected at baseline, ontological security collected in the postal surveys and quitting as dependent variables<sup>a</sup> (*continued*)

Variables	Well-being at 4 weeks		Well-being at 52 weeks	
	<i>n</i>	Beta (95% CI)	<i>n</i>	Beta (95% CI)
Age group (years)				
16–24	65	4.38 (–0.22 to 8.99)	28	4.97 (–1.34 to 11.27)
25–34	147	3.70 (0.25 to 7.15)	47	1.52 (–3.62 to 6.66)
35–44	194	1.96 (–1.20 to 5.13)	97	1.76 (–2.45 to 5.96)
45–54	229	0	109	0
55–64	210	1.17 (–1.92 to 4.26)	140	–0.22 (–4.06 to 3.62)
65–85	108	3.43 (–0.41 to 7.28)	58	1.79 (–3.10 to 6.69)
Gender				
Male	422	0.32 (–1.83 to 2.47)	267	1.05 (–1.75 to 3.84)
Female	531	0	212	0
SES				
Low SES (unemployed/basic education/social rent)	333	0	134	0
Mid SES	503	–2.26 (–4.64 to 0.12)	276	–2.09 (–5.32 to 1.15)
High SES (owns home and professional managerial/tertiary education)	117	–2.08 (–5.70 to 1.53)	69	–0.63 (–5.14 to 3.89)
Ethnicity				
White British	895	3.68 (–3.50 to 10.87)	454	N/A
Other white	21	0	8	–
Asian (including mixed Asian and white)	9	20.43 (7.50 to 33.36)	2	–
Ethnicity other or unknown	28	3.04 (–6.23 to 12.32)	15	–
Smoking dependence				
Not recorded as dependent	562	–	276	–
Dependent	391	–	203	–
Determination to quit				
Determined	873	–	425	–
Not recorded as determined	80	–	54	–
Quit attempt supported by spouse/partner				
Supported	511	–	235	–
Other	442	–	244	–
Proportion of friends and family who smoke				
Half or more do not smoke	165	–	83	–
Other	788	–	396	–
Took varenicline in first week				
Took varenicline	476	–	224	–
Varenicline not recorded	477	–	255	–

**TABLE 47** Multivariable regression modeling of well-being at 4 weeks and 52 weeks including data collected at baseline, ontological security collected in the postal surveys and quitting as dependent variables<sup>a</sup> (*continued*)

Variables	Well-being at 4 weeks		Well-being at 52 weeks	
	<i>n</i>	Beta (95% CI)	<i>n</i>	Beta (95% CI)
Mental health condition				
Yes	146	–	69	–
Not recorded	807	–	410	–
Heart, blood or circulatory conditions				
Yes	196	2.83 (0.10 to 5.56)	101	–
Not recorded	757	0	378	–
Respiratory or lung condition				
Yes	216	–	116	–
Not recorded	737	–	363	–
Has other condition not included above				
Yes	121	–	71	–
No condition or has one of above conditions	832	–	408	–
Ontological security				
I enjoy a challenge	–	2.40 (0.88 to 3.93)	–	2.21 (0.32 to 4.10)
I can deal with stress	–	4.28 (3.01 to 5.56)	–	–
I'm frightened of change (reversed)	–	–	–	–
I can do what I want, when I want	–	–	–	2.75 (1.27 to 4.23)
Most people would like a life like mine	–	2.32 (0.98 to 3.66)	–	–
I feel in control	–	5.49 (3.86 to 7.13)	–	6.78 (4.40 to 9.16)
I feel safe	–	–	–	3.46 (1.34 to 5.57)
I worry about things going wrong (reversed)	–	–	–	1.92 (0.56 to 3.29)
I feel I'm doing well in life	–	6.02 (4.51 to 7.52)	–	5.59 (3.43 to 7.75)
My life has a sense of routine	–	–	–	2.16 (0.35 to 3.97)
CO-validated quit rate				
Quit at 4 weeks	268	2.88 (0.45 to 5.31)	304	N/A
Not quit at 4 weeks	685	0	175	–
CO-validated quit rate				
Quit at 52 weeks	178	N/A	351	5.24 (2.03 to 8.46)
Not quit at 52 weeks	775	–	128	0
Practitioner variance	–	1.41 (3.0)	–	8.7 (6.9)
Client-level unexplained variance (standard error)	–	258.7 (12.2)	–	209.5 (14.5)
–2log-likelihood	–	8003.832	–	3936.1
Total	953	–	479	–

N/A, not applicable.

<sup>a</sup> Location was also included in the model but is not presented.

