Start2quit: a randomised clinical controlled trial to evaluate the effectiveness and cost-effectiveness of using personal tailored risk information and taster sessions to increase the uptake of the NHS Stop Smoking Services

Hazel Gilbert,[1]* Stephen Sutton,[2] Richard Morris,[1] Irene Petersen,[1] Qi Wu,[3] Steve Parrott,[3] Simon Galton,[4] Dimitra Kale,[1] Molly Sweeney Magee,[1] Leanne Gardner[1] and Irwin Nazareth[1]

[1]Research Department of Primary Care and Population Health, University College London, London, UK
[2]Institute of Public Health, University of Cambridge, Cambridge, UK
[3]Department of Health Sciences, University of York, York, UK
[4]Smokefree Camden (Public Health), NHS Camden, London, UK

*Corresponding author

Declared competing interests of authors: Irwin Nazareth is a member of the National Institute for Health Research Health Technology Assessment Funding Commissioning Panel.

Published January 2017
DOI: 10.3310/hta21030

Scientific summary

The Start2quit RCT

Health Technology Assessment 2017; Vol. 21: No. 3
DOI: 10.3310/hta21030

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Smoking is the leading cause of ill health and mortality, and remains a major public health problem. Government-funded specialist smoking cessation services, now known as the NHS Stop Smoking Services (SSSs), were established by Primary Care Trusts throughout England in 2000. However, the proportion of smokers in England using the SSSs in 2011 was only 4.1%. Furthermore, figures since 2012 show a continuing downward trend in the number of smokers attending the SSS; thus, these clinical interventions, provided free of charge by the NHS, reach only a small proportion of the total population of smokers in England. This research addressed the problem of how to persuade and motivate more smokers to seek, or accept, help to quit.

Objectives

The primary objective of the study was to assess the relative effectiveness and cost-effectiveness of a complex intervention, consisting of proactive recruitment by a brief computer-tailored personal risk letter and an invitation to a 'Come and Try it' taster session to provide information about the SSSs compared with a standard generic letter advertising the service, on attendance at the SSSs of at least one session.

Secondary objectives aimed to (1) assess the relative effectiveness of the intervention on biochemically validated 7-day point prevalent abstinence rates at the 6-month follow-up; (2) compare the cost-effectiveness of the intervention; (3) assess the relative effectiveness on additional periods of abstinence measured by self-report of not smoking for periods of 24 hours to 3 months at the 6-month follow-up; (4) assess the number of smokers attending the taster session and the number of smokers completing the 6-week NHS smoking cessation course; (5) assess the number of quit attempts made and any reduction in daily cigarette consumption; (6) explore the effectiveness of the intervention by socioeconomic status and social deprivation; (7) explore reasons for non-attendance and barriers to attendance at the SSS; and (8) determine predictors of attendance at the services and the taster sessions (in the intervention group).

Methods

The Start2quit study was a pragmatic, randomised controlled trial of a complex intervention, utilising general practices in England to recruit smokers into the trial. Recruitment, collection of baseline data and delivery of the intervention took place over 4 years, between January 2011 and December 2014.

Current smokers aged ≥ 16 years, able to read English, motivated to quit and who had not attended the SSS in the previous 12 months were eligible for inclusion in the study. For the purposes of this research, motivation to quit was defined as answering 'yes' to either or both of the following questions:

1. Are you seriously thinking of quitting in the next 6 months?
2. Would you think of quitting if appropriate help was offered at a convenient time and place?

The National Institute for Health Research Primary Care Research Network recruited SSSs, and also identified and recruited practices in the selected SSS areas. All smokers aged ≥ 16 years were identified from medical records in participating practices and were sent an invitation from their general practitioner (GP) to participate, together with a participant information sheet, a consent form and a screening questionnaire. The questionnaire assessed demographics, self-reported health, nicotine dependence,

smoking history, determination and confidence to quit. Participants were asked to consent to the use of information from their medical records and given in the screening questionnaire to send them information about quitting, and for the researchers to access relevant data from their attendance at the SSSs. Non-responders were sent a reminder and duplicate questionnaire after 3 weeks. All smokers returning the questionnaire and signed consent form, and who were eligible to participate, were randomised to the intervention group or the control group. Patients had the opportunity to decline to participate but to return the questionnaire with basic information to update their smoking status in their medical records.

Interventions

Participants allocated to the control group were sent a standard generic letter from the GP practice advertising the local SSS and the therapies available, and asking the smoker to contact the service to make an appointment to see an advisor.

Participants allocated to the intervention group received:

- a brief personalised and tailored letter sent from the GP that included information specific to the patient, using information obtained from the screening questionnaire and from their medical records
- a personal invitation and appointment to attend a 'Come and Try it' taster session to find out more about the services, run by advisors from the local SSS
- a repeated personal letter with a further invitation 3 months after the original if they failed to attend a taster session following the first letter and invitation.

The overall objectives of the letter were to communicate personal risk level if they continued to smoke, using individualised information on the risk of serious illness, and to encourage attendance at the SSS. The goal of the taster session was to offer information, to promote the SSS, to address any concerns or queries smokers may have and to encourage sign-up to a course. It was not intended to replicate the first session of a course.

Data management

The patient-level data collected comprised information downloaded from practice records and information provided by participants on the consent form and baseline questionnaire. The information from the practice record was used to generate letters inviting patients to participate in the trial. It was also used, along with baseline questionnaire information, to generate the tailored letters.

Randomisation, at the level of the study participant, was embedded into the computer program using permuted blocks. Participants were randomised in the ratio 3 : 2 (intervention to control) within practice, stratified by gender, and using a block size of five. It was not possible to blind participants to the receipt of a personally tailored letter and invitation to a taster session. Although the personal letter was generated in the practice by a research assistant, the remainder of the research team, in all cases, were blind to the allocation of the participant, which was enforced by the data management. In follow-up interviews, the interviewer was blinded to the allocation of the respondent.

At the end of the 6-month follow-up period in each SSS, valid data of attendance were collected from the SSSs using NHS monitoring data collected by smoking cessation advisors. In addition, a computer-assisted telephone interview was conducted 6 months after the date of randomisation by research interviewers, independent from the service providers, to assess self-reported SSS attendance, current smoking status and other outcome data. Participants claiming 7-day abstinence were asked to provide a salivary cotinine sample by post, using a saliva sample kit, to biochemically validate 7-day point prevalent smoking cessation at a 6-month follow-up.

Outcome measures

The primary outcome measure was the proportion of people entering the smoking cessation service (i.e. attending the first session of a 6-week course) over a period of 6 months from the receipt of the invitation letter, as measured by records of attendance at the SSSs.

Secondary outcome measures were:

- 7-day point prevalent abstinence at the 6-month follow-up, validated by salivary cotinine analysis
- additional periods of abstinence measured by self-report: 24-hour and 7-day point prevalent, 1- and 3-month prolonged abstinence
- validated 3-month prolonged abstinence
- self-reported changes in daily cigarette consumption, quit attempts, and changes in motivation and intention to quit in continuing smokers
- the number completing the 6-week NHS course.

Process measures included:

- the number of smokers attending the taster session (intervention group only)
- self-reported attendance data
- perception of the personal risk letters and taster session
- reasons for non-attendance at the taster session and barriers to attendance at the NHS services.

The economic component estimated the cost of providing the interventions using primary cost data from a NHS and Personal Social Services perspective. We also measured patients' use of health and social care services using comprehensive service use questionnaires. Quality-adjusted life-years (QALYs) were calculated from the European Quality of Life-5 Dimensions questionnaire using the area-under-the-curve method. A cost-effectiveness analysis compared the tailored letter plus the taster session with the generic letter.

Sample and analysis

To detect an increase in SSS attendance of 4.6% [from 8.9% to 13.5%; odds ratio (OR) 1.65] at 90% power at the 5% significance level required a sample of 1029 participants, 2058 in total. Allowing for a therapist intracluster correlation coefficient (ICC) of 0.005 and a therapist cluster size of 103 required inflation of our sample size by a factor of 1.51 in the intervention group to 1554 participants. Thus, we originally aimed to recruit 2583 participants in total. An extension to the trial, funded to permit evaluation of 7-day point prevalent abstinence at the 6-month follow-up, required an 80% increase in the sample size, to 4500 (1793 in the control group and 2707 in the intervention group) to detect a doubling of the quit rate from 2.2% to 4.4%, with 95% power.

A comparison of proportions was carried out for binary outcomes between the intervention and control groups. Univariable logistic regression analysis was carried out to take into account clustering at the SSS level and multivariable logistic regression was also carried out to take into account any imbalance in important baseline characteristics known to predict smoking cessation outcomes, nominated prior to examination of the trial data, between the groups.

Results

Eighteen SSSs and 99 practices within the SSS areas agreed to participate in the trial. Current cigarette smokers aged $\geq$ 16 years were identified from computer records in participating practices ($n = 141,488$;

14.7% of the total list size); 4384 gave consent and were eligible, a response rate of 4.1%, and were randomised to the intervention group ($n = 2636$) or to the control group ($n = 1748$). One participant from the intervention group withdrew from the study and 4383 were analysed.

Validated SSS attendance data were obtained for each participant from SSSs at the end of the 6-month follow-up period. Additional data were obtained by telephone interview or postal questionnaire from 3372 (76.9%) participants. Of those claiming abstinence, 595 (94.4%) agreed to send a saliva sample for biochemical validation of 7-day abstinence, 443 (70.3%) returned a sample and 44 had resumed smoking; 399 (63.3%) samples were sent for analysis.

The study sample was 50.9% male with a mean age of 49.3 years. A total of 50.7% were living in areas of high deprivation, defined as Index of Multiple Deprivation (IMD) quintiles 4 and 5, and 32% of the sample were living in a household with another smoker. One-quarter (26.5%) were highly nicotine dependent. Although 55.1% were not planning to quit in the next 30 days, motivation and determination to quit were relatively high (means 3.76 and 3.74, respectively, scored on a 1 to 5 scale) but confidence in the ability to quit was lower (mean 2.71).

Anonymised data of smokers who were invited to participate in the study, but did not accept, showed that males were under-represented in the study sample (50.9% vs. 54.3%) and participants were significantly older than non-participants (mean age 49.31 vs. 43.29 years). The IMD score was significantly different between participants and non-participants, but the difference (1.18) was small.

The proportion of people attending the first session of a 6-week SSS course was significantly higher in the intervention group than in the control group [17.4% vs. 9.0%; unadjusted OR 2.12, 95% confidence interval (CI) 1.75 to 2.57; $p < 0.001$]. Validated 7-day point prevalent abstinence at the 6-month follow-up was significantly higher in the intervention group than in the control group (9.0% vs. 5.6%; unadjusted OR 1.68, 95% CI 1.32 to 2.15; $p < 0.001$), as were all other periods of abstinence measured by self-report. The number completing the 6-week SSS course was also significantly higher in the intervention group than in the control group (14.5% vs. 7.0%; unadjusted OR 2.24, 95% CI 1.81 to 2.78; $p < 0.001$).

There was a slight reduction in the consumption of cigarettes per day in those continuing to smoke (of 2.6 cigarettes), and 23.7% had made a quit attempt. Intention and motivation to quit changed little in continuing smokers. There was no difference between the groups.

The effect of the intervention on attendance at the SSS was significantly greater for males (19% vs. 8%; OR 2.70, 95% CI 2.04 to 3.57) than for females (15.7% vs. 10.1%; OR 1.67, 95% CI 1.28 to 2.19), and also for validated 7-day point prevalent abstinence (males: OR 2.37, 95% CI 1.63 to 3.42; females: OR 1.23, 95% CI 0.88 to 1.72). Attendance at the SSS was lower in the control group for participants in IMD quintiles 2–4 (medium deprivation) than for those in quintiles 1 or 5. Overall attendance varied between SSSs from 2.1% to 23.1% (ICC 0.031, 95% CI 0.01 to 0.09) and validated 7-day abstinence from 2.1% to 13.4% (ICC 0.034, 95% CI 0.011 to 0.096), suggesting that around 3% of participants' tendency to attend and to quit smoking was explained by the SSS in which they were located.

The mean intervention cost per participant was £54 [standard deviation (SD) £12] and £0.87 (SD £2) in the intervention and control groups, respectively. Considering the wider health resource use, the estimated total mean costs over the 6-month period were £777 (SD £2176) in the intervention group and £679 (SD £1860) in the control group. Comparing the intervention with the control group, incremental cost-effectiveness ratios were estimated at £627 per additional attendee to the SSS, £2689 per additional quitter and £59,401 per QALY gained after 6 months. Using the National Institute for Health and Care Excellence decision-making threshold range of £20,000–30,000 per QALY gained, the probability that the intervention was more cost-effective was 20–27% in the short term and > 86% in the long term.

Conclusion

The Start2quit trial has added to the evidence that a proactive approach can be successful in reaching more smokers and informing them of the SSSs and consequently increasing the service uptake. An intensive intervention to deliver personalised risk information and provide a no-commitment introductory session, designed to inform smokers about the service and what it offers, more than doubled attendance at the SSSs. We also demonstrated that the increased attendance can translate to increased quit rates. The acceptability of both parts of the intervention was established.

Although the costs of the personal risk information and taster sessions compared with a standard generic letter suggest that it is less likely to be a cost-effective option in short term, the long-term results indicate that, over a lifetime horizon, the intervention has an 86% probability of being more cost-effective than the generic letter. Some adaptation to the method of recruitment could reduce costs without reducing the impact and, thus, increasing the viability of the strategy as a means to increase uptake of the SSSs and also reduce smoking prevalence.

Recommendations for research

- Further research to dismantle the components of the intervention in a factorial study to assess their separate effects and to identify the mechanisms of action.
- Further investigation into the long-term abstinence of smokers proactively recruited compared with those who self-refer.
- More exploration into the barriers to seeking help and to attendance at support services, and into possible changes to the format, content and timing of the introductory sessions.
- Qualitative work to break down the components of the personal risk letter and to investigate which type of smoker is likely to be prompted by the contents to attend.
- Experimentation with reactive and opportunistic recruitment to suggest ways in which initial recruitment to the research could be improved.

Implications for health care

Recent data have shown a significant decrease in the number of smokers accessing SSSs in the past few years. Efforts to reverse this trend should be a priority, as services offer smokers a significantly higher chance of stopping smoking than trying to quit without support.

The evidence suggests that a programme of proactive recruitment can be effective in raising awareness of the SSSs, and personal invitations, with or without additional risk information, may also offer the services an opportunity to promote the service in the form of introductory sessions to emphasise its approachability and empathy.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN76561916.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.058

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 08/58/02. The contractual start date was in June 2010. The draft report began editorial review in December 2015 and was accepted for publication in June 2016. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).