

Internet-based intervention for smoking cessation (StopAdvisor) in people with low and high socioeconomic status: a randomised controlled trial



Jamie Brown, Susan Michie, Adam WA Geraghty, Lucy Yardley, Benjamin Gardner, Lion Shahab, John A Stapleton [A;correct?], Robert West



Summary

Background Internet-based interventions for smoking cessation could help millions of people stop smoking at very low unit costs; however, evidence is scarce and such interventions might be less effective for smokers with low socioeconomic status [A:why?]. We aimed to assess a new interactive internet-based intervention (StopAdvisor) for smoking cessation in people with low and high socioeconomic status.

Methods We did this randomised controlled trial between Dec 6, 2011, and Oct 11, 2013, [A: correct?] at XX [A: please provide number of centres] centres in the UK. Participants aged 18 years and older who smoked every day were randomly assigned (1:1) to receive treatment with StopAdvisor or an information-only website. Randomisation was automated with an unseen random number function embedded in the website to establish which treatment was revealed after the online baseline assessment [A: was this stratified for SES?]. Participants, and researchers who obtained data and did laboratory analyses, were masked to treatment allocation. The primary outcome was 6 month sustained, biochemically verified abstinence [A:in the overall group and in the pre-specified SES subsamples?]. [A: data for secondary endpoints have been removed because we avoid their inclusion in the summary, but all details remain in the text and tables]. Analysis was by intention to treat. The study is registered as an International Standard Randomised Controlled Trial, number ISRCTN99820519.

Findings We randomly assigned 4613 participants to the StopAdvisor group (n=2321) or the control group (n=2292); 2142 participants were of lower socioeconomic status and 2471 participants were of higher status. The overall rate of smoking cessation was similar between participants in the StopAdvisor and control groups for the primary outcome (n=237 [10%] vs n=220 [10%]; relative risk [RR] 1.06, 95% CI 0.89–1.27; p=0.49). However, the intervention effect differed across socioeconomic status subsamples (RR 1.44, 95% CI 0.99–2.09; p=0.0562). StopAdvisor helped participants with lower socioeconomic status stop smoking compared with the information-only website (90 [8%] of 1088 participants vs 64 [6%] of 1054 participants; RR 1.36, 95% CI 1.00–1.86; p=0.0499, but did not improve cessation rates in those with higher socioeconomic status (147 [12%] of 1233 participants vs 156 [13%] of 12388 participants; 0.95, 0.77–1.17; p=0.61).

Interpretation StopAdvisor was more effective than an information-only website in smokers of lower, but not higher, socioeconomic status. [A: please add a sentence explaining the clinical implications of your findings. What should clinicians do now?]

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Introduction

Tobacco smoking is estimated to cause more than 6 million deaths worldwide every year,¹ and is a major contributor to health inequalities.² Almost all the mortality and morbidity associated with smoking could be avoided by smokers quitting before age 30 years;³ however, in most developed countries, less than a quarter of smokers quit before this age, despite most wanting and trying to stop.⁴ Face-to-face support combined with drugs is the most effective intervention for cessation, whereas unaided quitting is one of the least effective methods.^{5,6} Despite this finding, even in the UK, where treatment is widely accessible at little or no cost, most smokers do not use face-to-face support and almost half

attempt to stop unaided.⁷ Improved ways to help and engage smokers who are trying to stop are urgently needed, particularly for those from low socioeconomic status groups who want to stop as much as other smokers, but find it more difficult [A:why?], further widening social inequalities.⁸

Internet support is a low-cost option for treatment of smoking cessation, which could reach millions of smokers who would otherwise attempt to quit unaided. Roughly 70% of smokers in the UK have regular internet access and almost half are interested in use of online support during a future quit attempt.⁹ The internet could appeal to smokers who are reluctant to engage with face-to-face support by offering increased convenience,

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Cancer Research UK Health Behaviour Research Centre, Department of Epidemiology and Public Health (J Brown PhD, B Gardner DPhil, L Shahab PhD, Prof R West PhD) and Department of Clinical, Educational, and Health Psychology (Prof S Michie DPhil), University College London, London, UK; National Centre for Smoking Cessation and Training, London, UK (Prof S Michie, Prof R West); Primary Care and Population Sciences (A W A Geraghty PhD) and School of Psychology (Prof L Yardley PhD), University of Southampton, Southampton, UK; Addictions Department, Institute of Psychiatry, Kings College London, London, UK (J A Stapleton MSc)

Correspondence to:
Dr Jamie Brown, Health Behaviour Research Centre, Department of Epidemiology and Public Health, University College London, London WC1E 6BT, UK
jamie.brown@ucl.ac.uk

confidentiality, and reduced stigma, while presenting an alternative for those struggling to access face-to-face support because of mobility or geographical barriers. The benefits compared with other low-cost and convenient alternatives, such as written materials, include opportunities for interactivity and tailoring. Despite the potential of internet-based interventions, previous research into their effectiveness has produced mixed results and is limited by a scarcity of biochemically verified long-term outcomes.¹⁰ Furthermore, such interventions might be less effective for smokers with low socioeconomic status than for those with high status [A:why?].¹¹ Which components account for the differences in effectiveness [A: between SES groups?] is unclear, because internet interventions have often been presented as so-called black boxes, with restricted description of their content.¹⁰ To establish the crucial components of an effective intervention, researchers should report transparently the content of new smoking cessation websites.¹²

StopAdvisor is a new interactive smoking cessation website and, to promote transparency, details of both the content and development of the website have been published,¹³ and the website built with the open-source platform LifeGuide. The development of StopAdvisor was informed by addiction theory, previous research, and user-testing with smokers of low socioeconomic status [A:only low SES? Not Higher SES?]. In a pilot study, StopAdvisor showed promising short-term effectiveness and usability,¹⁴ we therefore aimed to assess the long-term effectiveness of the intervention in this trial.

Health inequality is a priority and to assess what affect new interventions have on different social groups is important.¹⁵ Most assessments of behavioural interventions have not been adequately powered to detect effects in low-income groups,¹⁶ and no previous trial of internet support for smoking cessation has focused on the effect within different socioeconomic status groups. This absence of research exists despite concerns that online support might be more effective for smokers with high socioeconomic status on the basis of their apparent greater literacy to engage with support websites compared with smokers with low status.¹¹ To address this issue, the pilot study of StopAdvisor reported analyses showing that the intervention was similarly effective and acceptable to users across the range of socioeconomic status groups.¹⁴ The implication was that typical inequalities in online literacy might have been successfully mitigated by user testing done in a panel of smokers with low socioeconomic status during the development of StopAdvisor.¹³ However, the robustness of this finding needed assessment within an adequately powered trial. As such, we did this study to examine the effectiveness of StopAdvisor in smokers of low and high socioeconomic status.

Methods

Study design and participants

We did this randomised controlled between Dec 6, 2011, and Oct 11, 2013, [A: correct?] at XX sites in the UK [A: at how many study sites in the UK?]. We enrolled participants aged 18 years and older who smoked every day and who were willing to make a serious quit attempt, use a stop-smoking website that sends email reminders, be followed up at 7 months, and be contacted by email and telephone. Participants were recruited mainly via a notice on the English Department of Health website called SmokeFree. The notice invited smokers to take part in a study comparing methods of online support, and included a link to the study website. Individuals interested in participating after reading the study information and eligibility criteria were asked for informed consent and to complete a baseline questionnaire. The study was designed with sufficient power to assess effectiveness [A: we use efficacy to refer to how well a drug works in a trial setting] within each socioeconomic status subsample separately in the event of heterogeneity; as such, recruitment continued until the required sample size had been achieved for subsamples of both higher and lower socioeconomic status. [A: edited to avoid repetition] The study was approved by the ethics committee of University College London (reference 2808/001). The protocol¹⁷ was approved by a trial steering committee.

Randomisation and masking

Participants who completed the baseline questionnaire were randomly assigned (1:1) to StopAdvisor or an information-only control website—a one-page static website giving brief standard advice,¹³ based on a widely used manual for smoking cessation for practitioners.¹⁹

Randomisation was at the individual level with no restriction (ie, no blocking) and was completely automated with no experimenter involvement by use of an unseen random number function embedded in the website code to identify which treatment website was revealed after participants clicked the submit button at the end of the questionnaire [A:was it stratified for SES group to ensure equal numbers for each intervention?]. After treatment allocation, the email address of each participant was secured to that website to prevent contamination. Participants, and researchers who obtained data and did laboratory analyses, were masked to treatment allocation. We did no formal assessment of the extent to which masking was successful.

Procedures

Development and content of the StopAdvisor website has been described in detail elsewhere.¹³ Briefly, the development was informed by 19 theoretical propositions identified from the PRIME theory of motivation and addiction,¹⁸ 33 evidence-based or theory-based behaviour change techniques, 26 web-design

For more about StopAdvisor see
[http://www.lifeguideonline.org/
 player/play/
 stopadvisordemonstration](http://www.lifeguideonline.org/player/play/stopadvisordemonstration)

principles, and nine principles from user testing with smokers of low socioeconomic status. The theme of the website was based on the success of the UK's National Health Service (NHS) Stop Smoking services and was aimed to simulate an expert stop smoking advisor who was both a source of useful information and a guide to help the smoker through the process of stopping with a structured quit plan. Tailored support was offered for up to 1 month before and after quitting. The website was presented on a standard template and used a hybrid navigational architecture combining choice of content from menus with tunnelled exposure to key messages. Before their quit date, participants had access to an interactive menu, which included a screencast explaining how to use the website, and up to five tunnelled dialogue sessions tailored according to their quit date, their intended use of smoking cessation [A;ok?] medicines, their success in obtaining and use of medicines, and reasons for quitting. These sessions presented behaviour-change techniques that focused on helping with goal setting and action planning around a quit date, emphasising the importance of abrupt cessation, acquiring appropriate medicines and how best to use them, making necessary changes in routines to minimise urges to smoke after the target quit date, developing specific coping strategies for anticipated difficulties in quitting [A;ok?], and having clear expectations about the natures of those difficulties. In each case, delivery of a technique was designed to make use of the interactive nature of the intervention—eg, an interactive calendar to set quit dates and email reminders. After their quit date, participants had access to a new interactive menu and up to 13 tunnelled sessions tailored on self-reported abstinence, urges to smoke, self-effectiveness, medicine use, and anticipated frequency of stressful or social events. The responses variously aimed to boost motivation and self-effectiveness and strengthen the identity of ex-smokers, and provided specific advice and behaviour-change techniques about how to address potential difficulties and plan for the future to minimise their occurrence. The post-quit menu included frequently asked questions, a "your progress" section, audio and video, and a link to the StopAdvisor Facebook page.¹³

Procedures

Follow-up was 7 months after enrolment to allow an outcome of at least 6 months abstinence; both websites advised quit dates within 1 month of enrolment. Follow-up data were obtained via an online questionnaire emailed to participants. Non-responders were sent reminders using both email and telephone contact details (at least one and up to three telephone numbers [daytime, evening, and mobile]), with invitations and contacts structured according to evidence-based methods for maximisation of response rates.²⁰ For example, all invitations were personalised, cited non-monetary

incentives for responding (eg, how the answer was important and would inform decisions about whether to make the websites more widely available), and referred to university sponsorship of the trial, while attempts at direct contact were preceded by a pre-contact, which informed the participant they would soon be contacted. Participants who reported meeting either 6 month sustained abstinence or point-prevalence criteria (defined as a self-report of not smoking in the previous 7 days at follow up) at 7-month follow up were asked to use a cotton dental roll to provide a saliva sample and post it back to a laboratory for analysis. To improve response rates, these participants received a £20 gift voucher, irrespective of whether or not they returned the sample [A: was the voucher only sent to those who quit/were to return a sample or all patients who completed the questionnaire irrespective of their quit status?].²⁰

On enrolment individuals were automatically classified into one of two socioeconomic status subsamples as established by their responses to the baseline questionnaire: (1) lower socioeconomic status, comprising individuals who have never worked, were long-term unemployed, or were from routine and manual occupations according to the National Statistics Socio-Economic Classification (NS-SEC) self-coded method,²¹ and (2) higher socioeconomic status, comprising individuals who were classified into all other occupational groups with the NS-SEC self-coded method.

Outcomes

The primary outcome was Russell Standard 6 month sustained abstinence (RS6), defined as self-reported non-smoking of more than five cigarettes in the previous 6 months and not smoking in the previous week, verified by a saliva cotinine concentration of less than 15 ng/mL²² or, for participants reporting use of nicotine replacement treatment (including electronic cigarettes) and with a saliva cotinine concentration of more than 14 ng/mL, a saliva anabasine concentration of less than 1 ng/mL.²³ This definition classified participants who self-reported not smoking but did not meet the biochemical verification criterion as continuing smokers.

Secondary outcomes were point prevalence abstinence,²⁰ verified by saliva cotinine or anabasine; and quantitative indices of website interaction (logins, page views, and time spent on website). We also assessed self-reported abstinence at months 2 and after enrolment, self-report of a serious quit attempt at the 7-month follow up, and satisfaction ratings of the website at months 2 and 7 after enrolment. Due to low response rates for these outcomes they were omitted from the main analyses before unblinding the data (appendix).

Measures recorded for outcome assessment at follow up were self-reported smoking behaviour in the previous 6 months and specifically the previous week, and a saliva sample to verify those reporting abstinence in the previous week.

See Online for appendix

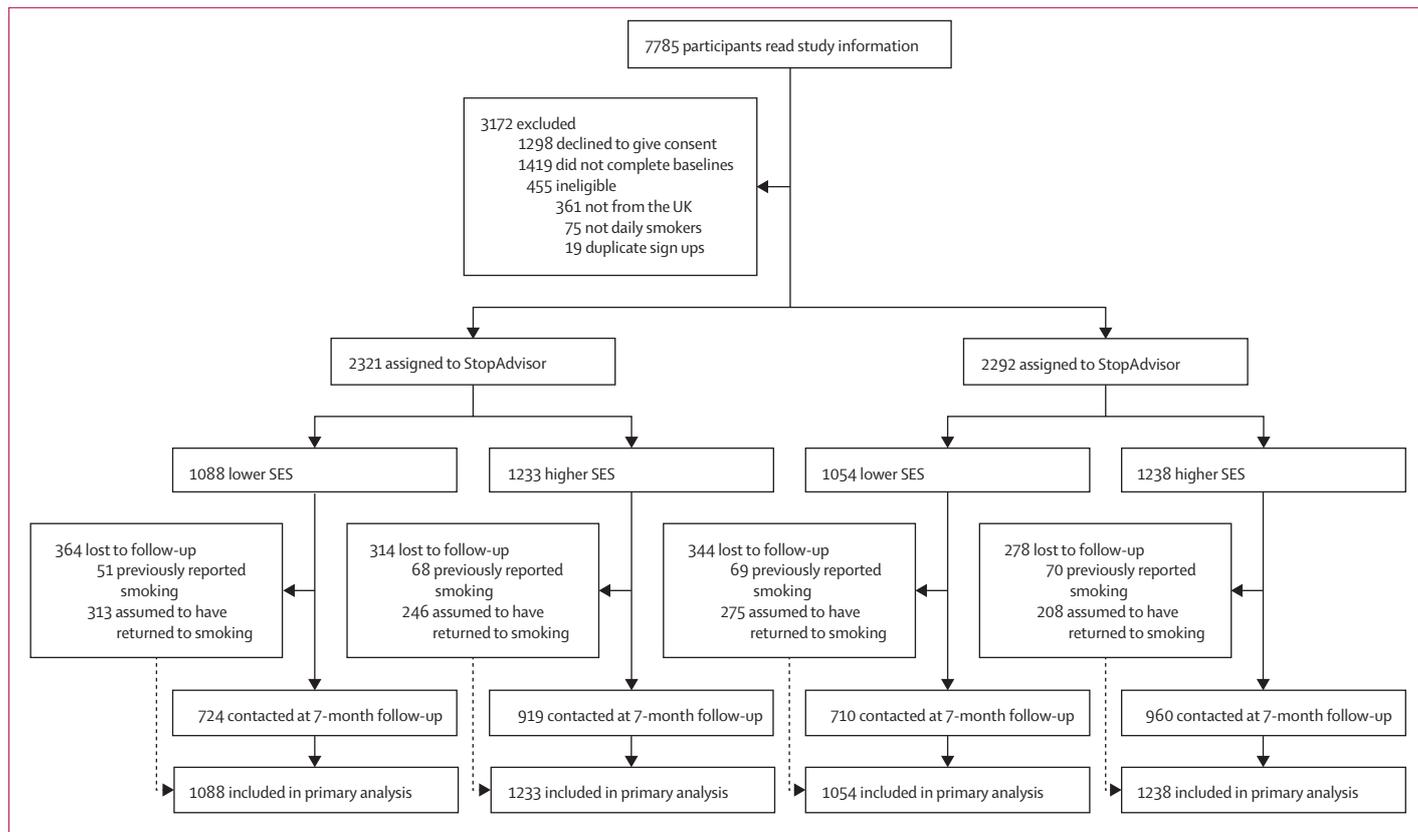


Figure 1: Trial profile

Eight participants violated the protocol by using an alternative email address to view the other website to which they were allocated (higher SES: StopAdvisor n=1, control n=4; lower SES: StopAdvisor n=2, control n=1). Per protocol, these participants were not excluded from the analysis and classified by the original treatment to which they were allocated. Only one of these participants met either the primary or secondary outcome abstinence criteria: the participant was from the higher SES subgroup and was allocated to the control website and viewed StopAdvisor. SES=socioeconomic status

Statistical analysis

The sample size was established with α and β (1-power) set at 5% for a projected 3% intervention difference (ie 8% vs 5%) in the whole sample, whilst ensuring at least 80% power to detect this difference in either socioeconomic status subsample in the event of heterogeneity. Although the anticipated effect size is smaller than usually observed with face-to-face behavioural support, it is clinically meaningful and potentially cost-effective.²⁴ Hence, a minimum total sample size of 4260 with at least 2130 in each subsample was required.

We used log-binomial regression to analyse the dichotomous primary and secondary outcomes, and calculated the associated relative risk and 95% CIs. The model allowed both the initial assessment of homogeneity of effect across subsamples by inclusion of an intervention by socioeconomic status interaction term and adjustment in sensitivity analyses for any chance imbalances in baseline characteristics between intervention and subsamples. The interaction term provided an assessment of the homogeneity of effect because it represented the ratio of the risk ratios (RRs) for the intervention effect in the subsample of

participants with lower socioeconomic status and the intervention effect in those with higher status. So far as the true intervention effect was the same in both subsamples, the RRs would be identical (except for sampling error) and their ratio would be about 1—ie, no interaction. Alternatively, an interaction in the initial analysis would show heterogeneous intervention effects across socioeconomic status subsamples, which should therefore be assessed separately within each subsample. We anticipated the possibility of heterogeneity and thus specified the threshold for absence of homogeneity of effect was specified at a p value of less than 0.10.^{25,26} The protocol specified logistic regression and associated odds ratios (ORs) as the measure of effect, but we used relative risk to improve understanding. On the basis of the intention-to-treat principle, individuals who did not respond to endpoint follow-up attempts were retained in the analyses and classified as continuing smokers according to the RS6 criteria.²² To provide per-protocol analyses, we also calculated ORs, percentage-point differences, and 95% CIs. As post-hoc sensitivity analyses, we re-examined the models: with exclusion of participants in full-time education from the

	Lower SES (N=2142)*		Higher SES (N=2471)		Total (N=4613)	
	StopAdvisor (n=1088)	Control (n=1054)	StopAdvisor (n=1233)	Control (n=1238)	StopAdvisor (n=2321)	Control (n=2292)
Female	658 (61%)	632 (60%)	804 (65%)	796 (64%)	1462 (63%)	1428 (62%)
Age (years)	39.8 (14.8)	39.4 (14.3)	39.2 (11.3)	38.3 (10.9)	39.5 (13.0)	38.8 (12.5)
Married	504 (46%)	490 (47%)	643 (52%)	641 (52%)	1147 (49%)	1131 (49%)
Having children	704 (65%)	690 (66%)	678 (55%)	656 (53%)	1382 (60%)	1346 (59%)
White ethnic origin	1029 (95%)	970 (92%)	1152 (93%)	1134 (92%)	2181 (94%)	2104 (92%)
Presently in full-time education	121 (11%)	116 (11%)	71 (6%)	71 (6%)	192 (8%)	187 (8%)
No post-16 years old educational qualification	548 (50%)	525 (50%)	321 (26%)	293 (24%)	869 (37%)	818 (36%)
Cigarettes smoked per day	20.5 (9.4)	20.3 (9.4)	17.1 (8.1)	16.9 (8.3)	18.7 (8.9)	18.5 (9.0)
Age of smoking initiation (years)†	16.2 (5.3)	16.2 (4.3)	17.2 (4.9)	17.1 (4.2)	16.7 (5.1)	16.7 (4.2)
Never previously used support in a quit attempt	431 (40%)	434 (41%)	450 (37%)	509 (41%)	881 (38%)	943 (41%)
Never previously used behavioural support in a quit attempt	616 (57%)	637 (60%)	721 (59%)	798 (65%)	1337 (58%)	1435 (63%)
Made quit attempt in the previous year	394 (36%)	353 (34%)	457 (37%)	441 (36%)	851 (37%)	794 (35%)
Confidence in stopping score (1–7)	4.8 (1.7)	4.7 (1.7)	4.6 (1.6)	4.7 (1.6)	4.7 (1.7)	4.7 (1.6)
Never stopped for more than 1 week	459 (42%)	433 (41%)	348 (28%)	388 (31%)	807 (35%)	821 (36%)
Usually smokes within 5 min of waking	465 (43%)	400 (38%)	324 (26%)	298 (24%)	789 (34%)	698 (31%)
HSI score (0–6)	3.5 (1.4)	3.4 (1.4)	2.8 (1.5)	2.7 (1.5)	3.1 (1.5)	3.0 (1.5)
FTND score (0–10)	5.6 (2.3)	5.5 (2.3)	4.6 (2.5)	4.5 (2.4)	5.1 (2.4)	5.0 (2.4)
Time with smoking urges score (0–5)	3.1 (1.1)	3.0 (1.1)	2.7 (1.0)	2.7 (1.0)	2.9 (1.1)	2.9 (1.0)
Strength of smoking urges score (0–5)	3.3 (1.0)	3.2 (1.0)	3.0 (1.0)	3.0 (1.0)	3.1 (1.0)	3.1 (1.0)
MPSS-mood subscale (0–4)‡	2.6 (0.9)	2.5 (0.9)	2.3 (0.8)	2.3 (0.8)	2.4 (0.9)	2.4 (0.9)
Time to complete online recruitment (min)	11.3 (6.8)	11.3 (6.0)	10.3 (5.9)	10.1 (6.1)	10.8 (6.4)	10.7 (6.1)
Pages viewed to complete online recruitment	19.2 (2.5)	19.1 (1.9)	19.7 (2.5)	19.5 (1.5)	19.5 (2.5)	19.3 (1.7)

Data are n (%) or mean (SD), unless otherwise indicated. SES=socioeconomic status. HSI=heaviness of smoking index.²⁸ FTND= Fagerström test for nicotine dependence.²⁸ MPSS=mood and physical symptoms scale. *Lower SES individuals were those who had never worked, were long-term unemployed, or were from routine and manual occupations according to the National Statistics Socio-Economic Classification self-coded method.²¹ †Data for age of smoking initiation were missing for seven participants (higher SES: n=1 StopAdvisor, n=1 control; lower SES: n=3 StopAdvisor, n=2 control). ‡The MPSS-mood subscale is the mean of responses to five separate states: depressed, irritable, restless, hungry, and poor concentration.

Table 1: Baseline characteristics [A: letters indicating significance have been deleted because any differences between groups at this stage should be due to chance (if randomised properly)]

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classification of those in the subsample with lower socioeconomic status to assess the effect on results of individuals who might have been inappropriately classified; with reclassification of individuals with lower socioeconomic status as those who did not have post-16 education to assess whether results extended across an alternative operationalisation of socioeconomic status; and with self-reported smoking cessation at the 7 month endpoint to show the effect of biochemical verification. We compared website usage with *t* tests without the assumption of equality of variance. We did analyses with SPSS (version 22.0.0.0).

The study is registered as an International Standard Randomised Controlled Trial, number ISRCTN99820519.

Role of funding source [A: edited based on our standard wording for when funders have had no role]

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. JB, JAS, and RW had full access to all the data in the study and JB had final responsibility for the decision to submit for publication.

Results

[A: our style is to not include subheadings in this section] [A: when data are shown in tables or figures, we avoid repeating them in the text]

Figure 1 shows the trial profile.²⁷ We randomly assigned 4613 participants to the StopAdvisor group (n=2321) or the control group (n=2292); 2142 participants were of lower socioeconomic status and 2471 participants were of higher status (figure 1). 1300 (28%) participants were lost to follow-up (figure 1). However, of these, 258 (20%) individuals reported usual smoking at an earlier time in the previous 6 months [A: correct?], which would have classified them as smokers by our sustained abstinence (RS6) primary outcome, meaning that the effective follow-up rate for the primary outcome was 77% (1300–258=1042, 4613–1042=3571, 3571/4613). This rate was not dissimilar between intervention groups, or between patients in different socioeconomic subsamples (figure 1). The remaining 1042 (23%) participants were assumed to have continued smoking according to RS6 criteria. Baseline characteristics of participants assumed to be smoking did not differ between intervention groups,

	StopAdvisor	Control	Relative risk (95% CI)*	Odds ratio (95% CI)†	Percentage-point difference (95% CI)	p value‡
Primary outcome (abstinence for 6 months)						
Higher SES	147/1233 (12%)	156/1238 (13%)	0.95 (0.77 to 1.17)	0.94 (0.74 to 1.19)	-0.68 (-3.27 to 1.91)	0.61
Adjusted [A1]	0.97 (0.78 to 1.19)§	0.95 (0.75 to 1.22)§	..	0.75
Lower SES	90/1088 (8%)	64/1054 (6%)	1.36 (1.00 to 1.86)	1.39 (1.00 to 1.94)	2.20 (0.02 to 4.38)	0.0499
Adjusted [A1]	1.43 (1.05 to 1.96)§	1.46 (1.04 to 2.05)§	..	0.025
Secondary outcome (point prevalence at 6 months)						
Higher SES	222/1233 (18%)	232/1238 (19%)	0.96 (0.81 to 1.13)	0.95 (0.78 to 1.17)	-0.74 (-3.79 to 2.32)	0.64
Adjusted [A1]	0.96 (0.82 to 1.14)§	0.95 (0.77 to 1.17)§	..	0.66
Lower SES	136/1088 (13%)	100/1054 (10%)	1.32 (1.03 to 1.68)	1.36 (1.04 to 1.79)	3.01 (0.37 to 5.66)	0.027
Adjusted [A1]	1.39 (1.09 to 1.78)§	1.41 (1.07 to 1.88)§	..	0.0081

Data are n/N (%), unless otherwise indicated. SES=socioeconomic status. The rate for reporting not smoking but failing to provide biochemical verification was 5% (207/4613) for the primary outcome and 9% (392/4613) for the secondary outcome; these rates were similar between the intervention groups in each SES subsample. Participants lost to follow-up were counted as treatment failures. *The primary analyses were all unadjusted. †Odds ratios rather than relative risks were specified as the measure of effect in the protocol. Relative risks were also calculated to improve understanding. ‡In the case of the adjusted analyses, p values relate to the log-binomial models used to calculate the relative risk. §Adjusted results are presented as a sensitivity analysis. The adjusted models include all characteristics presented in table 1. [A1: is this correct to have the row called adjusted?]

Table 2: Effect of StopAdvisor on biochemically verified smoking cessation

or between participants in different socioeconomic status subsamples (data not shown).

In the recruited sample, daily cigarettes smoked and measures of tobacco dependence²⁸ were high and a third of participants had not stopped for more than 1 week since becoming a regular smoker (table 1). About 60% of participants had never previously used any behavioural support during a quit attempt, while about 40% had never previously used any type of smoking cessation treatment (table 1). Baseline characteristics were mostly similar in the two intervention groups overall and among participants with different socioeconomic status; however, individuals in the control group were more likely than those in the StopAdvisor group to have never previously used behavioural support, a difference that was also evident in the higher, but not the lower, socioeconomic status subsample (table 1). Both intervention groups, irrespective of socioeconomic status, showed a similar level of engagement with the trial recruitment website, spending roughly 11 min to view and interact with a mean of 19 pages (table 1).

The overall rate of smoking cessation was similar between participants in the StopAdvisor and control groups for both the primary (n=237 [10%] vs n=220 [10%]; relative risk [RR] 1.06, 95% CI 0.89–1.27; p=0.49) and the secondary (n=358 [15%] vs n=332 [15%]; 1.06, 0.93–1.22; p=0.37) outcomes. However, analysis of the interaction between intervention and socioeconomic status showed clear evidence of non-ignorable heterogeneity of intervention effect by both primary (RR 1.44, 95% CI 0.99–2.09; p=0.0562) and secondary (RR 1.37, 1.02–1.84; p=0.0360) cessation measures. This finding was evident before and after adjustment for all other baseline characteristics (data not shown [A: ok?]). Consequently, the analysis of outcome was done separately within each of the two socioeconomic status subsamples.

In the subsample of patients with lower socioeconomic status, a benefit of StopAdvisor was evident for both primary and secondary measures compared with the information-only website, whereas in those with higher socioeconomic status, no evidence of a difference was shown (table 2). Adjustment for all baseline characteristics had a negligible effect on these comparisons (table 2). In a post-hoc sensitivity analysis, we re-examined the effect of StopAdvisor on biochemically verified smoking cessation in participants with lower socioeconomic status, after exclusion of those in full-time education from the classification (n=237). The benefit of StopAdvisor compared with the information-only website remained in both unadjusted (primary outcome 87 [9%] of 967 vs 60 [6%] of 938 participants; RR 1.41, 95% CI 1.03–1.93; p=0.0346; secondary outcome 130 [13%] vs 88 [9%] participants; 1.43, 1.11–1.85; p=0.0057) and adjusted (primary outcome 1.48, 1.07–2.04; p=0.0170; secondary outcome 1.52, 1.18–1.97; p=0.0013) models. In a second sensitivity analysis, we re-examined the models with lower socioeconomic status participants reclassified as those who did not have post-16 education. In this smaller subsample (n=1687), the results were consistent with the primary analyses for StopAdvisor versus information only, but were non-significant in both the unadjusted (primary outcome 80 [9%] of 869 vs 60 [7%] of 818 participants; RR 1.26, 95% CI 0.91–1.73; p=0.17; secondary outcome 111 [13%] vs 86 [11%] participants; 1.21, 0.93–1.58; p=0.15) and adjusted (primary outcome 1.27, 0.92–1.75; p=0.15; secondary outcome 1.21, 0.92–1.58; p=0.17) models. In a final post-hoc sensitivity analysis, we re-examined the effect of StopAdvisor with self-reported rather than biochemically verified measures of smoking cessation at the 7 month endpoint. On the basis of similar rates of failing the biochemical

verification criteria between intervention groups, the new analyses showed a similar pattern of results as those reported in table 2 (appendix). In the subsample with lower socioeconomic status, StopAdvisor showed benefit compared with information only; however, results were not significant (self-reported 6 month abstinence 141 [13%] of 1088 vs 114 [11%] of 1054 participants, unadjusted RR 1.20, 95% CI 0.95–1.51; $p=0.13$; adjusted RR 1.23, 0.97–1.56; $p=0.08$; self-reported point-prevalence 227 [21%] vs 195 [19%] participants, unadjusted RR 1.13, 0.95–1.34; $p=0.17$; adjusted RR 1.18, 0.99–1.40; $p=0.07$). That statistical tests in participants with low socioeconomic status subsample failed to reach significance was probably related to the decreased power to detect a percentage difference between the two groups because of the increased absolute rates.

StopAdvisor was used more regularly than the control website in terms of log-ins, page views, and time spent on the website (table 3). This effect was evident in both socioeconomic status subsamples, but was slightly larger in patients with higher socioeconomic status. In the StopAdvisor group, 1216 participants (52%; low socioeconomic status 535 [49%] of 1088 participants; high socioeconomic status 681 [55%] of 1233 participants) chose to use the interactive calendar to set a quit date and 741 (32%; low socioeconomic status 327 [30%]; high socioeconomic status 414 [34%]) opted to report use of a stop smoking drug and receive ongoing advice tailored to the drug type. In both socioeconomic status subsamples, in participants accessing the pre-quit interactive menu, the item most often selected at least once during the first visit was a section entitled 'what is the secret to success?', which aimed to boost motivation and self-effectiveness, strengthen ex-smoker identity, and offer advice about stop-smoking drugs (low socioeconomic status 302 [28%] of 1069 participants; high socioeconomic status 436 [36%] of 1223 participants). This item remained the most popular in participants who revisited the menu before their quit date (low socioeconomic status 105 [33%] of 319 participants; high socioeconomic status 133 [37%] of 359 participants). During the first post-quit date dialogue session, of participants who reported cravings and received a self-regulatory control tip, most requested at least one additional tip (low socioeconomic status 108 [53%] of 204 participants; high socioeconomic status 181 [65%] of 280 participants). Of participants visiting the post-quit interactive menu, the items most often selected at least once during the first visit by smokers of low socioeconomic status ($n=260$) were the 'your progress' section, which tracked days since quitting, money saved, and health benefits accrued ($n=68$ [26%]); audio of relaxation techniques ($n=54$ [21%]); and sections featuring a gallery of motivational pictures and music to improve mood and distract ($n=both$ 52 [20%]), whereas smokers with high socioeconomic status ($n=378$) selected sections monitoring 'your progress' (140 [37%]), why cigarettes are addictive (94 [25%]), and frequently asked

	StopAdvisor (n=2321)	Control (n=2292)	t test	Mean difference (95% CI)	p value
Log-ins*					
Higher SES	5.0 (6.2)	1.4 (0.7)	t(1267) 20.1	3.6 (3.2–3.9)	<0.0001
Lower SES	4.1 (5.7)	1.3 (0.6)	t(1113) 16.4	2.9 (2.5–3.2)	<0.0001
Total time (min)†					
Higher SES	26.9 (38.9)	1.3 (3.2)	t(1248) 23.1	25.6 (23.5–27.8)	<0.0001
Lower SES	22.1 (34.4)	1.1 (2.5)	t(1099) 20.1	21.1 (19.0–23.1)	<0.0001
Total page views					
Higher SES	93.1 (119.8)	6.1 (5.2)	t(1237) 25.5	87.0 (80.3–93.7)	<0.0001
Lower SES	75.5 (105.0)	5.3 (4.1)	t(1090) 22.0	70.2 (64.0–76.5)	<0.0001

Data are mean (SD), unless otherwise indicated. All analyses in this table are unadjusted. SES=socioeconomic status. *The modal number of log-ins was 1 for both treatments in each SES subsample. The appendix provides log-in data presented categorically. †Time on website is an underestimate—time on last page is always unknown in LifeGuide interventions. Interaction between a browser and LifeGuide server happens when a page is loaded. After that, there is no further communication until another page is loaded from the same server. Time on page is calculated by taking the exact time a page was loaded (from the LifeGuide server) and comparing it with the exact time that the previous page in the session was loaded. When a user closes their tab, or just types a different website in to the address bar, no interaction happens between the browser and the server, so it is not possible to identify the time the final action occurred. [A: what are the numbers in parentheses in the t test column?]

Table 3: Usage of StopAdvisor versus the control website

questions (91 [24%]). During re-visits to this menu, the 'your progress' section remained the most often selected at least once in both subsamples (low socioeconomic status 142 [67%] of 215; high socioeconomic status 219 [68%] of 320).

Assessment of outcomes omitted from the main analyses on the basis of low response rates (ranging from 21% to 48% [A: please provide exact numbers with percentages]) was consistent with analyses of the primary and secondary outcomes (appendix). Self-reported abstinence at 2 months and 4 months after enrolment was numerically, but not significantly, greater in participants allocated to StopAdvisor than in those allocated to the control website in the subsample with lower socioeconomic status, whereas the rates were almost identical in those with higher socioeconomic status (data not shown). Self-report of a serious quit attempt was similar between groups in both socioeconomic status subsamples, and the satisfaction ratings were consistently higher for StopAdvisor than with the control website (data not shown).

Discussion

Our findings show that overall rates of cessation were similar between participants allocated to the interactive StopAdvisor website and those in the brief-advice control group, but the intervention effect was dependent on socioeconomic status—StopAdvisor was an effective aid to smoking cessation in smokers of lower, but not higher, socioeconomic status. Furthermore, StopAdvisor resulted in greater usage than did the static, brief-advice website.

Health inequality is a global research priority. A strength of this study is that, to our knowledge, it is the first to focus on the effect of internet support on smoking

Panel: Research in context**Systematic review**

We consulted a recent Cochrane review and did a meta-analysis of the effectiveness of interactive internet-based smoking cessation interventions.^{10,36} The meta-analysis was done at the start of the project and included studies obtained from searches of computerised databases done in December, 2008: PubMed (1990–2008/12), PsycINFO (1990–2008/12), CINHAL Plus (1990–2008), EconLit (1990–2008/11), ISI Web of Science (SCI, SSCI, AHCI; 1990–2008) and CENTRAL (Cochrane Registry of Controlled Trials, 1990–2008).³⁶ We searched Medline with relevant MeSH terms {'('Online Systems' OR 'Internet') AND 'Smoking Cessation'] AND 'Randomized Controlled Trial'}. All other databases were searched with free text terms: {'('Internet' OR 'Online' OR 'Web') AND 'Smoking cessation'] AND ('RCT' OR 'Randomised controlled trial' OR 'Random* trial')}. We included 11 relevant randomized controlled trials and found a significant treatment effect (RR 1.5), but that there was also significant heterogeneity in effect size. The Cochrane review was done in April, 2013, and searched the Cochrane Tobacco Addiction Group register for records including the terms 'internet' or 'www*' or 'web' or 'net' or 'online'.

The specialised register included results from CENTRAL, MEDLINE, EMBASE, and PsycINFO. The review identified 28 relevant studies but clinical and statistical heterogeneity limited the ability to pool studies.¹⁰ Although there is a huge potential for these interventions to have a high effect at low-cost, our conclusion is that existing research has produced mixed results and is limited by a scarcity of biochemically verified long-term outcomes.¹⁰ Furthermore, internet-based smoking cessation interventions might be less effective for smokers with lower socioeconomic status [A:why?].¹¹ The present trial was, to our knowledge, the first to focus on the effect of internet support on smoking within different socioeconomic status groups.

Interpretation

Our findings show that the interactive internet-based smoking cessation intervention, StopAdvisor, is more effective than an information-only website in smokers with lower, but not higher, socioeconomic status. User testing of the website was done exclusively in smokers with lower socioeconomic status and seems to have been successful in producing an effective website for that group.¹³ Future research should explore whether this outcome was at the expense of meeting the needs of smokers with higher socioeconomic status. In the meantime, StopAdvisor could be implemented easily and made freely available; smokers with higher socioeconomic status would be unlikely to benefit, but there is no evidence that their use of the website would lead them to be any less successful.

within different socioeconomic status groups (panel [A: we need to cite the panel somewhere in the discussion. Ok here? If so I will renumber the references]). The finding that StopAdvisor helped smokers in lower but not higher socioeconomic status groups suggests that concern about online support being more effective for smokers in higher socioeconomic groups smokers is unwarranted.¹¹ Findings from previous studies have shown that smokers of lower socioeconomic status engaged less with internet-based support,¹¹ which may have arisen from inequalities in online literacy. However, the user testing of StopAdvisor was done exclusively in smokers with lower socioeconomic status and seems to have been successful in producing an effective website for that group.¹³ This outcome could have been at the expense of failing to meet the needs of smokers with

1 higher socioeconomic status. Future research should explore this possibility with a view to tailor the content of StopAdvisor to socioeconomic status. In the meantime, StopAdvisor could be implemented easily and made
5 freely available; smokers with higher socioeconomic status would be unlikely to benefit, but no evidence shows that use of the website would lead this group to be any less successful at quitting.

Although the effect on cessation in smokers with lower socioeconomic status was relatively modest (RR 1.4), this finding is clinically significant because of the huge health gains associated with stopping smoking. An effect of as little as 1% on rates of 6-month sustained abstinence would result in at least 3 additional years of life for every
15 100 40-year-old smokers treated.²⁴ Additionally, the effect size is not dissimilar to other modes of delivery for behavioural support (meta-analyses of cessation after at least 6 months compared with nothing or minimal controls: telephone counselling RR 1.3 [44 studies based
20 on 1557 successes from 12 388 vs 1201 of 12 423 participants]; individual counselling RR 1.4 [22 studies based on 564 of 4665 vs 433 of 4922 participants]; mobile-phone-based intervention RR 1.7 [five studies based on 444 of 4730 vs 240 of 4370
25 participants]),⁵ and internet-based interventions may be more cost-effective than other interventions because of the potential reach and relatively small ongoing costs.

The absolute rates of cessation were high in our study: 8% in the intervention group and 6% in the control group
30 in smokers of low socioeconomic status, and 12% across both [A: ok?] groups in those of high socioeconomic status. By comparison, the rate was 6% across treatment groups in the only other trial of internet support to have reported biochemically verified measures of sustained
35 abstinence,²⁹ whereas a frequently cited assessment of text-messaging support for cessation reported rates of 11% in the intervention group and 5% in the control group.²⁰ The relatively high rates in participants allocated to the control website in the present study draws attention
40 to the pragmatic nature of the trial, which tested the effect of StopAdvisor over and above all other available real-world treatments, including support offered on the site through which participants were recruited to the trial. The increased rates in smokers with higher socioeconomic
45 status compared with those of lower status shows the well-established gradient in success rates between the groups.⁸ Although the quit rates were reduced in participants allocated to StopAdvisor in smokers of lower socioeconomic status smokers compared with those of
50 higher status, the salient point is that the gradient seems reduced relative to those allocated to the control website in smokers of lower socioeconomic status.

The intervention engaged a large proportion (roughly 60%) of smokers who had never previously used
55 behavioural support. This finding should mitigate concern about internet support mainly engaging smokers who would otherwise have used treatments

with an established evidence base, such as face-to-face behavioural support. There is a law of attrition in electronic health care, which specifies a substantial proportion of users drop out before completion of treatment.³⁰ The mean usage of StopAdvisor was between four and five log-ins, which compares favourably with other relevant trials,³¹ but masks variability in users, whereby a substantial proportion of participants will only have used StopAdvisor once. Future research should examine how prompts and reminders can best engage an increased proportion of users to maintain interaction with treatment websites.

Our study has limitations. First, we recruited participants directly from the internet. As such, this study has shown that the intervention is effective for the kinds of smokers of lower socioeconomic status who have access to the internet. In the future, whether the intervention will be able to reduce health inequalities resulting from smoking will also be dependent on uptake. The issue is not straightforward, because on one hand, smokers with lower socioeconomic status tend to have less access to the internet than do those with higher status,³² but on the other hand, they are just as likely to express interest in use of online support,⁹ and the diffusion of internet access has been rapid and will only increase.³³ Second, the research was done in a high-income country. Our findings will not necessarily generalise to other countries where lower socioeconomic status groups might have less online experience and skills than do those in the UK. Although cost-effective population approaches to cessation, including internet-based support, are particularly appealing to individuals in low-income and middle-income countries, further assessment is needed within those contexts before the approach can be recommended confidently. Third, we were unable to comprehensively assess participants' use of other treatments during the trial. The effective use of other treatments—particularly stop-smoking drugs—might have been a key moderator of effectiveness. StopAdvisor is a complex intervention that has been developed on the basis of evidence, theory, user and web-design input, and with the primary intention that the website should be maximally effective. The finding that the difference in log-ins, time on webpages, and page views between the control and intervention websites was similar between socioeconomic status subgroups suggests that this type of usage did not mediate the effectiveness of StopAdvisor for smokers of lower socioeconomic status. Future research should identify the causal components, possibly in a series of fractionated factorial designs that could allow StopAdvisor to be refined and optimised.^{34,35} That the trial has been done with detailed and transparent reporting of the development and content of the website should aid this process.¹³ In the meantime, the trial has pragmatically shown that StopAdvisor is more effective than the types of websites that are typically used by smokers searching

for online support in the UK—ie, static information-only websites. Fourth, socioeconomic status is a complex concept and difficult to assess without an interviewer being present. Use of the NS-SEC measure benefitted from being validated, but use of an occupationally-based assessment of socioeconomic status was limited by the classification of never workers into the lower socioeconomic status group in the dichotomised version. This limitation likely accounted for the greater proportion of participants with lower socioeconomic status being in full-time education than those with higher socioeconomic status. However, the NS-SEC measure did seem to accurately report the effect of socioeconomic status in other respects: compared with smokers with high socioeconomic status, those with lower socioeconomic status were less likely to have post-16 qualifications or be married, and were more likely to be overweight [A:ok?], more dependent smokers who started smoking at a younger age. Consistent with this limitation, the benefit of StopAdvisor over the information-only control website seemed to be slightly greater in the post-hoc sensitivity analysis, which excluded smokers in full-time education from the subsample with lower socioeconomic status. [A: edited to avoid repetition. Please provide a couple of sentences stating what should happen next/what clinicians should do now]

Contributors

RW, SM, and LY conceived the original idea for the development of the website and this trial, and obtained funding. JB and AWAG coordinated the development of the website. JB, SM, JAS, and RW wrote the study protocol. JB managed the day-to-day running of the trial, including all participant follow-up. JAS, JB, and RW wrote and undertook the data analyses. This article was written by JB with input from all co-authors. JB is guarantor for this article. All authors read and approved the final version. [A: do LB and BG have specific roles?]

Declaration of interests

All authors report receiving grants from National Prevention Research Initiative during the study; JB reports grants from Pfizer, outside the submitted work. LS reports personal fees from Pharmaceutical companies that make smoking cessation products, outside the submitted work. RW reports receiving grants and personal fees from companies that develop and manufacture smoking cessation drugs, outside the submitted work, and has had a patent issued for the 'Nicotine Cannon' (novel nicotine delivery device).

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