



A pilot study of StopAdvisor: A theory-based interactive internet-based smoking cessation intervention aimed across the social spectrum

Jamie Brown ^{a,*}, Susan Michie ^{b,c}, Adam W.A. Geraghty ^d, Sascha Miller ^d, Lucy Yardley ^d, Benjamin Gardner ^a, Lion Shahab ^a, John A. Stapleton ^a, Robert West ^{a,c}

^a Cancer Research UK Health Behaviour Research Centre, Department of Epidemiology and Public Health, University College London, London, UK

^b UCL Medical School and Division of Psychology and Language Sciences, University College London, London, UK

^c NHS Centre for Smoking Cessation and Training, London, UK

^d School of Psychology, University of Southampton, Southampton, UK

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ABSTRACT

Background: This article reports a pilot study of a new smoking cessation website ('StopAdvisor'), which has been developed on the basis of PRIME theory, evidence, web-design expertise and user-testing. The aims were to i) evaluate whether cessation, website usage and satisfaction were sufficiently high to warrant a randomised controlled trial (RCT) and ii) assess whether outcomes were affected by socio-economic status.

Methods: This was an uncontrolled pilot study. Two hundred and four adult daily smokers willing to make a serious quit attempt were included. All participants received support from 'StopAdvisor', which recommends a structured quit plan and a variety of evidence-based behaviour change techniques for smoking cessation. A series of tunnelled sessions and a variety of interactive menus provide tailored support for up to a month before quitting through until one-month post-quit (<http://www.lifeguideonline.org/player/play/stopadvisordemonstration>). The primary outcome was self-report of at least 1 month of continuous abstinence collected at 2 months post-enrolment and verified by saliva cotinine or anabasine. Usage was indexed by log-ins and page views. Satisfaction was assessed by dichotomous ratings of helpfulness, personal relevance, likelihood of recommendation and future use, which were collected using an online questionnaire at 2 months post-enrolment. Outcomes according to socio-economic status were assessed.

Results: At 8 weeks post-enrolment, 19.6% (40/204) of participants were abstinent according to the primary outcome criteria (95% C.I. = 14.1% to 25.1%). Participants viewed a mean of 133.5 pages (median = 71.5) during 6.4 log-ins (median = 3). A majority of respondents rated the website positively on each of the four satisfaction ratings (range = 66.7% to 75.3%). There was no evidence of an effect of socio-economic status on abstinence (OR = 1.01, C.I. = 0.50–2.07), usage (page-views, $t(202) = 0.11, p = .91$; log-ins, $t(202) = 0.21, p = .83$), or satisfaction (helpfulness, OR = 1.09, C.I. = 0.41–2.88; personal relevance, OR = 0.55, C.I. = 0.20–1.56; recommendation, OR = 0.98, C.I. = 0.34–2.81; use in future, OR = 1.45, C.I. = 0.49–4.27).

Conclusions: The systematic application of theory, evidence, web-design expertise, and user-testing has resulted in a website that shows sufficiently promising efficacy and usability to warrant evaluation in a RCT. The website appears to be similarly effective and acceptable to users across the social spectrum.

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1. Introduction

Smoking remains the largest single preventable cause of premature death and illness worldwide (Shafey, Erikson, Ross, & Mackay, 2009; World Health Organisation, 2009). There is a pressing need to find better ways of helping smokers to stop, particularly those from

disadvantaged groups who want, and try, to stop as much as other smokers but find it more difficult (Kotz & West, 2009).

One largely untapped mode of support is the Internet, which has the potential for wide reach – 77% of British households now have Internet access (Office for National Statistics, 2011) – and for helping people who do not wish to engage in face-to-face behavioural support (Graham, Cobb, Raymond, Sill, & Young, 2007; Saul et al., 2007). It can also have extremely low cost per user (Swartz, Noell, Schroeder, & Ary, 2006). However, recent evidence from a nationally representative sample of 1237 English smokers showed that only 1.1% of those making a quit attempt in the previous year reported having used a website to help them (West & Fidler, 2010).

* Corresponding author at: Health Behaviour Research Centre, Department of Epidemiology and Public Health, University College London, 1–19 Torrington Place, London WC1E 6BT, UK. Tel.: +44 20 7679 53179; fax: +44 20 7679 8354.

E-mail address: jamie.brown@ucl.ac.uk (J. Brown).

The potential effectiveness of Internet-based smoking cessation interventions has been the subject of three recent systematic reviews (Civljak, Sheikh, Stead Lindsay, & Car, 2010; Myung, McDonnell, Kazinets, Seo, & Moskowitz, 2009; Shahab & McEwen, 2009). It is clear that Internet-based interventions can help smokers to stop compared with brief written materials or no intervention. However, all three reviews emphasised the considerable heterogeneity in the outcomes, design and usability of the interventions and the need for further research to evaluate the relative efficacy of specific components of online interventions. In order to allow this research to advance, there have been repeated calls for improved reporting in the content of Internet-based interventions (e.g., Crutzen, 2011; Michie, 2008; Strecher, 2008).

The 'digital divide' that characterises Internet use in the wider population is also true of smokers (Stoddard & Augustson, 2006). Smokers who use the Internet tend to be more affluent and educated than those who do not (Stoddard & Augustson, 2006). However, Internet access is increasing (Dutton, Helsper, & Gerber, 2009) and it is vital that more disadvantaged groups are not excluded or left behind due to their lack of access. To this end, there is evidence that digital divide issues can be mitigated by targeting interventions at disadvantaged groups and including them in the design process (Gilmour, 2007; Glasgow, 2007).

The development of the StopAdvisor website is reported in detail elsewhere (Michie et al., *in press*). Development was systematically informed by: i) the PRIME theory of motivation (West, 2006), ii) empirical evidence, iii) expertise in web-design, and iv) user-testing with a panel of socio-economically disadvantaged smokers. PRIME theory is an integrative theory of motivation which recognises that behaviour is determined by multiple sources on a moment-to-moment basis. PRIME describes the ways in which *plans* provide an overarching structure to our behaviour but in order to influence *responses*, they need to generate momentary *impulses/inhibition* which requires creation of *motives* (feelings of want or need) through *evaluations* (positive and negative beliefs). This influence may compete with other sources of motivation arising from internal states (such as drive states, arousal etc.) and external triggers and cues. Thus PRIME Theory provides a framework within which more specific theories can be understood and allows attention to be given to the full range of motivational constructs important in cigarette addiction and smoking cessation (e.g., creation of stimulus-impulse associations resulting in cue-driven urges; impairment of inhibitory control; provision of enjoyment resulting in 'wanting' to smoke; neuroadaptation leading to 'nicotine hunger', withdrawal symptoms and beliefs about benefits of smoking all of which can result in a 'need' to smoke; West, 2009). A systematic analysis of the behaviour change techniques (BCTs) used by Stop Smoking Services in England has revealed associations between specific BCTs and successful quitting (Michie, Churchill, & West, 2011; Michie, Hyder, Walia, & West, 2011; West, Evans, & Michie, 2011; West, Walia, Hyder, Shahab, & Michie, 2010). Additionally, there is evidence that interventions which use theory and a greater number of behaviour change techniques are often more effective than those which do not (Webb, Joseph, Yardley, & Michie, 2010). In an attempt to mitigate digital divide issues and make the website attractive across the social spectrum, we engaged disadvantaged smokers in user-testing of the prototype website. User-testing involved both in-depth interviews and 'think aloud' testing during which users worked through sections of the intervention and spoke whatever came to mind (Yardley, Morrison, Andreou, Joseph, & Little, 2010). Overall, the development was informed by 19 theoretical propositions derived from the PRIME theory of motivation, 33 evidence- or theory-based BCTs (Michie, Hyder, Walia, & West, 2011), 26 web-design principles and nine principles from user-testing (Michie, et al., *in press*).

The website was developed in LifeGuide, an open-source web development platform (Hare et al., 2009). This will facilitate future modification and experimental manipulation of specific intervention components, while also allowing the easy dissemination of successful

components. It will also support collaboration and data sharing between research groups.

Evaluating complex interventions is complicated and the UK's Medical Research Council (MRC) has published guidance to assist researchers in the design and evaluation of new interventions (Campbell et al., 2000; Craig et al., 2008). Piloting is recommended as an important phase in this process. Pilot studies permit an initial assessment of the acceptability of a new intervention to target groups. Additionally, pilots allow researchers to make an informed judgement as to whether an intervention shows sufficiently promising efficacy to warrant further evaluation. To this end, in well-established fields of research the inclusion of a control-arm for under-powered analysis is not necessarily useful or cost-effective. Instead, results can be cautiously interpreted by comparison with existing literature. This paper reports the results of a pilot study of a new Internet-based smoking cessation intervention aimed at engaging socio-economically deprived smokers. The pilot is an example of best practice as recommended by the MRC (Campbell et al., 2000; Craig et al., 2008).

The 'Law of Attrition', which specifies that a large proportion of users drop out before completing an intervention, is well documented in e-health (Eysenbach, 2005). However, two recent systematic reviews of online interventions for smoking and alcohol reported substantial ranges in retention across interventions of 39% to 94% at approximately 6-months following enrolment (smoking, Shahab & McEwen, 2009) and 33% to 100% at up to 12-months follow-up (alcohol, White et al., 2010). These ranges demonstrate that attrition is not universal but that it remains important for assessments of new Internet-based interventions to include measures of usage as indicators of acceptability in addition to ratings of satisfaction.

The objectives of this study were to: i) evaluate whether cessation, website usage and satisfaction were sufficiently high to warrant a RCT and ii) assess whether there was a social gradient in cessation, usage and satisfaction.

2. Methods

2.1. Study design

An uncontrolled pre and post intervention design with 8-week follow-up. The study was approved by the ethics committee of University College London (Study ID: 2808/001).

2.2. Intervention

The content of the website consists of a set of core BCTs (BM1-10; BS1-4, 6-8, 10-11; A1-3,5; RD1-2; RI4; RC1, 4-6,8-10 as labelled within the 'smoking taxonomy'; Michie, Hyder, Walia, & West, 2011) that are linked together under the umbrella of an overarching theme. Based on the success of the NHS Stop Smoking Services, the theme is an expert virtual Stop Smoking Advisor who is both a ready source of useful information and a guide to help the smoker through the process of stopping using a structured quit plan. The interactive and tailored website broadly follows the quit plan in operation in a well-run service with an emphasis on BCTs suited to delivery by the Internet. Personal contact is simulated as far as possible. The website is presented on a standard template and employs a hybrid navigational architecture combining choice of content from menus and 'tunnelled' exposure to key messages. A tunnelled format is one in which users are directed through a series of, often tailored, pages with little navigational control over the content.

Users follow a programme that takes them from preparation for the target quit date to the quit date itself and then encourages them to report important information; the programme uses this information to help them overcome difficulties they report. Prior to their quit date, users have access to an interactive menu and tunnelled sessions tailored according to how soon they intend to quit, their intended use of

medication, their success in obtaining and using medication, and reasons for quitting. They are offered up to five unique dialogue sessions and can opt to take up to two weeks to get medication and two weeks to set a quit date. The preparatory guidance they receive focuses on: acquiring appropriate medication and using it optimally, making necessary changes in routines to minimise difficulties and urges to smoke after the target quit date, developing specific coping strategies for when difficulties arise, and having clear expectations about the natures of those difficulties. After their quit-date users have access to a new interactive menu and up to thirteen tunnelled sessions tailored on self-reported 1) abstinence, 2) urges to smoke, 3) self-efficacy, 4) use of medication and 5) anticipated frequency of stressful or social events. The guidance they receive involves specific advice and BCTs on how to address these problems and plan for the future to minimise their occurrence. These sessions are available with decreasing frequency over the course of the first month following their quit date (seven sessions in the first week, three in the second, two in the third, and one in the fourth week). More detail on the content of the website is available elsewhere (Michie, et al., in press).

2.3. Inclusion/exclusion criteria

Participants were only eligible for inclusion if they were: adults from the UK who smoked every day; willing to make a serious quit attempt; willing to use a stop-smoking website which sends email reminders; willing to be followed up at 2 months post-enrolment; able to provide informed consent; and able to be contacted by email and telephone.

2.4. Recruitment

The sample was recruited via an advert placed on the UK Department of Health's smoking cessation portal for 4 days in June 2011. The advert generated 1310 hits from which 228 people signed up, 217 completed baseline measures and a total of 204 smokers were included. No participant withdrew consent and therefore all included smokers were contacted at follow-up. Those who did not respond were counted as smokers within the primary intention-to-treat analysis of cessation.

2.5. Procedure

After viewing the advert participants were directed to a host site where they read study information, gave informed consent and completed all baseline measures. Participants then proceeded with the fully-automated intervention, which allowed them up to 4 weeks to set a quit date, and only had contact with the research team for technical questions. At 8 weeks after their enrolment participants were sent a link to an online questionnaire, which included the self-reported abstinence and satisfaction outcome measures. Participants who reported being abstinent were asked to provide a saliva sample and those who agreed were sent a £20 gift voucher and a cotton dental roll, which they returned by post to a laboratory for analysis. Participants failing to respond to email invitations and reminders were followed-up using all other available contact details. All invitations and contacts were structured according to evidence-based methods for maximising response rates (Edwards et al., 2002; Free et al., 2011).

2.6. Measures

The primary outcome measure was self-report of at least 1 month of continuous (not a puff) abstinence assessed at 2 months post-enrolment and verified by a saliva cotinine level of <15 ng/ml (West, Hajek, Stead, & Stapleton, 2005), or by a saliva anabasine level of <1 ng/ml in participants who reported using medication (Jacob et al., 2002). The timing of the follow-up was related to target quit dates by the conservative assumption that all participants took the longest

possible time to set quit dates (i.e., four weeks). The follow-up period was linked to enrolment rather than individual quit dates as the provision of a quit date was not an inclusion criterion. Therefore, an attempt to tailor follow-up dates to quit dates would have created ambiguity over when to contact participants who used the website to make a quit attempt but failed to report a target quit date. In order for the intervention to warrant further evaluation in a RCT, it was agreed a priori with an independent steering committee that the primary outcome should be approximately 20% or higher, on the basis that that this is double the equivalent figure among those making a serious unaided quit attempt and lasting for 1–2 months, which is estimated to be 10% (West & Stapleton, 2008).

Secondary outcome measures were usage, indexed by log-ins and page views, and satisfaction, indexed by ratings (Stecher, Shiffman, & West, 2005). There were four separate rating scales each of which had a 'Yes' or 'No' response (Did you find the website helpful?; Did you find the website personally relevant?; Would you recommend the site to others?; Would you use the site in the future?).

Smoking history and socio-demographic variables were assessed at baseline including: Fagerström Test for Nicotine Dependence (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991), Mood and Physical Symptoms Scale to assess withdrawal (West & Hajek, 2004), cigarettes per day, years of smoking, longest abstinence during quit attempt, time since last quit attempt, confidence in quitting, age, sex and socio-economic status.

Socio-economic status was assessed by the occupationally-based National Statistics Socio-Economic Classification (NS-SEC) self-coding method (Office for National Statistics, 2005). Individuals were classified into one of two groups – Routine and Manual or Other occupations. An alternative classification according to attainment of post-age 16 educational qualifications was also used.

2.7. Data analyses

The primary outcome was calculated by intention to treat of all participants with those lost to follow-up counted as relapsers (West et al., 2005). As the pilot study was uncontrolled, the outcome measures are presented descriptively and compared with existing literature.

The effect on efficacy and satisfaction of socio-economic status was assessed by logistic regression. The effect on website usage was assessed using t-tests.

To validate the occupationally-based operationalisation of socio-economic status the effect on cessation, satisfaction and usage was re-assessed when smokers were classified according to whether or not they had received post-age16 educational qualifications.

3. Results

The baseline characteristics of participants included in the study are presented in Table 1. Self-reported abstinence at follow-up was available for 169 (83%) participants. Of the 48 (24%) participants self-reporting abstinence, 41 (20%) also provided samples for biochemical verification. Eighty one (40%) participants completed satisfaction ratings.

3.1. Cessation

At 8 weeks post-enrolment, 19.6% (40/204) of participants were biochemically-verified as abstinent according to the primary outcome criteria (95% C.I. = 14.1% to 25.1%). This is double the rate observed among smokers making a serious but unaided quit attempt (West & Stapleton, 2008) and satisfied the a priori criterion set by a steering committee.

Table 1
Baseline characteristics of the sample.

	Total (n) = 204	
Mean age in years (SD)	37.8	(11.8)
% Female (n)	57%	(116)
% Routine and manual occupation (n)	38%	(77)
% Without post-16 educational qualifications (n)	29%	(59)
Mean cigs per day (SD)	17.4	(9.4)
Mean years of smoking (SD)	20.8	(12.1)
Mean dependence (FTND) score (SD)	4.5	(2.8)
Mean cravings (MPSS-C) score (SD)	6.3	(1.7)
Mean physical withdrawal (MPSS-M) score (SD)	11.4	(3.8)
% Never quit or for less than a week (n)	27%	(55)
% Never quit or last attempt over a year ago (n)	63%	(129)
Mean confidence in stopping at this attempt (1–7) (SD)	4.6	(1.7)

3.2. Usage

Participants viewed a mean of 133.5 pages (SD = 124.3; median = 71.5) during a mean of 6.4 log-ins (SD = 6.8; median = 3). 6.4 log-ins was higher than in four out of five Internet-based smoking cessation interventions investigated in a recent RCT that reported relative usage (Pike, Rabijs, McAlister, & Geiger, 2007).

3.3. Satisfaction

Approximately three-quarters of the participants reported that they found the website helpful, would recommend it to a friend, and would use it again in the future while slightly fewer participants judged it personally relevant (see Table 2). Thus, a large majority of participants rated the website favourably. Although of a similar magnitude, this majority was less than the 85%–90% reported in studies of Internet-based smoking cessation interventions providing similar satisfaction data (Brendryen, Drozd, & Kraft, 2008; Brendryen & Kraft, 2008; Strecher et al., 2005).

3.4. Socio-economic status

There was no evidence of an effect on cessation, usage or satisfaction of socio-economic status (see Table 2). This finding remained when adjusting the logistic models for the baseline characteristics in Table 1 (data not shown). Last, this pattern of results was unchanged during a sensitivity analysis in which the effect on cessation, satisfaction and usage was re-assessed when smokers were classified according to whether or not they had received post-age16 educational qualifications (data not shown).

4. Discussion

This pilot study has demonstrated StopAdvisor to have sufficiently promising efficacy and usability to warrant the resources necessary to

evaluate the website in a RCT. There is also evidence that the website is similarly effective and acceptable to users across the social spectrum.

Evaluations of Internet-based smoking cessation interventions have often suffered from an under-reporting of content and consequently researchers are unclear as to the cause of the associated heterogeneity in efficacy (Civljak et al., 2010; Crutzen, 2011; Michie, 2008; Myung et al., 2009; Shahab & McEwen, 2009; Strecher, 2008). StopAdvisor was developed systematically and informed by a broad motivational theory (PRIME), empirical evidence, web-design expertise, and user-testing. We have previously shown that it is feasible to report this development and content transparently (Michie, et al., in press). This pilot study now demonstrates that a website developed in this manner has sufficient efficacy and usability to warrant further evaluation. We are currently running a two-arm randomised controlled trial, with participants randomised to the offer of StopAdvisor or a static website that presents brief and standard advice and followed up for 7 months post-enrolment (ISRCTN99820519). Insofar that the website is effective, transparent reporting and the use of free LifeGuide software should provide a basis for the multi-phase optimisation of Internet-based smoking cessation interventions.

Disadvantaged smokers tend to use the Internet less (Stoddard & Augustson, 2006). However, digital divide issues can be mitigated by including disadvantaged groups in the design process (Gilmour, 2007; Glasgow, 2007). During the development of StopAdvisor, we engaged a panel of socio-economically disadvantaged smokers in user-testing. There was no evidence in the current study that social status influenced efficacy, usage or satisfaction. The implication is that StopAdvisor is similarly effective and acceptable to users across the social spectrum, and that the usability testing conducted with socio-economically disadvantaged smokers during the development of the website was successful. The robustness of these findings in relation to socio-economic disadvantage is being investigated within our ongoing controlled trial.

Almost all effective smoking cessation interventions are also cost-effective because every year that stopping is delayed after the age of 35 loses the smoker 3 months of life on average (Doll, Peto, Boreham, & Sutherland, 2004). Internet-based smoking cessation interventions tend to be particularly cost-effective because the incremental cost per user is negligible – for example, StopAdvisor would have maintenance costs between £0–£2000 p.a. depending on the level of hosting and frequency of site updates. From a RE-AIM perspective (Reach × Efficacy × Adoption × Implementation fidelity × Maintenance), Internet interventions also perform excellently on the dimensions of Reach and Implementation fidelity (Glasgow, Vogt, & Boles, 1999). Traditionally, adoption across a range of settings (health departments, communities etc.) has mitigated the impact of Internet interventions; however, with regard to StopAdvisor it is planned that collaboration with relevant health departments during development will facilitate greater adoption. A quantitative assessment of cost-effectiveness will be conducted once longer-term effectiveness has been established.

Table 2
Outcome measures and the effect of socio-economic status.

	Total (n = 204)	Routine and manual (n = 77)	Other (n = 127)	Effect of socio-economic status
% Biochemically verified 4-week continuous abstinence (95% C.I.)	19.6 (14.1–25.1)	19.5 (10.4–28.5)	19.7 (12.7–26.7)	OR = 0.99 (95% C.I. = 0.48–2.02)
Usage				
Mean log-ins (SD)	6.4 (6.8)	6.5 (7.2)	6.4 (6.6)	$t(202) = 0.11, p = .91$
Mean page views (SD)	133.5 (124.3)	131.1 (126.7)	134.9 (123.4)	$t(202) = 0.21, p = .83$
	(n = 81)	(n = 28)	(n = 53)	
Satisfaction (% positive ratings)				
Helpfulness (95% C.I.)	75.3 (65.7–84.9)	67.9 (49.4–86.3)	79.3 (68.0–90.5)	OR = 0.55 (95% C.I. = 0.20–1.56)
Personal relevance (95% C.I.)	66.7 (56.2–77.2)	67.9 (49.4–86.3)	66.0 (52.9–79.2)	OR = 1.09 (95% C.I. = 0.41–2.88)
Recommendation (95% C.I.)	75.3 (65.7–84.9)	75.0 (57.9–92.1)	75.5 (63.5–87.4)	OR = 0.98 (95% C.I. = 0.34–2.81)
Use in future (95% C.I.)	74.1 (64.3–83.8)	78.6 (62.4–94.8)	71.7 (59.2–84.2)	OR = 1.45 (95% C.I. = 0.49–4.27)

The MRC recommends pilot studies as best practice in the design and evaluation of complex interventions (Campbell et al., 2000; Craig et al., 2008). The current study is strengthened by being the first pilot of an Internet-based smoking cessation intervention to report a biochemically verified measure of abstinence. Additionally, the follow-up procedures resulted in a retention rate of 83%. This compares favourably with best practice within the field; for example, in a review of online smoking cessation interventions retention rates between 1 and 3 month follow-ups ranged from 43% to 96% (Shahab & McEwen, 2009). A possible limitation is that it is uncontrolled. However, we believe that the inclusion of a control-arm for under-powered analysis would have added little value for the accompanying expense. Instead results were compared with existing literature to facilitate interpretation. Another possible limitation is that the primary outcome measure is conservative and is likely to under-estimate the true efficacy of the website. Specifically, we conservatively assumed that all participants took the longest possible time (four weeks) to set quit dates. Hence, it is likely that a significant proportion of smokers reporting 4-week abstinence at follow-up had been abstinent for longer than four weeks. Nonetheless, the observed quit rate remains favourable compared with a more standard measure of unaided quit rates among those making a serious attempt and lasting for 1–2 months (West & Stapleton, 2008) and the conclusion remains valid that StopAdvisor has a sufficiently promising efficacy to warrant evaluation in a RCT. This evaluation will more accurately estimate efficacy by the inclusion of a control condition with equivalent quit date advice and follow-up procedures.

5. Conclusions

There is a need for a generally available smoking cessation website that is attractive and engaging across the social spectrum and of proven effectiveness. This pilot study has demonstrated that the systematic application of theory, evidence, web-design expertise, and user-testing has resulted in a website that shows sufficiently promising efficacy and usability to warrant the resources necessary for evaluation in a RCT. Importantly, there is also evidence that the website is similarly effective and acceptable to users across the social spectrum.

Role of funding sources

The project is funded by a grant from the National Prevention Research Initiative (G0802035). NPRI had no role in the study design, collection, analysis or interpretation of the data, writing the manuscript, or the decision to submit the paper for publication.

Contributors

RW and SMichie conceived of the project. RW, SMichie and JB designed the pilot study, conducted literature searches and provided summaries of previous research studies. JB conducted the statistical analysis. JB wrote the first draft of the manuscript and SMichie provided significant input in re-drafting. All authors contributed to and have approved the final manuscript.

Conflict of interest

LS has received an honorarium for a talk and travel expenses from a pharmaceutical company that makes smoking cessation products to attend meetings and workshops. Prior to 2005, JAS acted as adviser to the manufacturers of smoking cessation medications, for which he has received remunerations and hospitality, and conducted clinical trials with support from the manufacturers of smoking cessation medications. RW undertakes research and consultancy and receives fees for speaking from companies that develop and manufacture smoking cessation medications (Pfizer, J&J, McNeil, GSK, Nabi, Novartis, and Sanofi-Aventis). He has a share of a patent for a novel nicotine delivery device. SMichie, JB, AG, SMiller, LY, and BG have no conflicts.

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