

Effectiveness and economic evaluation of self-help educational materials for the prevention of smoking relapse: randomised controlled trial

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Scientific summary

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Background

Smoking remains the leading preventable cause of premature deaths in the world. Pharmacotherapy and behavioural support are effective in helping motivated smokers to stop smoking. However, relapse rates among short-term quitters are high. In the NHS Stop Smoking Clinics, for example, about 75% of the 4-week quitters go back to regular smoking after between 4 and 52 weeks. The long-term success rates still make these interventions highly cost-effective, but there is a need to find effective interventions to reduce relapse rates after the initial treatment episode.

The results of previous systematic reviews indicated that the risk of smoking relapse may be reduced by self-help educational materials in unaided quitters who are highly motivated to remain smoking abstinent. Specifically, two randomised controlled studies found that the use of a series of eight booklets (*Forever Free*) was cost-effective for the prevention of smoking relapse among unaided self-quitters.

Objective

The objective of this randomised controlled study was to evaluate the effectiveness and cost-effectiveness of a set of eight *Forever Free* booklets in preventing smoking relapse in short-term quitters after intensive behavioural and pharmacological treatments in smoking cessation clinics.

Methods

This was an open, parallel-arm, individually randomised controlled trial. A qualitative process evaluation interviewed a purposive sample of trial participants, and also gathered views via focus groups of health-care professionals.

Trial participants

The target population was carbon monoxide (CO)-verified, 4-week quitters treated in NHS Stop Smoking Clinics who could read English and could give informed consent. The biochemically verified 4-week quitter is defined as a treated smoker who reports abstinence from at least day 14 post quit date to the 4-week follow-up point (or within 25–42 days of the quit date) and who blows an exhaled CO reading of < 10 parts per million (p.p.m.). We excluded 4-week quitters who were pregnant, unable to read booklets in English, from families at the same address and younger than 18 years. For participant recruitment, stop smoking advisors in NHS Stop Smoking Clinics introduced the study, gained consent for participation from their clients and collected baseline data. The trial co-ordinator or administrator randomly allocated recruited participants to the treatment and control groups, using a computerised allocation system provided by the Norwich Clinical Trials Unit.

Interventions investigated

After randomisation, researchers posted the self-help materials to participants' homes. The experimental intervention was the full pack of eight *Forever Free* booklets. Booklet 1 is a brief summary of all issues relevant to smoking relapse prevention. The remaining seven booklets provide more extensive information on important issues for relapse prevention, entitled *Smoking Urges*; *Smoking and Weight*; *What if You Have a Cigarette?*; *Your Health*; *Smoking, Stress, and Mood*; *Lifestyle Balance*; and *Life without Cigarettes*. The original *Forever Free* Booklets were prepared for users in the USA. We revised and updated the booklets in places where it was judged necessary or helpful, to make the material more suitable to British users and the UK NHS. The control leaflet *Learning to Stay Stopped* is commonly used in practice and contains brief but comprehensive information on issues related to smoking relapse and also provides brief recommendations on how to cope with cravings and tempting triggers.

Data collection, outcome measures and sample size

Four weeks after the quit date, stop smoking advisors gathered baseline information from participants who had consented to participate in the trial. Follow-up telephone interviews were conducted by researchers at 3 and 12 months after quit dates (or 2 and 11 months after enrolment). During the follow-up telephone interviews, researchers asked participants about receipt and use of the booklets or leaflet and assessed smoking-related outcomes. At the 12-month follow-up, participants who met the self-report criteria for at least 7-day abstinence were invited to attend a local centre to prove this by exhaled CO. People came to a clinic at the University of East Anglia or a researcher visited them at home for this test. To optimise CO test rates, we offered a shopping voucher (valued £20) to each of the participants who attended the CO test.

The primary end point was prolonged abstinence from months 4 to 12, during which time no more than five cigarettes in total were smoked, and confirmed by CO < 10 p.p.m. at the 12-month follow-up. The secondary outcomes were 7-day self-report abstinence at 3 months (2 months after enrolment), 7-day self-report and CO-validated abstinence at 12 months post quit date (11 months after enrolment).

We collected data on the resource use associated with self-help materials (including intellectual property, adaptation, printing and postage), any additional Stop Smoking Services and cessation products, general practitioner visits and hospital admissions at follow-up interviews. This enabled costs to be estimated from the viewpoint of the NHS and for NHS and participant medication costs. The European Quality of Life-5 Dimensions-3 Level was used to estimate the benefits in terms of the quality-adjusted life-year (QALY) during the study period.

Based on results of an exploratory meta-analysis, the prevalence of smoking abstinence at 12 months was estimated to be 25.0% in the control group and 32.4% in the intervention group. Assuming $\alpha = 0.05$ (type 1 error), $1 - \beta = 0.8$ (statistical power) and a dropout rate of 15%, about 700 participants were required in each arm. The target sample size for this trial was therefore 1400 in total.

The qualitative study sought a purposive sample of approximately 40 participants, selected for maximum variation in core characteristics. Participants undertook separate consent for qualitative interviews at 12-month follow-up and were offered a £20 voucher as reimbursement for their time.

Data analysis methods

The comparison of smoking abstinence outcomes (and any other binary outcomes) between the two trial groups was carried out using an odds ratio (OR) and its 95% confidence interval (CI) as the measure of treatment effect. Participants who declined biochemical verification or who did not respond to follow-up were classified as smokers, although participants who died or were known to have moved away were excluded from the numerator and denominator.

We used exploratory subgroup and logistic regression analyses with interaction terms to investigate possible effect-modifying variables. Association between mediating variables (use of booklets or leaflet) and smoking abstinence at 12 months was also quantitatively investigated by logistic regression or subgroup analyses. We conducted a qualitative process evaluation using data collected as part of the trial telephone follow-up interviews, and a further qualitative substudy of in-depth data collection. As part of a within-trial cost–utility analysis, based on the complete-case approach, regression analysis was used to estimate the mean incremental cost and QALY gain associated with the intervention.

Qualitative data were analysed following a grounded theory approach, inductively drawing out key themes of importance to participants. We explored views of the content, usefulness and practical use of the self-help relapse prevention materials. Analysis was undertaken iteratively alongside data collection and continued until saturation of themes was reached. Analysis was developed through triangulation of data sources, by also collecting the views of health-care professionals and feeding back findings in final participant focus groups.

Results

We randomly allocated 1407 eligible short-term quitters to the intervention or the control group. The participants in the two groups were comparable at baseline in terms of demographic and smoking-related variables. The follow-up rate was 93% at the 3 months and 86% at the 12 months. Three participants who died before the 12-month follow-up were excluded from the final data analysis. At the 12-month follow-up, 725 participants reported abstinence in the previous 7 days and were eligible for a CO test. Verification tests were carried out for 616 of these participants, while 109 participants declined or were unable to have the test.

Smoking abstinence results

The primary outcome was prolonged, CO-verified smoking abstinence from month 4 to 12, during which time no more than five cigarettes were smoked. The proportion of prolonged abstinence was 36.9% in the intervention group and 38.6% in the control group, and there was no statistically significant difference between the intervention and the control group (OR 0.93, 95% CI 0.75 to 1.15).

The 7-day self-report point prevalence of smoking was on average 21% at 3 months and 48% at 12 months, and there were no statistically significant differences between the intervention and the control groups (OR 0.99, 95% CI 0.76 to 1.27, at 3 months and OR 1.03, 95% CI 0.84 to 1.27, at 12 months). The CO-verified smoking abstinence at 12 months was 44% on average, and again there was no difference between the two groups (OR 1.02, 95% CI 0.83 to 1.26). Exploratory analyses found that the relative effect was not statistically significantly associated with participant characteristics at baseline.

Baseline variables and smoking abstinence at 12 months

Carbon monoxide-validated, prolonged smoking abstinence from month 4 to 12 was not statistically significantly associated with sex, education or the receipt of free prescriptions. However, older age was statistically significantly associated with prolonged smoking abstinence from 4 to 12 months ($p = 0.011$). In addition, the increased risk of smoking relapse was significantly associated with marital (single, separated or divorced compared with married or living with a partner) and employment status (unemployed compared with in paid employment).

Prolonged smoking abstinence from 4 to 12 months was not associated with stated reasons for quitting, stated importance, stated determinations or perceived chances of staying off cigarettes for good. Quitters who were treated by specialist level 3 advisors were less likely to return to smoking than those recruited from other types of Stop Smoking Services ($p = 0.023$). The increased risk of smoking relapse was associated with living with a smoking partner ($p = 0.046$), time to first cigarette after waking ($p = 0.005$), smoking more than 10 cigarettes per day before quitting ($p = 0.001$) and any previous quit attempts ($p = 0.001$).

Process and mediating variables

The percentage of participants who reported that they still possessed the booklets was higher in the treatment group than in the control group at the 3-month (83% vs. 62%) and 12-month follow-up (49% vs. 35%). There was no significant difference in the percentage of participants who reported that they had read the booklets or leaflet at 3 months (70% vs. 69%) and between 4 and 12 months (27% vs. 21%). Participants in the intervention group reported spending somewhat more time reading the booklets than control group participants.

The proportion of participants who reported that reading the booklets taught them no more than they knew already was lower in the treatment group at the 3-month follow-up (48% vs. 53%), but there was no difference between the groups at 12 months (49%). There were no significant differences between the groups in the percentages of participants who reported that reading the booklets taught them more about ways to handle urges to smoke at 3 and 12 months.

The percentage of all participants who reported one or more strategies was 87% at the 3-month follow-up and 65% at the 12-month follow-up, and there was no significant difference between the two groups. About 83% of all participants by 3 months and 60% between 4 and 12 months reported enacting a strategy to handle urges to smoke, with no significant differences between the groups.

Prolonged smoking abstinence from 4 to 12 months was statistically significantly associated with booklet reading by 3 months ($p < 0.001$), but not between 4 and 12 months ($p = 0.759$). The risk of relapse by 12 months was lower in participants who reported knowing more about risky situations or knowing more ways to handle urges because they had read the booklets. Participants who reported doing something to handle urges to smoke were less likely to relapse by 12 months than people who had no strategy to cope with urges. Of participants who reported they had tried to handle urges between 4 and 12 months, 48% remained smoking free by 12 months, compared with 23% of those who did not report a strategy.

Qualitative investigation results

With regard to the intervention booklets, participants seem either to be very motivated and to have really engaged with the booklets or to have disliked the booklets and in some cases not read them at all. For those reporting negative feelings towards the booklets, the overall sense was that the booklets did not offer any particularly new or novel insights to what was already known about smoking relapse prevention. Participants were often able to recall advice delivered face to face, but found it more difficult to recall content of the trial intervention booklets.

Economic evaluation results

There was no significant difference in mean costs or mean QALY scores between the intervention and control groups. Although the estimated mean incremental net benefit was positive [£74.79 in the base case at the (λ) value of £20,000 per QALY], the probability of cost-effectiveness was estimated to be only 64.4% according to the cost-effectiveness acceptability curve. Coupled with the aforementioned effectiveness results, this would suggest that we are not able to conclude that the provision of the intervention booklets is cost-effective.

Discussion

The current trial had adequate statistical power, so the result is unlikely to be a false negative. Whereas the present study found no differences in smoking abstinence by 12 months between the experimental and control interventions, the previous studies of the *Forever Free* booklets for smoking relapse prevention reported statistically significant group differences among unaided quitters. The *Forever Free* booklets were originally developed to aid self-quitters in place of more intensive face-to-face treatment, and the previous studies involved those smokers. In contrast, all participants of the current trial had received intensive behavioural support from stop smoking advisors before participating in the trial, and most of them (89%) had previous quit experience. Therefore, it is very likely that they had received information from stop smoking advisors similar to that in the *Forever Free* booklets. In addition, participants in the control group received a single leaflet containing the similar but much briefer points for smoking relapse prevention. The qualitative interviews found that study participants could recall some advice received from stop smoking advisors, while they found it difficult to recall information contained in the booklets.

Conclusions

There was no significant difference in smoking relapse between a set of eight revised *Forever Free* booklets and a single leaflet for the prevention of smoking relapse in quitters who had stopped smoking with the aid of intensive behavioural support. The risk of smoking relapse could not be reduced simply by posting more information to CO-validated 4-week quitters in NHS Stop Smoking Services.

Recommendations for research

1. Actual use of coping skills is associated with a lower risk of long-term smoking relapse. Further research should focus on interventions that may increase the use of coping skills when required.
2. Reasons for different longer-term smoking outcomes across different studies and among individual 4-week quitters need to be investigated. Improved understanding of variables related with smoking relapse may help develop novel interventions for smoking relapse prevention.

Trial registration

Current Controlled Trials ISRCTN36980856.

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