Efficacy and cost-effectiveness of a minimal intervention to prevent smoking relapse: dismantling the effects of amount of content versus contact

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study investigated the use of a smoking relapse prevention programme (named "Forever Free") in terms of different levels of content (one booklet versus 8 booklets) and contact (one mailing versus 8 mailings).

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis and cost-utility analysis.

Study population
The target population were former smokers who would not be attracted to intensive counselling. The initial inclusion criteria were any current smoker who was planning to quit within the next 6 months, and any previous smoker who had been abstinent for no more than 6 months. Criteria applied subsequently meant that the actual study population comprised participants who had abstained from smoking for a least 1 week at the time they completed the baseline questionnaires. Individuals aged at least 18 years who were able to read English and had a mailing address were eligible to enter the study.

Setting
The study was carried out in a community setting. The economic study was carried out in the USA.

Dates to which data relate
The dates to which the effectiveness data related were not stated. The resource use data were not presented separately and the costs were inflation-adjusted year 2000 prices.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same population sample as that used in the effectiveness study.

Study sample
No power calculations to determine the sample size for any of the four intervention groups were reported. The participants were responders to media advertisements offering free relapse prevention information to ex-smokers. Of 895 participants who met the initial eligibility criteria, 704 (78.6%) returned completed baseline questionnaires. A total
of 273 (39%) participants were excluded because they failed to meet the subsequent criteria on abstinence at baseline. Thus, 431 participants were randomised to one of the four interventions: 111 to (a), 115 to (b), 100 to (c) and 105 to (d). The study sample contained a large proportion of middle-aged white women who were formerly heavy smokers, well educated and in employment.

Study design
This was a single-centre, randomised controlled trial. The method of randomisation was not stated. Follow-up was carried out at 12, 18 and 24 months after return of the baseline questionnaires. Loss to follow-up was 25.1% (12 months), 17.4% (18 months) and 15.1% (24 months) at each follow-up, respectively.

Analysis of effectiveness
The primary outcome from the trial was the 7-day point-prevalence abstinence (whether participants had smoked any cigarettes in the 7 days prior to each follow-up assessment). The basis of the analysis was intention to treat. The secondary outcomes included measures of smoking behaviour preceding and during the follow-up periods. It appears that the study groups at baseline had similar demographic and smoking history, but not age. The repeated-mailing and low contact-low content groups had slightly lower mean ages (50.29 years and 50.43 years, respectively) than the other two groups (massed mailing 52.08 years, repeated letters 53.66 years), (p<0.05). It was unclear whether comparability remained at analysis, other than for follow-up response rates.

Effectiveness results
A logistic regression analysis was conducted for the primary outcome (7-day point prevalence abstinence) at each follow-up point. This involved the use of a dichotomous term for contact (high or low), a term for content (high or low) and an interaction term (contact x content).

The results for each intervention group were detailed in the paper. The authors summarised the relapse rates for high-versus low-content interventions as follows:

- at 12-month follow-up, 16.6% versus 25.4% (Wald = 3.87, p=0.049; odds ratio, OR=1.73, 95% confidence interval, CI: 1.00 - 3.00);
- at 18-month follow-up, 20.6% versus 31.4% (Wald = 5.24, p=0.022; OR 1.75, 95% CI: 1.08 - 2.84);
- at 24-month follow-up, 21.5% versus 32.2% (Wald = 5.28, p=0.022; OR 1.73, 95% CI: 1.08 - 2.77).

The results for the secondary outcomes also showed lower relapse rates for the high-content interventions (reported in the paper).

There were no significant effects or interactions based on the level of contact. In addition, the interventions were not differentially effective for participants who had quit smoking more recently.

Clinical conclusions
The authors concluded that a higher level of intervention content was a significant predictor of lower relapse rates at each follow-up point. Extended contact produced no better outcomes that did a single contact.

Measure of benefits used in the economic analysis
The measures of benefit used were differences in 24-month abstinence from smoking between the intervention and control conditions and the weighted quality-adjusted life-years (QALYs) produced by each difference. The valuation of QALYs was based on life-table parameters derived from the literature (1986 - 1996). Estimates of QALYs relating to successful smoking cessation for 12 age-sex groupings were averaged over the age-gender characteristics of the study population. The incremental QALY denominator term was the product of a sample-weighted QALY value and estimates of the probabilities of abstinence at different time points. The benefits were discounted using a conventional...
annual discount rate of 4%.

**Direct costs**
The incremental costs were reported, including those relating to materials (booklets), time-and-motion estimates of clerical input and an estimate of overhead costs. The research costs were not included. The cost of the comparator or control intervention was assumed to be completely research-based (and consequently set at zero), thus enabling an incremental analysis for the remainder of the interventions. Except for clerical charges, which were weighted by the hourly wage rate of correspondence clerks in the USA, the source of the costs was not reported. Prices were adjusted using the Consumer Price Index to inflation-adjusted year 2000, and were also adjusted to account for failures to complete the intervention protocol. The resource quantities and the costs were not presented separately (although it was possible to estimate them from the number of recipients and booklets). A survey of resource use revealed that 97% of participants had read the booklets, with no differences between groups. Owing to the intervention being carried out over 1 year, the costs were not discounted.

**Statistical analysis of costs**
The cost data were deterministic.

**Indirect Costs**
The indirect costs were not reported.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was reported.

**Estimated benefits used in the economic analysis**
In relation to the comparator or control (intervention), the incremental benefit (abstinence at the 24-month follow-up) was 11.4% for intervention (b), 2.4% for intervention (c) and 12.2% for intervention (d). The incremental gain in QALYs (discounted at 4% annually) was 0.2561 for intervention (b) and 0.2741 for intervention (d). The results for intervention (c) did not show any superior outcomes to the comparator or control.

**Cost results**
The intervention cost for the comparator or control (a) was zero. The incremental costs for interventions (b), (c) and (d) were $21.25, $26.00 and $43.94, respectively.

**Synthesis of costs and benefits**
The incremental cost-effectiveness ratios for interventions (b) and (d) (for the 7-day point prevalence abstinence at the 24-month follow up) were $186 and $360, respectively. The incremental cost per QALY gained for (b) and (d) were $83 and $160, respectively. The results for (c) were not statistically significant from the comparator or control.

**Authors’ conclusions**
The high-content interventions were very cost-effective. The amount of content was more important than extended contact over time. In this study, the mailing of 8 booklets at one time was effective and reduced the costs of repeated mailing by approximately 50%.
CRD COMMENTARY - Selection of comparators
The choice of the comparators was justified on the basis that a previous version of the booklet was deemed successful in a published study, and the dismantling of content and contact would enable the development of theoretical and applied knowledge for this particular smoking relapse intervention. You should decide if this represents a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
A randomised controlled trial was appropriate for the study question. The analysis was appropriately based on intention to treat, to allow comparison with smoking cessation studies. However, the difficulties in ascertaining the true effects of community-based interventions (due to possible confounding influences from other sources) were not fully discussed. The demographic profile of the study sample was unlikely to be representative of former smokers in general, to whom the application of study findings was intended. The absence of detail on the method of randomisation also poses a threat to the internal validity of the trial. Good response rates were noted at follow-up. However, the absence of power calculations meant that it was not possible to ascertain whether the results were due to the intervention or to chance.

Validity of estimate of measure of benefit
The 7-day point prevalence was selected on the basis of its concurrent validity (from the literature) and its specific relevance to a relapse-prevention programme. The QALYs were calculated using values from literature dating from 1986 to 1996.

Validity of estimate of costs
Given that the economic perspective of the study was not stated, it was unclear whether all the relevant categories and costs were included in the analysis. The absence of detail on the sources of the costs, together with the fact that the costs and the quantities were not reported separately, limits the reworking of the analysis in other settings. No sensitivity analysis of resources or statistical analysis of the costs was performed, thus limiting the interpretation of the findings. The price year was reported, which will aid any future reflation exercise.

Other issues
When compared with other studies, the authors claimed that the current study findings were either comparable or more favourable. The authors noted further uncertainty about the generalisability of the findings in terms of possible bias arising from the recruitment of self-selected (and possibly more motivated) participants. The potential biases associated with self-reported behaviour were also identified. In addition, the authors suggested that the racial and ethnic distribution of the sample could present a further possible limitation to the generalisability of the findings.

Implications of the study
The authors made several recommendations for future research. First, continued dismantling of the booklet content to determine mechanisms of success. Second, alternative methods of dissemination and diffusion to increase intervention reach and impact. Third, research should consider wider racial, ethnic and other sub-population requirements in the development of smoking-relapse interventions.

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