Short- and long-term smoking cessation for three levels of intensity of behavioral treatment

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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
Three levels of medical-behavioural treatment, used in conjunction with nicotine replacement therapy (NRT), were examined in smokers who smoked at least one pack of cigarettes a day. The low-intensity (LI) group received NRT for 8 weeks, institutional videotapes, and one advice and education (AE) session with a nurse practitioner. The moderate-intensity (MI) group received these treatments plus three brief nurse practitioner-delivered AE sessions. The high-intensity (HI) group received the same treatments as the MI group plus 12 weeks of individualised, manual-driven cognitive-behavioural therapy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised men and non-pregnant women, aged between 21 and 65 years, who smoked at least one pack of cigarettes daily. They had to have met the criteria defined by the American Psychiatric Association for nicotine dependence (see Other Publications of Related Interest), and reported at least one failed attempt at smoking cessation. Exclusion criteria were patients with any medical condition that could preclude the use of NRT. Psychiatric exclusion criteria were a non-substance use diagnosis of greater than moderate severity, substance abuse/dependence disorder in remission less than 6 months, current use of cocaine or non-prescribed amphetamine, organic mental disorder, current psychosis, or expressed homicidal or suicidal ideation.

Setting
The setting is likely to have been primary care. The economic study was conducted in the USA.

Dates to which data relate
No dates for the effectiveness and resource use data were reported. The price year was 1996.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was conducted prospectively on the same sample of patients as that used in the effectiveness study.
Power calculations, if performed, were not reported. The method used to select the sample was also not stated. An overall sample of 240 patients was recruited and allocated to three study groups. There were 80 patients in each group. In the LI group, the mean age was 40.9 (+/- 9.2) years, 48.8% were women, and the number of cigarettes smoked daily was 27.3 (+/- 10.6). In the MI group, the mean age was 40.1 (+/- 10.6) years, 45% were women, and the number of cigarettes smoked daily was 27.2 (+/- 9.5). In the HI group, the mean age was 39.6 (+/- 8.9) years, 53.8% were women, and the number of cigarettes smoked daily was 26.3 (+/- 9.8).

Study design
This was a prospective, randomised trial. Randomisation was conducted after the first AE session in week 1 when baseline evaluations of the patients had been concluded. Urn randomisation was used to balance the groups for gender, level of nicotine dependence, and psychiatric pathology. The outcome assessment was conducted at baseline and at weeks 1, 3, 6, 9, 26 and 52. There was no indication that the outcome assessors were blinded. At week 52, data were available for 224 of the 240 participants (93.3%). The loss to follow-up did not vary significantly across the three treatment groups.

Analysis of effectiveness
The primary analysis of effectiveness is likely to have been based on treatment completers only. The primary health outcome used in the effectiveness analysis was the abstinence rate at weeks 9, 26 and 52. Abstinence was based on self-reported measures and then confirmed using carbon monoxide breath samples and urinary cotinine analysis. A carbon monoxide level of greater than 9 parts per million was considered objective evidence of recent smoking. In a secondary analysis, intention to treat was considered the basis for the analysis of the effectiveness and the impact of potential confounding factors was evaluated. The study groups were shown to have been well balanced at baseline in their demographics and smoking habit characteristics.

Effectiveness results
The abstinence rates were:

at week 9, 35.4% in the LI group 26.9% in the MI group and 45.1% in the HI group, (p=0.082);

at week 26, 29.9% (LI group), 11.6% (MI group) and 36.8% (HI group), respectively, (p=0.0014), and

at week 52, 27% (LI group), 12% (MI group) and 34.7% (HI group), respectively, (p=0.0032).

None of the pre-treatment measures significantly affected the outcomes observed after 26 and 52 weeks. Similar results were obtained in the secondary analysis.

Clinical conclusions
The effectiveness study showed that the HI intervention was highly effective in terms of abstinence rates after one year of treatment.

Measure of benefits used in the economic analysis
No summary benefit measure was used in this analysis. The analysis was therefore a cost-consequences analysis.

Direct costs
Discounting was not relevant since the costs were incurred during 12 months. The unit costs were not reported separately from the quantities of resources used. The health services included in the economic analysis were personnel and patches. A standard university plant cost of 25% was added to personnel costs, which presumably referred to administration costs. Costs for specialised medical examinations or for research activities were not included. The cost/resource boundary adopted in the study appears to have been that of the health service provider. Resource use was
estimated on the basis of data from the patients involved in the effectiveness study. The unit costs were estimated using hourly costs for personnel. A fixed weekly cost was assumed for patches. The price year was 1996.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not included in the economic analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analyses were conducted.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total costs per participant were $308 ($170 for patches and $138 for LI treatment) in the LI group, $338 ($174 for LI treatment) in the MI group and $582 ($402 for treatment) in the HI group.

**Synthesis of costs and benefits**
Not relevant because a cost-consequences analysis was conducted.

**Authors’ conclusions**
Nicotine replacement therapy (NRT) in conjunction with behavioural treatments was effective in improving one-year abstinence rates among smokers. As the authors had hypothesised, more intense treatments led to higher abstinence rates, but also to higher costs.

**CRD COMMENTARY - Selection of comparators**
The authors did not justify the choice of the comparators. Clearly, other smoking cessation interventions were available but only NRTs were considered and different degrees of behavioural treatments were assessed. You should decide whether they represent widely used options for smoking cessation in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness used a randomised trial, which was appropriate for the study question. The method of randomisation was described, but there were no details of the procedure used to select the sample. Power calculations were not conducted and there was no evidence that the sample size was appropriate. The study groups were comparable at baseline and intention to treat results were reported, although in the primary analysis, only those who completed the treatment were considered. The authors evaluated the impact of potential pre-treatment patient characteristics on the outcome measure and found no significant relationship with the long-term outcomes. There was no evidence of blinding for the outcome assessors. Overall, the analysis had a high internal validity.
Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis. Thus, a cost-consequences analysis was, effectively, conducted.

Validity of estimate of costs
The perspective adopted in the study is likely to have been that of the service provider. It appears that all the relevant categories of costs have been included in the analysis. The authors stated that some costs were not considered and it was unclear what impact their inclusion would have had on the total expenses. The unit costs and the quantities of resources used were not analysed separately. The cost estimates were specific to the study setting and no sensitivity analyses were conducted. The price year was reported, thus facilitating reflation exercises in other settings. Both the costs and resource use data were treated deterministically.

Other issues
The authors did not compare their findings with those from other studies, nor address the issue of the generalisability of the study results to other settings. Sensitivity analyses were not conducted and the overall external validity of the study was low. The analysis referred to individuals who smoked at least one pack of cigarettes a day and were able to receive NRT. Thus, the conclusions of the analysis should be limited to this specific study population.

Implications of the study
The study results suggested that the combination of NRT and behavioural treatments led to significant improvements in the abstinence rates. However, the authors stated that more intense treatments should be limited to contexts where "funding is not a critical issue or for use with certain problematic populations”.

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Other publications of related interest

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