A pilot randomised trial to assess the methods and procedures for evaluating the clinical effectiveness and cost-effectiveness of Exercise Assisted Reduction then Stop (EARS) among disadvantaged smokers


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.

CRD summary
This study aimed to evaluate the feasibility and acceptability of the Exercise Assisted Reduction then Stop (EARS) programme. The cost-effectiveness model was based on a pilot trial. The authors concluded that the programme was likely to be cost-effective, but their trial participants were not ethnically diverse and follow-up was short. The reporting was thorough and transparent and the methods were generally appropriate. The authors’ conclusions were appropriately cautious.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The aim was to evaluate the feasibility and acceptability of the Exercise Assisted Reduction then Stop (EARS) programme, through a pilot trial. A cost-effectiveness model was built alongside the trial.

Interventions
The EARS programme was compared with brief advice. The programme included up to eight weeks of individual support for participants of low economic status who wanted to reduce their smoking. Health trainers provided an initial face-to-face session, followed by coaching and counselling in person and by telephone. The programme had components of client-centred motivation, self-determination theory, social cognitive theory, control theory, and research on stage-matched interventions. Participants set a smoking-reduction goal and explored ways of reaching it. Physical activity was encouraged and provided at a reduced cost. Brief advice was referral to the standard stop-smoking services.

Location/setting
UK/secondary care.

Methods
Analytical approach:
The outcomes of the small pilot trial were used to inform a lifetime cohort Markov model, with three states: smoker, ex-smoker and dead. The model had annual cycles, and was based on a published model (see Other Publications of Related Interest). The authors stated that they took a UK NHS perspective.

Effectiveness data:
The primary effectiveness outcome was abstinence confirmed by expired-air carbon monoxide, plus self-reported time since last cigarette, at four weeks after stopping. Secondary outcomes related to smoking, physical activity, health-related quality of life, and emotional state. Participants who were lost to follow-up or who withdrew from the trial were assumed to be smokers. A main driver of the model was the relative risk of death over time, by smoking status, which was from a 40-year observational study of British male doctors. Ex-smokers could relapse, with the risk based on the time since quitting. Relapse rates were derived from the literature for the first year after stopping, for years two to eight, and beyond eight years.

Monetary benefit and utility valuations:
Utility scores were derived from participants in the trial using the EQ-5D. The utility values for the model were dependent on age and smoking status, including time since stopping for quitters. These values were from a published study.

**Measure of benefit:**
The model assessed life-years gained, and quality-adjusted life-years (QALYs) gained. Future benefits were discounted at 3.5% annually.

**Cost data:**
Resource use was recorded for the health trainer's time for participant contacts, and non-contact activities, including: planning, supervision, caseload recruitment and service development. Electronic records were kept by the health trainers and assessed by the trial coordinator. Senior staff time, exercise aids and health trainer training by the trial coordinator were recorded. The unit costs were from the Personal and Social Service Research Unit for 2011. All costs were reported in UK £. Future costs were discounted at 3.5% annually.

**Analysis of uncertainty:**
Probabilistic, one-way, multivariate and threshold sensitivity analyses were undertaken. The one-way analyses varied the distribution of starting smoking status, the relapse rate using different sources, the distribution of smokers by age, intervention costs, smoking-related morbidity costs, and the utility value source. Multivariate analyses were presented for pessimistic and optimistic scenarios. Threshold analyses assessed the minimum quit rate, and maximum intervention cost required for cost-effectiveness at a willingness-to-pay of £20,000 for a QALY.

**Results**
The trial found that 14% of EARS participants and 4% of control participants were confirmed abstinent between four and eight weeks after quitting, and 10% with EARS versus 4% with control were abstinent at 16 weeks. Nearly twice as many EARS participants reduced smoking by 50% at week eight (31%, compared with 16% control) and week 16 (39%, compared with 20% control).

The additional cost per participant, compared with brief advice, was estimated as £192.

The cost per life-year gained for males was higher at all ages (40, 50, 60) than for females. For males, it varied from £3,573 to £4,367, while for females it ranged from £5,267 to £6,525. The cost per QALY gained for females was lower than for males at ages, ranging from £3,550 to £4,342 for females, and from £5,563 to £7,705 for males, with the values decreasing with increasing age.

In the probabilistic analysis, the EARS programme was cost-effective in 87% of simulations at a willingness-to-pay for a QALY of £20,000. The most influential factor in the sensitivity analyses was increasing the cost of the programme to £500 per participant which raised all the incremental cost-effectiveness ratios, but not above £25,000 per QALY gained. All other one-way analyses resulted in ratios well below £20,000 per QALY gained.

The pessimistic scenario assumed 25% lower efficacy, a 12-month relapse rate of 40% (28% in the original analysis), health-state values for moderate smokers (in those who stopped), and a £500 intervention cost. This resulted in ratios between £23,631 and £29,181 per QALY gained for females and above £30,000 for males (£34,095 to £43,794).

**Authors' conclusions**
The authors concluded that their model indicated that the low-cost EARS programme was likely to be cost-effective, but their trial participants were not ethnically diverse and follow-up was short.

**CRD commentary**
**Interventions:**
The interventions were clearly described and included usual UK practice, which was useful for decision makers. Including no intervention would have been appropriate, as some people might not be referred to standard stop-smoking services.

**Effectiveness/benefits:**
As acknowledged by the authors, the trial was only a pilot, so there were concerns about the external validity of the effectiveness data and its ability to detect effect differences, given the small sample. Follow-up was short; the few participants were ethnically homogenous; there was difficulty confirming abstinence at four weeks; and the health trainers might not have been representative. The authors acknowledged that they did not conduct a systematic review to identify the evidence, so some relevant evidence may not have been considered. Relapse rates were based on drug studies and long-term effectiveness could differ between drugs, and counselling and exercise (EARS). It was not clear if the relapse rates appropriately related to four-week abstinence. The model was simpler than the previous model and did not include morbidity due to smoking, which would underestimate the effects of smoking on health. The efficacy from the trial could have been modelled using a decision tree, which would have allowed the uncertainty in the estimate to be included in the probabilistic sensitivity analysis. There could be a relationship between those who are abstinent between four and eight weeks and those who quit permanently; the model did not account for this.

Costs:
The costs were clearly reported, and the methods and sources were appropriate. Smoking-related morbidity was crudely included in the costs, in a sensitivity analysis that applied a cost to smoking-related deaths. Given the broad range of smoking-related diseases, the costs of remaining a smoker were probably underestimated, which would overestimate the incremental cost-effectiveness ratio of the EARS programme.

Analysis and results:
The reporting of the modelling methods was clear and thorough. The results from the study and the model were clearly presented. The sensitivity analyses were generally clearly reported seemed reasonable, but the methods and distributions for the probabilistic sensitivity analysis were not reported. The authors thoroughly discussed the limitations of their trial and model, and were conservative in their analysis.

Concluding remarks:
This study had thorough and transparent reporting and generally appropriate methods. The authors’ conclusions were appropriately cautious and conservative.

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Other publications of related interest

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