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
Use of two lifestyle counselling interventions, a video-based lifestyle change programme (video) and a video programme plus written patient self-instructional materials (video plus self-help) in the framework of the cardiovascular disease (CVD) Risk Reduction in General Practice Programs for patients with one or more CVD risk factors. There were three sub-programmes in each intervention, a smoking cessation programme, a healthy eating programme and a physical activity programme. The sub-programmes applied both cognitive and behavioural strategies and educational techniques utilising a staged approach to promote adherence to a healthy lifestyle.

Type of intervention
Primary prevention.

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

Study population
The study population consisted of subjects aged between 18 and 69 years, with one or more modifiable CVD risk factors (total cholesterol greater than 5.5 mmol/l, BMI (body mass index) greater than 25, current smoker, elevated blood pressure (systolic between 140-155 mmHg, diastolic greater than 90 mmHg)).

Setting
Primary care. The economic study was carried out in Sydney, Australia.

Dates to which data relate
Effectiveness and resource use data related to March 1990 and mid-1991. Effectiveness data related to mortality risk after a myocardial infarction (MI) or stroke; and quality of life (utility weights) after a coronary heart disease (CHD) event were obtained from published and unpublished studies from 1994 and 1995. Resource use data related to treating each CHD event were obtained from a study published in 1995. The price year was 1994.

Source of effectiveness data
Effectiveness data were derived from a single study and a review of the literature.

Link between effectiveness and cost data
Costing for interventions was prospectively performed on a sub-sample of that used in the effectiveness analysis. Costing for the treatment of CHD events was retrospectively performed on a different sample from that used in the effectiveness analysis.
Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 82 GPs (out of 956 GPs invited) from 75 general practices. They were randomly allocated to either the routine care group (n=25) with a total of 255 eligible patients with a mean (SD) age of 53 (11) years for males and 56 (11) years for females, the video group (n=29) with a total of 269 eligible patients with a mean (SD) age of 51 (11) years for males and 52 (11) years for females, or to the video plus SH (self help) group (n=28) with a total of 269 eligible patients with a mean (SD) age of 50 (11) years for males and 51 (11) years for females.

Study design
Multi-centred, randomized controlled trial. The duration of follow up was 12-18 months. The number of GPs who were lost to follow-up was 5 in the routine care group, 0 in the video group and 4 from the video plus SH group. The corresponding figures in terms of number of patients were 125 (out of 255) from the routine care group, 70 (out of 269) from the video group, and 76 (out of 231) from the video plus SH group. No significant difference was found between those who completed the study and those who did not in terms of gender distribution. The unit of randomization was general practice. The cluster randomization procedure was used to assign GPs to the study groups.

Analysis of effectiveness
The principle used in the analysis of effectiveness was treatment completers only. The clinical outcome measure was patient risk factor status including blood pressure, body mass index (BMI), cholesterol and smoking status at entry to trial and after 1 year. The patients’ GPs carried out the measurement of the clinical outcomes. Furthermore, patients completed a Heart Health Questionnaire addressing physical activity, fat intake and smoking behaviours.

Effectiveness results
The mean differences between baseline and 12-month follow-up measurements for the cardiovascular risk factors revealing significant results were as follows:

(1) diastolic blood pressure (mmHg), 4.0 (range: 1.7-6.37) (p=0.001) for the females in the routine-care group; 4.0 (range: 1.97-6.02) (p=0.0002) for the males in the video plus SH group; and F(2,242)=3.55, (p=0.03) for female values;

(2) serum cholesterol (mmol/l), 0.58 (range: 0.27-0.88) (p=0.0005) for males in the routine-care group and 0.58 (range: 0.35-0.81) (p=0.0001) for females in the routine-care group; 0.45 (range: 0.27-0.62) (p=0.0001) for males in the video group and 0.46 (range: 0.24-0.68) (p=0.0001) for females in the video group; and 0.46 (range: 0.13-0.75) (p=0.0025) for males in the video plus SH group and 0.83 (range: 0.51-1.15) (p=0.0001) for females in the video plus SH group.

All other values related to diastolic blood pressure plus all the difference values related to body mass index and smoking status were found not to be significant. None of the other comparisons based on F statistic were significant.

The mean differences between baseline and 12-month follow-up measurements for the cardiovascular risk factors revealing significant differences for high risk individuals (DBP> 95 mm/Hg or total cholesterol> 6.5 mmol/l) were as follows:

(1) diastolic blood pressure (mmHg), 8.73 (range: 4.78-12.67) (p=0.0002) for the males in the routine-care group and 17.7 (range: 6.52-28.9) (p=0.0065) for the females in the routine-care group; 13.5 (range: 8.20-18.76) (p=0.0001) for males in the video group and 10.1 (range: 7.30-13.0) (p=0.0001) for the males in the video plus SH group and 8.6 (range: 4.07-13.12) (p=0.0017) for the females in the video plus SH group;

(2) serum cholesterol (mmol/l), 1.22 (range: 0.78-1.65) (p=0.0001) for males in the routine-care group and 1.05 (range: 0.72-1.39) (p=0.0001) for females in the routine-care group; 0.83 (range: 0.59-1.06) (p=0.0001) for the males in the video group and 0.80 (range: 0.48-1.12) (p=0.0001) for the females in the video group; and 0.79 (range: 0.37-1.21) (p=0.0005) for the males in the video plus SH group and 1.35 (range: 0.97-1.73) (p=0.0001) for the females in the video plus SH group. None of the comparisons based on F statistic were significant.
Clinical conclusions
A number of risk factors were statistically reduced by the interventions among specific sub-groups, between baseline and 12-month follow-up. However these did not lead to a reduction in CVD risk factor status over the period of analysis.

Modelling
A computer simulation model employing the Framingham risk functions was constructed to estimate the costs and effects associated with each lifestyle strategy.

Outcomes assessed in the review
The review assessed mortality risk after MI or stroke, and quality of life (utility weights using time trade-off method) after recognised MI, unrecognised MI, coronary insufficiency, angina, and stroke.

Study designs and other criteria for inclusion in the review
Not reported.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Two Australian studies were included in the review.

Methods of combining primary studies
Not reported.

Investigation of differences between primary studies
Not reported.

Results of the review
The results of the review were as follows:

quality of life (utility weights) after recognised MI, 0.90;
unrecognised MI, 0.95;
coronary insufficiency, 0.90;
angina, 0.90;
Mortality risk values after MI or stroke were not reported.

**Measure of benefits used in the economic analysis**
The benefit measures were life years saved (LYS) and quality-adjusted life-years (QALYs) gained.

**Direct costs**
Costs were discounted. Quantities were not reported separately from the costs. Cost items were reported separately. Cost analysis covered the costs of initial hospitalisation, rehabilitation, follow-up events and procedures, drug therapy, nursing home care, hostel care; and incremental costs of the two interventions including the video material, self help booklets, GP education and programme dissemination, drugs, patient time, and GP visits. The perspective adopted in the cost analysis was that of society. The effects of the interventions on changes in the costs of antihypertensive and cholesterol lowering medications were evaluated on a random sample of 29 GPs and 243 patients in the trial. The resource utilisation for treating each CHD event was based on 2,287 MI patients in 50 Australian hospitals participating in the GUSTO trial. The sources of cost data were different regional and national institutions or reports. The date of the price data was 1994.

**Indirect Costs**
Costs were discounted. Quantities were not reported separately from the costs. Cost items were reported separately. Cost analysis covered the annual indirect costs of production losses due to CHD events. The perspective adopted in the cost analysis was that of society. Data related to production losses were obtained from the GUSTO trial. Cost data were based on average weekly male and female earnings. The date of the price data was 1994.

**Currency**
Australian dollars (Aus$).

**Sensitivity analysis**
One-way sensitivity analyses were performed on indirect costs and maintenance of behavioural changes over time.

**Estimated benefits used in the economic analysis**
It was reported that the video group had no relative benefit with respect to LYS or QALYs. The corresponding values for the video plus SH group showed only negligible improvements (0.001492 for males and 0.000102 for females in terms of LYS and 0.001880 for males and 0.000028 for females in terms of QALYs gained). High-risk males in the video group gained 0.002713 LYS and 0.003618 QALYs. The corresponding values for other subgroups were less than 0. The discount rate considered for LYS was 5%.

**Cost results**
The discount rate considered for costs was 5%. The video group had an incremental cost of Aus$180 per person, while the corresponding value in the video plus SH group was Aus$318. The CHD-related events such as MI, angina, or stroke were reported to be associated with annual indirect costs of Aus$6,112, Aus$2,716, and Aus$16,300, respectively. Total costs for males in the video plus SH group were Aus$286 and for females, Aus$322. Total cost for high-risk males in the video group was Aus$107.

**Synthesis of costs and benefits**
Incremental cost per LYS and per QALY was calculated as the measures of cost-effectiveness and cost-utility analysis. The cost per LYS for males in the video plus SH group was Aus$191,689 and for females, greater than Aus$3 million.
The corresponding values in terms of cost per QALY were Aus$152,128 for males and greater than Aus$11 million for females. The cost per LYS for the males in the video group were Aus$39,440 and per QALY, Aus$29,574. The incremental cost-effectiveness or cost-utility ratios could not be calculated for other sub-groups of patients due to negative benefits associated with the interventions. The sensitivity analysis demonstrated that maintenance of behavioural changes over time was the key assumption of the model; if a small gain due to risk factor changes is maintained at 2 years and beyond, there is potential to improve the cost-effectiveness of life-style interventions.

Authors' conclusions
The lifestyle interventions had no significant effect on cardiovascular risk factors when compared to routine patient care. There remains insufficient evidence that lifestyle programmes conducted in general practices are effective. Resources for general practice-based lifestyle programmes may be better expended on high-risk patients who are contemplating changes in risk factor behaviours.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator. It represented the "current therapy" in the context in question.

Validity of estimate of measure of benefit
The internal validity of the estimates of benefits was restricted due to the high rate of loss to follow-up, the fact that the analysis of effectiveness was based on treatment completers only, and, more importantly, by the short-term follow-up period, as acknowledged by the authors. Although some risk factors were significantly reduced, they did not translate into health benefits over the period of analysis.

Validity of estimate of costs
Quantities were not reported separately from the costs, although adequate details of methods of cost estimation were given. Cost results may not be generalisable to other settings or countries.

Other issues
Given the limitations of the effectiveness analysis, lack of extensive sensitivity analysis and statistical analysis of the costs, the results may need to be treated with some caution. The issue of generalisability to other settings or countries was not addressed. Appropriate comparisons were made with other studies.

Implications of the study
The authors stated that only long-term follow-up of risk factor changes in trial patients would reduce the uncertainty surrounding the results. Although (the study) results suggest that lifestyle interventions targeted at high-risk males could be more cost-effective than for people at "standard risk", further evidence is needed to ascertain whether this was a chance result.

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Other publications of related interest
Fabri J. Personal communications. NHMRC Clinical Trials Centre, University of Sydney, 1995.

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