Effectiveness of individual lifestyle interventions in reducing cardiovascular disease and risk factors

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Authors' objectives
To assess the effectiveness of lifestyle interventions in reducing cardiovascular disease risk factors, morbidity and mortality among working-age adults, using a systematic review of randomised controlled trials.

Searching
MEDLINE (1966 to Dec 1998), DARE, EMBASE and the Cochrane Library (Issue 3, 1999) were searched (search terms listed). Further studies were identified through searching the bibliographies of retrieved articles and previous reviews, in addition to contacting national experts in the field. The searches were limited to English-language publications.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) with at least 60 participants. Studies had to follow participants for 1yr or longer and have a drop-out rate of less than 20% at 12mths. If studies had a drop-out rate of greater than 20% but less than 30% they had to include an intention to treat analysis. Studies were also excluded for other reasons including poor details of the randomisation process.

Specific interventions included in the review
Single and multifactorial lifestyle interventions included diet, exercise, smoking cessation, and alcohol intake reduction. Studies combining CVD drug treatment with lifestyle interventions were accepted only if the drugs were not the primary intervention.

Participants included in the review
Adults of working-age who are at risk of cardiovascular disease (CVD) (i.e. primary prevention) or who have experienced any CVD event such as coronary heart disease, hypertension, stroke, congestive heart failure, rhythm disturbances etc. (i.e. secondary prevention). Studies of only elderly persons (i.e. over 65yrs) were excluded. Most of the studies reported in the review included participants aged 18-65yrs. Six studies extended to older age groups (up to 75yrs) and one included 17-year-olds. Fifteen studies only included male participants whereas the remainder included both men and women.

Outcomes assessed in the review
Main outcomes included total mortality, cardiovascular mortality and new cardiovascular events. Secondary outcomes involved risk factor-specific outcomes such as changes in mean blood pressure, mean total cholesterol levels, mean weight, alcohol intake, mean sodium excretion, smoking cessation and increase in physical exercise.

How were decisions on the relevance of primary studies made?
Two authors independently evaluated each article for inclusion. If evaluations were discordant, a third opinion was taken.

Assessment of study quality
Study validity was assessed using the criteria described by the Evidence-Based Medicine Working Group (see Other Publications of Related Interest nos.1-4). In addition, the inclusion criteria ensured that only randomised controlled trials with at least 60 adult participants were included, if they had a drop-out rate of less than 20% at 12mths or used an intention-to-treat analysis (for studies where the drop-out rate was greater than 20% but less than 30%). Two authors independently evaluated the validity of the studies. If evaluations were discordant, a third opinion was taken.
Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction. Tables included in the review reported the following data: bibliographic details, participant age, gender, numbers, intervention type, and outcome measures and data. For each study the absolute risk reduction (ARR) and the number needed to treat (NNT) (both with 95% confidence intervals (CI)) were calculated, where possible, for binary outcomes such as morbidity, mortality and smoking cessation.

Methods of synthesis
How were the studies combined?
Pooled effect sizes were calculated for systolic blood pressure, diastolic blood pressure, weight and total cholesterol as mean net changes MNC = mean net change for intervention (MCi) - mean change for controls (MCc)). Significance levels of pooled effects were calculated using t-tests.

How were differences between studies investigated?
Primary and secondary prevention studies were assessed separately and subgrouped according to their intervention (i.e. single versus multifactorial intervention, and the specific intervention used). No specific statistical tests were performed to detect heterogeneity between studies.

Results of the review
Forty-two studies (over 111,866 participants), 20 on primary prevention and 22 on secondary prevention were included.

1. Morbidity and mortality (total and CVD-related).
   Total mortality was reported as an end-point in 19 studies (n=7 primary prevention and n=12 secondary prevention studies); CVD mortality in 18 studies (n=7 primary prevention and n=11 secondary prevention studies); and morbidity in 17 studies (n=7 primary prevention and n=10 secondary prevention studies). The NNTs for morbidity and mortality (total and CVD) varied widely and most confidence intervals showed an uncertain effect (up to infinity).
   For secondary prevention, four studies showed positive effects on total and CVD mortality and one additional study on CVD mortality only. In addition, a positive effect was shown on morbidity in three studies.
   Two multifactorial primary prevention studies showed a decrease in morbidity but no effect on mortality was observed.

2. Blood pressure.
   Nineteen studies (n=8 primary prevention and n=11 secondary prevention) reported changes in systolic blood pressure and one additional study (multifactorial, primary prevention) reported only changes in diastolic blood pressure. All of the multifactorial primary prevention studies reported a decrease in systolic pressure favouring the intervention group, and the two single primary prevention studies showed mixed results. Overall, the diastolic blood pressure findings showed similar decreases. The pooled mean net change in systolic blood pressure was -3.0mmHg for the intervention and -1.4mmHg for the control; and for diastolic blood pressure -4.2mmHg for the intervention and -3.1mmHg for the control. This was not statistically significant and only clinically modest.
   All except one of the 12 secondary prevention studies (n=3 single intervention and n=8 multifactorial studies) showed decreases in both systolic and diastolic blood pressure favouring the intervention group. The pooled mean net change in systolic blood pressure was -2.8mmHg for the intervention and +0.6mmHg for the control; and for diastolic blood pressure -2.9mmHg for the intervention and -1.0mmHg for the control. This was not statistically significant and only clinically modest.

3. Cholesterol.
   Twenty-one studies (n=9 primary prevention and n=12 secondary prevention) examined changes in cholesterol levels. Levels decreased in the intervention group of all seven multifactorial primary prevention studies, with two studies reaching clinical significance. One of these studies also reached statistical significance. The one single intervention...
study also showed a decrease. The mean net change in cholesterol for the multifactorial intervention was -0.36mmol/L (p=0.08) and for all studies was -0.33mmol/L (p=0.08) taking into account the single primary intervention study.

Data from three of the 12 secondary prevention studies could not be evaluated. Two single intervention studies showed a decrease favouring the intervention group while the other single intervention study showed no change. Six out of seven of the multifactorial intervention studies showed a decrease in favour of the intervention group. Overall, the pooled mean net change in cholesterol for multifactorial studies was -0.43 for the intervention and -0.07mmol/L for the control (p=0.007).

4. Weight loss.

Nineteen studies looked at weight loss as an outcome measure. One of the two single primary intervention studies reported weight reduction among the calorie-restricted group. In three of the five multifactorial primary prevention studies a significant weight loss was reported in favour of the intervention group, with the exception of one study group in one trial (mean weight change was -0.9kg vs. +1.2kg, p=0.023, pooled mean net change in weight was >-1kg).

Twelve secondary prevention studies looked at weight loss. Weight loss was reported in the intervention group of seven out of eight multifactorial intervention studies, but only significant in six of the studies. However, the absolute weight loss was less than 1kg and the pooled mean change for intervention participants was -0.6kg vs. +1.3kg for the controls (p=0.026). One single intervention exercise study showed a clinically but not statistically significant decrease in weight favouring the intervention group, as did the remaining multifactorial study.

5. Smoking.

Eighteen studies looking at interventions aimed at smoking cessation. Four of the studies were effective (one person stopped smoking for every 4-14 smokers targeted), but NNTs could not be calculated because of missing data in four of the studies.

6. Alcohol consumption.

One primary and three secondary multifactorial interventions used reported a decrease in alcohol consumption as an outcome. Only one study reported a statistically significant difference between study groups in favour of the intervention group (decrease of 37% vs. 5%, p=0.02). A further three single intervention studies used reduction in heavy drinking as an outcome measure. Two larger studies showed a decrease in the intervention group (statistical significance not stated) and the final small study reported a non-significant difference.

7. Sodium decrease.

Two primary prevention studies showed a significant reduction in sodium excretion, favouring the intervention groups. Six secondary prevention studies looked at sodium decrease. One study had insufficient data for analysis. One reported decreases favouring the intervention group and presented findings for obese and non-obese participants separately. Two multifactorial studies reported statistically significant changes favouring the intervention group, whilst the remaining two studies failed to show any changes in sodium excretion.

8. Changes in exercise habits.

Four studies were of primary prevention and 10 used multifactorial interventions. The outcome measures varied considerably preventing statistical pooling. However, ten of the 16 studies reported positive outcomes.

Eight studies used exercise as an intervention with morbidity and mortality as end points. Two showed an effect on CVD mortality (one on total mortality as well) and one on CVD morbidity.

Quality of the studies.

The size and quality of the studies varied. The type of randomisation was seldom stated. Dropout rates were given in most studies and drop-outs were excluded from the analyses. The results of the studies were reported using either net
differences or intergroup differences. Baseline values were not available in any of the studies. Finally, statistically significant differences were well reported, but non significant results were not always mentioned.

Authors’ conclusions
In secondary prevention, both single and multifactorial lifestyle interventions were shown to reduce morbidity and mortality, and multifactorial approaches reduced cholesterol levels. Primary prevention was found to reduce risk factors efficiently, especially when the intervention is multifactorial. Effect sizes were heterogeneous with wide confidence intervals.

CRD commentary
This is a clearly reported review based on clearly defined inclusion criteria. The review methodology is explicit and avoids potential biases with the possible exception of the extraction of data from the studies. In this case, the authors fail to clearly state how many reviewers were involved in the process of data extraction. The literature searches used to identify studies are also reasonable, but by limiting the searches to only English-language publications and making no specific attempts to locate unpublished data the review may be subject to publication bias. This risk of publication bias is acknowledged by the authors in their discussion of the limitations of the review. Details of the studies are presented in tables and quality issues were assessed. However, it would have been helpful in the tables to state alongside the outcome effect whether outcomes were clinically or statistically significant, and where studies were pooled (i.e. for blood pressure, cholesterol, weight etc.) what the pooled mean net change was. Absolute risk reduction (ARR) and numbers needed to treat (NNT) are used to summarise the findings of studies reporting mortality and morbidity outcomes. Studies were not pooled if there were differences between the studies. For instance, in how the outcome was measured. This limited the opportunities for pooling in terms of NNTs. However, some mean net changes were pooled and it is difficult to comment on the validity of this pooling without additional information about the studies. Overall, the review findings would appear to be reasonable, but they should be viewed with caution in view of limitations highlighted by the authors themselves and those discussed in this commentary. The recommendations for further research would appear to be relevant given the data presented.

Implications of the review for practice and research
Practice: The authors state that ‘practising physicians should decrease the risk of illness and death in their populations by instituting good, evidence-based, individually targeted prevention programmes’. Also, until a more detailed meta-analysis is available ‘clinical emphasis should be on secondary multifactorial prevention for patients with multiple risk factors for CVD’.

Research: The authors state that ‘more evidence is needed on the effect of diet (in primary prevention) and smoking intervention on morbidity and mortality’. A promising area for future research was identified as exercise. In addition, ‘standards for outcome measurement in CVD prevention studies would greatly assist evaluations of effectiveness...together with transparent reporting’.

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Other publications of related interest
1. Guyatt GH, Sackett DL, Cook DJ. Users’ guides to the medical literature. II. How to use an article about therapy or

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.