Effectiveness of brief structured interventions on risk factor modification for patients with coronary heart disease: a systematic review

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CRD summary
This well-conducted review reported that there was inconclusive, but supportive, evidence to suggest that brief interventions in adults with coronary heart disease were effective in terms of risk factor modification and disease progression. The authors' cautious conclusions and recommendations for further research appear reliable.

Authors' objectives
To evaluate the effects of brief structured interventions on risk factor modification in patients with coronary heart disease.

Searching
MEDLINE, CINAHL, EMBASE, Current Controlled Trials Register and the Cochrane Library (Issue 2, 2006) were searched up to 2006. Search terms were reported. No restrictions were placed on language or date of publication. Searches of reference lists, key papers, the World Wide Web, conference abstracts and grey literature were also carried out. Relevant experts and companies were contacted for information about ongoing or future research.

Study selection
Randomised controlled trials (RCTs), quasi-RCTs and clustered trials evaluating the effects of brief interventions in adults (aged over 18 years) with risk factors for coronary heart disease, were eligible for inclusion in the review. Trials investigating the primary prevention of coronary heart disease were excluded from the review. Trials undertaken in children with the purpose of promoting a healthy lifestyle and studies of brief interventions as part of an extended program were excluded. Population-based studies, studies comparing different diets and exercise regimens, and studies of health promotion were excluded. Brief interventions were defined as any verbal or written communication aimed at modifying risk factors and provided by a healthcare professional. Eligible comparisons included: brief intervention versus usual care for single or multiple risk factor modification; brief intervention versus extensive interventions for single or multiple risk factor modification. Primary outcomes included: self monitoring or reports of smoking, cholesterol level, physical activity, dietary habits, blood sugar levels or blood pressure; body mass index; and admission for acute coronary syndrome, chest pain or stroke.

Included trials were conducted in the USA, Australia, UK, the Netherlands, Denmark and Canada. Participants included both males and females, with the exception of one trial of female smokers. The majority of mixed gender trials included more males than females. The age of participants ranged from 37 to 86 years. Most trials were conducted in single centres using a parallel group design. Interventions focused mainly on written information, postal reminders, telephone support and personalised risk factor cards, delivered mainly by nurses and dieticians. Trials were followed-up for between three weeks and 30 months.

Two reviewers independently assessed the eligibility of studies for inclusion using a specially designed form.

Assessment of study quality
Two reviewers independently assessed the validity of trials using the Joanna Briggs quality assessment tool for experimental studies. Assessment criteria included: clear description of inclusion and exclusion criteria used for sample selection; use of concealed allocation; use of valid outcome measures; clear description of withdrawals and drop-outs; and evidence of any potential bias in outcome assessment. Any disagreements were resolved through discussion with a third reviewer.

Data extraction
Relative risks with 95% confidence intervals were calculated for dichotomous outcomes and means and standard deviations for continuous outcomes. Where cluster randomised trials were analysed using appropriate statistics,
extracted an exact estimate of treatment effect. If a cluster-effect analysis was not reported, the number of clusters randomised to each study group, the average cluster size and the treatment effect were extracted and used to estimate an effect size using an external estimate of the intra-cluster coefficient.

Two reviewers independently extracted data using a piloted data extraction tool. Discrepancies were resolved through discussion. Where data were missing attempts were made to contact the relevant authors.

**Methods of synthesis**
Clinical heterogeneity was assessed and statistical heterogeneity assessed using the $I^2$ statistic. Where there was no evidence of significant heterogeneity trials were grouped by type of comparison and outcome, and relative risks or weighted mean differences with 95% confidence intervals pooled using a random-effects analysis. If there was no evidence of statistical heterogeneity and the trials were sufficiently similar, the trials were pooled using a fixed-effect analysis. The authors planned to combine cluster randomised trials using generic inverse variance methods, but there were insufficient numbers of trials, to carry out this analysis. Where meta-analysis was not appropriate, trials were combined in a narrative synthesis.

**Results of the review**
Seventeen parallel group trials (n=4,725) were included in the review. Three trials compared effects on diet modification, seven trials compared effects on smoking cessation and seven trials compared effects on multiple risk factors.

**Trial quality:** Overall, the quality of the trials was described as excellent, with a mean number of 10 quality criteria being described and two trials describing all 11 criteria. Eight trials used an intention-to-treat analysis. All except one trial indicated baseline comparability between study groups. All but one trial followed-up at least 80% of randomised participants. Blinding was not possible in the majority of trials, but four trials reported outcome assessors were blinded to the intervention.

**Brief interventions versus usual care for dietary modification:** Two trials comparing brief interventions with usual care for dietary modification (n=76 participants) reported beneficial, but not statistically significant losses in weight at 12 weeks follow-up. Target cholesterol levels were met at six months follow-up. One small trial (n=36 participants) of brief intervention versus an extensive dietary modification intervention, reported a significant reduction amongst those participants in the extensive intervention, in the amount of energy (percentage) obtained from fat and saturated fat intake. However, there was no apparent difference in the amount of fish, vegetables and fruit consumed.

**Brief interventions versus usual care for smoking cessation:** Of the six trials (n=2,020 participants) comparing brief intervention with usual care for smoking cessation, none of the trials reported a difference in smoking cessation rates at three or six weeks follow-up. However, benefits in favour of the brief intervention groups were reported for smoking cessation rates at three, six and 12 months follow-up. One trial (n=254 participants) comparing brief intervention with an extensive intervention for smoking cessation reported no significant difference between the two study groups in terms of the likelihood of smoking cessation.

**Brief interventions versus usual care for multiple risk factors:** Seven trials compared brief intervention with usual care for multiple risk factor modification. Evidence suggested brief intervention was associated with beneficial changes in behaviour, including statistically significant benefits in terms of fat intake (three out of four trials), weight loss (two out of three trials), reduction in BMI (two out of two trials), smoking cessation (pooled relative risk 0.70; 95% confidence interval: 0.50 to 0.97; five trials) and physical activity (one trial out of four trials). There was no conclusive evidence regarding the effects on blood pressure (three trials), blood glucose levels (two trials) and lipid profiles (four trials).

**Cost information**
One trial included an assessment of cost-effectiveness. It reported a gross saving in costs of $1,418 per patient due to a reduction in cardiovascular events (15.7% in the intervention group and 4.1% in the control group; p=0.053). This represented a 213% return on investment.
Authors' conclusions
The evidence to support the effectiveness of brief interventions in adults with coronary heart disease was inconclusive but suggestive of a beneficial effect in terms of risk factor modification and disease progression. Further research is required.

CRD commentary
This review answered a clearly defined research question, searching a wide variety of literature sources for both published and unpublished studies. Appropriate methods were used during the review process to reduce the risk of reviewer error and bias. Assessments of both study validity and heterogeneity were performed and these were used to inform the analysis and conclusions. Overall, given the evidence presented, the authors' cautious conclusions and recommendations for further research appear to be reliable.

Implications of the review for practice and research
Practice: The authors stated that there was strong evidence to support the use of brief interventions for risk modification for long term (up to one year) smoking cessation in adults with coronary heart disease. However, there was insufficient evidence to support a role of brief interventions in modifying other risk factors, in patients with coronary heart disease.

Research: The authors stated that further large randomised controlled trials are required, using consensus methods to standardise definitions and using well-defined, validated outcome measures. Future trials should use robust methods including adequate follow-up periods to assess the effects of brief interventions and the costs involved. Large single and multi-centre trials are also required, to allow the secondary analysis of specific subgroups of patients (e.g. women, lower socio-economic subgroups and patients with heart failure). Such robust evidence is required to inform decisions by clinicians and policy makers about the most appropriate use of brief interventions.

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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.