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SHORT REPORT

Systematic versus opportunistic risk assessment for the primary prevention of cardiovascular disease: Cochrane systematic review protocol

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Abstract

A large number of people, considered at increased risk of vascular disease, remain unidentified, untreated and not reached by lifestyle advice or intervention, despite public health and clinical efforts. This has prompted the initiation of national screening/systematic risk assessment programmes for vascular disease in healthy populations. These exist in addition to the more ad hoc opportunistic risk assessment initiatives undertaken worldwide. There is currently not enough indisputable evidence either showing clear clinical or economic benefits of systematic screening-like programmes over opportunistic risk assessment of cardiovascular disease (CVD) in primary care.

We present the rationale and methodology of a Cochrane systematic review, assessing the effectiveness, costs and adverse effects of systematic risk assessment compared to opportunistic risk assessment for the primary prevention of CVD.

Keywords: cardiovascular disease, Cochrane systematic review protocol, risk assessment.

Introduction

Description of the condition

Many risk factors contribute to the development of cardiovascular disease (CVD), most of which are related to lifestyle, such as physical inactivity, smoking and unhealthy diet (1). In more than 90% of cases, the risk of a first heart attack is related to nine potentially modifiable risk factors (2): smoking/tobacco use; poor diet; high blood cholesterol; high blood pressure; insufficient physical activity; overweight/obesity; diabetes; psychosocial stress and excess alcohol consumption. The combined effect of different coexisting cardiovascular risk factors determines the total or global risk of developing CVD. Many people are unaware of their risk status and total risk assessment is potentially useful for finding high-risk individuals and guiding clinical decisions (3). Such a risk stratification approach is particularly suitable to settings with limited resources (1). Short emphasises that there is no advantage in assessment, without the ability to intervene and to make changes to lower that risk (4). Efficient and effective means of identifying high-risk individuals and then providing the support to enable them to modify their lifestyles requires a delivery system which gives priority to preventive services rather than focusing on treatment (5).

Description of the intervention

The main objectives of a risk assessment are to assess health status, to estimate health risk, and to inform and provide feedback to participants in order to reduce health risks (6).

Systematic risk assessment

Systematic risk assessment (SRA) for primary prevention of CVD is defined here as a screening-like programme, involving a pre-determined process for selection of people, who are systematically invited to attend a CVD health check in a primary care or similar setting. The selection, invitation and follow-up processes are determined in advance, for example specific inclusion/ exclusion criteria; a unified method of invitation, such as letter/birthday card/phone call; and there is a system for providing feedback or referral. Such a programme is repeated at pre-defined intervals, for example every five or ten years. The assessment process includes finding out and measuring risk factors as well as estimating the total (global) CVD risk, using a specific risk scoring tool.

The target population for such systematic risk assessment includes healthy individuals (not previously diagnosed with CVD but may already have been diagnosed with one or more CVD risk factors).

Similarly to other screening programmes, SRA can be realised in two ways: population (universal/mass), including the general population in a certain age group with no regard to any underlying risk factors; high-risk - targeted to a specific group of individuals, considered potentially to be at increased risk of CVD due to some pre-existing risk factors.

Opportunistic risk assessment

Opportunistic risk assessment (ORA) for primary prevention of CVD is defined here as occurring sporadically in a primary setting, including primary care, pharmacy chains, supermarket chains, food companies, occupational health departments or small businesses. The range of such activities varies from no CVD risk assessment at all (no risk factors are measured/no total risk is scored in healthy individuals); through random (opportunistic) risk assessment in patients attending primary care for another reason; to incentivised case-finding, for example through the Quality and Outcomes Framework for UK general practitioners (7).

How the intervention might work

According to the NHS Health Checks programme (8), a standard assessment, based on simple questions and measurements to identify the risk of coronary heart disease (CHD), stroke, diabetes and kidney disease, would be effective. After assessing the levels of the main risk factors and the total CVD risk, a follow-up is organised with an individually tailored assessment, setting out the person's level of vascular risk and what steps they could take to reduce it. Modelling work around the Health Checks approach has predicted that it would deliver significant benefits for the UK population: preventing at least 9500 heart attacks and strokes a year (2000 of which would be fatal); preventing at least 4000 people a year from developing diabetes; and detecting diabetes or kidney disease at least a year earlier for 25,000 people. It has predicted high levels of both clinical and cost-effectiveness against a range of assumptions when this approach is applied to all those aged 40 to 74 years (9).

Recent research suggests that targeting high-risk individuals (high risk based SRA) rather than mass population screening is a preferred route (10,11). Lawson identified that 16 people were needed to be screened, following the population approach, to identify one individual at high risk of CVD, costing GBP 370 per high-risk person. The alternative, e.g. targeted screening of deprived communities, estimated that only six people would need to be assessed for the identification of one high risk individual, reducing the costs to GBP 141 per positive identification. Jackson et al identify that a screening programme targeted at individuals with likely or known CVD risk factors would be preferable from a cost-effectiveness point of view (12).

Previous research (13) suggests that when a population screening programme is undertaken, there is a persistent level of non-attendance and that whilst cardiac risk score for non-attenders is similar to those who attended, non-attenders have significantly more risk behaviours such as smoking. Population-based (universal) risk assessment every five years was found to be cost-effective when compared with no screening; however a cost-analysis was not conducted on whether universal risk assessment would remain cost-effective when compared to targeted high-risk screening.

Objective: The primary objective of this review is to assess the effectiveness, costs and adverse effects of SRA compared to ORA for the primary prevention of CVD.

Methods

Types of studies: Randomised controlled trials (RCTs).

Types of participants: Healthy adults (18 years old or over) from the general population, including those at moderate to high risk of CVD.

Intervention: SRA for primary prevention of CVD, defined as a screening-like programme, involving a predetermined selection process of people, systematically invited to attend a CVD health check in a primary care or similar setting, assessing at least two of the following risk factors:

- Blood pressure (systolic and/or diastolic) or lipid profile (total cholesterol, LDL, LDL/HDL); and
- Any other modifiable risk factor (smoking, weight, diet, exercise, alcohol, stress).

Control: ORA for primary prevention of CVD, defined as a range of activities, occurring sporadically in any primary setting - from no risk assessment at all to incentivised case finding.

Outcome measures

Primary outcomes

- All-cause mortality;
- Cardiovascular mortality;
- Non-fatal endpoints, including CHD, MI, CABG, PTCA, stroke, transitory ischaemic attack (TIA) and peripheral artery disease.

Secondary outcomes

- CVD major risk factors: blood pressure, lipid levels, type 2 diabetes;
- Intermediate (programme) outcomes (if reported): attendance rates (number of individuals who came for examination); case finding rates (number of high-risk individuals, identified by the health check); acceptability and participants' satisfaction; and follow-up rates (number of cases who were followed with some intervention in primary and secondary care);
- Costs;
- Adverse effects.

Search methods for identification of studies

Electronic searches

The following electronic databases were searched:

- The Cochrane Library (including the Cochrane Central Register of Controlled Trials (CENTRAL) and NHS Centre for Reviews and Dissemination (CRD) databases: Health Technology Assessment (HTA), Database of Abstracts of Reviews of Effects (DARE) and NHS Economic Evaluation Database (NEED);
- MEDLINE (OVID);
- EMBASE (OVID);
- Science Citation Index Expanded (SCI-EXPANDED), Social Sciences Citation Index (SSCI), Conference Proceedings Citation Index - Science (CPCI-S) on Web of Science;
- AMED - Allied and Complementary Medicine Database. We will use medical subject headings (MeSH) or equivalent and text word terms. We will design searches in accordance with the Cochrane Heart Group methods and guidance. We will impose no language restrictions.

Searching other resources

Open Grey for grey literature; meta-Register of controlled trials (m-RCT) (www.controlled-trials.com/mrct); clinicaltrials.gov (www.clinicaltrials.gov) and WHO International Clinical Trials Registry platform (ICTRP) (http://apps.who.int/trialsearch/).

Data collection and analysis

Data collection and analysis is realised through: selection of studies; data extraction and management; assessment of risk of bias in included studies; measures of treatment effect; assessment of heterogeneity; subgroup analysis, if sufficient studies are found.

We will also examine the effects of the intervention design (setting, personnel involved, invitation and follow-up system). We will carry out sensitivity analyses excluding studies with a high risk of bias. If there are sufficient trials, we will undertake assessment of funnel plots and tests of asymmetry (14) to assess possible publication bias.

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