Patient education in the contemporary management of coronary heart disease (Protocol)

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[Intervention Protocol]

Patient education in the contemporary management of coronary heart disease

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

1. To assess the effects of patient education compared with usual care on mortality and morbidity in patients with CHD.
2. To explore the potential study level predictors of the effects of patient education in patients with CHD.

BACKGROUND

Description of the condition

Cardiovascular disease is the lead cause of death globally: in 2004 there were an estimated 7.2 million deaths attributable to coronary heart disease (CHD) (WHO 2010). Low and middle income countries are disproportionally affected and CHD produces a significant economic burden globally (WHO 2010). It is estimated that over a decade (2006 to 2015) China will loose $558 billion from national income due to a combination of CHD, stroke and diabetes (WHO 2010). Public health interventions aimed at CHD prevention are important in reducing this burden and there is a need to increase its capacity to further manage CHD effectively.
It is widely accepted that the effective management of CHD is multimodal with appropriate revascularization, drug therapy and cardiac rehabilitation (CR). Guidelines for CHD treatment and content of CR are regularly updated in light of the growing evidence base (Balady 2007; SIGN 2002; Smith 2006).

Description of the intervention

The Scottish Intercollegiate Guidelines Network define CR as "the process by which patients with cardiac disease, in partnership with multidisciplinary team of health professionals, are encouraged and supported to achieve and maintain optimal physical and psychosocial health" (SIGN 2002).
Consensus statements from the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation have stated that CR programmes "should offer a multifaceted and multidisciplinary approach...and that programmes that consist of exercise training alone are not considered CR" (Balady 2007). CR is multifaceted and consists of several intervention modalities and can be divided into three broad intervention groupings: exercise-based interventions, psychological interventions and patient education. Exercise and psychological interventions has recently been the subject of Cochrane systematic review updates (Jolliffe 2001; Rees 2004). Whilst these reviews have considered trials that have included education as co-intervention, there has been no Cochrane review to date that specifically focused the impact of educational component of cardiac rehabilitation for patients with CHD.

Why it is important to do this review

Two meta-analyses of education in patients with CHD were published in the 1990s (Dusseldorp 1999; Mullen 1992). The first meta-analysis (Mullen 1992) demonstrated a significant mortality reduction with patient education (weighted average effect size 0.24 standard deviation units [0.14-0.33]). This translated into a 19% improvement in mortality. The average effects for morbidity (reinfarction and rehospitalisation) were not found to be significant but one outlying RCT was excluded from the analysis for demonstrating a large positive effect size (Rahe 1979). The second meta-analysis (Dusseldorp 1999) investigated the co-interventions of health education and stress management concluding that these programmes yielded a 34% reduction in cardiac mortality and a 29% reduction in reinfarction. However, there are concerns about the applicability of these results with regard to policy formation on the current provision and planning of rehabilitation services, on several grounds:

1. the scope of these meta-analyses were 'psycho-social' interventions. It is not readily possible to establish the independent effect education;
2. inclusion of both randomised and non-randomised evidence which may have substantially increased the risk of bias;
3. inclusion of trials that enrolled primarily white, middle-class males and as such the elderly, women and ethnic minorities were underrepresented;
4. usual care has evolved significantly since these previous systematic reviews (there have been many advances in all areas of management of CHD in the last decade) and this may affect the benefit from CR in the form of patient education (Taylor 2004);
5. the continued development of educational interventions based on Internet technology (Dellifraine 2008; Neubeck 2009).

With the existence of new evidence a current review of the effectiveness of patient education as part of CR is indicated.
We concluded that current clinical practice in the management of cardiovascular disease has evolved rapidly and that usual care prior to 1990 is not representative of current usual care and therefore the transferability of any trial results would be of limited value. This time period is in keeping with similar recent systematic review into cardiac rehabilitation (Taylor 2004).
Thus, this Cochrane review will be undertaken to update previous meta-analyses of the effects of education for patients with coronary heart disease, and formally explore the heterogeneity and variation in education intervention effects using meta-regression.

OBJECTIVES

1. To assess the effects of patient education compared with usual care on mortality and morbidity in patients with CHD.

2. To explore the potential study level predictors of the effects of patient education in patients with CHD.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) where patient education was the primary intention of the intervention, with a follow up period of at least six months. Only trials after 1990 have been considered as trials prior to this are subject to medical practice that is significantly different from contemporary practice (Taylor 2004).

Studies of CR where exercise or psychological intervention were the primary focus for investigation will be excluded. These later components of CR have been investigated previously in Cochrane systematic reviews (Jolliffe 2001; Rees 2004).

Types of participants

The study population will include adults;

- who have suffered a myocardial infarction (MI), or
- who have undergone revascularization (coronary artery bypass grafting (CABG), percutaneous transluminal coronary angioplasty (PTCA) or coronary artery stenting), or
- who have angina pectoris or CHD defined by angiography

Studies of participants undertaking education programmes following heart valve surgery, with heart failure, with heart transplants or implanted with either cardiac-resynchronisation therapy or implantable defibrillators will be excluded.

Types of interventions

For the purposes of this review patient education is defined as instructional activities organised in a systematic way. Education should involve personal direct contact between a health professional and CHD patients (and significant others e.g. spouse, family member) to facilitate potential changes in risk factors for CHD. Delivered in an inpatient, outpatient or community-based intervention setting or programme including some form of structured knowledge transfer about CHD, its causes, treatments or methods of secondary prevention. We will include face-to-face education whether in groups or on a one-to-one basis. We will also include alternative interactive methods of educational delivery such as "telehealth" (telephone, e-mail, Internet and teleconference between educator and patient). We will exclude general information provision, which is not organised in a systematic way (e.g. information leaflet given on leaving the cardiac care unit, personal communication with a healthcare provider) and consider this to be usual care.

Given that multifaceted nature of CR we will also include studies where exercise and/or psychological therapies are provided although patient education must be a primary interventional focus of investigation.

We will particularly seek studies where the effect of education could be evaluated independently (e.g. patient education plus usual care vs usual care alone; patient education and usual care plus exercise vs usual care and exercise alone; patient education and usual care plus psychological intervention vs usual care and psychological intervention alone).

Types of outcome measures

Primary outcomes

- Total mortality
  - Cardiovascular mortality
  - Non-cardiovascular mortality
- Total cardiovascular (CV) events
  - fatal and/or non-fatal MI
  - other fatal and/or non-fatal CV events

Secondary outcomes

- Total revascularizations
  - CABG
  - PTCA +/- restenting
- Hospitalisations
  - Total number cardiac related patient admissions in the follow-up period following the intervention.
  - Proportion of patients requiring admission in the follow-up period following the intervention.
- Validated measures of health-related quality of life (HRQoL) (e.g. SF-36, EQ-5D, MacNew)
- Withdrawals from intervention arm (as a surrogate for potential adverse events)
- Costs and cost effectiveness

Search methods for identification of studies

Electronic searches

We will be searching the following databases: *The Cochrane Library* (Cochrane Central Register of Controlled Trials - CENTRAL, Cochrane Database of Systematic Reviews - CDSR, Database of Abstracts of Reviews of Effects - DARE, Health Technology Assessment Database - HTA, NHS Economic Evaluation Database - EED), MEDLINE, EMBASE, PsycINFO and CINAHL. The search strategy was designed with reference to previous systematic reviews of education for the prevention of CHD (Dusseldorp 1999; Mullen 1992) and Cochrane reviews that considered education as an intervention (Deakin 2005; Duke 2009). Consideration was given to variations in terms used and spellings of terms in different countries so that studies will not be missed by the search strategy because of such variations. The literature search will contain a mixture of subject heading index terms and free text to maximise retrieval.

Ongoing trials will be identified from searching the following trial registries:

- UKCRN (http://public.ukcrn.org.uk),

- *meta*Register of Controlled Trials (controlled-trials.com/mrct/) (includes clinicaltrials.gov),
- ICTRP WHO International Clinical Trials Registry Platform (apps.who.int/trialsearch/).

Searches will be limited to randomised controlled trials, systematic reviews, and meta-analyses and a filter will be applied to limit by humans and date (from 1990 - in order to reflect 'modern' clinical management of CHD (Taylor 2004). No language limitations will be imposed. Reference lists of all eligible trials, systematic reviews and meta-analyses will be searched for additional studies. Authors of included studies will be contacted for further details and information on ongoing or unpublished trials.
The strategy designed for CENTRAL (Appendix 1) will be adapted for use with the other databases.
The reporting of search results will be conducted in accordance with PRISMA. A flow diagram will be included which will provide information about the number of studies identified, included and excluded, and the reasons for exclusion.

Data collection and analysis

Selection of studies

The titles of studies identified by the search strategy will be screened by two independent authors (JB and RST) and clearly irrelevant studies discarded. In order to be selected, abstracts should clearly meet the inclusion and exclusion criteria identified above. The full-text reports of all potentially relevant trials will be obtained and assessed independently for eligibility. Any disagreement will be resolved by discussion or where agreement cannot be reached, by consultation with an independent third person.

Data extraction and management

Standardised data extraction forms will be used. Details of study design, participants, interventions, and outcomes, risk of bias (randomisation, blinding, attrition and outcome reporting) and results will be extracted. Data abstraction will be carried out by JB and RST independently. Excluded studies and reasons for exclusion will be detailed in a Characteristics of Excluded Studies table.

Assessment of risk of bias in included studies

Factors which will be considered will include the quality random sequence generation and allocation concealment, description of drop-outs and withdrawals (including analysis by intention-to-treat), blinding (participants, personnel and outcome assessment) and selective outcome reporting. The risk of bias in eligible trials will be assessed by two independent authors (JB and RST). The Cochrane Collaboration's risk of bias tools will be applied (Higgins 2009).

Data synthesis

Data will be processed as described in the Cochrane Handbook for Systematic Reviews of Interventions (Deeks 2009). For dichotomous variables risk ratios and 95% confidence intervals (CI) will be derived for each outcome. For continuous variables mean differences and 95% CI will be calculated for each outcome. Heterogeneity amongst included studies will be explored qualitatively (by comparing the characteristics of included studies) and quantitatively (using the chi-squared test of heterogeneity and I^2 statistic). Where appropriate and possible, results from included studies will be combined for each outcome to give an overall estimate of treatment effect. A fixed-effect model will be used except where statistical heterogeneity is identified and instead a random-effects model will be used.

Subgroup analysis and investigation of heterogeneity

When possible, subgroup analyses stratified meta-analysis, sensitivity analysis and meta-regression will be used to explain heterogeneity and examine potential treatment effect modifiers. We will test the following a priori hypotheses that there may be differences in the effect of education on total mortality across particular subgroups by:

- CHD case mix (myocardial infarction-only trials vs other trials)
- Dose and nature of structured patient education (assessed on the basis the number and nature of education sessions e.g. training of who delivers the education, health care professional, specific educational training, feedback or reinforcement given i.e. literature, audiovisual follow-up material))
- Method of structured education delivery (one-to-one vs group vs combination)
- Theoretical v no-theoretical basis to educational intervention
- Involvement of significant others (e.g. spouse, family member) in the education
- Timing of the education following the index event
- Length of the educational intervention
- Follow-up period (< 12 months vs >12 months)
- Year of Publication (before 2000 vs 2000 or later)
- Measures of study bias (e.g. quality of concealment of randomisation vs. not)
- Other potential relevant subgroups may become apparent and identified for analysis during the process of the review, even if they have not been defined in advance of any analyses.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategy

CENTRAL

#1 MeSH descriptor Myocardial Infarction explode all trees
#2 MeSH descriptor Angina Pectoris explode all trees
#3 MeSH descriptor Coronary Disease explode all trees
#4 MeSH descriptor Myocardial Revascularization explode all trees
#5 myocardial infarct*
#6 angina pectoris
#7 angor pectoris
#8 stenocardia*
#9 coronary artery bypass*
#10 CABG
#11 aortocoronary bypass*
#12 coronary NEAR/3 angioplast*
#13 PTCA
#14 coronary NEAR/2 dilatation*
#15 coronary NEAR/2 disease*
#16 coronary artery stent*
#17 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16)
#18 MeSH descriptor Health Education, this term only
#19 MeSH descriptor Telemedicine, this term only
#20 (patient* NEAR/6 (educat* or communicat* or interacti* or inform* or advi*))
#21 (educat* NEAR/6 (intervention* or rehabilation* or program*))
#22 (education NEAR/6 (service* or group* or program* or session*))
#23 education NEAR/6 prevent*
#24 ((rehabilitati* or educat*) NEAR/6 (literature or audiovisual or av or audio-visual or internet or web* or telecare or telemedicine or telephone* or phone* or teleconference* or telehealth or transtelephonic* or podcast* or email* or e-mail* or mp3*))
#25 ((educat* or intervent*) NEAR/6 (communit* or famil* or spouse* or nurs*))
#26 MeSH descriptor Patient Education as Topic, this term only
#27 (#18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26)
#28 (#17 AND #27)

HISTORY

Protocol first published: Issue 12, 2010

CONTRIBUTIONS OF AUTHORS

Protocol: JB and RST jointly developed and wrote the review protocol. Database search strategies were developed by KW. The protocol was checked and refined with input from AMC and HD.

Review: JB and RST will act as the independent reviewers screening the identified studies and will review the abstracts and full-text reported to decide on papers meeting inclusion criteria. JB and RST will co-ordinate the review process. KW will run the search strategies in all stated electronic databases. JB and RST will extract the data from the included studies. JB will be responsible for drafting the review text and RST, AMC and HD will each contribute to the review drafting. The final text and conclusions of the review will be agreed by all authors.

DECLARATIONS OF INTEREST

None declared.

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