

# Patient education in the management of coronary heart disease (Review)

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[Intervention Review]

# Patient education in the management of coronary heart disease

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## ABSTRACT

### Background

Cardiac rehabilitation (CR) is a complex multifaceted intervention consisting of three core modalities: education, exercise training and psychological support. Whilst exercise and psychological interventions for patients with coronary heart disease (CHD) have been the subject of Cochrane systematic reviews, the specific impact of the educational component of CR has not previously been investigated.

### Objectives

1. Assess effects of patient education on mortality, morbidity, health-related quality of life (HRQoL) and healthcare costs in patients with CHD.
2. Explore study level predictors of the effects of patient education (e.g. individual versus group intervention, timing with respect to index cardiac event).

### Search methods

The following databases were searched: *The Cochrane Library*, (CENTRAL, CDSR, DARE, HTA, NHSEED), MEDLINE (OVID), EMBASE (OVID), PsycINFO (EBSCOhost) and CINAHL (EBSCOhost). Previous systematic reviews and reference lists of included studies were also searched. No language restrictions were applied.

### Selection criteria

1. Randomised controlled trials (RCTs) where the primary interventional intent was education.
2. Studies with a minimum of six-months follow-up and published in 1990 or later.
3. Adults with diagnosis of CHD.

### Data collection and analysis

Two review authors selected studies and extracted data. Attempts were made to contact all study authors to obtain relevant information not available in the published manuscript. For dichotomous variables, risk ratios and 95% confidence intervals (CI) were derived for each outcome. For continuous variables, mean differences and 95% CI were calculated for each outcome.

## Main results

Thirteen RCTs involving 68,556 subjects with CHD and follow-up from six to 60 months were found. Overall, methodological quality of included studies was moderate to good. Educational 'dose' ranged from a total of two clinic visits to a four-week residential stay with 11 months of follow-up sessions. Control groups typically received usual medical care. There was no strong evidence of an effect of education on all-cause mortality (Relative Risk (RR): 0.79, 95% CI 0.55 to 1.13), cardiac morbidity (subsequent myocardial infarction RR: 0.63, 95% CI 0.26 to 1.48, revascularisation RR: 0.58, 95% CI 0.19 to 1.71) or hospitalisation (RR: 0.83, 95% CI:0.65 to 1.07). Whilst some HRQoL domain scores were higher with education, there was no consistent evidence of superiority across all domains. Different currencies and years studies were performed making direct comparison of healthcare costs challenging, although there is evidence to suggest education may be cost-saving by reducing subsequent healthcare utilisation.

This review had insufficient power to exclude clinically important effects of education on mortality and morbidity of patients with CHD.

## Authors' conclusions

We did not find strong evidence that education reduced all cause mortality, cardiac morbidity, revascularisation or hospitalisation compared to control. There was some evidence to suggest that education may improve HRQoL and reduce overall healthcare costs. Whilst our findings are generally supportive of current guidelines that CR should include not only exercise and psychological interventions, further research into education is needed.

## PLAIN LANGUAGE SUMMARY

### Patient education for coronary heart disease

Coronary heart disease (CHD) includes chest pain, heart attacks, and the need for heart surgery and is a major cause of premature death and disability. Education is a common element of care for people with CHD aiming to decrease mortality and morbidity as well as improving quality of life. This review shows that there is not enough information available to fully understand the impact of educational interventions on mortality, morbidity and health-related quality of life of patients with CHD. Nevertheless, our findings broadly support current guidelines that people with CHD should receive comprehensive rehabilitation that includes education. Further research is needed to evaluate the most clinically and cost-effective ways of providing patient education on CHD.

## BACKGROUND

### Description of the condition

Cardiovascular disease is the largest 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 disproportionately affected and CHD produces a significant economic burden globally (WHO 2010). For example, it is estimated that over a decade (2006 to 2015) China will lose \$US 558 billion from national income due to a combination of CHD, stroke and diabetes (WHO 2010). CHD causes significant morbidity and mortality, as a chronic disease it contributes significantly to disability in developed countries. CHD accounts for 11.1% of total disability adjusted life years in European countries (WHO 2008). CHD results in difficulties performing ev-

eryday activities such as housework or cooking meals and it can impair sexual function (Racca 2010). This leads to a potentially preventable significantly decreased quality of life (Gravelly-Witte 2007). Public health interventions aimed at CHD prevention are important to reduce this burden.

It is widely accepted that the effective management of CHD is multi-modal, including appropriate revascularisation, drug therapy and cardiac rehabilitation (CR). Guidelines for CHD treatment and content of CR are regularly updated to reflect the growing evidence base (Balady 2007; SIGN 2002; Smith 2006).

### Description of the intervention

The Scottish Intercollegiate Guidelines Network defines CR as "*the process by which patients with cardiac disease, in partnership with*

*a multidisciplinary team of health professionals, are encouraged and supported to achieve and maintain optimal physical and psychosocial health (SIGN 2002).*” In terms of the timing and target audience for CR, the British Heart Foundation state *“cardiac rehabilitation is a programme of exercise and information sessions... available to anyone who has a heart attack, coronary angioplasty or heart surgery and starts as soon as you go into hospital for your angioplasty or surgery (BHF 2011).”*

Consensus statements from the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation state 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 consists of several intervention modalities and can be divided into three broad intervention groupings: exercise training, psychological support and patient education. Exercise and psychological interventions have recently been the subject of Cochrane systematic review updates (Heran 2010; Whalley 2011). Whilst these reviews have considered trials that have included education as a co-intervention, there has been no Cochrane review to date that specifically focused on the impact of the educational component of CR for patients with CHD.

Patient education is defined as *“the process by which health professionals and others impart information to patients that will alter their health behaviours or improve their health status” (Koongstvedt 2001).* There is a substantial variety in the delivery of patient education. It can be classroom or home based, group or individual, tailored or generic. Duration and reinforcement of education also differs between programmes. Some programmes are developed according to validated educational theory and by trained professionals whilst others are delivered by peers.

### 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, 95% CI: 0.14 to 0.33), which translated into a 19% improvement in mortality. The average effects for morbidity (reinfarction and rehospitalisation) were not found to be significant. However, one RCT was excluded from analysis because it was an outlier as it demonstrated a large positive effect size (Rahe 1979). The second meta-analysis (Dusseldorp 1999) investigated the co-interventions of health education and stress management and concluded that these programmes yielded a mean reduction of 34% in cardiac mortality and a 29% reduction in the risk of reinfarction. There are concerns on several grounds about the applicability of these results to policy formation and the current provision and planning of CR services:

1. The scope of both meta-analyses were education combined with 'psycho-social' interventions. It is not readily possible to establish the independent effect of education.

2. The inclusion of both randomised and non-randomised evidence may have substantially increased the risk of selection bias.

3. Trials enrolled primarily Caucasian and middle-class males. The elderly, women and ethnic minorities were under represented.

4. Usual care for CHD has evolved significantly since these studies were undertaken, transferability of any trial results is of limited value. Routine care has been influenced by the introduction of national guidelines such as the National Service Framework for CHD in the United Kingdom (DoffH 2000).

5. Educational interventions are continuously developing to reflect advancing Internet technology (Bailey 2010; Dellifraire 2008; Neubeck 2009).

Several new studies have been completed since the previous systematic reviews of the literature (Clark 2000; Clark 2009; Esposito 2008; Hanssen 2007; Lie 2009; Lisspers 1999; Peikes 2009; Pogosova 2008; Southard 2003; Tingstrom 2005). This new information and the concerns about the existing meta-analyses indicate that an up-to-date review is appropriate. This Cochrane review uses meta-regression to assess the available evidence base for effects of education on patients with CHD and formally explore the heterogeneity and variation in education intervention.

## OBJECTIVES

1. To assess the effects of patient education compared with usual care on mortality, morbidity, health-related quality of life (HRQoL) and healthcare costs in patients with CHD.

2. To explore the potential study level predictors of the effects of patient education in patients with CHD (e.g. individual versus group intervention, timing with respect to index event).

## METHODS

### Criteria for considering studies for this review

#### Types of studies

To reflect contemporary CHD practice we included randomised controlled trials (RCTs) published after 1990.

## Types of participants

We included studies where subjects were adults:

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

We excluded studies of participants who undertook education programmes:

- following heart valve surgery,
- suffered from heart failure,
- were subject to heart transplantation,
- were implanted with either cardiac-resynchronisation therapy or
- defibrillators.

## Types of interventions

We identified RCTs where patient education was the primary intention of the intervention with a follow-up period of at least six months. We excluded studies of CR where exercise or psychological intervention were the primary focus for investigation. These later components of CR have been investigated previously in Cochrane systematic reviews (Jolliffe 2001; Rees 2004) and recently updated by the Cochrane reviews of exercise-based rehabilitation (Heran 2010) and psychological interventions for people with CHD (Whalley 2011).

For the purposes of this review, patient education was defined as the following:

- (1) Instructional activities organised in a systematic way involving personal direct contact between a health professional and CHD patients with or without significant others: e.g. spouse, family member;
- (2) Delivered as an inpatient, outpatient in a community-based intervention setting or programme;
- (3) Include some form of structured knowledge transfer about CHD, its causes, treatments or methods of secondary prevention;
- (4) Delivered in a face-to-face format, in groups or on a one-to-one basis. We also included alternative interactive methods of educational delivery such as “telehealth” (telephone, e-mail, Internet and teleconference between educator and patient);

We included only study interventions that met all the above criteria.

We excluded general information provision, which is not organised in a systematic way (e.g. written guidance given to a patient on leaving the cardiac care unit or personal communication with a healthcare provider), as we considered this to be usual care.

Given the multifaceted nature of CR we excluded studies where exercise and/or psychological therapies were provided and patient education was not stated to be a primary intervention.

We particularly sought studies designed to assess the independent effect of education (e.g. patient education plus usual care versus

usual care alone; patient education, usual care and exercise versus usual care and exercise alone; patient education, usual care and psychological intervention versus usual care and psychological intervention alone).

## Types of outcome measures

The aim of the review was to include studies that reported event data (e.g. mortality, cardiovascular events). We excluded alternative outcomes, for instance, changes in smoking, diet, blood pressure or effect of education on patient’s knowledge. We elected not to include these outcomes because we considered event rates to be more significant.

## Primary outcomes

- Total mortality
  - Cardiovascular mortality
  - Non-cardiovascular mortality
- Total cardiovascular (CV) events
  - Fatal and/or non-fatal myocardial infarction
  - Other fatal and/or non-fatal CV events

## Secondary outcomes

- Total revascularisations
  - CABG
  - PTCA with or without stenting
- Hospitalisations
  - Total number of 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 HRQoL (e.g. Short Form Health Survey SF-36, Sickness Impact Profile, Nottingham Health Profile)
- Withdrawals/drop-outs
- Healthcare costs and cost-effectiveness

We excluded studies that did not report these outcomes.

## Search methods for identification of studies

### Electronic searches

We searched the following databases: *The Cochrane Library, Issue 3 of 4 2010*, (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 - NHSEED); OvidSP Database platform - MEDLINE (including pre-medline in-process & other indexed citations), 1990 to August 2010, and EMBASE, 1990 to August 2010; and EbscoHOST Database platform, PsycINFO, 1990 to August 2010, and CINAHL, 1990 to August 2010. 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). We searched terms using alternate terminology and spelling to capture all relevant studies conducted throughout the world. The literature search contained a mixture of subject heading index terms and free text to maximise retrieval.

Ongoing trials were identified from searching the following trial registries:

- UK Clinical Research Network Portfolio Database - UKCRN (<http://public.ukcrn.org.uk>),

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

All searches were carried out in August 2010.

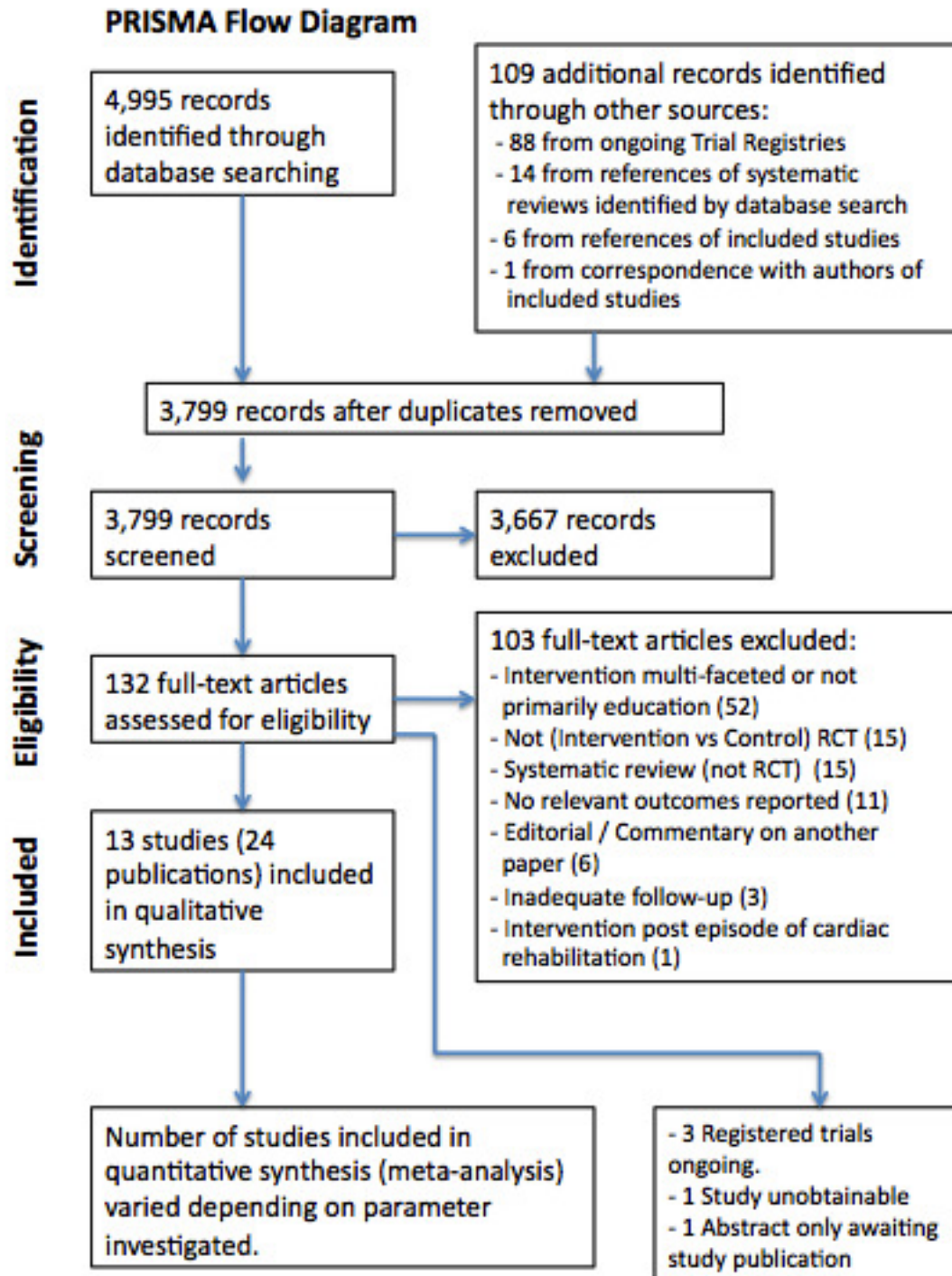
Searches were limited to RCTs, systematic reviews, and meta-analyses. A filter was applied to limit results to human-only trials published in 1990 or later. No language restrictions were imposed. Reference lists of all eligible trials, systematic reviews and meta-analyses were searched for additional studies. Attempts were made to contact all study authors to obtain relevant information not available in the published manuscript.

The strategy designed for CENTRAL was adapted for use with the other databases (Appendix 1).

The reporting of search results was conducted in accordance with PRISMA (Moher 2009). A flow diagram is included, which provides information about the number of studies identified, included and excluded, and the reasons for exclusion Figure 1.



Figure 1.





## Data collection and analysis

### Selection of studies

Titles and abstracts of studies identified by the search strategy were screened by two independent review authors (JB & RST) and obviously irrelevant studies were discarded. The full-text reports of all potentially relevant abstracts were obtained (JB) and assessed independently for eligibility (JB & RST). Any disagreement was resolved by discussion or where agreement was not reached, by consultation with an independent third reviewer (AC or HD). Excluded studies and reasons for exclusion are detailed in the “*Characteristics of Excluded Studies*” table.

### Data extraction and management

We used standardised data extraction forms. We extracted details about study design, participants, interventions, outcomes, risk of bias data and results. Due to constraints of time and resources, data extraction was initially carried out by JB and independently checked by RST.

### Assessment of risk of bias in included studies

Risk of bias tools were applied as described in the Cochrane Handbook for Systematic Reviews of Intervention (Higgins 2009). Factors that were considered included; the quality of random sequence generation and allocation concealment, description of drop-outs and withdrawals (including analysis by intention-to-treat), blinding (outcome assessment) and selective outcome reporting. Due to constraints of time and resources, assessment of the risk of bias in eligible trials was initially carried out by JB and independently checked by RST.

### Data synthesis

Data was processed as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009). For dichotomous variables, risk ratios and 95% confidence intervals (CI) were derived for each outcome. For continuous variables, mean differences and 95% CI were calculated for each outcome. Heterogeneity amongst included studies was explored qualitatively (by comparing the characteristics of included studies) and quantitatively (by using the chi-squared test of heterogeneity and  $I^2$  statistic). Where appropriate and possible, results from included studies were combined for each outcome to give an overall estimate of treatment effect. Given the degree of clinical heterogeneity seen in participant selection, interventions and comparators across studies, we decided it was appropriate to pool studies using random-effects modelling.

The review did not identify sufficient data to allow stratified meta-analysis at different common follow-up timings (e.g. 6 or 12 months post-randomisation). Instead, we pooled studies at their longest follow-up unless otherwise stated.

The funnel plot and the Egger test were planned to examine small study bias (Egger 1997).

### Subgroup analysis and investigation of heterogeneity

We intended to undertake subgroup analysis and stratified meta-analysis, sensitivity analysis and meta-regression in order to examine potential treatment effect modifiers. As stated in the protocol, we intended to test the following a priori hypotheses that there may be differences in the effect of education on total mortality across particular sub groups:

- CHD case mix (myocardial infarction-only trials versus other trials)
- Dose and nature of structured patient education. Assessed on the basis of 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 educational delivery (one-to-one versus group versus combination)
- Theoretical versus 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 ( $\leq 12$  months versus  $>12$  months)
- Year of publication (before 2000 versus 2000 or later)
- Measures of study bias (e.g. quality of concealment of randomisation versus not)

However, there was insufficient data to analyse by these sub groupings.

## RESULTS

### Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of studies awaiting classification](#); [Characteristics of ongoing studies](#).

## Results of the search

We identified 4,995 records through our electronic database search. We identified 109 additional records through alternate sources: 88 titles of ongoing studies found on trials registries, with two considered of potential future interest to the review (Lear 2008; McGillion 2006); one study protocol was identified from the database search (Hawkes 2009); 14 were drawn from reviewing references of systematic reviews identified by the database search (Bell 1998; Bethell 1990; Chan 2005; Engblom 1997; Enzenhofer 2004; Haskell 1994; Jenny 2001; Koertge 2003; Lisspers 1999; Moore 2002; Ornish 1990; P.RE.COR Group 1991; Vonder 2002; Zutz 2007); six from reviewing references in included studies (Ades 2001; Cundey 1995; Cupples 1994; Janz 1999; Thompson 2000; Thompson 2002); and one from direct correspondence with study authors from included studies (Hanssen, 2009).

After de-duplication, 3,799 abstracts were screened for inclusion, of which 3,667 were excluded. We retrieved 132 full texts and assessed them for eligibility; we then excluded 103 studies. Three trials were still ongoing, one was unavailable to the review authors and one was in abstract pre-publication and could not be assessed. In total, we included 24 papers reporting on 13 studies. Details of the exclusion process and reasons for exclusion are summarised in a PRISMA flow diagram (Figure 1) and in the “*Characteristics of excluded studies*” section.

Attempts were made to contact the lead authors (or contact author, if different) of all included studies. Responses were received from seven authors responsible for nine of the studies (Clark 1997; Clark 2000; Clark 2009; Cupples 1994; Esposito 2008; Hanssen 2007; Lie 2009; Lisspers 1999; Tingstrom 2005).

## Included studies

Six studies were based in the USA (Clark 1997; Clark 2000; Clark 2009; Esposito 2008; Peikes 2009; Southard 2003), two in Norway (Hanssen 2007; Lie 2009) and Sweden (Lisspers 1999; Tingstrom 2005) and one each in the UK (Northern Ireland) (Cupples 1994), France (P.RE.COR Group 1991) and Russia (Pogosova 2008).

Overall, 68,556 participants were included in the trials, with an average age of 61.9 years. Overall, 82% were Caucasian and there was a 58% male preponderance. A range of CHD diagnoses and interventions were identified amongst the included participants

(n=3,641): 3% CHD (not further defined), 42% angina, 37% post-MI, 17% post-CABG and 14% post-PTCA patients. These diagnoses and interventions are not mutually exclusive and do not include patients from Esposito 2008 and Peikes 2009. The two largest studies (n=64,915) (Esposito 2008; Peikes 2009) included some patients that were not within the scope of this review (i.e. they considered patients with congestive cardiac failure and diabetes). However, CHD patients contributed 69% and 61%, respectively, to these studies. Where possible, data from the CHD subgroup analysis was used. One study included patients with cardiac failure as well as those with CHD (Southard 2003).

Four studies involved group sessions (Clark 1997; Clark 2000; Pogosova 2008; Tingstrom 2005), five involved individualised education (Cupples 1994; Esposito 2008; Hanssen 2007; Lie 2009; Peikes 2009) and three utilised both session types (Lisspers 1999; P.RE.COR Group 1991; Southard 2003), with one study comparing the two approaches (Clark 2009)). Ten studies involved face-to-face sessions (Clark 1997; Clark 2000; Clark 2009; Cupples 1994; Esposito 2008; Lie 2009; Lisspers 1999; P.RE.COR Group 1991; Pogosova 2008; Tingstrom 2005), three were reliant on telephone contact (Esposito 2008; Hanssen 2007; Peikes 2009) and one involved interactive use of the Internet (Southard 2003). The intensity of the education varied substantially from a total of two visits by a healthcare professional (Lie 2009; P.RE.COR Group 1991) to a four-week residential stay reinforced with 11 months of nurse led follow-up sessions (Lisspers 1999). Description of the educational content of the programs was mostly brief. Table 1 gives a summary of educational intervention details.

Many studies reported outcomes at several endpoints. Six studies reported at six months (Clark 1997; Esposito 2008; Hanssen 2007; Lie 2009; Pogosova 2008; Southard 2003), nine at 12 months (Clark 1997; Clark 2000; Clark 2009; Esposito 2008; Lisspers 1999; P.RE.COR Group 1991; Peikes 2009; Pogosova 2008; Tingstrom 2005), four at 18 months (Clark 1997; Clark 2009; Esposito 2008; Hanssen 2007), three at 24 months (Clark 2000; Cupples 1994; P.RE.COR Group 1991) and two at 60 months (Cupples 1994; Lisspers 1999).

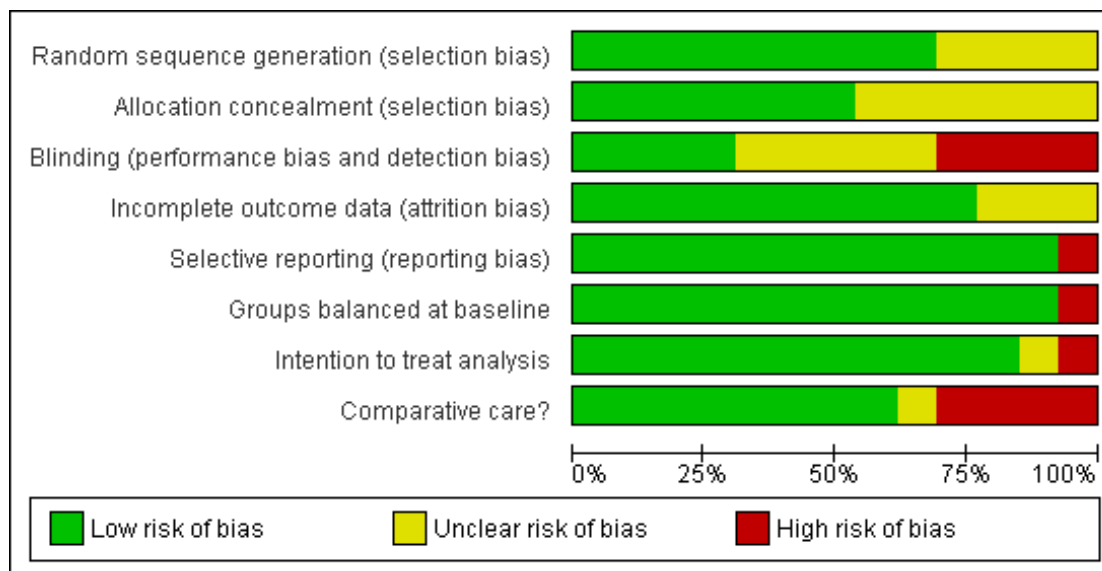
## Risk of bias in included studies

Several studies did not report sufficient methodological detail in order to allow full assessment of potential risk of bias. Risk of bias results are summarised in Figure 2 and Figure 3.

**Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Groups balanced at baseline	Intention to treat analysis	Comparative care?
Clark 1997	+	+	+	?	+	+	-	+
Clark 2000	+	?	+	+	+	-	+	+
Clark 2009	+	+	+	+	+	+	+	+
Cupples 1994	+	+	+	+	+	+	+	+
Esposito 2008	?	?	?	+	+	+	+	-
Hanssen 2007	+	+	?	+	+	+	+	-
Lie 2009	+	+	?	+	+	+	+	+
Lisspers 1999	?	?	-	+	+	+	+	-
P.RE.COR Group 1991	?	?	?	+	+	+	+	+
Peikes 2009	+	+	-	?	+	+	+	-
Pogosova 2008	?	?	?	?	+	+	?	+
Southard 2003	+	?	-	+	-	+	+	?
Tingstrom 2005	+	+	-	+	+	+	+	+

**Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**



### Allocation and concealment

Nine studies were judged to provide evidence of adequate random sequence generation (Clark 1997; Clark 2000; Clark 2009; Cupples 1994; Hanssen 2007; Lie 2009; Peikes 2009; Southard 2003; Tingstrom 2005), with seven of these studies reporting adequate concealment (Clark 1997; Clark 2009; Cupples 1994; Hanssen 2007; Lie 2009; Peikes 2009; Tingstrom 2005).

### Blinding

Details of random sequence generation, concealment of random allocation and blinding were the most frequent poorly reported parameters. Due to the nature of the educational intervention, it is not possible to blind those providing the education or the participants of the trials, but we investigated evidence as to whether those collecting, assessing or analysing outcome data were blinded to group allocation. Blinding of this nature was confirmed in four studies (Clark 1997; Clark 2000; Clark 2009; Cupples 1994).

### Incomplete outcome data

Eight studies clearly stated withdrawal or numbers lost to follow-up; this is detailed in Table 2. Overall 18.5% in the intervention group and 20% in the control group were lost to follow-up. Most authors assessed the subjects lost to follow-up for systematic differences when compared to those completing the study.

### Selective reporting

We compared the reported outcomes in the results sections to the outcomes described in the methods of the published paper. No attempt was made to identify original study protocols and compare these to reported outcomes. Only one study demonstrated selective reporting by not reporting the results of a HRQoL measure (Southard 2003).

### Baseline balance

Twelve studies had a good balance of their subjects' baseline characteristics between intervention and control groups. Two studies demonstrated a statistically significant imbalance between groups at baseline (Clark 2000; Peikes 2009). In Clark there were differences in baseline disease symptoms and weight (Clark 2000). Peikes highlights 11 differences in 255 baseline characteristics compared between groups, which they qualified with, "less than the expected number of statistical significant differences than would be observed by chance (Peikes 2009)."

### Intention-to-treat analysis

Eleven studies analysed results on an intention-to-treat basis (Clark 2000; Clark 2009; Cupples 1994; Esposito 2008; Hanssen 2007; Lie 2009; Lisspers 1999; P.RE.COR Group 1991; Peikes 2009; Southard 2003; Tingstrom 2005). In most cases, this involved analysing those patients remaining at follow-up according to initial randomisation. Clark did not present intention-to-treat data,

but presented patients who had attended at least one of the four intervention sessions (Clark 1997).

### Comparative care

Probably the largest source of bias in this review was the potential imbalance in co-interventions received by intervention and control subjects. We specifically sought to investigate the impact of education. However, in addition to education (the primary intervention) in a number of studies participants appeared to receive other interventions such as exercise or psychological therapy. In a number of studies it was often unclear how much of these co-interventions were received by control patients resulting in a performance bias (Esposito 2008; Hanssen 2007; Lisspers 1999; Peikes 2009; Southard 2003).

## Effects of interventions

### Mortality

Six studies reported all-cause mortality. One study reported deaths at 12 months (Clark 2000), two at 18 months (Clark 2009; Hanssen 2007), four at 24 months (Clark 2000; Cupples 1994; Lisspers 1999; P.RE.COR Group 1991) and two at 60 months (Cupples 1994, Lisspers 1999). No studies demonstrated a significant difference in mortality between education and control. There was weak evidence of a reduction in total mortality at the last reported follow-up: random effects RR: 0.79, 95% CI: 0.55 to 1.13,  $p=0.20$  (Analysis 1.1). Individual causes of mortality were poorly reported across studies.

### Cardiac Events

Three studies reported cardiac events, including MI or subsequent revascularisation - CABG or PTCA (Lisspers 1999; Southard 2003; P.RE.COR Group 1991). It was possible to pool the results for two of these studies (Lisspers 1999; P.RE.COR Group 1991). There was weak evidence of a reduction in morbidity with education: for MI, random effects RR: 0.63, 95% CI 0.26 to 1.48,  $p=0.29$ ; Analysis 2.1 and for CABG random effects RR: 0.58, 95% CI 0.19 to 1.71,  $p=0.32$ ; Analysis 3.1).

Southard reported a difference in "major cardiovascular-related events" less events occurring in the intervention group ( $p=0.053$ ) (Southard 2003). These were defined as events needing hospitalisation either as an in-patient or to the emergency room.

### Hospitalisations

Six studies reported hospitalisations (Clark 2000; Esposito 2008; Hanssen 2007; Lisspers 1999; Peikes 2009; Southard 2003).

It was possible to pool the results of the four studies that reported the number of patients hospitalised (Esposito 2008; Hanssen 2007; Lisspers 1999; Southard 2003). There was weak evidence of a reduction in hospitalisation with education (random effects RR: 0.83, 95% CI 0.65 to 1.07,  $p=0.16$ , Analysis 4.1).

Due to the method of reporting hospitalisations in Clark and Peikes it was not possible to include these in the pooled analysis (Clark 2000; Peikes 2009).

Using intention-to-treat analysis Clark found no statistically significant difference in the total number of hospital admissions be-

tween intervention and control (Clark 2000). Analysis of the heart-related admissions in those participants who attended at least one intervention session revealed statistically significant reductions in the intervention group: participants in the intervention group had 41% fewer heart-related admissions ( $p=0.05$ ) and 61% fewer heart-related inpatient days ( $p=0.02$ ) than in the control group (Clark 2000).

Peikes reported the rate of hospitalisations across 15 different U.S. study sites (Peikes 2009). Overall, there was no clear evidence of effect of intervention, with only two out of 15 sites showing a significant difference in hospital admissions. One reported an increase in admissions in the intervention group and the other reported an increase in the control group. No between-group statistical difference was found in average annualised admission rates 0.91 (intervention) versus 0.95 (control) ( $p=0.145$ ).

### Health-Related Quality of Life

Eleven studies reported HRQoL (Clark 1997; Clark 2000; Clark 2009; Cupples 1994; Esposito 2008; Hanssen 2007; Lie 2009; Lisspers 1999; Pogossova 2008; Southard 2003; Tingstrom 2005). These studies used several generic HRQoL instruments, i.e. SF-36 (Hanssen 2007; Lie 2009; Pogossova 2008; Tingstrom 2005), Nottingham Health Profile (Cupples 1994), Sickness Impact Profile (Clark 1997; Clark 2000) a five-point patient assessment scale of quality of life (Cupples 1994) and two disease-specific HRQoL instruments (Seattle Angina Questionnaire (Lie 2009) and AP-QLQ (Angina Pectoris-Quality of Life Questionnaire) (Lisspers 1999)). The wide variation in HRQoL outcomes and methods of reporting meant that we were unable to meta-analyse results across studies. Instead, we undertook a detailed tabulation of the overall and domain HRQoL scores from each of the trials with a particular focus on intervention-control differences at follow-up. In order to provide some level of overall synthesis, we assessed for each study, whether total and domain HRQoL between-group differences were statistically different and, if so, the direction of effect (Table 3; Table 4; Table 5; Table 6; Table 7; Table 8; Table 9; Table 10; Table 11; Table 12; Table 13; Table 14).

Whilst overall we found no consistent difference in HRQoL total or domain score at follow-up between intervention and control, a number of studies demonstrated statistically significant differences in HRQoL domains in favour of intervention (Clark 1997; Clark 2000; Cupples 1994; Lie 2009; Pogossova 2008). Pogossova 2008 demonstrated an improvement in all SF-36 domain scores and Lie 2009 an improvement in the overall mental score in the intervention groups. No studies reported HRQoL scores that favoured the control group.

Although Southard reported Dartmouth COOP Quality of Life scores at trial entry, there were no reports of this outcome at follow-up (Southard 2003). Esposito reported on a HRQoL questionnaire undertaken in a randomly selected subgroup of patients from the overall trial (Esposito 2008). No significant differences were found between the intervention and control groups in a number of measures of mental and physical status, including: "Primary



condition interfered a lot or somewhat with enjoyment of life in the last 4 weeks" (between-group difference -3.6% [in favour of intervention]  $p=0.379$ ); "Beneficiary felt primary condition placed a burden on family in the past 4 weeks" (between-group difference 0.5%  $p=0.897$ ); "Beneficiary felt depressed about living with primary condition in the past 4 weeks" (between-group difference 1.2% [in favour of control]  $p=0.766$ ).

#### Healthcare costs and utilisation

Five studies reported healthcare utilisation and costs (Clark 2000; Cupples 1994; Esposito 2008; Southard 2003; Peikes 2009). No studies reported cost-effectiveness. Given that cost results are presented in different currencies and were incurred in different years it is difficult to directly compare studies. Furthermore, although studies assessed healthcare costs, there was variation in the particular aspects of healthcare costs that were quantified. Components of costs considered included inpatient admissions, primary care visits, emergency attendances, use of drugs, investigations and subsequent procedures performed. To compare studies and gain an overall impression of the differences in healthcare between intervention and control, we undertook a detailed tabulation of the overall and component healthcare costs for each of the included studies Table 15.

Reflecting the different education modalities and intensities of the interventions, the reported cost of provision per patient varied from £49 (Cupples 1994) to US\$453 (Southard 2003). The largest trials, investigating the efficiency of the Medicare system in the USA (Esposito 2008; Peikes 2009), did not investigate the cost of providing the intervention but instead reported the charge associated with providing this service negotiated by the company supplying it (*care coordination fee*). A mean of US\$196 per month (Peikes 2009) or US\$162 per month (Esposito 2008).

Two studies reported an overall average net saving, after subtracting costs of intervention provision. This was US\$965 per patient at six-months follow-up (Southard 2003) and US\$1420 per patient at 24-months follow up (Clark 2000). One study reported an increase in average net costs of US\$52 per patients; six out of the 15 programmes investigated had higher costs for the intervention group (Peikes 2009). The two remaining trials found no difference in between-group net costs (Cupples 1994; Esposito 2008).

#### Withdrawal/drop out

Studies failed to report the number of individuals who dropped out because they were unable to complete the intervention. Therefore, we have reported the drop outs at follow-up in Table 2. There was no evidence of a difference between the groups: random effect RR: 1.03, 95% CI 0.83 to 1.27,  $p=0.80$ ; Analysis 5.1.

Clark reported a combined drop out of 181 patients from both groups. A differential breakdown was not given, but there was "no appreciable differences in dropout rates between the intervention and control group" demonstrated (Clark 1997).

Numbers lost to follow-up were unclear in a number of studies (Esposito 2008; Lisspers 1999; Peikes 2009; Pogossova 2008).

#### Meta-regression and stratified meta-analysis

There was an insufficient number of studies to undertake either meta-regression or stratified meta-analysis.

#### Small study bias

There was an insufficient number of studies and outcome data to assess small study bias by means of funnel plots.

## DISCUSSION

### Summary of main results

We included 13 RCTs involving 68,556 participants with CHD where education was the primary interventional intent. The 'dose' of the education intervention varied substantially across studies from a total of two visits from a healthcare professional (Lie 2009, P.R.E.COR Group 1991) to a four-week residential stay reinforced with 11 months of nurse-led follow up sessions (Lisspers 1999). Control subjects typically received usual medical care without a formalised education programme.

We found no strong evidence that education reduced all-cause mortality (RR: 0.79, 95% CI: 0.55 to 1.13), cardiac morbidity (subsequent MI [RR: 0.63, 95% CI 0.26 to 1.48], revascularisation [RR: 0.58, 95% CI 0.19 to 1.71]) or hospitalisation (0.83, 95% CI 0.65 to 1.07) compared to control. However, as most studies had a relatively short follow-up, only a few studies reported events. As the event rate was low, our meta-analysis lacks sufficient statistical power to make definitive conclusions on the impact of educational interventions in people with CHD. However, effect size of the summative effects of education on mortality (25% risk reduction) and morbidity (17-42% risk reduction) are clinically important, particularly in the context of the large number of individuals with CHD. These potential clinical benefits alone underline the importance of further trials to increase the power of future meta-analyses.

Although HRQoL was reported by almost all included studies, we were unable to pool findings across studies due to the heterogeneity of measures. Whilst there was some evidence of higher HRQoL in some domain scores, overall there was not consistent evidence of superior HRQoL following education compared to control. Many studies used generic HRQoL measures that are known to lack sensitivity with cardiac treatment, particularly in comparison with disease-specific measures (Oldridge 2003; Taylor 1998).

The intention of including analysis of withdrawal from the intervention was to use it as a surrogate for the 'adverse effects' of the intervention, e.g. the educational intervention was so demanding that it could not be completed by patients. However, withdrawal was not consistently reported across studies.

The different currencies and the year that the study was conducted makes it difficult to directly compare healthcare costs across studies. The cost of the educational intervention varied widely (between GB£49 and US\$453 per patient), reflecting the differing

intensity and requirements for provision of the interventions investigated. There was some evidence that when compared to usual care, patient education may be cost-saving as a result of a reduction in downstream healthcare utilisation.

## Overall completeness and applicability of evidence

In designing this review we decided to narrow the scope in three specific ways:

- (1) to those studies published in 1990 or later,
- (2) to include only studies where the educational component was the primary intention of the intervention and
- (3) to include studies that reported event data (e.g. mortality) as opposed to intermediate outcomes (e.g. blood pressure, exercise tolerance).

We believe these limitations in scope were crucial in allowing us to address the specific research question: what is the 'added value' of patient education in the context of contemporary cardiovascular management? The interpretation of previous systematic reviews of patient education have been potentially confounded by including multi-component rehabilitation interventions, of which education was only an element, and reporting on studies using surrogate outcomes (e.g. health knowledge, blood pressure).

Many of the trials identified and considered in this review process investigated alternative outcomes, for instance, changes in smoking, diet, blood pressure or effect of education on patient's knowledge of CHD disease processes or risk factors.

In spite of the focus of this review, there was considerable heterogeneity of participants and interventions. It could be argued that a benefit of this heterogeneity is that the results are more likely to be applicable to the wider population of CHD patients and clinical practice. It is unusual in practice to find patients with an isolated diagnosis of CHD. Several studies included CHD in combination with diabetes, hypertension or a degree of heart failure (Esposito 2008; Peikes 2009; Southard 2003). Different aspects of the educational intervention may contribute to the composite independent effect of education to varying extents e.g. the impact of teacher efficacy, variability in teacher instructional strategies or teacher experience.

Previous reviews of patient education, and more broadly CR, have identified the paucity of research into outcomes in women and the elderly. However, this review includes several studies with a substantive proportion of women (Clark 2000) and older people (Clark 2009) specifically addressing this disparity. Nevertheless, ethnic minorities remain under-represented (80% of subjects were Caucasian).

## Quality of the evidence

The overall methodological quality of the studies included in this review were judged to be moderate to good. Details were of-

ten poorly reported and confirmation of methodology had to be sought from authors. Two specific areas of potential risk of bias in this review were assessment bias (lack of outcome blinding) and performance bias (imbalance of co-interventions across intervention and control arms). Few studies provided sufficient details in order to judge if outcomes were assessed by researchers blinded or independent to the trial.

We specifically selected studies on the basis of education being the primary intervention. However, a number of studies appeared to include additional elements (e.g. behaviour modification) in the educational intervention arm, this led to a risk of performance bias. Whilst the decision to include studies was made independently by two review authors, the decision of study inclusion was ultimately one of judgement based on the description of the intervention provided by the authors. During correspondence the lead author of one included study stated: *"I would not define our program as "patient education" (at least according to the way I define this term) - more as a "behaviour change program".....we ....very much tried to develop active program components which actually and concretely supported the behaviour change process in the short term and for the long-term maintenance"* (Lisspers 1999). We would argue that a key objective of patient education is to change behaviour, i.e. through education, patients learn to understand the reasoning for improved diet, exercise regime and compliance with medication and are, therefore, more likely to modify their behaviour. This objective is consistent with adult learning theory; learning is the outcome of education and can be defined as, *"a relatively permanent change in behaviour as a result of experience, training or practice"* (Reece 2007).

## Potential biases in the review process

Although unpublished data was sought during this review, no relevant studies were identified. Lack of consideration of unidentified, unpublished trials with negative findings are a potential bias faced by all systematic reviews. Given the low number of included studies and inconsistent reporting of outcomes, we were unable to judge the degree of publication bias.

CHD patients agreeing to participate in RCTs may not be representative of the general CHD population, they may be more motivated to engage with education and, consequently, make behavioural and lifestyle changes.

## Agreements and disagreements with other studies or reviews

In contrast to previous systematic reviews by Mullen 1992 and Dusseldorp 1999, we were unable to demonstrate a statistically significant reduction in either mortality or morbidity in patients with CHD following an educational intervention. We believe the differences in findings may reflect the following factors in previous studies:

- (1) their inclusion of studies with multi-dimensional interventions



(e.g. education plus psychological interventions) that may have inflated the effect on outcomes compared to education alone, (2) their inclusion of non-randomised studies, which is likely to increase selection bias and (3) their inclusion of studies pre-1990 (exclusively in Mullen 1992) and, therefore, a background of CHD usual care that is likely not to be representative of present day practice.

## AUTHORS' CONCLUSIONS

### Implications for practice

Our findings are consistent with the belief that educational interventions are beneficial for patients with CHD. Further research is needed to determine the most effective and cost-effective format, duration, timing (relative to index event) and methods of education delivery.

In accordance with current evidence and international guidelines for secondary prevention and CR (Balady 2007; DofH 2011; NICE 2007; SIGN 2002; Heran 2010; Whalley 2011), educational interventions for CHD patients should be considered as part of a comprehensive programme that includes exercise and psychological support.

### Implications for research

The heterogeneity in the educational interventions seen in the

studies included in this review reflects uncertainty about the optimal approach of offering education to CHD patients. Further research is required to assess the relative costs and benefits of differing methods and approaches to delivering educational content in CHD (e.g. group versus individual, face to face or using a self help manual). Research methods should not only include well-designed RCTs, but also qualitative methods so as to better understand the information expectations and needs of patients. Such studies need to be done in the context of a multi-interventional approach to secondary prevention and rehabilitation as well as report sufficient information to allow replication of the interventional approach. Furthermore, future studies should include under-represented groups (i.e. ethnic minorities or those of lower social-economic class).

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- \* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

Clark 1997

Methods	RCT
Participants	<p><b>N Randomised:</b> 636 (Intervention (Rx) and control group N not reported)  <b>Trial Recruitment period:</b> N/A  <b>When Randomised:</b> Not Reported (N/R)  <b>Recruitment from:</b> Review of outpatient cardiology clinics in four hospitals in Southern Eastern Michigan  <b>CV Diagnosis (% of Patients (pts)):</b>  <b>Post (Myocardial infarction) MI:</b> 45%  <b>Angina:</b> 57%  <b>Post CABG:</b> 32%  <b>Post PTCA:</b> 25%            These groups are not mutually exclusive.  <b>Mean Age:</b> 69.6 yrs (60-93)  <b>Percentage male:</b> 59%  <b>Percentage white:</b> 88%  <b>Inclusion criteria:</b>            &gt;60 yrs; diagnosed cardiac disease (arrhythmia, angina, MI, valvular disease); treated daily by at least one heart medication; seen by a physician at least once every six months  <b>Exclusion criteria:</b>  <i>"If physicians felt that they wouldn't be able to benefit fully for the program due to medical reasons (e.g. terminal illness, memory loss, significant hearing loss)"</i></p>
Interventions	<p><b>Description / Content:</b> Take PRIDE  <b>Teaching Modalities:</b> Videotape, guidebook, group teaching.  <b>Who taught by:</b> Health educator  <b>Dose:</b>  <b>Duration</b> 4 weeks  <b>No of sessions</b> 4  <b>Length of session</b> 2 hours  <b>Involvement of Family:</b> N/R  <b>Time of start after event:</b> six months to 20 yrs after initial diagnosis  <b>Follow up further reinforcement</b> N/R  <b>Theoretical basis for intervention</b> Yes  <i>Problem Identification, Researching one's routine, Identifying a management goal, Developing a plan to reach it, Expressing one's reactions and Establishing rewards for making progress.</i></p>
Outcomes	<p>HRQoL- Sickness Impact Profile            Withdrawal from Rx &amp; control group</p>
Follow up	6, 12 and 18 months

Clark 1997 (Continued)

Control	<b>Usual care consisted of:</b> <i>"Seeing their physicians at the intervals specified by the particular physician and receiving any information or communications that would be provided as part of routine care in that setting."</i>	
Country	USA	
Notes	Patients with arrhythmias and CCF also included. The following paper produced from the results of the same trial were used to inform the data collected: Clark 1992	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<i>"Use of random number table"</i>
Allocation concealment (selection bias)	Low risk	<i>"As the numbers were generated, each was placed in a sealed envelope. They were stored in a locked drawer in my office. As participants completed their baseline interview I was given their names and opened the next envelope in the numerical sequence."</i> Correspondence with author J. Dodge.
Blinding (performance bias and detection bias) All outcomes	Low risk	<i>"Data collectors and data analysts were blinded. The health educators who delivered the intervention obviously knew who had been randomized to the intervention, but had no involvement with the collection of quantitative evaluation data at baseline or follow-up."</i> Correspondence with author J. Dodge.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	455 out of 636 had complete data at 18/12. <i>"No appreciable difference in dropout rates between the intervention and control groups were found."</i> Similarity of demographic details of those loss to follow up not discussed
Selective reporting (reporting bias)	Low risk	All outcomes listed in the methods are reported in the results
Groups balanced at baseline	Low risk	<i>"There were no baseline differences between the experimental and control groups"</i> .
Intention to treat analysis	High risk	<i>"Data analyses reported....participants who attended at least one of the four sessions."</i>
Comparative care?	Low risk	Other than the stated intervention both groups appeared to have been treated similarly

Methods	RCT
Participants	<p><b>N Randomised:</b> 571 (n Rx 309; n control 262) - 55:45 allocation ratio</p> <p><b>Trial Recruitment period:</b> Not Reported</p> <p><b>When Randomised</b> on agreeing to participate in study. Median of 13 yrs since initial cardiac diagnosis (Range 6 months - 20 years)</p> <p><b>Recruitment from:</b> Physician practices affiliated with six medical centers in Southeastern Michigan</p> <p><b>CV Diagnosis (% of pts):</b></p> <p><b>Post MI</b> 39%</p> <p><b>Angina</b> 45%</p> <p><b>Post CABG</b> 26%</p> <p><b>Post PTCA</b> 29%</p> <p>These groups are not mutually exclusive.</p> <p><b>Mean Age:</b> 71.9 yrs (Range 60-93)</p> <p><b>Percentage male:</b> 0%</p> <p><b>Percentage white:</b> 87%</p> <p><b>Inclusion criteria:</b></p> <p>&gt;60; Female; Cardiac disease treated daily with at least one medication; Cardiac disease can be arrhythmia, angina, MI or valvular disease</p> <p><b>Exclusion criteria:</b></p> <p><i>"If physicians felt they could not benefit fully from the program due to medical reason (e.g. terminal illness or significant hearing loss)"</i></p>
Interventions	<p><b>Description / Content:</b> Specific information related to heart disease in women signs and symptoms of heart disease, effective communication with clinicians</p> <p><b>Teaching Modalities:</b> Classroom group sessions (Groups 6-8 women). Workbook for use at home on the intervening days. Handouts summarising classroom sessions, daily self-monitoring logs. Weekly telephone call during program period</p> <p><b>Who taught by:</b> Trained health educators and peer leaders (selected graduates from the program that received extra training)</p> <p><b>Dose:</b></p> <p><b>Duration</b> 4 weeks</p> <p><b>No of sessions</b> weekly (4)</p> <p><b>Length of session</b> 2-2.5hrs</p> <p><b>Involvement of Family:</b> N/R</p> <p><b>Time of start after event</b> N/A</p> <p><b>Follow up further reinforcement</b> letter 3 months after program and a telephone call 6 months after</p> <p><b>Theoretical basis for intervention</b></p> <p>Yes - PRIDE <i>Problem Identification, Researching one's routine, Identifying a management goal, Developing a plan to reach it, Expressing one's reactions and Establishing rewards for making progress.</i></p>
Outcomes	<p>Total Mortality</p> <p>HRQoL - Sickness Impact Profile</p> <p>Adverse Events (Withdrawal from Rx group)</p> <p>Hospitalisations (number of admissions, number of inpatient days, hospital inpatient charges) (Wheeler 2003)</p> <p>Cost-effectiveness (Wheeler 2003)</p>

**Clark 2000** (Continued)

Follow up	12 months and 24 months (economic data (Wheeler 2003)).	
Control	Usual care was determined by individual responsible physicians who were not aware of group allocation	
Country	USA	
Notes	The following paper produced from the results of the same trial were used to inform the data collected: Wheeler 2003	
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	"...women were assigned, by use of random number tables (Clark 2000)"
Allocation concealment (selection bias)	Unclear risk	Not Reported
Blinding (performance bias and detection bias) All outcomes	Low risk	"Interviewers were blind to women's participation in the program. (Clark 2000)"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Table detailing withdrawals
Selective reporting (reporting bias)	Low risk	Outcomes in methods reported in results
Groups balanced at baseline	High risk	Demographically similar but statistically significant differences in baseline disease symptoms and weight
Intention to treat analysis	Low risk	Data was analysed in two different phases, one "an analysis of all women randomized" the other "all program women who attended one or more program sessions (Clark 2000)"
Comparative care?	Low risk	"In an effort to assure similar care to both the program and the control groups, no feedback about individual participants was provided to medical or nursing staff. The clinical staff had no knowledge of which patients had agreed to participate in research (Clark 2000)."

Clark 2009

Methods	RCT - 3 groups
Participants	<p><b>N Randomised:</b> 575 (n Rx Self Directed: 201; n Rx Group Format: 190; n control: 184)</p> <p><b>Trial Recruitment period:</b> N/A - list compiled from physicians patient rota.</p> <p><b>When Randomised:</b> After collecting baseline data.</p> <p><b>Recruitment from:</b> Five hospital sites in Southeastern Michigan.</p> <p><b>CV Diagnosis (% of pts):</b></p> <p><b>Post MI</b> 42%</p> <p><b>Angina</b> 38%</p> <p><b>Post CABG</b> - N/R</p> <p><b>Post PTCA</b> - N/R</p> <p>These groups are not mutually exclusive.</p> <p><b>Mean Age:</b> 72.8</p> <p><b>Percentage male:</b> 0%</p> <p><b>Percentage white:</b> 82.8%</p> <p><b>Inclusion criteria:</b></p> <p>&gt;60 years; diagnosed cardiac condition (arrhythmia, angina, MI, congestive heart failure, valvular disease); treated by daily heart medication; seen by a physician in the last year; living within 1 hr drive of the study site</p> <p><b>Exclusion criteria:</b></p> <p>If not able to fully participate because of medical reasons.</p>
Interventions	<p><b>Description / Content:</b></p> <p>Content of the materials used in both groups was identical. Both 6 units</p> <p><b>Teaching Modalities - Self Directed:</b></p> <p>Single orientation session then:</p> <p><b>Dose:</b></p> <p><b>Duration</b> program at home in six weeks</p> <p>The self directed group also have an instructional video tape that gives examples of group discussions</p> <p><b>Teaching Modalities - Group:</b></p> <p>6-8 women.</p> <p><b>Dose:</b></p> <p><b>Duration</b> 6 sessions</p> <p><b>No of sessions</b> weekly</p> <p><b>Length of session</b> 2-2.5 hrs</p> <p>Both groups received weekly telephone calls from a health educator during the study period</p> <p><b>Who taught by:</b> Trained health educators and peer leaders</p> <p><b>Involvement of Family:</b> N/R</p> <p><b>Time of start after event</b> N/A</p> <p><b>Follow up further reinforcement.</b></p> <p>3 monthly - both groups receive news letter</p> <p>6 months - Group attend a reunion. Self directed participants receive an in depth telephone call</p> <p><b>Theoretical basis for intervention:</b></p> <p>Yes, described in separate paper.</p>



Outcomes	Total Mortality HRQoL - Sickness Impact Profile (SIP) Withdrawal from treatment	
Follow up	12 and 18 months	
Control	<i>"see their physician on the routine schedule and receive any information that would normally be provided as part of regular care in the practice."</i>	
Country	USA	
Notes		
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<i>"...complied using....book of random numbers."</i>
Allocation concealment (selection bias)	Low risk	<i>"Sealed opaque and sequentially numbered envelopes."</i>
Blinding (performance bias and detection bias) All outcomes	Low risk	<i>"Those assessing outcomes were blinded to the group allocation unless the participant happened to reference program participation during the follow-up telephone interviews or at the physical assessment visit." "Correspondence with author, J. Dodge."</i>
Incomplete outcome data (attrition bias) All outcomes	Low risk	Clear description of withdrawals from trial given.
Selective reporting (reporting bias)	Low risk	Sickness Impact Profile numerical scores were not individually reported as no significant difference was found. These were subsequently made available through correspondence with the author, J Dodge
Groups balanced at baseline	Low risk	Described in table one. <i>"no significant differences among study conditions....."</i>
Intention to treat analysis	Low risk	<i>"Analyses were carried out using the women as they were randomized to each of the three study conditions"</i>
Comparative care?	Low risk	<i>"In an effort to ensure similar care to all participants, no feedback about individual study participants was provided to health care personnel at the study sites."</i>

## Cupples 1994

Methods	RCT
Participants	<p><b>N Randomised:</b> 688 (n Rx 342 n control 346)</p> <p><b>Trial recruitment period:</b> Data collected between 1990 and 1993.</p> <p><b>When randomised:</b> Not reported</p> <p><b>Recruitment from:</b> 18 General Practices in Greater Belfast</p> <p><b>CV Diagnosis (% of pts):</b></p> <p><b>Angina 100%</b></p> <p><b>Mean age:</b> Rx 62.7 Control 63.6</p> <p><b>Percentage male:</b> 59%</p> <p><b>Percentage white:</b> Not reported</p> <p><b>Inclusion criteria:</b> ≥6 month history of angina diagnosed by classical history.</p> <p><b>Exclusion criteria:</b> No other severe illness</p>
Interventions	<p><b>"Personal health education intervention"</b></p> <p><b>Description / Content:</b></p> <p><i>"Patients in the intervention group were given practical relevant advice regarding cardiovascular risk factors. They were reviewed at four monthly intervals and given appropriate health education (Cupples 1994)."</i></p> <p><i>"Visited by a health visitor, whose brief was to discuss ways of living more easily with their disease and ways in which risks of further events might be reduced (O'Neill 1996)."</i></p> <p><i>"The education involved giving information which was tailored to the individuals' coronary risk factors and the use of medication (Cupples 1996)."</i></p> <p><b>Teaching modalities:</b> Individual one to one visits</p> <p><b>Who taught by:</b> health visitor</p> <p><b>Dose:</b></p> <p><b>Duration</b> 2 years</p> <p><b>No of sessions</b> 6 visits (every 4 months for 2 years)</p> <p><b>Length of session</b> Not Reported</p> <p><b>Involvement of Family:</b> No</p> <p><b>Time of start after event</b> N/A</p> <p><b>Follow up further reinforcement:</b> Not following 2 year intervention</p> <p><b>Theoretical basis for intervention</b> none stated</p>
Outcomes	<p>Total Mortality</p> <p>Cardiovascular related mortality</p> <p>Hospitalisations recorded as part of cost analysis (not independently reported) (O'Neill 1996)</p> <p>HRQoL (Nottingham Health Profile Questionnaire) (Cupples 1996)</p> <p>Adverse Events (Withdrawal from Rx group)</p> <p>Cost Analysis (O'Neill 1996)</p>
Follow up	Patients reviewed at 2 years (Cupples 1994; O'Neill 1996) and 5 years (Cupples 1999)
Control	<p><b>Usual care consisted of:</b></p> <p>Had the same screening interview as the intervention group but once randomised to control had no further intervention</p>
Country	Northern Ireland, UK.

**Cupples 1994** (Continued)

Notes	The following papers produced from the results of the same trial were used to inform the data collected: Cupples 1996; Cupples 1999; O’Neill 1996	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	“generated by a computer program using permuted blocks (Cupples 1996).”
Allocation concealment (selection bias)	Low risk	“The health visitor opened an opaque, sealed, and numbered envelope containing the allocation (Cupples 1994).”
Blinding (performance bias and detection bias) All outcomes	Low risk	“After 2 years both groups were reviewed by a research worker who had not previously been involved with the subjects (Cupples 1994).” At five year follow-up: “nurse (performing interview) was blind to trial group allocation (Cupples 1999).”
Incomplete outcome data (attrition bias) All outcomes	Low risk	Detailed report of drop outs and losses to follow up reported Cupples 1994 Yes Cupples 1996 No O’Neill 1996 No Cupples 1999 No
Selective reporting (reporting bias)	Low risk	All relevant outcomes listed in methods were reported in methods
Groups balanced at baseline	Low risk	“No significant differences were found between the two groups at baseline (Cupples 1994).”
Intention to treat analysis	Low risk	“We also analysed the data in an intention to treat basis, with baseline or adjusted values being substituted for missing data, but this did not alter the conclusions (Cupples 1999).”
Comparative care?	Low risk	Both groups received same usual care and only difference between groups was the educational intervention

**Esposito 2008**

Methods	RCT
Participants	<b>N Randomised:</b> 46,606 (n Rx - 33,267 n Control - 13,339) <b>Trail Recruitment period:</b> All Florida Medicare beneficiaries enrolled in Medicaid as of March 2006 who met eligibility criteria

	<p><b>When Randomised</b> “<i>When eligible beneficiaries are identified.</i>”</p> <p><b>Recruitment from:</b> Medicare database</p> <p><b>CV Diagnosis (% of pts):</b>          69% Coronary Artery Disease (Not further defined)          10% in combination with heart failure          19% in combination with diabetes          12% with all three diagnoses</p> <p><b>Mean Age:</b> 68.4 yrs</p> <p><b>Percentage male:</b> 34%</p> <p><b>Percentage white:</b> 55%</p> <p><b>Inclusion criteria:</b>          Enrolled in Medicare and receiving Medicaid benefits; have congestive cardiac failure, diabetes or coronary artery disease</p> <p><b>Exclusion criteria:</b>          Psychiatric inpatient therapy of more than 14 consecutive days in the prior 12 months; long term nursing home residence</p>
Interventions	<p><b>Description / Content:</b> The education component: “<i>Nurse case managers provided education to patients on the recognition of signs and symptoms of their disease; how to monitor vital signs; the cause of diseases; how to better adhere to diet, exercise, and medication regimes; and strategies to cope with chronic illness. When providing education to patients, nurses use pre-designed scripts. Geared towards educating patients on how to attain clinical goals.</i>”</p> <p><b>Teaching Modalities:</b> “<i>The intervention is primarily telephonic, but also had an in-person component.</i>”</p> <p><b>Who taught by:</b> Individually assigned “<i>nurse care manager</i>”</p> <p><b>Dose:</b></p> <p><b>Duration</b> - 18 months</p> <p><b>No of sessions</b> - patients has 1.1 contacts per active month, on average.</p> <p><b>Length of session-</b> N/R</p> <p><b>Involvement of Family:</b> - N/R</p> <p><b>Time of start after event</b> - N/A</p> <p><b>Follow up further reinforcement</b> - Intervention continued until end of follow up period</p> <p><b>Theoretical basis for intervention</b> - N/R</p>
Outcomes	<p>Hospitalisations - Emergency and inpatient use</p> <p>HRQoL [Survey of selected 613 enrollees only and claims based quality of care measures]</p> <p>Cost Analysis</p>
Follow up	6 months, 1 yr and 18 months
Control	<p><b>Usual care consisted of:</b>          Not Reported</p>
Country	USA
Notes	<p>Analysed 1<sup>st</sup> and second 6 month periods, first year and 18 months.</p> <p>Population based study that only a relatively small proportion of those assigned to the intervention group actually actively continued to participate in. Therefore treatment</p>

	effect may be difficult to statistically demonstrate	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Divided patients in to mediated - those that fully engaged with the intervention and instructional - those that were less that fully engaged but did not opt out. Breakdown of mediated patients demonstrated in a table
Selective reporting (reporting bias)	Low risk	Primary outcomes stated in methods were reported in the results
Groups balanced at baseline	Low risk	Detailed table (Table 4) of pre-enrollment characteristics showed no statistically significant differences seen. Authors reported that there was a difference in that the treatment group utilised health services 5% more in 2 year run up period to the trial (not statistically significant)
Intention to treat analysis	Low risk	<i>"intention of treat study design."</i>
Comparative care?	High risk	Education only part of the intervention: <i>"intervention components include patient assessment, care planning, routine nurse monitoring, patient self-monitoring, education, care co-ordination, and service arrangement."</i> Physicians were alerted to <i>"important changes in patients' health."</i>

**Hanssen 2007**

Methods	RCT
Participants	<p><b>N Randomised: 288</b> (n Rx: 156 n control: 132)  <b>Trail Recruitment period:</b> Sept 2001 to Sept 2005  <b>When Randomised:</b> After hospitalisation of at least 2 days  <b>Recruitment from:</b> 413 patients in Haukeland University Hospital, Bergen, Norway  <b>CV Diagnosis (% of pts):</b>  <b>Post Myocardial Infarction</b> 100%  <b>Mean age:</b> 60  <b>Percentage male:</b> 81%</p>

	<p><b>Percentage white:</b> Not reported</p> <p><b>Inclusion criteria:</b> All patients with confirmed Acute Myocardial Infarction (AMI) and admitted to the hospital</p> <p><b>Exclusion criteria:</b> Severe co-existing chronic disabling disease; Nursing home resident; unable to receive telephone calls; unable to fill in questionnaires; if expected to have CABG in that admission; In the first year of the study &gt;80 yr olds were excluded, after the first year they were included</p>
Interventions	<p><b>Description / Content:</b> “structured intervention encompassing telephone follow up and an open telephone line” “to provide patients with information, education and support on the basis of individual needs. To provide patients with information about what are common questions after AMI and encourage elaboration on the issues if desired. One issue was addressed in each call.” (Detailed list of topics covered itemised in paper)</p> <p><b>Teaching Modalities:</b> Telephone follow up</p> <p><b>Who taught by:</b> “nurses with interests and experience in counselling and providing information to patients with ischaemic heart disease.”</p> <p><b>Dose:</b> <b>Duration</b> 6 months (could stop earlier if requested) but encouraged to have at least the first 5 months intervention <b>No of sessions weekly</b> first 4 weeks, then weeks 6,8,12 and 24. 8 sessions in total <b>Length of session</b> as long as required (mean telephone call 6.88 mins (SD 3.89))</p> <p><b>Involvement of Family:</b> [telephone] “Lines were open to patients and relatives/relations”</p> <p><b>Time of start after event:</b> On discharge following the event</p> <p><b>Follow up further reinforcement:</b> none</p> <p><b>Theoretical basis for intervention:</b> “intervention was developed on the basis of the Lazarus and Folkmans theory on stress, appraisal and copy, principles about patient education, findings from previous research and according to guideline recommendations.”</p>
Outcomes	<p>HRQoL (SF36)</p> <p>Rehospitalisation</p> <p>Mortality</p>
Follow up	<p>6 and 18 months</p>
Control	<p><b>Usual care consisted of:</b> “Managed in accordance with current clinical practice. One visit to a physician at the outpatient clinic 6-8 weeks after discharge, and subsequent visits to the patient’s general practitioner.”</p>
Country	<p>Norway</p>

Hanssen 2007 (Continued)

Notes	The following paper produced from the results of the same trial were used to inform the data collected: Hanssen 2009	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<i>"A simple randomization procedure using a computer-generated list of random numbers"</i>
Allocation concealment (selection bias)	Low risk	<i>".group allocation in sealed opaque envelopes prepared by the researcher."</i>
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not clear from as to whether researchers were blinded to group allocations
Incomplete outcome data (attrition bias) All outcomes	Low risk	CONSORT diagram of trial flow reported with details of drop out and loss to follow up
Selective reporting (reporting bias)	Low risk	Outcomes in methods reported in results.
Groups balanced at baseline	Low risk	<i>"No statistically differences were found"</i> in baseline characteristics
Intention to treat analysis	Low risk	Although intention to treat analysis not explicitly stated, the groups were analysed according to original random allocation
Comparative care?	High risk	Intervention included both education and counselling - psychological based intervention <i>"Providing emotional support and alternative coping strategies".</i> Which was not received by control group

Lie 2009

Methods	RCT
Participants	<p><b>N Randomised:</b> 203 (n Rx: 101 &amp; n control 102)  <b>Trial Recruitment period:</b> August 2003 to 2004  <b>When Randomised:</b> Not stated  <b>Recruitment from:</b> All N=502 elective CABG admitted to a single hospital  <b>CV Diagnosis (% of pts):</b>          Post CABG 100%  <b>Mean Age:</b> 62  <b>Percentage male:</b> 89.5%  <b>Percentage white:</b> Not stated  <b>Inclusion criteria:</b> All elective CABG patients 18-80 yrs  <b>Exclusion criteria:</b></p>

	More than 3 hrs driving distance	
Interventions	<p><i>"A psychoeducative intervention"</i></p> <p><b>Description / Content:</b> Structured information and psychological support for the topics of angina symptoms, medications, sexuality, anxiety, and depression. Material developed for the study</p> <p><b>Teaching Modalities:</b> Home based, 2 x 1-hr home visits at 2 &amp; 4 post CABG.</p> <p><b>Who taught by:</b> <i>"Masters prepared critical care nurse with 12 years experience"</i></p> <p><b>Dose:</b></p> <p><b>Duration</b> 4 weeks</p> <p><b>No of sessions</b> 2 (at 2 and 4 weeks)</p> <p><b>Length of session</b> 1 hr</p> <p><b>Involvement of Family:</b> Not stated</p> <p><b>Time of start after event:</b> Post CABG 2 and 4 weeks</p> <p><b>Follow up further reinforcement:</b> No</p> <p><b>Theoretical basis for intervention:</b></p> <p>None stated</p>	
Outcomes	HRQoL - SF-36 and Seattle Angina Questionnaire (SAQ)	
Follow up	6-months post CABG	
Control	<p><b>Usual care consisted of:</b></p> <p><i>"Patients in the intervention group and the control group received standard discharge care that involved a non-standardised short talk with the nurse/doctor."</i></p>	
Country	Norway	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<i>"Statistician made the randomisation codes by using a computer program."</i>
Allocation concealment (selection bias)	Low risk	<i>"a secretary created sealed opaque envelopes containing individual codes with sequential numbers."</i>
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	Clear table demonstrating patients excluded and the attrition. All accounted for at the end of the trial Minimal incomplete data from responses in each group in both questionnaires e.g. <i>"number of respondents for each subscale and each measurement point ranged between 74 and 92 for each group"</i>



Lie 2009 (Continued)

Selective reporting (reporting bias)	Low risk	All stated outcomes SAQ and SF-36 at 6 months reported
Groups balanced at baseline	Low risk	Baseline characteristics “ <i>did not differ significantly between groups</i> ”.
Intention to treat analysis	Low risk	ITT not explicitly stated. Reported patient flow chart suggests that groups analysed according to original random allocation
Comparative care?	Low risk	“ <i>Patients in the intervention group and the control group received standard discharge care that involved a non-standardised short talk with the nurse/doctor.</i> ”

Lisspers 1999

Methods	RCT
Participants	<p><b>N Randomised:</b> 87 (n Rx 46; n control 41)  <b>Recruitment period:</b> Recruited Feb 1993 and Dec 1995.  <b>When Randomised:</b> not reported  <b>Recruitment from:</b> 151 consecutive referrals to cardiology outpatients of 1 hospital  <b>CV Diagnosis (% of pts):</b>  <b>Post PTCA</b> 100%  <b>Average (SD) Age:</b> 53 (7)  <b>Percentage male:</b> 75%  <b>Percentage white:</b> not reported  <b>Inclusion criteria:</b>  <i>“at least one coronary stenosis suitable for PTCA and at least one additional clinically insignificant coronary atherosclerotic lesion that could be evaluated by quantitative computerized angiography Hofman-Bang 1999”</i>; employed; able to perform bike test  <b>Exclusion criteria:</b>  Absence of other disease that would prevent completion of programme; age &gt;65; un-employed</p>
Interventions	<p><b>Description / Content:</b> 4 week residential stay, which was focused on health education and the achievement of behaviour change. During the first year of follow-up, a maintenance programme included regular contacts with a nurse...The second year did not contain any active intervention  <b>Teaching Modalities:</b> 4 weeks residential stay (group of 5-8)  Seminars/Lectures/Discussion /Skills (e.g. food preparation/ relaxation)  Then 11 month structured maintenance programme. Nurse led.  <b>Who taught by:</b> Individualisation of material by trained nurse (“<i>personal coach (Lisspers 1999)</i>”)  <b>Dose:</b>  <b>Duration</b> -12 months  <b>No of sessions</b> - Not reported  <b>Length of session</b> - 4 weeks then not reported  <b>Involvement of Family:</b> Not reported  <b>Time of start after event</b> Not reported</p>

	<b>Follow up further reinforcement</b> yes for 1 year (“regular follow-up contacts between the patient and his/her personal coach for verbal feedback, problem-solving, and replanning discussions when needed (Lisspers 1999)”). <b>Theoretical basis for intervention stated</b> no	
Outcomes	Total Mortality, Total CV Events, non fatal MI Total Revascularisations (both CABG and PTCA) Hospitalisations HRQoL: Angina Pectoris Quality of Life Questionnaire (AP-QLQ)	
Follow up	12, 24, 30 and 60 months	
Control	<b>Usual care consisted of:</b> PTCA, one outpatient visit. Then referral to family physician	
Country	Sweden	
Notes	In direct communication with the author he would describe the program as a “ <i>behaviour change program</i> ” primarily and he viewed patient education as “ <i>secondary and supportive to behavior change procedures.</i> ” The following papers produced from the results of the same trial were used to inform the data collected: Hofman-Bang 1999; Lisspers 2005	
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not Reported.
Allocation concealment (selection bias)	Unclear risk	Not Reported
Blinding (performance bias and detection bias) All outcomes	High risk	Not reported in the paper but from direct communication with the author it was confirmed that those analysing the results were not blinded to the group allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	“Two patients in the intervention and four in the control group were excluded soon after randomization at their own request leaving 87 subjects as the final patient population Hofman-Bang 1999.”
Selective reporting (reporting bias)	Low risk	All stated rehabilitation and secondary prevention endpoints in methods documented in results
Groups balanced at baseline	Low risk	Patient characteristics table and statistical comparison included. Apart from beta-blocker usage, groups not different

Lisspers 1999 (Continued)

Intention to treat analysis	Low risk	Intention to treat (ITT) not stated in the test but calculations stated in the results appear to be analysed according to original allocation worked out on an ITT basis
Comparative care?	High risk	As well as education: intervention group received stress management, exercise, smoking habits and dietary advice

PRE.COR Group 1991

Methods	RCT
Participants	<p><b>N Randomised:</b> 182 (intervention (“rehabilitation”: n=60; n control I (“counselling programme” n= 61 control II (“usual care”): 61)</p> <p><b>Trial Recruitment period:</b> Feb 1981 to May 1984</p> <p><b>When Randomised:</b> 30-60 days post MI</p> <p><b>Recruitment from:</b> 1308 patients with suspected MI</p> <p><b>CV Diagnosis (% of pts):</b></p> <p>Post MI 100%</p> <p><b>Age:</b></p> <p>Mean Age Control: 51, Intervention: 51</p> <p><b>Percentage male:</b> 100%</p> <p><b>Percentage white:</b> Not reported</p> <p><b>Inclusion criteria:</b> MI &lt; 65 yrs</p> <p><b>Exclusion criteria:</b></p> <p>Contraindicaton to exercise: recent stroke, disability lower limbs, uncontrolled heart failure, severe rhythm disturbances, SBP &gt; 250 mmHg, severe angina pectoris, severe hypotension, chest pain or low HR on exercise</p>
Interventions	<p><b>Description/Content:</b></p> <p>Education/counselling: Recommendations on cardiovascular risk factors and exercise-control CVS risk factors</p> <p><b>Teaching Modalities:</b></p> <p>One group session</p> <p>Plus individual session with Cardiologist - full medical and personal adjusted recommendations</p> <p><b>Who taught by:</b> (the group session)</p> <p>Cardiologist, psychiatrist, nutritionist &amp; physiotherapist</p> <p><b>Dose:</b></p> <p><b>Duration</b> Not reported</p> <p><b>No of sessions</b> one</p> <p><b>Length of session</b> Not reported</p> <p><b>Involvement of Family:</b> “<i>spouse/partner encouraged to attend</i>”</p> <p><b>Time of start after event</b> Not reported</p> <p><b>Follow up further reinforcement</b> - no</p> <p><b>Theoretical basis for intervention stated-</b></p> <p>no</p>

P.RE.COR Group 1991 (Continued)

Outcomes	Total Mortality Cardiovascular mortality Other cardiovascular events Total Revascularisations (CABG)	
Follow up	12 & 24 months	
Control	<b>Usual care consisted of:</b> "Referral to private practitioner and/or cardiologist"	
Country	France	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons for exclusions pre-randomisation given. "Exclusion of women and men above the age of 65 alone contributed to almost 60% of all reasons for non-eligibility...the reasons for non-inclusion in the other patients were either inability to perform the exercise test or major ECG abnormalities." "No patient was lost to follow-up" but number actually completing interventions not reported. Results for all those randomised, reported for non-fatal events and mortality outcomes
Selective reporting (reporting bias)	Low risk	All outcomes listed in methods reported in results.
Groups balanced at baseline	Low risk	"No statistically significant differences were observed among the treatment groups for any of the tested variable."
Intention to treat analysis	Low risk	"The analysis followed the intention-to-treat principle; patients were counted in the groups in which they were allocated"
Comparative care?	Low risk	Intervention and control group received identical care other than the intervention stated

Methods	RCT
Participants	<p><b>N Randomised:</b> 18,402 n Rx 9,427, n control 8,975</p> <p><b>Trial Recruitment period:</b> April 2002 and June 2005</p> <p><b>When Randomised</b></p> <p><b>Recruitment from:</b> “Eligible-fee for service Medicare patients...who volunteers to participate”</p> <p><b>CV Diagnosis (% of pts):</b> 61% CHD, 48% congestive heart failure</p> <p><b>Age</b> Not Reported</p> <p><b>Percentage male:</b> 45%</p> <p><b>Percentage white:</b> 85%</p> <p><b>Inclusion and Exclusion criteria:</b> “Each program was allowed to define within broad boundaries its own target population and exclusion criteria, and designed its intervention accordingly.”</p> <p>10/15 sites required a hospital admission within the previous year, 4/15 sites excluded &lt;65 yrs old &amp; 14/15 excluded “<i>terminal illness and conditions that affected their ability to learn self management</i>”</p>
Interventions	<p><b>Description / Content:</b> “Nurses provided patient education and monitoring.” The Interventions varied and are described in detail in Brown 2008. “<i>All but 1 of the programs educated patients to improve adherence to medication, diet, exercise, and self-care regimens, mostly through the nurses conveying factual information.</i>”</p> <p><b>Teaching Modalities:</b></p> <p><b>Who taught by:</b> Care co-ordinator. Licensed or registered nurses (4 programs required a BSc level qualification in nursing studies)</p> <p><b>Dose:</b></p> <p><b>Duration:</b> on average 30 months eligibility (range 18-31 months)</p> <p><b>No of sessions:</b> 11 programs: 1-2.5 times / month: 3 programs 4-8 times / month. Other programs did not record contact frequency</p> <p><b>Length of session:</b> Not Reported</p> <p><b>Involvement of Family:</b> Not Reported</p> <p><b>Time of start after event</b> Not Reported</p> <p><b>Follow up further reinforcement:</b> N/A</p> <p><b>Theoretical basis for intervention:</b> Not Reported</p>
Outcomes	<p>Hospitalisations</p> <p>HRQofL</p> <p>Cost Analysis - monthly Medicare expenditure</p>
Follow up	At least 1 year. Mean F/U 51 months.
Control	Not reported.
Country	USA
Notes	The following paper produced from the results of the same trial were used to inform the data collected:

**Peikes 2009** (Continued)

Brown 2008		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly generated concealed 4-digit "strings".
Allocation concealment (selection bias)	Low risk	Randomised assignment was returned via the trial Web site.
Blinding (performance bias and detection bias) All outcomes	High risk	"Because of the nature of the intervention, no individuals were blinded to which group participants were randomized." Peikes 2009
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Observations are weighted by the number of months in the follow-up period that the same member meets eligibility requirements." Peikes 2009. A full breakdown of periods that patients were eligible is not given
Selective reporting (reporting bias)	Low risk	All outcomes stated in the methods are reported in the results
Groups balanced at baseline	Low risk	"Across all of the 15 programs and the baseline characteristics the treatment and control groups differed significantly on only 11 of the 255 comparisons at the $p < 0.05$ level, less than the expected number of statistical significant differences that would be observed by chance." Peikes 2009
Intention to treat analysis	Low risk	"Effects were calculated using .... an intention to treat design." Peikes 2009
Comparative care?	High risk	"7 of the programs used behaviour change models. 14 programs attempted to improve communication between patients and physicians." Peikes 2009 Education was not the only intervention that the treatment groups received

**Pogosova 2008**

Methods	RCT
Participants	<p><b>N Randomised: 100</b> (n Rx = 50 &amp; n control = 50)  <b>Trial Recruitment period:</b> NR (total study period: March 2004 - January 2006)  <b>When Randomised</b> NR  <b>Recruitment from:</b> Ambulatory patients of the Moscow polyclinic Nr112 (n=100) with stable angina of 1-3 functional class, aged between 47-65  <b>CV Diagnosis (% of pts):</b>  <b>Post MI</b> = 52% in Rx; 48% in control</p>

	<p><b>Angina</b> = all  <b>Post CABG</b> = 14% in Rx; 8% in control  <b>Post PTCA</b> = 18% Rx; 14% in control  (transluminal balloon angioplasty)  <b>Age:</b> Mean 59.9 (SD 0.4)  <b>Percentage male:</b> 60% in Rx; 58% in control  <b>Percentage white:</b> NR  <b>Inclusion criteria:</b> Diagnosis of CHD, stable angina, age &lt;65  <b>Exclusion criteria:</b> acute coronary syndromes and acute cerebrovascular disorders in 6 months before selection; patients with severe somatic disorders (life-threatening arrhythmia, heart failure (3-4 functional class), kidney or liver failure; decompensated diabetes, severe bronchial asthma), psychiatric disorders and alcoholic, narcotic and prescription drug addictions</p>
Interventions	<p><b>Description / Content:</b> A course at the “<i>Health school for CHD patients</i>”; Structured programme of 6 sessions (90 min each, twice a week), during which 1 or 2 risk factors were discussed. Evaluation of knowledge about the disease and risk factors after the course.  <b>Teaching Modalities:</b> NR  <b>Who taught by:</b> NR  <b>Dose:</b> twice a week  <b>Duration:</b> 3 weeks  <b>No of sessions:</b> 6 sessions  <b>Length of session:</b> 90 min  <b>Involvement of Family:</b> NR  <b>Time of start after event</b>  <b>Follow up further reinforcement</b> NR  <b>Theoretical basis for intervention:</b>  Organisation of Health Schools for CHD patients in practical health-care setting. Organisational-methodical letter. Appendix 2. M 2003</p>
Outcomes	HRQoL: SF-36
Follow up	6 and 12 months post randomisation
Control	<p>Usual care (for all patients) consisted of 3 visits during a 12 months follow-up  1<sup>st</sup> visit - evaluating inclusion criteria, giving informed consent, randomisation, evaluation of knowledge about the disorder and risk factors; clinical examination; blood test for lipids and glucose; psychological survey  2 and 3<sup>rd</sup> visits - 6 and 12 months after the start of the study; consisted of clinical examination (blood test for lipids and glucose), evaluation of knowledge and psychological survey</p>
Country	Russia
Notes	
<i>Risk of bias</i>	

Pogosova 2008 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Likely, description of the results in text indicates missing data but no breakdown given
Selective reporting (reporting bias)	Low risk	All outcomes are accounted for in the results in either table, graphical or text format
Groups balanced at baseline	Low risk	Groups at baseline were comparable.
Intention to treat analysis	Unclear risk	Not reported
Comparative care?	Low risk	Control group received standard care only.

Southard 2003

Methods	RCT
Participants	<p><b>N Randomised:</b> 104 (n Rx: 53; n control: 51)</p> <p><b>Trail Recruitment period:</b> 10 months</p> <p><b>When Randomised:</b></p> <p><b>Recruitment from:</b> 46 Outpatient facilities throughout SW Virginia) or through news paper adverts (number of patients screened prior to randomization not reported)</p> <p><b>CV Diagnosis (% of pts):</b> "diagnosed coronary heart disease, congestive heart failure or both"</p> <p>Breakdown not reported.</p> <p><b>Mean age:</b> 62</p> <p><b>Percentage male:</b> 75%</p> <p><b>Percentage white:</b> 97%</p> <p><b>Inclusion criteria:</b></p> <p>Diagnosis of CHD or CHF or both</p> <p>Approval of either primary care physician or cardiologist</p> <p>Needs access to the Internet</p> <p><b>Exclusion criteria:</b></p> <p>None reported</p>
Interventions	<p><b>Description / Content:</b> Log in on to the site at least once a week for 30 mins, communicating with a case manager through a secure form of e-mail, completing education modules assigned by the case manager, and entering data into progress graphs. They had</p>



	<p>the opportunity to use an on-line discussion group. There were material incentives for active participation. Also dietary input</p> <p><b>Teaching Modalities:</b> "interactive, multiple choice, self tests followed by feedback."</p> <p><b>Who taught by:</b> "Case Managers" and dieticians</p> <p><b>Dose:</b></p> <p><b>Duration:</b> 6 months</p> <p><b>No of sessions:</b> one/week</p> <p><b>Length of session:</b> at least 30 mins</p> <p><b>Involvement of Family:</b> Not stated</p> <p><b>Time of start after event:</b> Not relevant</p> <p><b>Follow up further reinforcement:</b> No</p> <p><b>Theoretical basis for intervention:</b> None stated</p>	
Outcomes	<p>Total CV Events (fatal / none fatal MI and other fatal / nonfatal CV event)</p> <p>Total Revascularisations (PTCA)</p> <p>Hospitalisations</p> <p>HRQoL - Dartmouth COOP QofL</p> <p>Cost Analysis</p>	
Follow up	6 months post randomisation	
Control	Usual care (details not explicitly stated)	
Country	USA	
Notes	<p>n.b. included heart failure not just CHD patients; percentage with just heart failure not clear; the breakdown table shows "multiple diagnoses"</p> <p>Included a proportion of patients who had previously received cardiac rehabilitation</p>	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	"Randomly assigned to SI or UC on the basis of a computer-generated random number." "study population was stratified on the basis of minority status, participation in cardiac rehabilitation, and acute status (time since event)"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) All outcomes	High risk	Case managers collected number of outcomes (height, weight, blood pressure) at follow up and were not blind to intervention or control
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Of the 104 subjects randomized to the study, 6-month follow-up data was obtained on 100. Four subjects were lost to follow up evaluation." Details of drop outs /loss to follow up reported

**Southard 2003** (Continued)

Selective reporting (reporting bias)	High risk	Dartmouth COOP Quality of life taken at entry and exit. Results reported on entry but not at exit
Groups balanced at baseline	Low risk	Table of demographics and baseline outcome values presented and baseline statistical analysis did not demonstrate any differences
Intention to treat analysis	Low risk	Although not explicitly stated, there groups appear to have been analysed according to initial random allocation
Comparative care?	Unclear risk	Not clear whether intervention group received same usual care as control arm

**Tingstrom 2005**

Methods	RCT
Participants	<p><b>N Randomised:</b> 207 (<b>n Rx</b> 104 &amp; <b>n control</b> 103)</p> <p><b>Trail Recruitment period:</b> Not reported</p> <p><b>When Randomised:</b> Not reported</p> <p><b>Recruitment from:</b> 427 consecutive patients from 2 participating hospitals</p> <p><b>CV Diagnosis (% of pts):</b></p> <p><b>Post MI</b> n=84 (40.5%)</p> <p><b>MI &amp;/or Post CABG</b> n=46 (22%) (just CABG 46 MI &amp; CABG</p> <p><b>MI &amp;/or Post PTCA-</b> n=77 (37%) just PCI 77 MI with PCI</p> <p><b>Age:</b> 59 (SD 7)</p> <p><b>Percentage male:</b> 74%</p> <p><b>Percentage white:</b> Not Specified</p> <p><b>Inclusion criteria:</b> Recent CAD; MI &amp;/or PTCA &amp;/or CABG</p> <p><b>Exclusion criteria:</b> Planned CABG; senility; psychiatric medication; expected poor prognosis within a year; deficient in Swedish; participation in other studies</p>
Interventions	<p><b>Description / Content:</b> Problem based learning rehabilitation <i>“real life situations or scenarios were presented to the group...consisted of pictures, press cuttings, or short texts about exercise, food, drugs, smoking and cholesterol.”</i> Planned curriculum programme explicitly stated.</p> <p><b>Teaching Modalities:</b> Groups of 6-8 people.</p> <p><b>Who taught by:</b> <i>“ Tutor - member of rehabilitation team, trained to take the role of the facilitator”</i></p> <p><b>Dose:</b> (weekly for the first month, every other week for the next month and the spread over the year)</p> <p><b>Duration:</b> 1 year</p> <p><b>No of sessions:</b> 13 group sessions</p> <p><b>Length of session</b> 1.5hrs</p> <p><b>Involvement of Family:</b> Not Stated</p> <p><b>Time of start after event:</b> Not Stated</p>

	<b>Follow up further reinforcement</b>	
	<b>Theoretical basis for intervention:</b> Yes, Schmidt seven step model of problem solving.	
Outcomes	HRQoL - Ladder of Life, Self-Rated Health, SF-36, Cardiac Health Profile Withdrawal from intervention group	
Follow up	12-months post-randomisation	
Control	<b>Usual care consisted of:</b> "Standard treatment from the rehabilitation team....The standard treatment included visits to a nurse and physician during the study period. All patients were also offered the possibility of taking part in physical exercise groups, smoking cessation groups and individual counselling by a dietician."	
Country	Sweden	
Notes	High attendance rate to the educational sessions. Mean 9.4 (median 11) out of 13 sessions	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Not reported in the study itself but from communication with the author it was confirmed that sealed envelopes were randomly organised by a person outside of the research team
Allocation concealment (selection bias)	Low risk	Not reported in the study. However, from communication with the author a sealed envelope method was utilised
Blinding (performance bias and detection bias) All outcomes	High risk	Not reported in the study. Confirmed by communication with author
Incomplete outcome data (attrition bias) All outcomes	Low risk	QUORUM trial flow diagram reported with exclusions and attrition documented and reasons given
Selective reporting (reporting bias)	Low risk	All stated outcomes in methods are reported in results at pre and post tests. Although the self rated health score was not reported in detail
Groups balanced at baseline	Low risk	Table of baseline characteristics showed no statistically differences
Intention to treat analysis	Low risk	Confirmed by communication with the author. "For all analyses intention to treat was used."

Tingstrom 2005 (Continued)

Comparative care?	Low risk	<i>“both groups were offered standard treatment by the rehabilitation team...”</i>
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**Characteristics of excluded studies** [ordered by study ID]

Study	Reason for exclusion
Ades 2001	Identified from <a href="#">Lie 2009</a> . Review not a RCT
Allen 2010	Systematic Review: 21 references identified and reviewed as being of potential interest to this review
Allison 2000	Education not primary aim of intervention. (Risk Factor intervention clinic)
Arthur 2000	Performance bias, intervention included exercise as well as education
Bagheri 2007	Education not primary aim of intervention. (Psychological Counselling)
Barnason 1995	<i>“quasi-experimental”</i> investigating patient satisfaction with teaching.
Barnason 2006	Performance bias: education only part of the intervention.
Barnason 2009	Education not primary aim of intervention: symptom management intervention (pain management / incremental physical exercise.)
Barnason 2009a	Performance bias: education only part of the intervention.
Bell 1998	Identified from <a href="#">Clark 2007</a> . Not RCT.
Benson 2000	A review of a meta-analysis Dusseldorp 1999
Beranova 2007	Systematic Review: 2 references identified and reviewed as being of potential interest to this review
Bethell 1990	Identified from <a href="#">Clark 2005</a> . Education not primary aim of intervention (Exercise based intervention)
Bettencourt 2005	Not education: exercise intervention.
Bitzer 2002	Not a RCT.
Boulay 2004	Performance bias, intervention included exercise as well as education. Not a RCT compared with historical controls
Brand 1998	Performance bias, intervention included exercise as well as education
Brugemann 2007	Education not primary aim of intervention. Psychological - <i>“Rational Emotive behavioural therapy”</i> .

(Continued)

Campbell 1998	Education not primary aim of intervention (nurse intervention clinic)
Campbell 1998a	Education not primary aim of intervention (nurse intervention clinic)
Cannon 2002	Review of implementation of Acute Coronary Syndrome patient pathway. Not an intervention
Cebeci 2008	No relevant outcomes - self care questionnaires.
Chan 2005	Identified from <a href="#">Eshah 2009</a> . Not RCT: Prospective pre-test / post-test design.
Chen 2005	No specified follow-up period.
Clark 2005	Systematic Review: 45 references identified and reviewed as being of potential interest to this review
Clark 2007	Systematic Review: 35 references identified and reviewed as being of potential interest to this review
Cobb 2006	Systematic Review: 3 references identified and reviewed as being of potential interest to this review
Costa 2008	Education not primary aim of intervention - multidisciplinary interventional clinic
Coull 2004	Entrance into study after cardiac rehabilitation.
Cundey 1995	Identified from <a href="#">Hanssen 2007</a> . Review not an RCT
DeBusk 1994	Education not primary aim of intervention. Nurse led intervention
Delaney 2008	Education not primary aim of intervention - a nurse led intervention clinic
Dolan 1992	Duplicate of <a href="#">Mullen 1992</a> ; Systematic Review: 0 references identified (all pre1990)
Dusseldorf 2000	Commentary on a meta-analysis: <a href="#">Dusseldorf 1999</a>
Dusseldorf 1999	Systematic Review: 12 references identified and reviewed as being of potential interest to this review
Engblom 1992	Performance bias: Intervention multifactorial involves exercise and psychological therapy
Engblom 1994	Performance bias: Intervention multifactorial involves exercise and psychological therapy
Engblom 1996	Performance bias: Intervention multifactorial involves exercise and psychological therapy
Engblom 1997	Performance bias: Intervention multifactorial involves exercise and psychological therapy
Enzenhofer 2004	Identified from <a href="#">Beranova 2007</a> . Not relevant outcomes.
Eshah 2009	Systematic Review: 8 references identified and reviewed as being of potential interest to this review

(Continued)

Espinosa 2004	Education not primary aim of intervention- Performance bias
Fattirolli 1998	Education not primary aim of intervention: Exercise intervention
Fernandez 2009	Intervention cognitive behavioural therapy compared with standard cardiac rehabilitation (including education)
Frasure-Smith 1997	Education not primary aim of intervention: Individualised psychological intervention
Fredericks 2009	Individualised educational intervention in CABG patients: Study designed to investigate the time of delivery of education - both groups received the same intervention
Fredericks 2009a	Systematic Review: 7 references identified and reviewed as being of potential interest to this review
Froelicher 1994	Not relevant outcomes (patients recruited between 1977 and 79)
Gao 2007	Not education, exercise is the primary focus post CABG.
Ghali 2004	Commentary: paper excluded education not primary intervention
Goodman 2008	Follow-up period only 3 months post discharge from CABG.
Harbman 2006	Commentary on meta-analysis Clark, A.M., et al., Meta-analysis: Secondary prevention programs for patients with coronary artery. <i>Annals of Internal Medicine</i> , 2005. 143(9): p. 659-672+I87
Haskell 1994	Identified from <a href="#">Clark 2007</a> . Education not primary aim of intervention
Hedback 1993	Education not primary aim of intervention - Performance bias
Hedback 2001	Education not primary aim of intervention - Performance bias
Heidarnia 2005	Not RCT “ <i>experimental design</i> ”
Hobbs 2002	Editorial referring to <a href="#">Shuldham 2002</a> , Pre-CABG education. No relevant outcomes investigated.
Jackson 2009	Systematic Review: 0 references identified
Janz 1999	Identified from <a href="#">Clark 2009</a> . No relevant outcomes.
Jenny 2001	Identified from <a href="#">Beranova 2007</a> . Outcomes; Effectiveness of education package in promoting learning only
Johansen 2003	Not education, psycho-social intervention, post MI.
Khunti 2007	Education not primary aim of intervention. Nurse led clinic.

(Continued)

Koertge 2003	Identified from <a href="#">Eshah 2009</a> . Education not primary aim of intervention (diet and stress management and social support)
Lindsay 2009	Education not primary aim of intervention: computer support group - comparison of moderated and unmoderated access
Mayou 2002	Education not primary aim of intervention
McGillion 2004	Systematic Review: 0 references identified
McGillion 2008	Education not primary aim of intervention: Psychological intervention - cognitive behavioural therapy
McGillion 2008a	Education not primary aim of intervention-Psychological intervention
Moore 2002	Identified from <a href="#">Fredericks 2009</a> . Education not primary aim of intervention. Symptom management program using audiotapes
Mosca 2010	No relevant outcomes
Mullen 1992	Duplicate of <a href="#">Dolan 1992</a> ; Systematic Review: 0 references identified (all pre1990)
Murchie 2003	Education not primary aim of intervention: secondary prevention clinic
Murchie 2004	Education not primary aim of intervention: secondary prevention clinic
Neubeck 2009	Systematic Review: 11 references identified and reviewed as being of potential interest to this review
Niebauer 1997	Identified from <a href="#">Clark 2007</a> . Education not primary aim of intervention (exercise and low fat diet)
Nisbeth 2000	Education not primary aim of intervention: psychological intervention
Nordmann 2001	Education not primary aim of intervention: case management - not relevant outcomes (only risk factor modification)
Oldenburg 1995	Education not primary aim of intervention: psychological intervention
Ornish 1990	Identified from <a href="#">Clark 2007</a> . Education not primary aim of intervention
Ornish 1998	Education not primary aim of intervention: lifestyle regime
Paez 2006	Education not primary aim of intervention: nurse managed cholesterol control program
Parry 2009	No relevant outcomes
Raftery 2005	Education not primary aim of intervention
Redfern 2009	Non-standard RCT design with non-randomised control group.

(Continued)

Robertson 2003	Not RCT. <i>“True experimental post-test only, control group design, including the process of randomisation.”</i>
Rubenfire 2008	Commentary on a Systematic Review, subsequently reviewed and demonstrated: 9 references identified and reviewed as being of potential interest to this review
Sherrard 2000	Education not primary aim of intervention, combined with psychological counselling and no relevant outcomes
Shuldham 2001	Systematic Review: 0 references identified
Shuldham 2002	pre-CABG education. No relevant outcomes investigated.
Sinclair 2005	Follow-up only 100 days.
Thompson 2000	Identified from <a href="#">Hanssen 2007</a> . Review not an RCT
Thompson 2002	Identified from <a href="#">Hanssen 2007</a> . Review not an RCT
Tranmer 2004	Education not primary aim of intervention, telephone nurse management
Turner 2008	Cost analysis of <a href="#">Khunti 2007</a> ; Education not primary aim of intervention
Vale 2003	Education not primary aim of intervention: Program is a risk factor targeted prompting of treatment
van Elderen 1994	No relevant outcomes.
van Elderen 2001	Not RCT - <i>“quasi-experimental pre-test / post test control group design.”</i>
Vonder 2002	Identified from <a href="#">Eshah 2009</a> . Not RCT: Retrospective Study
Wallner 1999	Dietary intervention, Education not primary aim of intervention
Williams 2009	Systematic Review: 0 references identified.
Zalenskaya 2005	No relevant outcomes.
Zhao 2009	Education not primary aim of intervention-Performance bias
Zutz 2007	Identified from <a href="#">Neubeck 2009</a> . No relevant outcome measures



## Characteristics of studies awaiting assessment *[ordered by study ID]*

### Wang 2007

Methods	
Participants	
Interventions	
Outcomes	
Notes	Unable to gain access to paper.

### Williamson 2008

Methods	RCT
Participants	Post CABG patients. n=88
Interventions	Weekly, individualized, telephone, educational intervention.
Outcomes	Difficult to ascertain from abstract alone
Notes	Abstract only

## Characteristics of ongoing studies *[ordered by study ID]*

### Hawkes 2009

Trial name or title	Randomised controlled trial of secondary prevention program for myocardial infarction patients ('ProActive Heart')
Methods	RCT
Participants	Post MI patients recruited from Brisbane Hospitals.
Interventions	6 month telephone delivered secondary prevention program
Outcomes	SF-36, Cost-effective analysis
Starting date	December 2007
Contact information	
Notes	<a href="#">Hawkes 2009</a>

**Lear 2008**

Trial name or title	Randomised Trial of Cardiac Rehabilitation Program Delivered Remotely through the Internet
Methods	RCT
Participants	Men and Women > 18. Diagnosed Ischaemic Heart Disease. Aim to recruit 74 patients from consecutive inpatient admissions with acute coronary syndrome or revascularisation procedure
Interventions	4 month interactive Internet based CR program. Input from nurse, dietitian and exercise specialist
Outcomes	Healthcare utilisation at 16 months
Starting date	
Contact information	Dr S.C. Lear. slear@providencehealth.bc.ca
Notes	clinicaltrials.gov identifier NCT00683813

**McGillion 2006**

Trial name or title	A Psychoeducation Trial for People with Chronic Stable Angina
Methods	RCT
Participants	CHD for at least 6 months
Interventions	Supportive and educational self-management program (Chronic Angina Self-Management Program (CASMP))
Outcomes	HRQoL (SF-36 and SAQ)
Starting date	9/2003
Contact information	Dr MH McGillion, University of Toronto, Toronto, Ontario, Canada M5T 1P8
Notes	clinicaltrials.gov identifier NCT00350922

## DATA AND ANALYSES

### Comparison 1. Total Mortality

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Total mortality at the end of the follow up period	6	2330	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.55, 1.13]

### Comparison 2. Cardiovascular Events

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Myocardial Infarction at the end of the follow up period	2	209	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.26, 1.48]

### Comparison 3. Revascularisations

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patients requiring Coronary Artery Bypass Grafting (CABG) at end of follow-up period	2	209	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.19, 1.71]

### Comparison 4. Hospitalisations

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Cardiac Hospitalisations at end of follow up period	4	12905	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.65, 1.07]

## Comparison 5. All cause withdrawal / drop-out at follow-up

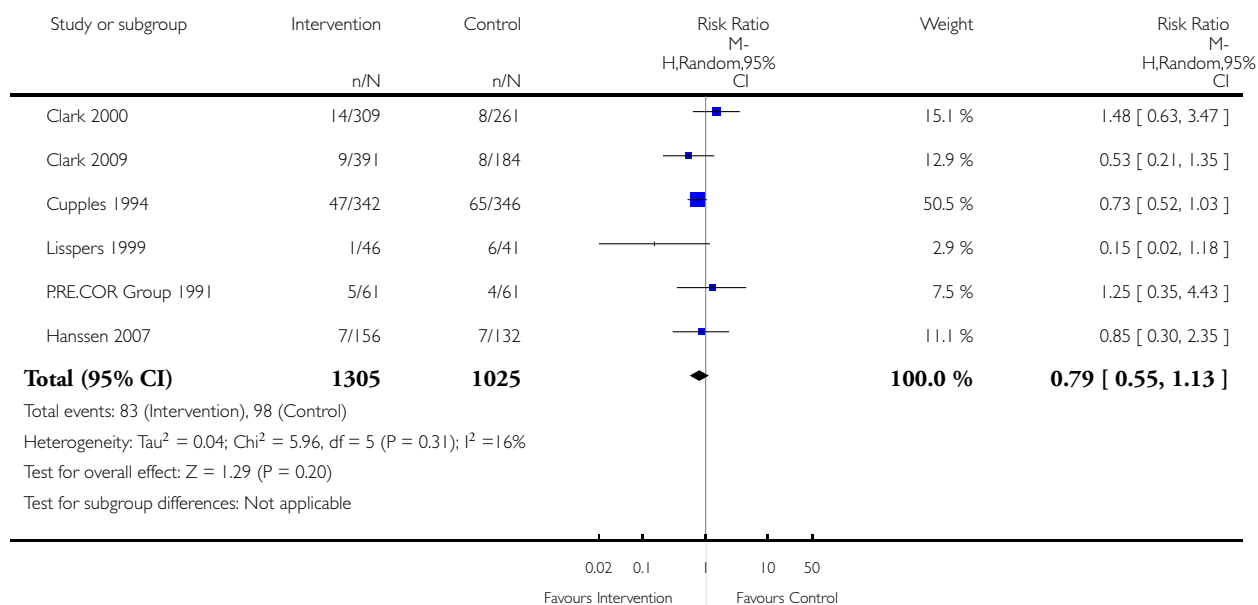
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 All cause withdrawal / drop-out at follow-up	8	2862	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.83, 1.27]

### Analysis 1.1. Comparison 1 Total Mortality, Outcome 1 Total mortality at the end of the follow up period.

Review: Patient education in the management of coronary heart disease

Comparison: 1 Total Mortality

Outcome: 1 Total mortality at the end of the follow up period

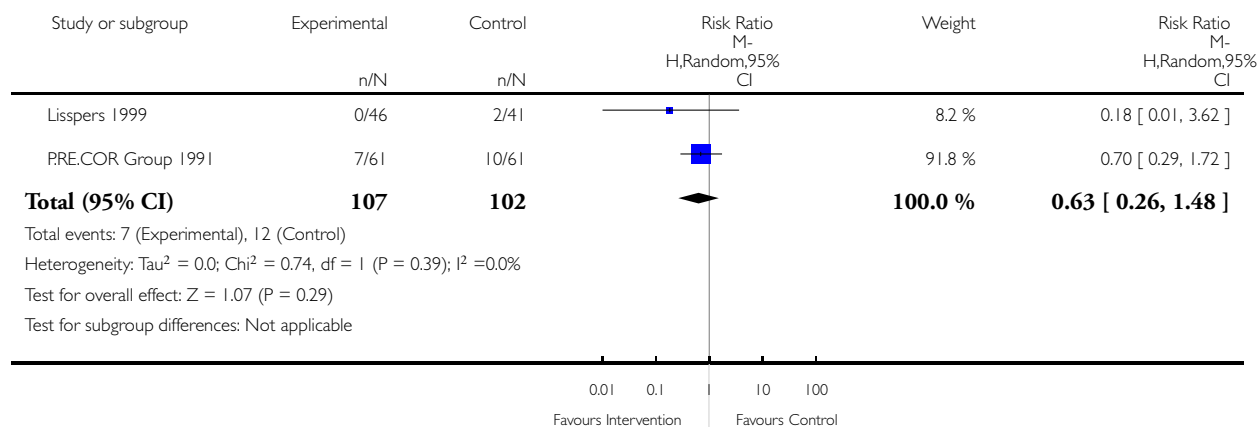


## Analysis 2.1. Comparison 2 Cardiovascular Events, Outcome 1 Myocardial Infarction at the end of the follow up period.

Review: Patient education in the management of coronary heart disease

Comparison: 2 Cardiovascular Events

Outcome: 1 Myocardial Infarction at the end of the follow up period

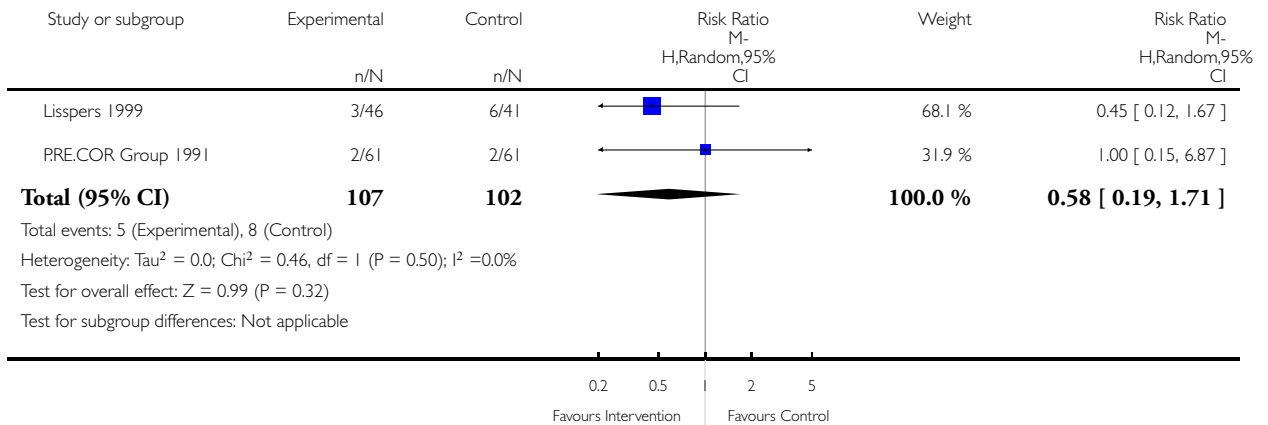


### Analysis 3.1. Comparison 3 Revascularisations, Outcome 1 Patients requiring Coronary Artery Bypass Grafting (CABG) at end of follow-up period.

Review: Patient education in the management of coronary heart disease

Comparison: 3 Revascularisations

Outcome: 1 Patients requiring Coronary Artery Bypass Grafting (CABG) at end of follow-up period

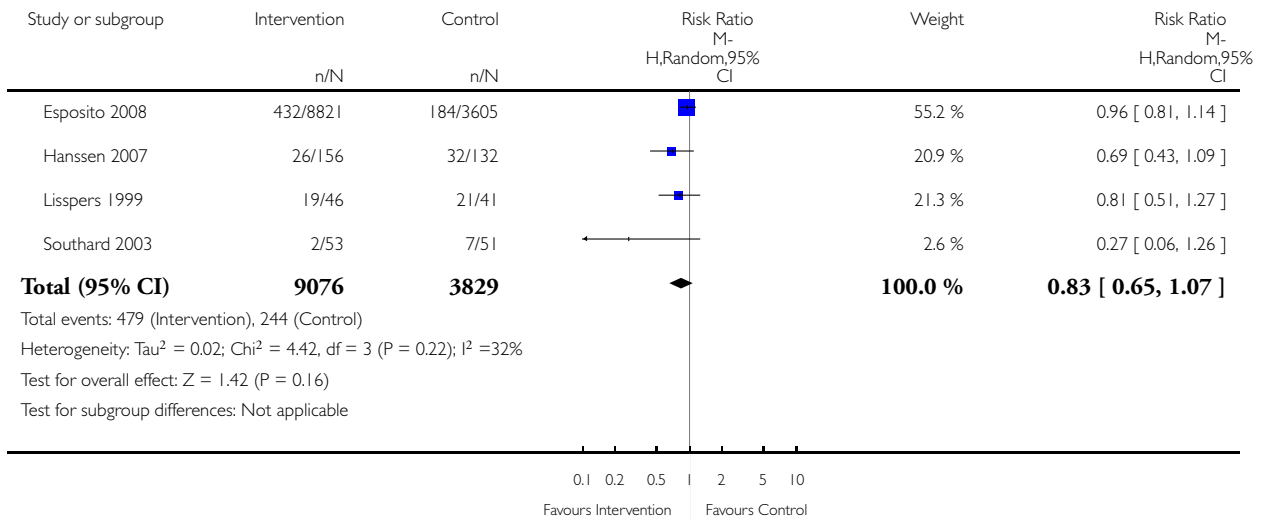


### Analysis 4.1. Comparison 4 Hospitalisations, Outcome 1 Cardiac Hospitalisations at end of follow up period.

Review: Patient education in the management of coronary heart disease

Comparison: 4 Hospitalisations

Outcome: 1 Cardiac Hospitalisations at end of follow up period

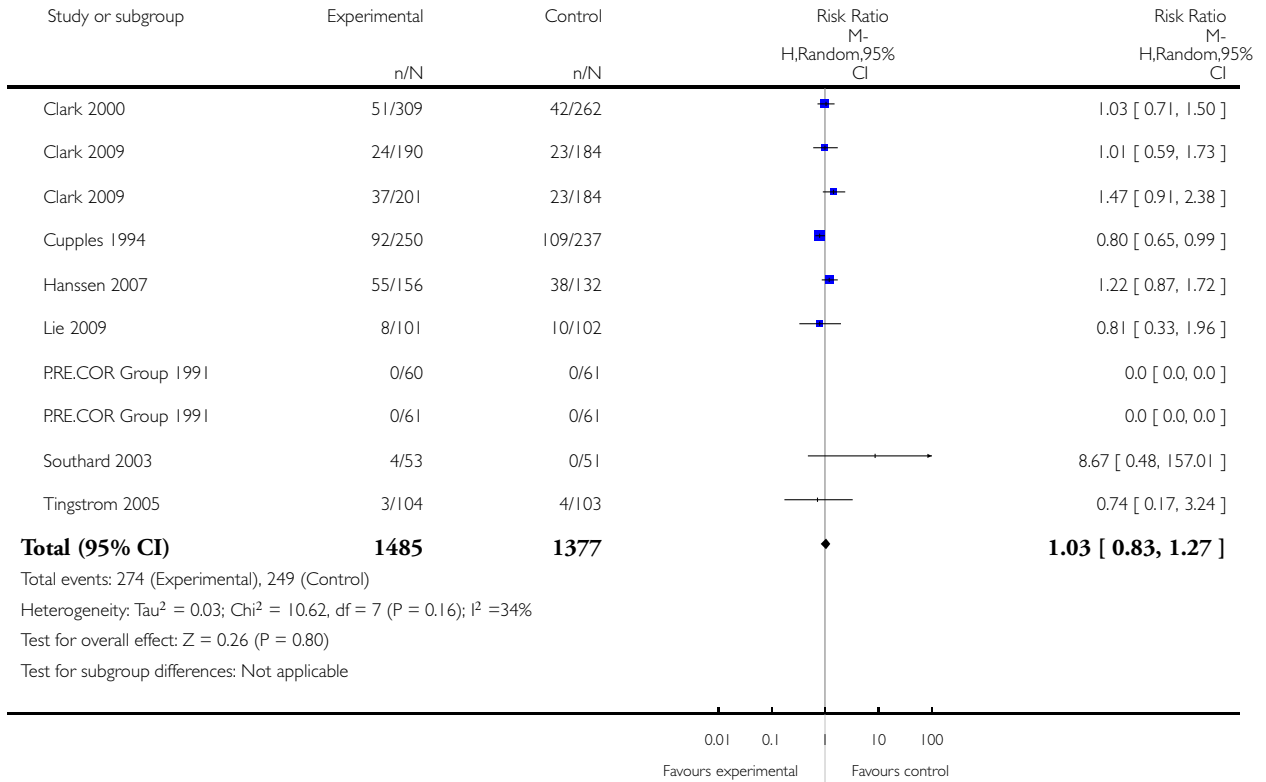


**Analysis 5.1. Comparison 5 All cause withdrawal / drop-out at follow-up, Outcome 1 All cause withdrawal / drop-out at follow-up.**

Review: Patient education in the management of coronary heart disease

Comparison: 5 All cause withdrawal / drop-out at follow-up

Outcome: 1 All cause withdrawal / drop-out at follow-up



**ADDITIONAL TABLES**

**Table 1. Summarising educational content of programs in included studies**

	Description of Intervention	Theoretical Basis	Tailored	Duration	One to One	Group	Face Face	to Telephone	Internet	Notes
<b>Clark 1997</b>	*PRIDE	Y	Y	Once a week for 4 weeks		Y	Y			Taught by health educator.



**Table 1. Summarising educational content of programs in included studies** (Continued)

										Videotape and work-book aids.
<b>Clark 2000</b>	*PRIDE	Y	Y	Once a week for 4 weeks		Y	Y			Taught by health educator. Videotape and work-book aids.
<b>Clark 2009</b>	*PRIDE	Y	Y	Once a week for 6 weeks	Y	Y	Y			3 groups (self-directed and group intervention and a control)
<b>Cupples 1994</b>	Practical tailored advice on cardiovascular risk factors and appropriate health education	N/S	Y	3 times a year for 2 years	Y		Y			Delivered at home by health visitor
<b>Esposito 2008</b>	Pre-designed scripts to provide education on various aspects of care, geared to personalised clinical goals	N/S	Y	Average 1.1 contacts a month for 18 months	Y		Y	Y		Nurse case manager, primarily by telephone but also face to face
<b>Hanssen 2007</b>	Individualised education from a menu of topics	Y	Y	6 months (8 sessions in total)	Y			Y		Structured element and an on-call element

**Table 1. Summarising educational content of programs in included studies** (Continued)

	to be covered									
<b>Lie 2009</b>	A psychoeducative intervention. Structured information and psychological support	N/S	N/S	2 visits (1 hour each)	Y		Y			Critical care nurse, home based.
<b>Lisspers 1999</b>	Health education and achievement of behavioural change.	N/S	Y	4 week residential then 11 month one to one individual sessions	Y	Y	Y			Trained nurses (personal coaches) . Seminars, lectures, discussion and skills sessions
<b>PRE.Cor Group 1991</b>	Education and counselling on management of cardiovascular risk factors and exercise	N/s	Y	1 group session, 1 individual session with cardiologist	Y	Y	Y			Multi-disciplinary input to group. Cardiologist tailors therapy
<b>Piekes 2009</b>	Variable - nurse provision of patient education.	N/s	N/S	1- 2.5 times a month for an average of 30 months	Y			Y		15 different programs, majority telephone, one-to-one
<b>Pogosova 2008</b>	Structured program	Y	N/S	6 Sessions (twice a week, 90		Y	Y			

**Table 1. Summarising educational content of programs in included studies** (Continued)

	address- ing differ- ent risk factors in each ses- sion			mins)						
<b>Southard 2003</b>	Modular in- ternet ses- sions, In- teractive multi- ple choice and self tests fol- lowed by feedback	N/S	N/S	Once a week for 6 months (at least 30 mins)	Y	Y			Y	Communi- cation with case manager and on-line discussion group
<b>Tingstrom 2005</b>	Prob- lem based rehabil- itation to teach a planned curricu- lum	Y	N/S	13 ses- sions over 1 year		Y	Y			Trained Fa- cilitator

**PRIDE** = Problem Identification, **R**esearching one's routine, **I**dentifying a management goal, **D**eveloping a plan to reach it, **E**xpressing one's reactions and **E**stablishing rewards for making progress.

Y = Yes

N/S = Not Stated

**Table 2. Table: All-cause withdrawal / drops out at follow-up**

Study		Number Randomised	Number Lost at Follow-up*	Notes
<b>Clark 2000</b>	Intervention	309	51	36 withdrew, 14 died, 1 data missing
	Control	262	42	33 withdrew, 8 died, 1 data missing
<b>Clark 2009</b>	Intervention	201	37	Self-directed program 33 withdrew, 4 died
	Intervention	190	24	Group format 19 withdrew, 5 died

**Table 2. Table: All-cause withdrawal / drops out at follow-up (Continued)**

	Control	184	23	15 withdrew, 8 died
<b>Cupples 1994</b>	Intervention	250	92	45 defaulted, 47 died 21 defaulted at 2 yrs
	Control	237	109	44 defaulted, 65 died 25 defaulted at 2 yrs
<b>Hanssen 2007</b>	Intervention	156	55	40 withdrew, 7 died, 8 missing data
	Control	132	38	21 withdrew, 7 died, 10 missing data
<b>Lie 2009</b>	Intervention	101	8	6 withdrew, 2 medical exclusions
	Control	102	10	5 withdrew, 5 medical exclusions
<b>P.R.E.COR 1991</b>	Intervention	60	0	Comprehensive cardiac rehabilitation
	Intervention	61	0	Counseling program without exercise
	Control	61	0	
<b>Southard 2003</b>	Intervention	53	4	<i>Reasons for drop out stated;</i> Relocation, dietary intervention instead, psychiatric diagnosis, loss of interest
	Control	51	0	
<b>Tingstrom 2005</b>	Intervention	104	3	Out of the 7 lost to follow-up 2 died and 5 did not attend
	Control	103	4	
<b>Combined Results</b>	<b>Intervention</b>	<b>1485</b>	<b>274</b>	<b>18.5%</b>
	<b>Control</b>	<b>1132</b>	<b>226</b>	<b>20.0%</b>

\* All causes of drop out from follow up included (including mortality)

**Table 3. Table summarising HRQoL data: Specific HRQoL Measures 1**

Seattle Angina Questionnaire					
Lie 2009 (6 months)	Absolute mean (SD) outcome values at follow-up	Comparison			
		Rx	p-value	Control	p-value

**Table 3.** Table summarising HRQoL data: *Specific HRQoL Measures 1* (Continued)

<b>Physical Limitation</b>	86.4(15.6)	p<0.001	83.2(18.7)	p<0.001	Rx=Control
<b>Angina Frequency</b>	91.7(16.6)	p<0.001	90.8(18.9)	p<0.001	Rx=Control
<b>Treatment Satisfaction</b>	89.2(15.4)	NS	88.0(16.1)	NS	Rx=Control
<b>Disease Perception</b>	77.8(20.2)	p<0.001	73.9(24.2)	p<0.001	Rx=Control

**Table 4.** Table summarising HRQoL data: *Specific HRQoL Measures 2*

<b>AP-QLQ (Angina Pectoris - Quality of Life Questionnaire)</b>					
Lisspers 1999 (24 Months)	Mean (SD) score at follow-up		Between group p-value	Comparison	
	Rx	Control			
<b>QLQ (Total)</b>	4.7(0.8)	4.3(1.0)	NS	Rx=Control	
<b>Somatic symptoms</b>	4.8(1.0)	4.3(1.1)	NS	Rx=Control	
<b>Physical Activity</b>	4.8(1.0)	4.1(1.2)	NS	Rx=Control	
<b>Emotional Distress</b>	4.8(0.8)	4.6(1.1)	NS	Rx=Control	
<b>Life Satisfaction</b>	4.2(1.0)	3.9(1.2)	NS	Rx=Control	

Figures quoted represent an absolute score on a self-rating scale.

**Table 5.** Table summarising HRQoL data: *Generic HRQoL Measures 1*

<b>SF-36* (Short Form 36 item survey)</b>			
	Between group difference in mean change from baseline (95% CI) at follow-up	Between group p-value	Comparison
<b>Hanssen 2007 (6 months)</b>			
<b>Overall Physical</b>	-2.33 (-4.54,-0.12)	0.039	Rx=Control
<b>Physical Functioning</b>	-1.16 (-3.28,0.95)	0.28	Rx=Control

**Table 5.** Table summarising HRQoL data: *Generic HRQoL Measures 1* (Continued)

<b>Role Physical</b>	-1.84 (-5.32,1.64)	0.299	Rx=Control
<b>Bodily Pain</b>	-1.74 (-4.54,1.05)	0.22	Rx=Control
<b>General Health</b>	-0.36 (-2.64,1.91)	0.752	Rx=Control
<b>Overall Mental</b>	1.07 (-1.71,3.86)	0.447	Rx=Control
<b>Vitality</b>	-0.07 (-2.23,2.10)	0.951	Rx=Control
<b>Social Functioning</b>	0.36 (-2.96,3.67)	0.832	Rx=Control
<b>Role Emotional</b>	0.78 (-3.29,4.84)	0.706	Rx=Control
<b>Mental Health</b>	0.4 (-1.81,2.60)	0.723	Rx=Control
<b>Hanssen 2007 (18 months)</b>			
<b>Overall Physical</b>	-1.44 (-3.89,1.02)	0.25	Rx=Control
<b>Physical Functioning</b>	-0.79 (-3.06,1.48)	0.491	Rx=Control
<b>Role physical</b>	-0.94 (-4.76,2.88)	0.627	Rx=Control
<b>Bodily Pain</b>	-0.77 (-4.00,2.47)	0.641	Rx=Control
<b>General Health</b>	0.25 (-2.15,2.64)	0.838	Rx=Control
<b>Overall Mental</b>	1.65 (-1.35,4.65)	0.28	Rx=Control
<b>Vitality</b>	0.58 (-1.95,3.12)	0.65	Rx=Control
<b>Social Functioning</b>	0.55 (-3.95,2.85)	0.751	Rx=Control
<b>Role Emotional</b>	2.59 (-1.58,6.77)	0.221	Rx=Control
<b>Mental Health</b>	0.31 (-2.11,2.73)	0.8	Rx=Control

\* Negative baseline-follow-up difference favours intervention and positive favours control.

Table 6. Table summarising HRQoL data: *Generic HRQoL Measures 2*

SF-36* (Short Form 36 item survey)				
Tingstrom 2005 (12 months)	Mean change from baseline (SD)		Between group p-value <sup>+</sup>	Comparison
	Rx	Control		
Physical Functioning	3.6 (17.6)	4.4 (15.1)	0.749	Rx=Control
Role Physical	38.2 (46.9)	33.8 (42.4)	0.504	Rx=Control
Bodily Pain	5.69 (31.1)	6.18 (29.1)	0.911	Rx=Control
General Health	1.4 (15.9)	1.8 (16.3)	0.862	Rx=Control
Vitality	5.3 (22.7)	4.9 (21.8)	0.921	Rx=Control
Social Functioning	9.7 (24)	9.1 (25.3)	0.869	Rx=Control
Role Emotional	15.8 (48.1)	16.5 (41.1)	0.913	Rx=Control
Mental Health	2.9 (16.6)	4.2 (17.8)	0.566	Rx=Control

\*Positive values indicate improvement in HRQoL from baseline

+p-values are calculated on the difference between groups at pre-test and on the mean change (post test minus pre-test).

Table 7. Table summarising HRQoL data: *Generic HRQoL Measures 3*

SF-36 (Short Form 36 item survey)			
Pogosova 2008 (12 months)	Mean change from baseline p-value		Comparison
	Control	Rx	
Overall Physical	p>0.05	p≤0.05	Favours Rx
Physical Functioning	p>0.05	p≤0.05	Favours Rx
Bodily Pain	p>0.05	p≤0.05	Favours Rx
Overall Mental	p>0.05	p≤0.05	Favours Rx
Vitality	p>0.05	p≤0.05	Favours Rx
Social Functioning	p>0.05	p≤0.05	Favours Rx

**Table 7. Table summarising HRQoL data: *Generic HRQoL Measures 3* (Continued)**

<b>Mental Health</b>	p>0.05	p≤0.05	<b>Favours Rx</b>
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There were no significant changes demonstrated in the control group but no statistical comparison of the mean change between the groups was reported.

**Table 8. Table summarising HRQoL data: *Generic HRQoL Measures 4***

SF-36 (Short Form 36 item survey)					
Lie 2009 (6 months)	Absolute mean (SD) outcome values at follow-up				Comparison
	Rx	p-value	Control	p-value	
<b>Overall Physical</b>	47.4 (9.6)	p<0.001	47 (10)	p<0.001	Rx=Control
<b>Physical Functioning</b>	82.2 (19.2)	p<0.001	82.3 (19.8)	p<0.001	Rx=Control
<b>Role Physical</b>	64 (41.2)	p<0.001	57.2 (43.3)	p<0.001	Rx=Control
<b>Bodily Pain</b>	77.2 (22.3)	p<0.001	78.5 (25.2)	p<0.001	Rx=Control
<b>General Health</b>	69.9 (23.3)	NS	65.7 (27.2)	NS	Rx=Control
<b>Overall Mental</b>	52.1 (10.7)	p<0.05	50.5 (10.8)	NS	<b>Favours Rx</b>
<b>Vitality</b>	61.9 (23.9)	p<0.001	60.5 (21.6)	p<0.001	Rx=Control
<b>Social Functioning</b>	86.3 (21.4)	p<0.001	84.3 (21.9)	p<0.001	Rx=Control
<b>Role Emotional</b>	73.3 (38.2)	p<0.01	67.4 (41.6)	p<0.01	Rx=Control
<b>Mental Health</b>	81.9 (17.3)	p<0.001	78.5 (21)	p<0.01	Rx=Control

**Table 9. Table summarising HRQoL data: *Generic HRQoL Measures 5***

Nottingham Health Profile+				
Cupples 1994 (24 months)	Mean change from baseline (SD) at follow-up			Comparison
	Rx	Control	Between group p-value	



**Table 9.** Table summarising HRQoL data: *Generic HRQoL Measures 5* (Continued)

<b>Emotional Reaction</b>	-0.79 (19.52)	-1.91 (21.31)	0.52	Rx=Control
<b>Energy</b>	-3.88 (33.97)	-6.52 (35.87)	0.33	Rx=Control
<b>Physical Mobility</b>	-1.49 (16.17)	-6.19 (18.12)	0.003	<b>Rx&gt;Control</b>
<b>Pain</b>	-1.23 (20.5)	-2.7 (23.46)	0.92	Rx=Control
<b>Sleep</b>	-1.67 (26.22)	-0.1 (24.95)	0.38	Rx=Control
<b>Social Isolation</b>	1.42 (16.96)	-3.01 (21.27)	0.08	Rx=Control

+ Higher scores reflect poorer quality of life

**Table 10.** Table summarising HRQoL data: *Generic HRQoL Measures 6*

<b>Nottingham Health Profile+</b>			
<b>Cupples 1994 (60 months)</b>	<b>Mean difference (95% CI) between groups in change from baseline at follow-up</b>	<b>Between group p-value</b>	<b>Comparison</b>
<b>Emotional Reaction</b>	-2.1 (-7.5,3.3)	NS	Rx=Control
<b>Energy</b>	-4.7 (-13.2,3.7)	NS	Rx=Control
<b>Physical Mobility</b>	-1.3 (-6.3,3.6)	<0.05	<b>Rx&gt;Control</b>
<b>Pain</b>	-3.4 (-9.2,2.3)	<0.05	<b>Rx&gt;Control</b>
<b>Sleep</b>	-2.4 (-9.3,4.5)	NS	Rx=Control
<b>Social Isolation</b>	0.0 (-4.3,4.3)	NS	Rx=Control

+ Higher scores reflect poorer quality of life

The value quoted is the mean difference (CI) between groups from baseline to follow-up  
p-value related to t-tests (two tailed)

Table 11. Table summarising HRQoL data: *Generic HRQoL Measures 7*

Sickness Impact Profile+++				
	Absolute mean outcome values at follow-up++			Comparison
	Rx	Control	Between group p-value	
Clark 1997 (12 months)				
Total Score	7.26	8.09	NS	Rx=Control
Psychosocial Dimension	5.52	7.05	≤0.05	Rx>Control
Physical Dimension	5.89	6.00	NS	Rx=Control
Clark 1997 (18 months)				
Total Score	7.93	7.41	NS	Rx=Control
Psychosocial Dimension	6.05	6.23	NS	Rx=Control
Physical Dimension	6.40	5.25	NS	Rx=Control

++ for mean scores at follow-up (adjusted for baseline scores)

+++lower score higher HRQoL

Table 12. Table summarising HRQoL data: *Generic HRQoL Measures 8*

Sickness Impact Profile				
Clark 2000 (12 months)	Absolute means at follow-up++			Comparison
	Rx	Control	Between group p-value	
Psychosocial Dimension	5.15	5.91	0.144	Rx=Control
Physical Dimension	7.09	7.66	0.05	Rx>Control

Means were adjusted to take account of baseline values.

Table 13. Table summarising HRQoL data: *Generic HRQoL Measures 9*

Sickness Impact Profile					
	Absolute means (SD) at follow-up				Comparison
	Rx group	Rx self directed	Control	Between group p-value	
<b>Clark 2009 (12 months)</b>					
<b>Total Score</b>	8.13 (8.63)	9.79 (10.17)	9.49 (9.46)	NS	Rx=Control
<b>Psychosocial Dimension</b>	5.84 (8.02)	7.31 (10.74)	6.75 (9.39)	NS	Rx=Control
<b>Physical Dimension</b>	8.07 (9.63)	9.46 (10.11)	9.85 (10.79)	NS	Rx=Control
<b>Clark 2009 (18 months)</b>					
<b>Total Score</b>	8.44 (9.13)	8.98 (10.29)	9.64 (9.45)	NS	Rx=Control
<b>Psychosocial Dimension</b>	5.74 (9.68)	6.16 (8.20)	7.17 (10.40)	NS	Rx=Control
<b>Physical Dimension</b>	8.27 (10.02)	8.98 (9.33)	9.65 (10.19)	NS	Rx=Control

n.b. the analysis of this data was reported in the paper but the individual results were not. These have been obtained by direct contract with the author.

Table 14. Table summarising HRQoL data: *Generic HRQoL Measures 9*

Patients' Assessment of their Quality of Life on a five-point scale						
Cupples 1994 (24 months)	Initial scores (% of patients)		Follow-up Scores (% of patients)		Between group p-value	Comparison
	Rx	Control	Rx	Control		
<b>Poor</b>	6.3	5.3	6.9	8.3	p<0.03	Rx>Control
<b>Fair</b>	27.8	23.3	18.9	21.7		
<b>Average</b>	35	39	33.1	33.7		
<b>Good</b>	22.7	22.7	29.3	25.3		

**Table 14. Table summarising HRQoL data: *Generic HRQoL Measures 9* (Continued)**

<b>Very Good</b>	8.2	9.7	11.7	11		
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n.b. for Table 13 the between group p value represents the overall “comparison of change in individuals’ assessment for intervention and control groups” the significant difference being in favour of the intervention group.

**For all tables summarising HRQoL Data (Tables 2-13)**

**Rx:** Intervention

**NS:** No significant difference demonstrated

**Rx=Control:** no significant difference ( $p>0.05$ ) in HRQoL between the intervention and the control groups at follow-up.

**Rx>Control:** significant difference ( $p\leq 0.05$ ) in HRQoL in favour of the intervention group at follow-up.

**Control>Rx:** significant difference ( $p\leq 0.05$ ) in HRQoL in favour of the control group at follow-up.

**Favours Rx:** Available evidence favours the intervention group but direct statistical comparison between intervention and control groups was not reported.

**Favours Control:** Available evidence favours the control group but direct statistical comparison between intervention and control groups was not reported.

**Table 15. Table: Cost summary of intervention & comparison of health care costs incurred by intervention & control groups during follow-up period**

Variable	Clark 2000	Cupples 1994	Esposito 2008				Southard 2003	Peikes 2009
<b>Follow-up</b>	24 months	24 months	6 months	7-12 months	12 months	18 months	6 months	25 months
<b>Year of Costs</b>	2000	NR	2005-6				NR	2002-2005
<b>Currency</b>	US\$	GBP£	US\$				US\$	US\$
<b>Mean cost of cardiac rehabilitation program per patient</b>								
<b>Total Costs</b>	\$187	£49.72	\$162				\$453	\$196
<b>Costs Considered</b>	Personnel, Instructional Materials, Telephone Supplies, Ongoing Staff Training	Direct Costs by Health Visitors (Staff Time), Travel Costs.	Average monthly fee paid to the program per member				Nurse Salary Overheads Subscription Costs	Average monthly fee paid to the program per member
<b>Comments</b>	Participating site overheads were not measured,	Costs of the health visitor also included time spent						Cost varied between the included 15 studies. Ne-

**Table 15. Table: Cost summary of intervention & comparison of health care costs incurred by intervention & control groups during follow-up period (Continued)**

	a “conservatively high” estimate of these was taken to double the cost of the Rx to \$374	recording data collection for the study						go-tiated locally with center of Medicare and Medicaid Services. (Range \$50-\$444)
<b>Mean total healthcare costs per patient</b>								
<b>Total Cost (Intervention)</b>	\$3300 (calc)	£1801	\$1627	\$2356	\$2288	\$1793	\$635	\$1283 *
<b>Total Cost (Control)</b>	\$6500	£1812	\$1632	\$2464	\$2372	\$1818	\$2053	\$1314 *
<b>Between Group Difference</b>	\$1800*	£9.60	\$5	\$107	\$84	\$25	\$1418	\$144 (80% CI 99 to 188)
<b>p value</b>	NR	NS	0.895	0.077	0.132	0.365	NR	<0.001
<b>Cost Saving per pt (when cost of intervention taken into account\$)</b>	\$1610 or \$1420 if estimated overheads are included.	£40	-\$157	-\$55	-\$78	-\$137	\$965	-\$52
<b>Additional Healthcare Costs Considered</b>	Number of Admissions (Heart Related), Number of in-patient days, In patient cost. Emergency Dept costs	Prescription of drugs, visits to the GP, Visits to hospital as in-patients and out-patients, all tests investigations and treatments carried out	Medicare Medical Claims				Cardiovascular related emergency room visits and hospitalisations	

**Table 15. Table: Cost summary of intervention & comparison of health care costs incurred by intervention & control groups during follow-up period (Continued)**

<b>Comments</b>	Expenditure was calculated from differences in % utilisation of hospital services. i.e. Hospital charges for participants were on average 49% lower and the average annual expenditure was \$6500 * There was a calculated saving of a hospital charge of \$3200, the ratio of payments to charges was 0.56 therefore \$1800 actual saving.	There was a difference in the drug usage at baseline which is not accounted for in these figures although this would make minimal impact to the results. The intervention group were more costly for drugs, procedures and service use	Claims quoted are per member per month.		*Expenditure/pt/month enrolled  Overall costs were increased by 11% when the care coordination fees were taken into account
<b>Summary Difference Between Groups</b>	<b>Favours Rx</b>	Rx=Control	Rx=Control (for all time periods studied)	<b>Favours Rx</b>	<b>Favours Control</b>

§ = Negative mean difference indicates a net cost of the intervention group

NR = Not Recorded

NS = Not Significant

## APPENDICES

### Appendix I. Search strategies

#### THE COCHRANE LIBRARY (CENTRAL/ CDSR / DARE / HTA/ NHSEDD)

- #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 rehabilitation\* 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)

#### MEDLINE SEARCH STRATEGY (OVID)

- 1 Myocardial Infarction/
- 2 Coronary Artery Bypass/
- 3 Angina Pectoris/
- 4 Angioplasty, Transluminal, Percutaneous Coronary/
- 5 Coronary Disease/pc, rh, th [Prevention & Control, Rehabilitation, Therapy]
- 6 (PTCA or CABG).tw.
- 7 "coronary heart disease".tw.
- 8 "angina pectoris".tw.
- 9 or/1-8
- 10 Patient Education as Topic/
- 11 Health Education/
- 12 Psychotherapy, Group/
- 13 Health Promotion/
- 14 Telemedicine/
- 15 Counseling/
- 16 "Continuity of Patient Care"/
- 17 Self Care/
- 18 behavior therapy/ed, mt

- 19 (behavior?r\* adj5 intervention\*).tw.  
 20 (lifestyle\* adj5 (intervention\* or education\*)).tw.  
 21 Health Knowledge, Attitudes, Practice/  
 22 Preventive Health Services/  
 23 Secondary Prevention/  
 24 risk reduction behavior/  
 25 Inpatients/ed [Education]  
 26 Outpatients/ed [Education]  
 27 consumer participation/  
 28 "cardiac rehabilitation".tw.  
 29 (rehabilitat\* adj5 (service\* or group\* or program\* or session\* or educat\*)).tw.  
 30 \*rehabilitation/  
 31 audiovisual aids/  
 32 "patient information".tw.  
 33 "patient education".tw.  
 34 "education\* intervention\*".tw.  
 35 (behavior?r\* adj5 educat\*).tw.  
 36 (educat\* adj5 rehabilitation).tw.  
 37 (program\* and (literature or audiovisual or "av" or Internet or website\* or telecare or telemedicine or telephone or phone or teleconference or telehealth or transtelephonic\* or podcast\*)).tw.  
 38 (rehabilitation and (literature or audiovisual or "av" or Internet or website\* or telecare or telemedicine or telephone or phone or teleconference or telehealth or transtelephonic\* or podcast\*)).tw.  
 39 (instruction\* and (literature or audiovisual or "av" or Internet or website\* or telecare or telemedicine or telephone or phone or teleconference or telehealth or transtelephonic\* or podcast\*)).tw.  
 40 (teach\* and (literature or audiovisual or "av" or Internet or website\* or telecare or telemedicine or telephone or phone or teleconference or telehealth or transtelephonic\* or podcast\*)).tw.  
 41 (learn\* and (literature or audiovisual or "av" or Internet or website\* or telecare or telemedicine or telephone or phone or teleconference or telehealth or transtelephonic\* or podcast\*)).tw.  
 42 (educat\* and (literature or audiovisual or "av" or Internet or website\* or telecare or telemedicine or telephone or phone or teleconference or telehealth or transtelephonic\* or podcast\*)).tw.  
 43 ("public health" adj (intervention\* or program\* or scheme\*)).tw.  
 44 "education\* program\*".tw.  
 45 psychoeducation\*.tw.  
 46 educat\*.tw.  
 47 (program\* and (risk adj1 reduc\*)).tw.  
 48 (patient\* adj3 (instruct\* or teach\* or taught or learn\* or knowledge)).tw.  
 49 "community based intervention\*".tw.  
 50 or/10-49  
 51 Randomized Controlled Trials as Topic/  
 52 randomized controlled trial.pt.  
 53 controlled clinical trial.pt.  
 54 Controlled Clinical Trial/  
 55 placebos/  
 56 random allocation/  
 57 Double-Blind Method/  
 58 Single-Blind Method/  
 59 (random\* adj2 allocat\*).tw.  
 60 placebo\*.tw.  
 61 ((singl\* or doubl\* or trebl\* or tripl\*) adj (blind\* or mask\*)).tw.  
 62 Research Design/  
 63 ((random\* or control\*) adj5 (trial\* or stud\*)).tw.  
 64 randomly.ab.  
 65 (randomized or randomised).ab.



66 meta analysis as topic/  
67 meta analysis.pt.  
68 meta analy\*.tw.  
69 metaanaly\*.tw.  
70 meta analysis/  
71 academic\* review\*.tw.  
72 meta regress\*.tw.  
73 (systematic\* adj (review\* or overview\* or synthes\*)).tw.  
74 (quantitative\* adj (review\* or overview\* or sythes\* or pool\*)).tw.  
75 research synthes\*.tw.  
76 (pool\* adj4 result\*).tw.  
77 (pool adj4 estimate\*).tw.  
78 hand search\*.tw.  
79 manual search\*.tw.  
80 data extraction.ab.  
81 (cochrane or medline or pubmed or embase or cinahl or psychinfo or pyschlit or “science citation index”).tw.  
82 or/51-81  
83 9 and 50 and 82  
84 (letter or editorial or comment).pt.  
85 83 not 84  
86 limit 85 to yr=“1990 -Current”

#### **EMBASE SEARCH STRATEGY (OVID)**

1 heart infarction/  
2 Coronary Artery Bypass Graft/  
3 Angina Pectoris/  
4 Transluminal Coronary Angioplasty/  
5 Coronary Artery Disease/  
6 (PTCA or CABG or “coronary artery stenting”).tw.  
7 (“MI” or “myocardial infarction”).tw.  
8 “coronary heart disease”.tw.  
9 “angina pectoris”.tw.  
10 or/1-8  
11 secondary prevention/  
12 10 and 11  
13 heart infarction/rh or Coronary Artery Bypass Graft/rh or Angina Pectoris/rh or Transluminal Coronary Angioplasty/rh or Coronary Artery Disease/rh  
14 12 or 13  
15 Patient Education/  
16 Health Education/  
17 Telemedicine/  
18 Patient Counseling/  
19 Telehealth/  
20 Self Care/  
21 (behavio?r\* adj5 intervention\*).tw.  
22 (lifestyle\* adj5 (intervention\* or education\*)).tw.  
23 Preventive Health Service/  
24 “cardiac rehabilitation”.tw.  
25 (rehabilitat\* adj5 (service\* or group\* or program\* or session\* or educat\*)).tw.  
26 heart rehabilitation/  
27 rehabilitation center/  
28 \*rehabilitation/  
29 health program/  
30 community program/

31 audiovisual aids/  
 32 "patient information".tw.  
 33 "patient education".tw.  
 34 "education\* intervention\*".tw.  
 35 (educat\* adj5 rehabilitation).tw.  
 36 (program\* adj5 (literature or audiovisual or "av" or Internet or website\* or telecare or telemedicine or telephone or phone or teleconference or telehealth or transtelephonic\* or podcast\*)).tw.  
 37 (rehabilitation adj5 (literature or audiovisual or "av" or Internet or website\* or telecare or telemedicine or telephone or phone or teleconference or telehealth or transtelephonic\* or podcast\*)).tw.  
 38 (education\* adj5 (literature or audiovisual or "av" or Internet or website\* or telecare or telemedicine or telephone or phone or teleconference or telehealth or transtelephonic\* or podcast\*)).tw.  
 39 "education\* adj3 program\*".tw.  
 40 psychoeducation\*.tw.  
 41 (program\* and (risk adj1 reduc\*)).tw.  
 42 "community based intervention\*".tw.  
 43 or/15-42  
 44 Randomized Controlled Trial/  
 45 Controlled study/  
 46 placebo/  
 47 controlled clinical trial/  
 48 random allocation/  
 49 Double Blind Procedure/  
 50 Single Blind Procedure/  
 51 (random\* adj2 allocat\*).tw.  
 52 placebo\*.tw.  
 53 ((singl\* or doubl\* or trebl\* or tripl\*) adj (blind\* or mask\*)).tw.  
 54 ((random\* or control\*) adj5 (trial\* or stud\*)).tw.  
 55 randomly.ab.  
 56 (randomized or randomised).ab.  
 57 meta analysis/  
 58 meta analy\*.tw.  
 59 metaanaly\*.tw.  
 60 meta analysis/  
 61 academic\* review\*.tw.  
 62 "systematic review"/  
 63 (systematic\* adj (review\* or overview\* or synthes\*)).tw.  
 64 (quantitative\* adj (review\* or overview\* or sythes\* or pool\*)).tw.  
 65 hand search\*.tw.  
 66 manual search\*.tw.  
 67 (cochrane or medline or pubmed or embase or cinahl or psychinfo or pyschlit or "science citation index").ab.  
 68 or/44-67  
 69 14 and 43 and 68  
 70 10 and (15 or 16 or 17 or 19 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39)  
 71 68 and 70  
 72 69 or 71  
 73 \*heart infarction/ or \*Coronary Artery Disease/ or \*Angina Pectoris/ or \*Transluminal Coronary Angioplasty/  
 74 "coronary heart disease".ti,ab.  
 75 73 or 74  
 76 43 and 68 and 75  
 77 72 or 76  
 78 limit 77 to yr="1990 -Current"  
**PsycINFO SEARCH STRATEGY (EBSCO)**  
 S1 TX "coronary heart disease"

S2 TX "coronary disease"  
 S3 TX myocardial infarct\*  
 S4 TX angina pectoris  
 S5 TX stenocardia\*  
 S6 TX coronary artery bypass\*  
 S7 TX CABG or TX PCTA  
 S8 TX coronary N3 angioplast\*  
 S9 TX myocardial revasculari\*  
 S10 TX coronary artery revascularization or TX coronary artery revascularisation  
 S11 TX coronary revascularization or TX coronary revascularisation  
 S12 TX CHD  
 S13 DE "Heart Disorders" OR DE "Angina Pectoris" OR DE "Coronary Thromboses" OR DE "Myocardial Infarctions"  
 S14 TX aortocoronary bypass\*  
 S15 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14  
 S16 DE "Telemedicine"  
 S17 DE "Health Education"  
 S18 DE "Rehabilitation Education"  
 S19 TX cardiac rehabilitat\*  
 S20 TX patient\* educat\*  
 S21 TX patient\* information  
 S22 TX information provi\*  
 S23 DE "Intervention" or DE "Early Intervention" OR DE "Family Intervention" OR DE "Group Intervention"  
 S24 DE "Lifestyle Changes" OR MM "Health Behavior"  
 S25 DE "Educational Counseling"  
 S26 S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or  
 S27 TX (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\*)  
 S28 TX educat\*  
 S29 S27 and S28  
 S30 S26 or S29  
 S31 S15 and S30  
 S32 DE "Between Groups Design"  
 S33 TX (random or randomly or randomised or randomized)  
 S34 TX controlled trial\*  
 S35 TI (trial or trials or study or studies)  
 S36 S32 or S33 or S34 or S35  
 S37 S31 and S36  
 S38 PY 1990-2010  
 S39 S37 and S38

**CINAHL SEARCH STRATEGY (EBSCO)**

S1 (MH "Myocardial Infarction")  
 S2 (MH "Coronary Disease+")  
 S3 (MH "Coronary Artery Bypass")  
 S4 (MH "Angioplasty, Transluminal, Percutaneous Coronary")  
 S5 (MH "Angina Pectoris")  
 S6 TX coronary revasculari?ation  
 S7 TX CABG  
 S8 TX PTCA  
 S9 TX "coronary heart disease"  
 S10 TX coronary N5 stent\*  
 S11 TX "angina pectoris"  
 S12 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11  
 S13 (MH "Rehabilitation") or (MH "Cardiac Rehabilitation) (Saba CCC)“)

S14 (MH "Rehabilitation Patients") or (MH "Rehabilitation, Cardiac") or (MH "Rehabilitation, Community-Based")  
 S15 (MH "Rehabilitation Nursing")  
 S16 (MH "Rehabilitation Centers")  
 S17 TX rehabi\*  
 S18 (MH "After Care")  
 S19 TX (multidisciplinary N5 intervention\*)  
 S20 TX (multidisciplinary N5 program\*)  
 S21 TX "secondary prevention"  
 S22 S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21  
 S23 S12 and S22  
 S24 (MH "Patient Education+")  
 S25 TX patient\* N5 educat\*  
 S26 TX inpatient\* N5 educat\*  
 S27 TX outpatient\* N5 educat\*  
 S28 TX (audiovisual or AV or telemedicine or telecare or telehealth or transtelephonic or teleconferenc\* or telephon\* or phone or phoning or phones or podcast  
 S29 (MH "Audiovisuals")  
 S30 TX educat\*  
 S31 psychoeducat\*  
 S32 TX (Internet or website)  
 S33 S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32  
 S34 S23 and S33  
 S35 (MH "Clinical Trials+")  
 S36 (MH "Double-Blind Studies") or (MH "Single-Blind Studies") or (MH "Triple-Blind Studies")  
 S37 (MH "Random Assignment") or (MH "Simple Random Sample") or (MH "Stratified Random Sample") or (MH "Systematic Random Sample")  
 S38 (MH "Placebos")  
 S39 TX randomi?ed controlled trial  
 S40 TX random\* N5 trial\*  
 S41 (MH "Systematic Review") or (MH "Cochrane Library")  
 S42 (MH "Meta Analysis")  
 S43 S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42  
 S44 S34 and S43

## CONTRIBUTIONS OF AUTHORS

All authors were involved in the conception and design of the protocol and the review. KW developed and ran the search strategy. JB and RST undertook the study selection, data extraction and risk of bias assessment. JB wrote the first draft of the protocol and review text. All authors contributed to the review and editing of subsequent draft versions. The final manuscript was approved by all authors.

## DECLARATIONS OF INTEREST

None declared.

## SOURCES OF SUPPORT

### Internal sources

- No sources of support supplied

### External sources

- NIHR, UK Cochrane Collaboration Programme Grant, UK.

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the protocol we stated that we planned to use meta-regression and stratified meta-analyses to explore heterogeneity and to compare and investigate the different modalities of education delivery as well as to investigate particular subgroups of CHD patients. However, as outlined in the report of this review, there was insufficient data to undertake such analyses.

## NOTES

Searches were completed in August 2010 after submission and finalisation of the revised protocol to Cochrane Heart Group. The protocol was published in December 2010.

## INDEX TERMS

### Medical Subject Headings (MeSH)

\*Coronary Disease [economics; mortality; rehabilitation]; \*Health Care Costs; \*Health Status; \*Patient Education as Topic; \*Quality of Life; Health Services Needs and Demand [utilization]; Myocardial Infarction [prevention & control]; Randomized Controlled Trials as Topic

### MeSH check words

Adult; Humans; Middle Aged