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## Sexual counselling for sexual problems in patients with cardiovascular disease (Review)

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[Intervention Review]

# Sexual counselling for sexual problems in patients with cardiovascular disease

Molly Byrne<sup>1</sup>, Sally Doherty<sup>2</sup>, Bengt GA Fridlund<sup>3</sup>, Jan Mårtensson<sup>4</sup>, Elaine E Steinke<sup>5</sup>, Tiny Jaarsma<sup>6</sup>, Declan Devane<sup>7</sup>

<sup>1</sup>School of Psychology, National University of Ireland, Galway, Galway, Ireland. <sup>2</sup>Department of Population and Health Science, School of Psychology, RCSI, Dublin, Ireland. <sup>3</sup>School of Health Sciences, Jönköping University, Jönköping, Sweden. <sup>4</sup>Department of Nursing, School of Health Sciences, Jönköping University, Jönköping, Sweden. <sup>5</sup>School of Nursing, Wichita State University, Wichita, Kansas, USA. <sup>6</sup>Department of Social and Welfare Studies, University of Linköping, Norrköping, Sweden. <sup>7</sup>School of Nursing and Midwifery, National University of Ireland Galway, Galway, Ireland

Contact address: Molly Byrne, School of Psychology, National University of Ireland, Galway, St. Anthony's, Galway, County Galway, Ireland. [molly.byrne@nuigalway.ie](mailto:molly.byrne@nuigalway.ie).

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## ABSTRACT

### Background

Sexual problems are common among people with cardiovascular disease. Although clinical guidelines recommend sexual counselling for patients and their partners, there is little evidence on its effectiveness.

### Objectives

To evaluate the effectiveness of sexual counselling interventions (in comparison to usual care) on sexuality-related outcomes in patients with cardiovascular disease and their partners.

### Search methods

We searched CENTRAL, MEDLINE, EMBASE, and three other databases up to 2 March 2015 and two trials registers up to 3 February 2016.

### Selection criteria

Randomised controlled trials (RCTs) and quasi-RCTs, including individual and cluster RCTs. We included studies that compared any intervention to counsel adult cardiac patients about sexual problems with usual care.

### Data collection and analysis

We used standard methodological procedures expected by Cochrane.

### Main results

We included three trials with 381 participants. We were unable to pool the data from the included studies due to the differences in interventions used; therefore we synthesised the trial findings narratively.

Two trials were conducted in the USA and one was undertaken in Israel. All trials included participants who were admitted to hospital with myocardial infarction (MI), and one trial also included participants who had undergone coronary artery bypass grafting. All trials followed up participants for a minimum of three months post-intervention; the longest follow-up timepoint was five months.

One trial (N = 92) tested an intensive (total five hours) psychotherapeutic sexual counselling intervention delivered by a sexual therapist. One trial (N = 115) used a 15-minute educational video plus written material on resuming sexual activity following a MI. One trial (N = 174) tested the addition of a component that focused on resumption of sexual activity following a MI within a hospital cardiac rehabilitation programme.

The quality of the evidence for all outcomes was very low.

None of the included studies reported any outcomes from partners.

Two trials reported sexual function. One trial compared intervention and control groups on 12 separate sexual function subscales and used a repeated measures analysis of variance (ANOVA) test. They reported statistically significant differences in favour of the intervention. One trial compared intervention and control groups using a repeated measures analysis of covariance (ANCOVA), and concluded: "There were no significant differences between the two groups [for sexual function] at any of the time points".

Two trials reported sexual satisfaction. In one trial, the authors compared sexual satisfaction between intervention and control and used a repeated measured ANOVA; they reported "differences were reported in favour of the intervention". One trial compared intervention and control with a repeated measures ANCOVA and reported: "There were no significant differences between the two groups [for sexual satisfaction] at any of the timepoints".

All three included trials reported the number of patients returning to sexual activity following MI. One trial found some evidence of an effect of sexual counselling on reported rate of return to sexual activity (yes/no) at four months after completion of the intervention (relative risk (RR) 1.71, 95% confidence interval (CI) 1.26 to 2.32; one trial, 92 participants, very low quality of evidence). Two trials found no evidence of an effect of sexual counselling on rate of return to sexual activity at 12 week (RR 1.01, 95% CI 0.94 to 1.09; one trial, 127 participants, very low quality of evidence) and three month follow-up (RR 0.98, 95% CI 0.88 to 1.10; one trial, 115 participants, very low quality of evidence).

Two trials reported psychological well-being. In one trial, no scores were reported, but the trial authors stated: "No treatment effects were observed on state anxiety as measured in three points in time". In the other trial no scores were reported but, based on results of a repeated measures ANCOVA to compare intervention and control groups, the trial authors stated: "The experimental group had significantly greater anxiety at one month post MI". They also reported: "There were no significant differences between the two groups [for anxiety] at any other time points".

One trial reporting relationship satisfaction and one trial reporting quality of life found no differences between intervention and control.

No trial reported on satisfaction in how sexual issues were addressed in cardiac rehabilitation services.

### **Authors' conclusions**

We found no high quality evidence to support the effectiveness of sexual counselling for sexual problems in patients with cardiovascular disease. There is a clear need for robust, methodologically rigorous, adequately powered RCTs to test the effectiveness of sexual counselling interventions for people with cardiovascular disease and their partners.

## **PLAIN LANGUAGE SUMMARY**

### **Sexual counselling interventions for sexual problems in people with heart disease**

#### **Review question**

Are sexual counselling interventions helpful in reducing sexual problems for people with heart disease and their partners?

#### **Background**

People with heart disease are more likely than people without heart disease to report sexual problems. Sexual counselling for people with heart disease is when a health professional supports a person to safely return to sexual activity after their heart event, by giving them information and helping them to deal with their concerns and anxieties.

### **Study characteristics**

We searched the international literature up to March 2015 for studies that compared any intervention designed to address and counsel people with heart disease in relation to sexual problems with usual care.

### **Key results**

Three randomised controlled trials (clinical trials where people are allocated at random to one of two or more treatments) that included 381 participants in total met our inclusion criteria. The interventions tested in these studies were quite different from each other. All studies included people who had been admitted to hospital with a heart attack.

These studies do not provide strong evidence that sexual counselling can improve sexual outcomes for people with heart disease or their partners. One study, which reported the effects of an intensive intervention, involved five hours of sexual counselling provided by a psychotherapist. It reported improved sexual functioning and satisfaction, and reduced length of time taken for people to return to sexual activity following a cardiac event, in people that received the intervention compared to usual care. The other two studies reported no differences between people that received the intervention and usual care on these outcomes (both studies measured rate of return to sexual activity following a cardiac event; one of these two studies measured sexual functioning and satisfaction). There was no evidence that sexual counselling has an effect on quality of life (measured in one study) or marital satisfaction (measured in one study). One study found that patients who received a 15-minute sexual counselling educational video plus written material had higher levels of anxiety than usual care, as well as better knowledge about sex after a heart attack, one month after their cardiac event, but not at any other timepoints.

### **Quality of the evidence**

The evidence was of very low quality. We judged the included studies to be at high risk of bias and study results were poorly reported. Bearing this in mind, the results of this review should be interpreted with caution.

## SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Sexual counselling compared with usual care for patients with cardiovascular disease			
<p><b>Participant or population:</b> participants with cardiovascular disease  <b>Setting:</b> health services  <b>Intervention:</b> sexual counselling interventions  <b>Comparison:</b> usual care</p>			
Outcomes	Effect sexual counselling for participants with cardiovascular disease	Number of participants (studies)	Quality of the evidence (GRADE)
Sexual function	One study found higher levels of sexual function (assessed using the Sexual Function for Cardiac Patient Questionnaire) in the intervention group in comparison to the control group at one and four month follow-up. Another study found no difference in sexual function (assessed using the Watts Sexual Function Questionnaire (WSFQ)) between intervention and control groups at any timepoint	207 (2 RCTs)	⊕○○○ very low <sup>1,2</sup>
Sexual satisfaction	One study found higher levels of satisfaction with the quality of sexual relations with partner (assessed as a subscale of the Sexual Function for Cardiac Patient Questionnaire) in the intervention group in comparison to the control group. Another study found no difference in sexual satisfaction (assessed as a subscale of the WSFQ) between intervention and control groups at any timepoint	207 (2 RCTs)	⊕○○○ very low <sup>1,2</sup>
Relationship satisfaction	One study found no difference in relationship satisfaction (assessed using Olson's Enrich Marital Satisfaction questionnaire) between intervention and control groups at any timepoint	92 (1 RCT)	⊕○○○ very low <sup>2,3</sup>

Quality of life	One study found no difference in quality of life (assessed using the Ferrans and Powers Quality of Life Index (QLI Cardiac Version III) between intervention and control groups at any timepoint	115 (1 RCT)	⊕○○○ very low <sup>2,4</sup>
Anxiety	One study found no difference in anxiety (assessed using Speilberger's Anxiety Scale) between intervention and control groups at any timepoint. Another study found higher levels of anxiety (assessed using Speilberger's Anxiety Scale) in the intervention group in comparison to the control group at one month follow-up, but not at other timepoints	207 (2 RCTs)	⊕○○○ very low <sup>1,2</sup>
Resumption of sexual activity after a cardiac event (Resumption of sex)	All three studies reported the number of patients returning to sexual activity following myocardial infarction (MI) as an outcome. One study found some evidence of an effect of sexual counselling on reported rate of return to sexual activity (yes/no) at 4 months after completing the intervention (relative risk (RR) 1.71, 95% CI 1.26 to 2.32; 1 trial, 92 participants, very low quality of evidence). Two studies found no evidence of an effect of sexual counselling on rate of return to sexual activity at 12 weeks (RR 1.01, 95% CI 0.94 to 1.09; 1 trial, 127 participants, very low quality of evidence) and 3 months follow-up (RR 0.98, 95% CI 0.88 to 1.10; 1 trial, 115 participants, very low quality of evidence)	334 (3 RCTs)	⊕○○○ very low <sup>5,6</sup>

Satisfaction in how sexual issues are addressed in cardiac rehabilitation services (Satisfaction with health services)	No included studies reported (0 studies) satisfaction with how sexual issues were addressed in cardiac rehabilitation services	
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\* **The risk in the intervention group** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**Abbreviations:** **CI:** confidence interval; **RR:** risk ratio; **OR:** odds ratio; **MI:** myocardial infarction; **RCT:** randomised controlled trial; **WSFQ:** Watts Sexual Function Questionnaire.

#### GRADE Working Group grades of evidence

**High quality:** we are very confident that the true effect lies close to that of the estimate of the effect.

**Moderate quality:** we are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

**Low quality:** our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

**Very low quality:** we have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

<sup>1</sup>Downgraded by one for risk of bias. One study was at unclear risk for sequence generation; 2 studies were at unclear risk for allocation concealment; 2 studies were at high risk for blinding of participants, incomplete outcome data, and other biases; and 2 studies were at unclear risk for blinding of outcome assessment.

<sup>2</sup>Downgraded by two for imprecision. The total sample size was less than 400 (this is a threshold rule-of-thumb value suggested by GRADE Working Group, which uses the usual alpha and beta, and an effect size of 0.2 SD, representing a small effect).

<sup>3</sup>Downgraded by one for risk of bias. This trial was at unclear risk for sequence generation, allocation concealment and blinding of outcome assessment; and at high risk for blinding of participants, incomplete outcome data, and other biases].

<sup>4</sup>Downgraded by one for risk of bias. This trials was at unclear risk for allocation concealment and blinding; and at high risk for blinding, incomplete outcome data, and other biases.

<sup>5</sup>Downgraded by two for risk of bias. Two studies were at unclear risk for sequence generation; three studies were at unclear risk for allocation concealment; three studies were at high risk for blinding of participants; incomplete outcome data, and other biases; and one study was at high risk and two studies were at unclear risk for blinding of outcome assessment.

<sup>6</sup>Downgraded by one for imprecision. The total number of events was less than 300 (a threshold rule-of-thumb value suggested by the Grade Working Group).

## BACKGROUND

### Description of the condition

Sexual problems, such as erectile dysfunction among men and pain during intercourse among women, can occur frequently in relation to cardiac disease and its associated risk factors, medications, and psychological sequelae (Jaarsma 2010a; Jaarsma 2010b). Such problems are more prevalent among both men (Schumann 2010) and women (Kutmeç 2011) with cardiovascular disease than those without cardiovascular disease; the prevalence rates for men

range from 20% (Schumann 2010) to 70% (Mulat 2010), and for women from 43% (Kriston 2010) to 87% (Schwarz 2008).

Reasons for the association between sexual problems and cardiovascular disease include physical vascular causes (Dong 2011), fear of sexual activity provoking cardiac symptoms or a cardiac event (Katz 2007), patient-partner relationship changes following a cardiac event (Dalteg 2011), and associations with psychological problems such as depression (Kriston 2010). Although there is evidence to suggest that some cardiac medications, including beta blockers and lipid-lowering medications, may have sexual side effects, more recent analyses concluded that cardiovascular medica-

tions are uncommonly the true cause of sexual problems (Levine 2012).

Sexual dysfunction can impact negatively on quality of life, psychological well-being, and marital or partnership satisfaction (Traeen 2007; Günzler 2009). Social support and strong intimate relationships are important predictors of outcomes for people with chronic cardiovascular illness, and poor marital quality can predict patient mortality (Coyné 2001). Sexual problems also impact cardiac patients' partners, who rate sexual concerns as one of the most prevalent stressors related to their partner's condition (O'Farrell 2000).

Return to sexual activity after an acute cardiac event, or maintenance of a satisfactory sex life when living with chronic cardiovascular disease, can pose challenges for cardiovascular patients and their partners. It has been recommended that sexual problem assessment and counselling should form part of routine care for cardiovascular patients (Steinke 2013a). While those with cardiac disease view information about return to sexual activity as an important component of their general rehabilitation (Steinke 1998; Mosack 2009), health professionals have been reluctant to address sexual counselling in practice (Byrne 2010; Djurović 2010; Ivarsson 2010; Jaarsma 2010c; Goossens 2011; D'Eath 2013), including staff in cardiac rehabilitation (Barnason 2011; Doherty 2011). Reasons for provider reluctance include a lack of confidence and education required to address these concerns adequately (Byrne 2010; Doherty 2011; Hoekstra 2012a).

## Description of the intervention

"Counselling" refers to "systematic consultations in primary care for addressing emotional, psychological and social issues that influence a person's health and well-being" (WHO 2015). There is some evidence for the effectiveness of sexual counselling, psychoeducational, and psychological therapeutic approaches for sexual problems on general sexual function and satisfaction for general populations. A Cochrane review of psychosocial interventions for erectile dysfunction, which included 11 trials involving 398 men with erectile dysfunction, concluded that group psychotherapy was more likely than the control group (who received no treatment) to reduce the number of men with "persistence of erectile dysfunction" post-treatment (Melnik 2007). A systematic review in the area of cancer, which included eight trials, concluded that there was some evidence that psychoeducational interventions improved sexual function and reduced 'sexual bother' in men following prostatectomy for prostate cancer (Lassen 2013). Sexual counselling may also enhance the effectiveness of other treatments for sexual dysfunction. For example, sexual counselling improved self-administration of pharmacological interventions for sexual dysfunction among people that received treatment for cancer (Miles 2007) and reduced levels of drop-out from drug therapy interventions that targeted erectile dysfunction among the general population (Melnik 2007).

Although most research focuses on sexual dysfunction in men, some research supports the effectiveness of psychoeducational interventions for sexual problems among women. For example, a brief three-session psychoeducational intervention significantly improved aspects of sexual response, mood, and quality of life in women with gynaecological cancer (Brotto 2008). A review of psychological interventions for couples coping with breast cancer concluded that they are effective in improving sexual functioning and sexual satisfaction among women (Brandão 2014).

The aims of sexual counselling (hereafter referred to as counselling) interventions for cardiac patients are to assess existing sexual problems, provide information on concerns, and support safe return to sexual activity after a cardiac event or procedure. Counselling interventions address specific psychological or interpersonal factors, sexual performance concerns, and issues related to medication and co-morbid conditions that may affect sexual functioning (Lue 2004). Non-sexual aspects of a relationship may also be addressed in a counselling intervention, such as the need for intimacy in the relationship (Steinke 2004). A range of different types of health professionals or other appropriately trained individuals may administer counselling interventions. These interventions may be delivered as separate, stand-alone interventions or as a component of more comprehensive rehabilitation interventions, such as in hospital cardiac rehabilitation following a cardiac event or procedure. Counselling interventions may involve a one-to-one exchange between a health professional and patient (in person or over the telephone) or may be delivered by a health professional to a group of cardiac patients. They may use one or a number of didactic and counselling approaches, including oral information or dialogue, visual information, written materials, audiovisual materials, and practical training. Counselling interventions may involve the cardiac patient alone or the cardiac patient with his or her partner or spouse. Interventions can be short-term, for example provision of brief information on return to sexual activity (Kushnir 1976; Fridlund 1991), or longer-term, for example providing cognitive behavioural therapy directed towards both psychological and physical aspects of sex and intimate relations (Klein 2007; Song 2011). Interventions may involve a single encounter or multiple encounters with a health professional.

Many issues related to both the health professional and the patient and their partner influence the delivery and effectiveness of counselling interventions. These can include gender and age differences of the health professional and the recipient, cultural and religious issues, and sexuality of the couple (Klein 2007; O'Donovan 2007; Hoga 2010; Goossens 2011). The nature and extent of the cardiac event itself may vary in complexity (Jaarsma 2010c), and more complex conditions require a more focused and specialised sexual counselling intervention (Ivarsson 2009; Ivarsson 2010). Health professionals' own beliefs about sexuality may influence the delivery of counselling interventions, for example health professionals may adhere to myths and biases regarding the need for counselling based on the age of the patient experiencing the cardiac event and

their gender (Kazemi-Saleh 2008; Taylor 2011; Hoekstra 2012a; Hoekstra 2012b). Apart from the individual health professional, organisational structures related to financial resources, availability of staff, time restrictions, and availability of private spaces can impact on the delivery and organisation of counselling interventions (Song 2011; Steinke 2012).

### How the intervention might work

Counselling interventions are likely to work by providing useful information, which may reduce anxiety related to sexual problems and fears about resuming sexual activity after a cardiac event. They may also increase confidence in sexual abilities and potential, improve patient-partner communication around changes to sexual activity required following a cardiac event, provide practical guidance, and teach skills to support couples in returning to sex. In such interventions, health professionals may assess any risk associated with sexual activity and develop an individualised plan to guide safe resumption of sexual activity following a cardiac event or procedure (Gamel 1993; Levine 2012). Such information is likely to alleviate fears associated with return to sexual activity and provide patients and partners with greater confidence in their ability to assess if, and when, it is right for them to return to sexual activity. Counselling interventions aim to provide correct information and dispel myths about how cardiac disease impacts on sexual activity. By giving cardiac patients the opportunity to express their sexual concerns, interventions in this area are likely to 'normalise' these concerns and reassure patients and their partners that sexual problems are common after a cardiac event and can be addressed. Counselling interventions may also provide practical guidance to patients about how to return to sexual activity (Mosack 2009). Such guidance may include aspects such as ideal timing (when the patient is not tired) and setting (comfortable and familiar), and warn against things that may increase risks associated with sexual activity, for example sex should generally be avoided following a heavy meal (Levine 2012).

The effectiveness of interventions can be evaluated by assessment of outcomes that reflect the ways in which the intervention is likely to work. These include changes in sexual activity levels and resumption of sexual activity following a cardiac event or procedure, sexual knowledge, sexual function and satisfaction, and quality of life (Bertie 1992; Klein 2007; Song 2011; Steinke 2012).

### Why it is important to do this review

Worldwide, cardiovascular disease is a leading cause of morbidity and mortality. However, survival rates are increasing which is resulting in an increasing number of people living in the community with some form of cardiovascular disease (WHO 2011). Counselling for patients and their partners or spouses has been recommended as an important component of cardiac rehabilita-

tion (Levine 2012; Steinke 2013a). There is ample literature to indicate that counselling of cardiac patients is infrequently provided in practice (Steinke 1998; Goossens 2011; Steinke 2011a). However, when asked, cardiac patients (Byrne 2013) and their partners (O' Farrell 2000; Fisher 2005; Agren 2009) generally report that this is something they would appreciate. While health professionals report responsibility for, and some knowledge of, counselling provision (Steinke 2011b), there is a lack of follow-through in implementation of counselling interventions in daily practice (Pouraboli 2010; Yildiz 2012). Published trials have examined the effectiveness of counselling interventions, yet there is currently no systematic review of these studies. A well-conducted systematic review is needed to inform health professionals, patients and their partners, and policy makers about the effectiveness of such interventions. In addition, an evaluation of interventions may provide insights into which strategies might be most or least effective for cardiac patients, as well as which interventions may be most amenable to use in busy practice settings by health professionals.

## OBJECTIVES

To evaluate the effectiveness of sexual counselling interventions (in comparison to usual care) on sexuality-related outcomes in patients with cardiovascular disease and their partners.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomised controlled trials (RCTs) and quasi-RCTs (including individual and cluster RCTs) were eligible for inclusion. We included studies that compared any form of sexual counselling with usual care.

#### Types of participants

Adults (aged 18 years or more) with cardiac disease including those who experienced a myocardial infarction (MI), a revascularisation procedure (coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty), those with angina or angiographically-defined coronary heart disease, heart failure, and congenital heart disease. We also included participants with heart transplants or implanted with either cardiac resynchronisation therapy or implantable defibrillators. We included the partners of these patients, when they were included in the study.

## Types of interventions

We considered all interventions designed to address and counsel cardiac patients in relation to sexual problems that may have arisen as a result of their cardiac condition.

For the purpose of this Cochrane review we used the following operational definitions.

A sexual counselling intervention is any intervention delivered by a health professional or appropriately trained individual (for example, a sex therapist) with the aim of providing cardiac patients with information on sexual concerns and safe return to sexual activity after a cardiac event or procedure, as well as assessment, support, and specific advice related to psychosexual and sexual problems related directly to their cardiac condition. Sexual counselling interventions may be delivered as a component of hospital cardiac rehabilitation following a cardiac event or procedure. Sexual counselling interventions may involve a one-to-one exchange between a health professional and patient (in person or over the telephone) or may be delivered by a health professional to a group of cardiac patients. Sexual counselling interventions may use one or more didactic approaches, including oral information or dialogue, visual information, written materials, audiovisual materials, and practical training. Sexual counselling interventions may involve the cardiac patient alone or the cardiac patient with his or her partner or spouse. Sexual counselling interventions can be short-term (for example, brief provision of information and counselling in the acute care setting) or longer-term (for example, ongoing counselling in the office setting on repeat patient visits) and may involve a single encounter with a health professional or multiple encounters.

We only considered trials where the comparison group was usual care or no sexual counselling intervention, and reported follow-up for at least three months post-intervention. 'Usual care' consisted of standard cardiac care, without the addition of sexual counselling as described above.

## Types of outcome measures

We included outcome measures from both patients with cardiac disease and their partners, where available.

### Primary outcomes

#### Participant

- Sexual function or sexual dysfunction, using validated instruments including:
  - Index of Erectile Function-5 (IIEF-5) (Rosen 1997);
  - Brief Male Sexual Function Inventory (BMSFI) (Mykletun 2006);
  - Female Sexual Function Index (FSFI) (Rosen 2000);
  - Brief Index of Sexual Functioning for Women (BISF-W) (Taylor 1994);

- Derogatis Interview for Sexual Functioning (DISF) and Derogatis Interview for Sexual Functioning - Self-Report (DISF-SR) (Derogatis 1997);
  - Changes in Sexual Functioning Questionnaire (CSFQ) (Clayton 1997) and Changes in Sexual Functioning-Short Form (CSFQ-SF) (Keller 2006);
  - Arizona Sexual Experience Scale (ASEX) (McGahuey 2000);
  - Sexual Function Questionnaire (SFQ) (Syrjala 2000);
  - Sexual Function Questionnaire (Quirk 2002);
  - European Male Ageing Study Sexual Function Questionnaire (EMAS-SFQ) (O'Connor 2008).
- Sexual satisfaction, using validated instruments including:
    - Sexual Self-Perception and Adjustment Questionnaire (SSPAQ) (Steinke 2013b);
    - Sexual Satisfaction Scale for Women (SSS-W) (Meston 2005).

#### Partner

- Sexual satisfaction, using validated instruments including:
  - SSPAQ (Steinke 2013b).

### Secondary outcomes

#### Patient

- Marital or relationship satisfaction, using validated instruments including:
    - ENRICH Marital Satisfaction Scale (Fowers 1993).
  - Quality of life, using validated instruments including:
    - Ferrans and Powers Quality of Life Index (QLI) - Cardiac Version III (Ferrans 1985);
    - 36-item Short Form Health Survey (SF-36) (Ware 1992) or the 12-item Short Form Health Survey (SF-12) (Ware 1995).
    - Psychological well-being (including anxiety and depression), using validated instruments including:
      - Spielberger's State-Trait Anxiety Inventory (Spielberger 1983).
      - Satisfaction in how sexual issues are addressed in cardiac rehabilitation services.
      - Resumption of sexual activity after a cardiac event: (a) presence or absence of sexual activity; (b) frequency of sexual activity; and (c) time taken to resume sexual activity after cardiac event or procedure, using validated instruments including:
        - Return to Sexual Activity Inventory (Steinke 2004).
      - Knowledge about sex after an MI, using a validated instrument such as:
        - 25-item Sex After MI Knowledge Test (Steinke 2004).
- We did not include this outcome in the protocol for this review,

Byrne 2014, but we later identified and included it in the review as a potentially useful outcome to consider.

### Partner

- Satisfaction in how sexual issues are addressed in cardiac rehabilitation services.
- Marital or relationship satisfaction, using validated instruments including:
  - ENRICH Marital Satisfaction Scale (Fowers 1993).
- Quality of life or psychological well-being, using validated instruments including:
  - SF-36 (Ware 1992) or the SF-12 (Ware 1995).

### 'Summary of findings' table

We only included outcomes stated in the Cochrane protocol, Byrne 2014, in the 'Summary of findings' table of this Cochrane review. We have listed these outcomes below.

- Sexual function.
- Sexual satisfaction.
- Relationship satisfaction.
- Quality of life.
- Psychological well-being/anxiety.
- Resumption of sexual activity after a cardiac event.
- Satisfaction in how sexual issues are addressed in cardiac rehabilitation services.

## Search methods for identification of studies

### Electronic searches

The Cochrane Heart Group Trials Search Co-ordinator searched the following databases up to 2 March 2015 (except CENTRAL) without restrictions on language: CENTRAL (Issue 1 of 12, 2015; the Cochrane Library) (searched 21 March 2015); MEDLINE (OVID) (1946 to Feb week 4 2015); EMBASE (OVID) (1980 to 2015 week 09); CINAHL Plus with Full Text (EBSCO) (1937 to 02 March 2015); PsycINFO (OVID) (1806 to Feb week 4 2015); Conference Proceedings Citation Index - Science (CPCIS) on Web of Science (Thomson Reuters) (1990 to 27 February 2015). We searched Clinicaltrials.gov ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) and the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (<http://apps.who.int/trialsearch/>) up to 03 February 2016 and used the terms 'counselling' and 'sexual dysfunction'.

In the protocol, Byrne 2014, we proposed that we would "search reference lists of eligible papers and reviews" and "contact the principal investigators of identified studies to ascertain if they are aware of any other relevant published or unpublished studies in the area". We did not conduct these additional searches of other resources

as we, internationally experienced people in this field, considered it highly likely that we captured all ongoing intervention research activity via the core search strategies.

We applied the Cochrane sensitivity maximising RCT filter (Lefebvre 2011) to MEDLINE and adaptations of it to the other databases as applicable. The search strategies and search terms for all the databases are in Appendix 1.

### Searching other resources

We did not conduct any formal additional searches of resources. As outlined above, we considered it highly likely that we captured all ongoing intervention research activity via the core search strategies.

## Data collection and analysis

We used the *Cochrane Handbook for Systematic Reviews of Interventions* to inform the Methods (Higgins 2011).

### Selection of studies

One review author (MB) imported citations into a reference management software package (EndNote), and removed duplicates. MB then imported citations into the Covidence online systematic review management system ([www.covidence.org/](http://www.covidence.org/)). Using Covidence, two review authors (MB and SD) independently screened titles and abstracts for potentially eligible studies. We resolved any discrepancies by consensus.

We retrieved full-text publications of potentially eligible studies. Two review authors (MB and SD) independently determined study eligibility using a standardised inclusion form. We resolved any disagreements about study eligibility by discussion and, if necessary, we asked a third review author (DD) to arbitrate.

In the 'Characteristics of excluded studies' table we have listed all potentially eligible papers that we excluded from the review at the full-text stage, along with the reasons for exclusion.

We reported the screening and selection process in an adapted PRISMA flow chart. While we identified no ongoing studies in this Cochrane review, in future updates we will provide citation details and any available information about ongoing studies.

### Data extraction and management

For included studies, two review authors (MB and SD) independently extracted study characteristics and outcome data using a standardised data collection form we created for this Cochrane review.

We extracted the following data from each included study.

- Study details: author, year, research question, or study aim; country where the research was carried out; recruitment source (e.g. patients attending hospital cardiac rehabilitation); inclusion and exclusion criteria; study design (RCT; individual or cluster

RCT, and single- or multi-centre); length of follow-up; description of usual care.

- Intervention details: setting of intervention (hospital, general practice); delivered to individuals or groups; targeting patients only, or patient and partner dyads; degree of training of the person who provided the intervention; topics covered in the intervention; number of sessions in intervention; overall duration of intervention; timing of delivery of intervention in relation to cardiac history; mode of intervention (e.g. written information, DVD, lecture or talk, individual counselling).
- Participant characteristics: primary cardiac diagnosis; age; sex; socioeconomic status; ethnicity; reported co-morbidities.
- Primary and secondary outcomes.
- Numbers of participants randomised and assessed at specified follow-up points.
- Adherence to intervention and rate of attrition.

We resolved any discrepancies in data extraction by consensus. One review author (MB) transferred the extracted data into Review Manager (RevMan) (RevMan 2014) and a second review author (SD) spot-checked the data for accuracy.

### Assessment of risk of bias in included studies

Two review authors (MB and SD) independently assessed the risk of bias in included studies using the Cochrane 'Risk of bias' assessment tool (Higgins 2011). The 'Risk of bias' assessment comprised a judgement and a support for the judgement for each entry in a 'Risk of bias' table, where each entry addressed a specific feature of the study. The judgement for each entry involved assessment of the risk of bias as either 'low risk', 'high risk', or 'unclear risk', and the last category indicated either lack of information or uncertainty over the potential for bias.

We included the following 'Risk of bias' items.

- Random sequence generation (checking for possible selection bias).
- Allocation concealment (checking for possible selection bias).
- Blinding of participants and personnel (checking for possible performance bias).
- Blinding of outcome assessment (checking for possible detection bias).
- Incomplete outcome data (checking for possible attrition bias through withdrawals, people lost to follow-up, protocol deviations).
- Selective reporting (checking for reporting bias).
- Other bias (checking for other potential sources of bias not covered in the categories above).

Three review authors (MB, SD, and DD) resolved any discrepancies regarding 'Risk of bias' assessments by consensus.

### Measures of treatment effect

For dichotomous data, we presented the results as summary risk ratios (RRs) with 95% confidence intervals (CIs) where possible. For continuous data, we used the mean difference value with 95% CI for outcomes. In future updates, we will use the standardised mean difference with 95% CI to combine data that measured the same outcome but used different scales.

### Unit of analysis issues

We did not identify any cluster RCTs in our literature searches. In future updates of this Cochrane review, if we identify any cluster RCTs we will include them along with individually RCTs. We will adjust their sample sizes using the methods described in the *Handbook for Systematic Reviews of Interventions* (Higgins 2011) and using an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial, or from a study of a similar population. If we use ICCs from other sources we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify cluster RCTs and individually RCTs, we will synthesise the relevant information. We will consider it reasonable to combine the results from both where there is little heterogeneity between the study designs and where we consider that there is unlikely to be an interaction between the effect of the intervention and the choice of randomisation unit. We will acknowledge heterogeneity in the unit of randomisation and perform a sensitivity analysis to investigate the effects of this heterogeneity on the review findings.

### Dealing with missing data

We noted the levels of attrition in the included studies. However, we were unable to perform any data analysis in this review. If possible, we will perform analyses on an intention-to-treat basis for all outcomes in future updates of this Cochrane review.

### Assessment of heterogeneity

We were unable to pool data, and therefore we did not need to consider statistical heterogeneity.

In future updates of this review, if we are able to pool data, we will assess statistical heterogeneity in each meta-analysis using the Tau<sup>2</sup> (tau-squared) statistic, I<sup>2</sup> statistic, and Chi<sup>2</sup> test. We will regard heterogeneity as substantial if the I<sup>2</sup> statistic value is high (above 30%); and either there is inconsistency between trials in the direction or magnitude of effects (judged visually), or a low (less than 0.10) P value in the Chi<sup>2</sup> test for heterogeneity or the estimate of between-study heterogeneity (Tau<sup>2</sup>) is above zero.

### Assessment of reporting biases

As fewer than 10 studies met the inclusion criteria of this Cochrane review, we did not investigate publication bias using funnel plots.

In future updates of this review, if we include 10 or more studies in a meta-analysis, we will investigate publication bias using funnel plots by assessment of funnel plot asymmetry visually and by use of formal tests for funnel plot asymmetry. For continuous outcomes we will use the test proposed by [Egger 1997](#), and for dichotomous outcomes we will use the test proposed by [Harbord 2006](#). If we detect asymmetry in any of these tests, or it is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

### Data synthesis

We did not conduct any data synthesis.

We produced a narrative 'Summary of findings' table ([Higgins 2011](#)) using the GRADEpro Guideline Development Tool (GDT) ([www.gradepr.org](http://www.gradepr.org)). We summarised the quality of evidence and the strength of recommendations using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach for each of the seven outcomes pre-specified in our Cochrane protocol ([Byrne 2014](#)).

In future updates of this review, if meta-analysis of results is possible (as diversity is likely in the types and content of interventions included in the trials), we will use a random-effects model meta-analysis to produce an overall summary of the average treatment effect across all included trials. For each reported outcome, we will present the results of the random-effects model analyses as the average treatment effect with its 95% CI and the estimates of the  $\text{Tau}^2$  and the  $I^2$  statistic.

### Subgroup analysis and investigation of heterogeneity

We were unable to conduct any subgroup analysis as we did not pool findings from individual studies. In future updates of this review, if we include a sufficient number of studies in the meta-analyses (10 trials should be available for each characteristic modelled), we will perform subgroup analyses for the following.

- Delivery mode of intervention: intervention delivered to group versus delivered to individual.
- Delivery mode of intervention: 'face to face' versus 'distance delivery'.

- Target of intervention: intervention delivered to individuals (cardiovascular patients only) versus delivered to dyads or couples (cardiovascular patients plus their partners).
- Gender of intervention participant: male versus female.

We will assess subgroup differences by the interaction tests available in RevMan ([RevMan 2014](#)). We will report the results of subgroup analyses and quote the  $\text{Chi}^2$  test and P value, and the  $I^2$  statistic value of the interaction test.

### Sensitivity analysis

We did not perform a sensitivity analysis as we were unable to pool data from the individual included studies. In future updates of this Cochrane review, we will perform a sensitivity analysis by limiting analyses to studies at low risk of bias. We will do this by exclusion of studies at 'high' or 'unclear' risk of bias for sequence generation, allocation concealment, and incomplete outcome data.

## RESULTS

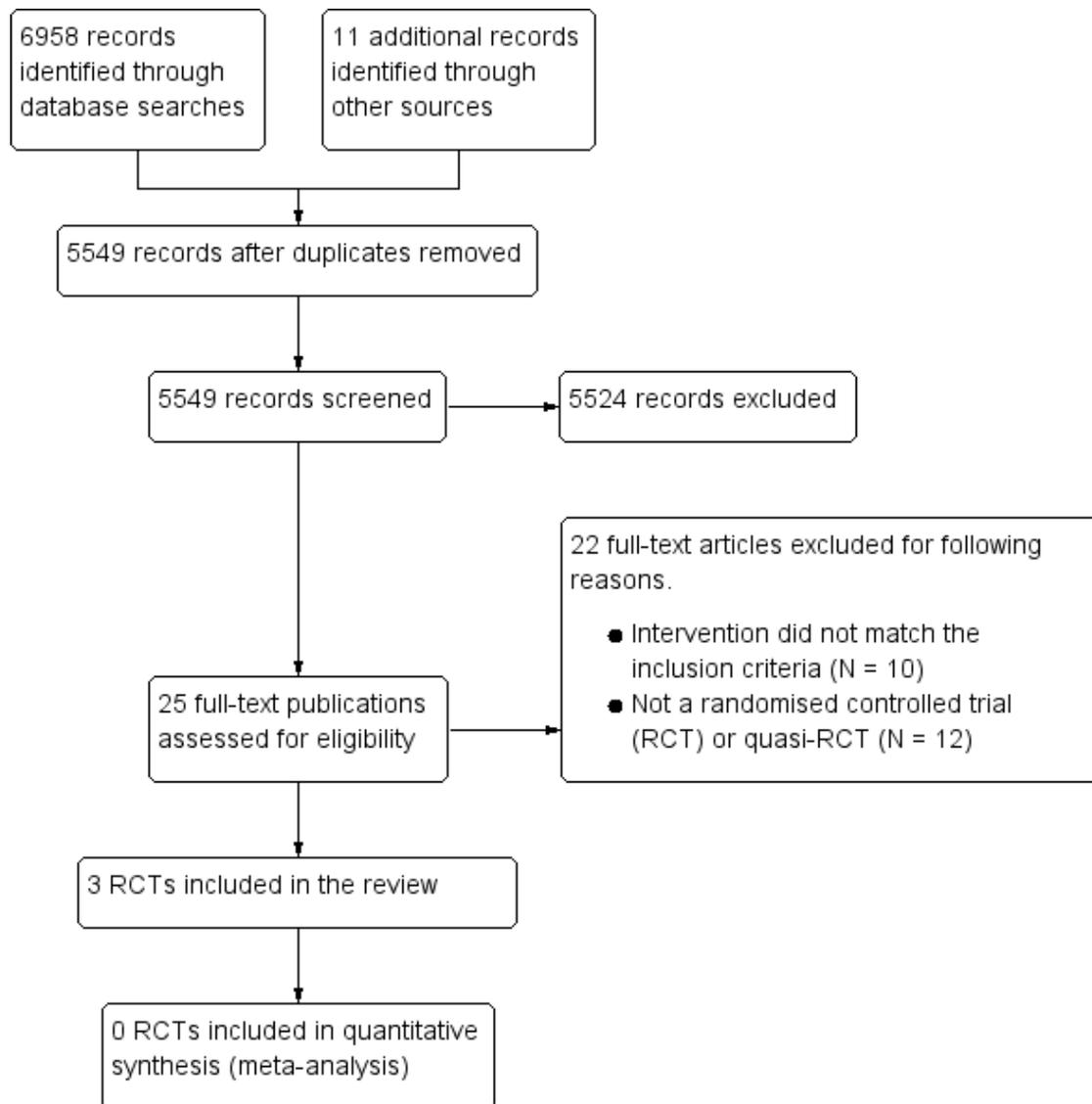
### Description of studies

See the '[Characteristics of included studies](#)' and '[Characteristics of excluded studies](#)' tables.

### Results of the search

We identified 6958 records through our electronic database searches and 11 through clinical trial register searches. After de-duplication, we screened 5549 abstracts for inclusion and excluded 5524 records. We retrieved 25 articles for full-text review and assessed them for eligibility; we then excluded 22 studies (see the '[Characteristics of excluded studies](#)' table). In total we included three papers (see the '[Characteristics of included studies](#)' table) that reported three separate studies (see [Figure 1](#) for the PRISMA flowchart).

Figure 1. Study PRISMA flow diagram.



### Included studies

We described the interventions according to what the study authors wrote in the papers (see the 'Characteristics of included studies' table). We did not contact the study authors for further information regarding intervention content. The included studies were undertaken in the USA (Froelicher 1994; Steinke 2004) and Israel (Klein 2007). All studies included participants who had been admitted to hospital with myocardial infarction (MI); Klein 2007 included participants who had undergone coronary artery

bypass grafting (CABG), in addition to participants with MI. The interventions in the three studies differed substantially, and therefore meaningful pooling of results from individual studies was not possible.

The intervention in Froelicher 1994 (N = 174) was usual care plus an exercise programme plus an education-counselling cardiac rehabilitation programme that contained a component that focused on resumption of sexual activity following a MI. This study had two comparison groups: one received usual care only, and the other received usual care plus an exercise programme. As we were

interested in the added benefit of the sexual education-counselling intervention, we treated the group that received usual care plus an exercise programme as the control group, and usual care plus an exercise programme plus an education-counselling cardiac rehabilitation programme with the component focused on sexual activity as the intervention group.

[Klein 2007](#) (N = 92) used a sexual counselling intervention that consisted of three meetings (total five hours) between a sexual therapist(s) and the participant (with the option of including their sexual partner). The counselling sessions involved education around issues related to sexual activity in general and after MI and CABG in particular; instructions, assignments, and sensate focusing exercises; discussion of experience with the exercises, cognitive behavioural techniques, and additional medical checks and medication prescription where necessary. Participants in the control group underwent the regular cardiac rehabilitation programme. The intervention in [Steinke 2004](#) (N = 115) was a 15-minute educational video plus written material developed by clinical experts and distributed to participants in the intervention group before they left hospital following a MI. Participants in the control group received the written material only (usual care). The video

contained content on the effect of the heart attack on sexuality and sexual function, communicating with the partner, the impact of cardiac risk factors on sexual function, specific suggestions on when and how to resume sexual activity, and the effects of various medications on sexual function.

### **Excluded studies**

Of the 5539 unique citations detected, we excluded 5514 after title and abstract screening. We excluded a further 22 studies after we screened the full-text article and listed the reasons in the ' [Characteristics of excluded studies](#)' table.

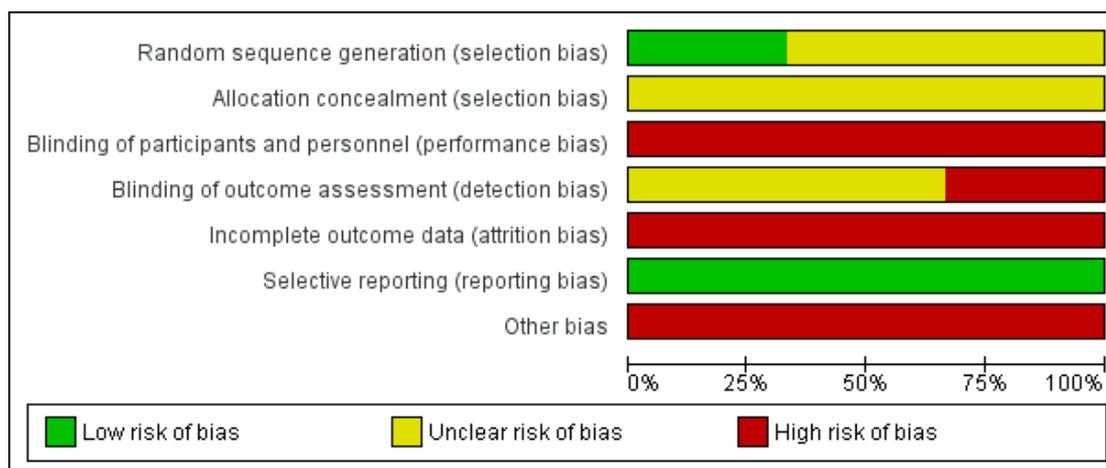
### **Risk of bias in included studies**

We have summarised the 'Risk of bias' results in [Figure 2](#) ('Risk of bias' summary: review authors' judgments about each 'Risk of bias' item for each included study) and [Figure 3](#) ('Risk of bias' graph: review authors' judgments about each 'Risk of bias' item presented as percentages across all included studies). Incomplete reporting was an obstacle to the assessment of bias or quality of all three included studies.

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 of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Froelicher 1994	?	?	-	-	-	+	-
Klein 2007	?	?	-	?	-	+	-
Steinke 2004	+	?	-	?	-	+	-

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



### Allocation

We judged only one study as at low risk of bias in relation to adequate random sequence generation (Steinke 2004). The other two studies did not provide any details of this process (Froelicher 1994; Klein 2007), so we judged these as 'unclear'. We deemed all three included studies at unclear risk regarding allocation concealment, as the studies did not provide any details on the process.

### Blinding

We judged all three included studies as at high risk of performance bias, as blinding of participants to their group allocation is not possible in this type of research.

Froelicher 1994 was at high risk of detection bias as research nurses were involved in both intervention delivery as well as data collection. We judged detection bias as unclear for Steinke 2004 and Klein 2007, as these studies provided limited details regarding whether those collecting the outcome data were blinded to group assignment.

### Incomplete outcome data

We deemed all three included studies at high risk of attrition bias as they reported greater than 20% missing data for the main analysis. In Froelicher 1994, the attrition rate for the intervention and control groups was 25% (44/174) at 24 weeks follow-up. Data

were unavailable to determine overall attrition rates at 12 weeks follow-up.

In Klein 2007, the attrition rate was 42% (38/92) at four months follow-up for sexual satisfaction. Data were unavailable to determine attrition rates for other outcomes at four months follow-up or any attrition rates at one month follow-up.

In Steinke 2004, the attrition rate was 34% (39/115) at one month follow-up, 37% (43/115) at three months follow-up, and 40% (46/115) at five months follow-up.

### Selective reporting

There were an insufficient number of included studies to test for publication bias using a funnel plot. However, we minimised reporting bias by conducting a comprehensive search for studies that met the eligibility criteria. Furthermore, included studies did not provide strong evidence that sexual counselling can improve sexual outcomes for patients, and information from experts did not suggest that there were relevant unpublished studies.

Selective reporting of outcomes cannot be excluded as no study protocols were available. However all outcomes mentioned in the methods were reported in the results sections.

### Other potential sources of bias

All three included studies were at high risk regarding additional sources of bias as they used self-reported measures for their outcomes. Such measures are subject to reporting bias, whereby participants are at risk of selectively revealing or suppressing information.

The intervention in [Froelicher 1994](#) was conducted between 1977 and 1979, but the paper included in this review was published in 1994. Perhaps as a result, the level of detail reported of the intervention content lacked specificity. In addition, the time difference between study conduct and study reporting may cause additional problems in interpretation and modern relevance of the study's findings. The study authors noted that "These data were collected between 1977 and 1979. Thus temporal changes that have occurred since then, such as treatment alternatives, medications and other practice changes, may have different effects today".

In [Klein 2007](#), the study authors reported that differences observed at baseline between intervention and control groups may have biased the results. They stated: "The significant differences observed between the treatment and control groups with regard to the proportions with CABG and previous MI is a potentially important limitation". More participants reported a previous CABG in the intervention group (21/47, 44.7%) compared to the control group (12/45, 26.7%). More participants in the control group reported a previous MI (37/45, 82.2%) than in the intervention group (28/47, 60.0%). They suggested that future studies should stratify for these pre-existing characteristics. The study authors reported that their small sample size may be a limitation. They stated that "the sample size does not provide enough power to detect smaller effects. In fact, several outcome measures showed a promising trend, but the limited power of our sample did not allow the detection of significant effects".

In [Steinke 2004](#), there was a potential threat to external validity as the manager of cardiac rehabilitation identified and selected participants for inclusion. Generalisability of study findings may be limited, as the study authors stated that "participants in the study were primarily married, white and educated, thereby limiting the generalisability of the findings". Small sample size was another potential source of bias. The study authors stated: "Through power analysis it was anticipated that 45 participants were needed for each group". However, this sample size was not achieved at any of the follow-up time

points. Data were available for 76 participants in total at one month follow-up, for 72 participants as three months follow-up, and 69 participants at five months follow-up. There was also a greater attrition rate reported for the intervention group in comparison to the control group (45% versus 27%).

## Effects of interventions

See: [Summary of findings for the main comparison](#) Sexual counselling compared with usual care for patients with cardiovascular disease

## Primary outcomes - patients

### Sexual function

Two included studies reported sexual function as an outcome ([Steinke 2004](#); [Klein 2007](#)).

[Klein 2007](#) assessed sexual function at baseline (entry to the intervention), one month, and four months follow-up. Sexual function was measured using the Sexual Function for Cardiac Patient Questionnaire, which is a compilation of items from several sources, including the International Index of Erectile Dysfunction. It includes 12 items, namely: fear to have sex; desire; confidence in maintaining an erection; satisfactory sexual relationship; sexual pleasure; frequency of erection; erection solid enough for penetration; satisfaction in frequency of sex; premature ejaculation; achieving orgasm; frequency of satisfaction in sexual intercourse; and health problems during sexual relations. The study authors developed this tool.

The study authors reported mean scores for each of the 12 items at each of the three timepoints for intervention and control groups. Scores for each item ranged from one (not at all/never) to five (a large extent/always). They conducted a repeated measured analysis of variance (ANOVA) test to compare intervention and control groups in magnitude of change in mean score across the three timepoints for each scale item. They reported only the results of statistical analysis for the items for which they found statistically significant differences. They reported differences in favour of the intervention in confidence in maintaining an erection ( $F(2,72) = 7.32, P < 0.001$ ), satisfactory sexual relationships ( $F(2,53) = 4.23, P < 0.02$ ), frequency of erection ( $F(2,53) = 4.23, P < 0.02$ ), joy of sex ( $F(2,58) = 3.35, P < 0.04$ ) and levels of sexual desire ( $F(2,58) = 3.16, P < 0.04$ ). There were no differences reported on the remaining indices on this questionnaire.

[Steinke 2004](#) assessed sexual function at pretest and at 1, 3, and 5 months follow-up. Sexual function was measured using the Watts Sexual Function Questionnaire (WSFQ), which is a 17-item scale with 4 subscales, i.e. sexual desire, arousal, orgasm, and satisfaction. Sexual function was calculated as a total score of all four WSFG items. Raw scores for sexual function were not reported. The study authors reported the results of a repeated measures analysis of covariance (ANCOVA) of changes in means over the three timepoints. In these analyses they included the covariates of age, gender, level of education, return to sexual activity, and prior value of the variable being considered. In describing their results from this analysis in relation to sexual function, the study authors stated: "There were no significant differences between the two groups [for sexual function] at any of the timepoints".

### Sexual satisfaction

Two included studies reported sexual satisfaction as an outcome ([Steinke 2004](#); [Klein 2007](#)).

In Klein 2007, sexual satisfaction was assessed by one of the 12 items of the Sexual Function for Cardiac Patient Questionnaire (described above) 'satisfactory sexual relationship (or satisfaction with the quality of sexual relationships with partner)'. Scores for this item ranged from one (not at all/never) to five (a large extent/always). The study authors reported mean indices (where a higher score indicates higher levels of satisfaction) for intervention group at time 1, time 2, and time 3 as 3.75, 4.62, and 4.37, and for the control group at time 1, time 2, and time 3 as 3.75, 3.71, and 3.63. They reported the findings of a repeated measured ANOVA test to compare intervention and control groups in magnitude of change in mean 'satisfactory sexual relationships' score across the three timepoints, and stated that "differences were reported in favour of the intervention [F(2,53)=4.23, P<0.02]"

Steinke 2004 assessed sexual satisfaction and reported scores from one of the four subscales of the Watts Sexual Function Questionnaire (WSFQ) (described above). Raw scores for sexual satisfaction were not reported. The study authors reported results of a repeated measures ANCOVA of changes in means over the three timepoints, and stated: "There were no significant differences between the two groups [for sexual satisfaction] at any of the timepoints".

### Primary outcomes - partners

None of the included studies reported any outcomes from partners.

### Secondary outcomes

#### Marital or relationship satisfaction

One study reported marital satisfaction as an outcome (Klein 2007).

Klein 2007 assessed marital satisfaction at baseline (entry to the intervention), one month, and four months follow-up using Olson's Enrich Marital Satisfaction questionnaire. No scores were reported, but the study authors stated: "No treatment effects were observed on marital satisfaction as measured in three points in time".

#### Quality of life

One study reported quality of life as an outcome (Steinke 2004). Steinke 2004 assessed quality of life at pretest and at 1, 3, and 5 months follow-up using the Ferrans and Powers Quality of Life Index (QLI) - Cardiac Version III. Raw scores for quality of life were not reported. The study authors reported results of a repeated measures ANCOVA of changes in means over the three timepoints, and stated: "There were no significant differences between the two groups [for quality of life] at any of the timepoints".

### Psychological well-being

Two studies reported psychological outcomes, and in both cases assessed anxiety using the Spielberger's State Trait Anxiety Inventory (Steinke 2004; Klein 2007).

Anxiety was assessed in Klein 2007 at baseline (entry to the intervention), and at one and four months follow-up. No scores were reported but the study authors stated: "No treatment effects were observed on state anxiety as measured in three points in time".

Anxiety was assessed in Steinke 2004 at baseline and at 1, 3, and 5 months follow-up. No scores were reported, but based on results of a repeated measures ANCOVA of changes in means over the three timepoints, they stated: "The experimental group had significantly greater anxiety at one month post MI [F(2,75)=2.78, P<0.05]. The study authors reported: "There were no significant differences between the two groups [for anxiety] at any other timepoints".

### Satisfaction in how sexual issues are addressed in cardiac rehabilitation services

No study reported this outcome.

### Resumption of sexual activity after a cardiac event

Three included studies reported resumption of sexual activity after a cardiac event as an outcome (Froelicher 1994; Steinke 2004; Klein 2007).

All three studies reported the number of patients that returned to sexual activity following MI as an outcome.

While Klein 2007 reported significant differences between intervention and control groups on this outcome variable, neither Froelicher 1994 nor Steinke 2004 reported differences between the groups on this outcome.

Klein 2007 reported proportions of patients who had returned to regular sexual activity (yes/no) at four months follow-up. The study authors reported that: "The proportion of return to regular sexual activity was higher among participants in the treatment group (87 versus 50% in the control group,  $X^2 = 4.55$ , d.f. = 1,  $P < 0.05$ )". Compared with the control group, participants in the intervention group were statistically significantly more likely to have returned to regular sexual activity at four months follow-up (relative risk (RR) 1.71, 95% confidence interval (CI) 1.26 to 2.32; one trial, 92 participants).

In Froelicher 1994, the total number of participants who returned to sexual activity (yes/no) by 12 weeks follow-up of the total 183 participants were 63 (96% of 66) in the control group and 59 (97% of 61) in the intervention group. In a comparison of the intervention and control groups, there were no significant differences on this outcome at 12 weeks follow-up (RR 1.01, 95% CI 0.94 to 1.09; one trial, 127 participants).

In Steinke 2004, there were no significant differences between the experimental and control groups on return to sexual activity at three months follow-up (RR 0.98, 95% CI 0.88 to 1.10; one trial,

115 participants). There were no differences on this outcome at any time using Chi<sup>2</sup> test at one month (Chi<sup>2</sup> test = 1.33, P = 0.25) and Fisher's exact test at three and five months (P = 1.00 and P = 0.71, respectively).

#### Other outcomes (not prespecified in our protocol)

One study reported knowledge about sex after an MI as an outcome (Steinke 2004).

Steinke 2004 assessed knowledge about sex after an MI using the 25-item Sex After MI Knowledge Test at baseline and at 1, 3, and 5 months follow-up. No scores were reported, but based on results of a repeated measures ANCOVA of changes in means over the three timepoints, as described above, the study authors concluded: "The experimental group had significantly greater knowledge at one month post MI [F(2,75)= 10.47, P<0.01]". They reported: "There were no significant differences between the two groups [for knowledge] at any other timepoints".

## DISCUSSION

Sexual problems are more commonly reported by men and women with cardiovascular disease than those without cardiovascular disease (Schumann 2010; Kutmeç 2011). Such problems negatively impact on quality of life, psychological well-being, and marital or partnership satisfaction (Traeen 2007; Günzler 2009). Whilst sexual counselling for patients and their partners or spouses has been recommended as an important component of cardiac rehabilitation (Levine 2012; Steinke 2013a), there is currently little evidence on the effectiveness of sexual counselling for improving outcomes. This Cochrane review assessed the effectiveness of sexual counselling for sexual problems among people with cardiovascular disease. We included three studies and 381 participants in total. We considered the interventions within these trials to be too heterogeneous to permit meta-analysis, so we provided a narrative synthesis of the findings in this review.

### Summary of main results

#### Primary outcomes

Two of the three included studies reported a sexual function outcome (Steinke 2004; Klein 2007). These studies used sexual function measures that each contained a subscale that measured sexual satisfaction. Klein 2007 reported significantly higher levels of sexual function and satisfaction in the intervention group at one and four months follow-up after sexual counselling in comparison to the control group. There were no differences in these measures between the intervention and control groups in Steinke 2004.

#### Secondary outcomes

Klein 2007 was the only included study to assess marital satisfaction as an outcome; the study authors found no significant differences between groups at any of the three timepoints. Steinke 2004 included quality of life as an outcome, and found no significant differences between groups at any of the timepoints. Two studies reported anxiety outcomes (Steinke 2004; Klein 2007); only Steinke 2004 reported significant differences between the groups, with larger increases in anxiety among the intervention group from baseline to one month follow-up than the control group, but no differences at any other timepoint. All three studies reported the number of patients returning to sexual activity following myocardial infarction (MI) as an outcome. While Klein 2007 reported significant differences between intervention and control groups on percentage returning to sexual activity following MI (more participants in the intervention group had returned to sexual activity than in the control group), neither Froelicher 1994 nor Steinke 2004 reported differences between the groups on this outcome. Steinke 2004 reported knowledge about sex after MI as an outcome. Higher levels were reported among the intervention group than the control group at one month follow-up, but not at other timepoints.

None of the included studies reported on partner-reported outcomes.

#### Overall completeness and applicability of evidence

Due to the heterogeneous nature of the three included trials and based on the primary and secondary outcomes included in this Cochrane review, there is little evidence on which to base a decision on the overall effectiveness of sexual counselling interventions for people with cardiovascular disease or their partners.

#### Quality of the evidence

We judged the overall methodological quality of the included trials to be very low. Details of trial methodology and intervention content were generally poorly reported. For example, Froelicher 1994 and Klein 2007 did not provide any information about the randomisation sequence generation or allocation concealment. Blinding of outcome assessment was not done in Froelicher 1994 or it was unclear whether it was done or not in Klein 2007. All three studies suffered from high risk of attrition bias.

There are always risks of bias associated with outcome measures that rely on self-reporting. All outcomes within this Cochrane review were self-reported measures.

#### Potential biases in the review process

We have taken every step to minimise bias in the review process. We performed a systematic and comprehensive search for studies. We strictly adhered to study inclusion criteria, and well-defined data extraction and managements protocols. Two review authors (MB and SD) independently assessed and agreed on all included and excluded studies. There was very little disagreement on inclusion and exclusion of studies. When there was a disagreement, MB and SD discussed it with a third review author (DD) and reached consensus.

### **Agreements and disagreements with other studies or reviews**

We did not identify any other reviews of sexual counselling for people with cardiovascular disease. The World Health Organization (WHO) recently rated the evidence that 'brief sexuality-related counselling' is more effective than 'usual standard of care' in reducing sexual difficulties and sexual distress as strong (scoring 8.4 out of a possible maximum rating of nine) (WHO 2015). However, most of this evidence comes from research in the context of HIV/AIDS. A previous review of sexual counselling for sexual dysfunction among the general population found that group psychotherapy was more likely than the control group (who received no treatment) to reduce the number of men with "persistence of erectile dysfunction" at post-treatment (Melnik 2007). It would be useful for future research to explore the effectiveness of group-based sexual counselling interventions tailored to people with cardiovascular disease, as this intervention format is likely to be feasible to deliver as a component of hospital cardiac rehabilitation programmes.

## **AUTHORS' CONCLUSIONS**

### **Implications for practice**

Our Cochrane review includes only three studies which assessed the effect of three quite different types of interventions. In addition, all included studies were at high risk of bias. Therefore, our review provides limited evidence to support sexual counselling for sexual problems in people with cardiovascular disease.

One study, Klein 2007, suggested that a high intensity intervention (five hour total duration of sexual therapy of patients and their

partners, with clinical social worker and a medical doctor trained in sexual co-therapy) may result in improved sexual outcomes for patients. They reported that patients that received such an intervention were likely to return to sexual activity more quickly following a myocardial infarction (MI), and reported higher levels of sexual function and sexual satisfaction in comparison to control patients that received only usual care. However, there are a number of possible sources of bias within this study, including selection bias, performance bias, and detection bias. Therefore the findings should be treated with some caution. In addition, included participants may not be representative of patients more generally, as they were all recruited through one medical centre. Furthermore, such a resource and time intensive intervention is unlikely to be feasible or practicable in most health service settings.

The two other studies of lower intensity interventions did not report significant benefits to the intervention group in comparison to the control group (Froelicher 1994; Steinke 2004). Steinke 2004 did find some evidence that a 15-minute video improved short term knowledge about resuming sexual activity following a MI among the intervention group. Both of these studies has small sample sizes and were underpowered to detect an effect of the intervention.

### **Implications for research**

There is a clear need for robust, adequately powered, methodologically rigorous randomised controlled trials (RCTs) of sexual counselling interventions. Such interventions must be pragmatically designed and have the potential to be implemented into general health services. They should be feasible for health service providers to deliver and acceptable to patients and their partners. Group-based sexual counselling interventions tailored to people with cardiovascular disease show some promise (Melnik 2007) and warrant future research. Future studies should describe clearly intervention content and delineate proposed mechanisms of action of interventions, as this will provide insight into which strategies might be most or least effective for people with cardiovascular disease.

## **ACKNOWLEDGEMENTS**

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problems in patients with cardiovascular disease. *Cochrane Database of Systematic Reviews* 2014, Issue 2. [DOI: 10.1002/14651858.CD010988]

\* *Indicates the major publication for the study*

## CHARACTERISTICS OF STUDIES

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

Froelicher 1994

Methods	<p><b>Study design:</b> randomised controlled trial (RCT) with 3 groups. We only compared 2 groups in this review</p> <p><b>Data collection timepoints:</b> 3 data collection timepoints: Time 1, baseline (prior to intervention); Time 2, 12 week follow-up; Time 3, 24 week follow-up</p>
Participants	<p><b>Setting:</b> participants were recruited on admission to coronary care units of 7 Seattle hospitals, USA</p> <p><b>Inclusion criteria</b></p> <ul style="list-style-type: none"> <li>• Primary diagnosis of confirmed acute myocardial infarction, free from complications for a minimum of 24 hours.</li> <li>• Able to walk without aid.</li> <li>• Under 71 years of age.</li> <li>• Able to speak and read English.</li> <li>• Free from serious non-cardiac complications before this admission.</li> <li>• Resided within a 50 mile radius from the University of Washington.</li> </ul> <p><b>Exclusion criteria:</b> none documented.</p> <p><b>Participants randomised:</b> 258 participants in total; 219 men and 39 women, randomised to 3 groups</p> <p>Group 1: 84 patients were randomly assigned to the control group (usual care); Group 2: 88 patients were randomly assigned to the first intervention group (usual care plus exercise); Group 3: 86 patients were randomly assigned to the intervention group (usual care plus exercise plus education-counselling intervention)</p> <p>As we were interested in groups 2 and 3 for our comparison (see below), we included a total of 174 patients for this review</p>
Interventions	<p><b>Control:</b> this study had two comparison groups.</p> <ul style="list-style-type: none"> <li>• Received usual care only, which involved conventional medical and nursing management throughout all phases of hospitalisation and convalescence at home.</li> <li>• Received usual care plus an exercise programme which was delivered during the 3 months following discharge from hospital. Patients in this group received exercise prescriptions based on treadmill test results before discharge from hospital. For 3 months following discharge from the hospital, the patients attended weekly 30 minute outpatient appointments with a research nurse and a physical or occupational therapist. During these sessions, the prior week's activities were reviewed, and patients were given a renewed exercise prescription.</li> </ul> <p>As we were interested in the added benefit of the sexual education-counselling intervention, in our review we treated the group that received usual care plus an exercise programme as the control group</p> <p><b>Intervention:</b> patients in the intervention group received usual care, plus an exercise intervention described above (as outlined for the control group above), plus they attended a series of 12 1-hour group educational counselling sessions. One of these sessions included education-counselling on resumption of sexual activity following a MI. Other topics covered within the series of education-counselling sessions were: cardiac anatomy, physiology of MI, coronary artery disease risk factors, nutrition, dietary changes, activi-</p>

**Froelicher 1994** (Continued)

	ties and exercise, stress and relaxation, issues relating to resumption of work, and emotional reactions to MI. The intervention was delivered to groups of patients. Spouses and friends were encouraged to attend the sessions to assist with problem solving, develop knowledge and skills, and provide family support. Research staff cardiovascular clinical nurse specialists delivered the intervention	
Outcomes	<b>Outcomes relevant to this review</b> <ul style="list-style-type: none"> <li>• One item of the Activity Summary Questionnaire: 'Have you resumed sexual activity? Yes or no'.</li> </ul>	
Notes	The study was conducted between 1977 and 1979, yet this analysis was conducted and reported in 1994	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	No details given as to how people were allocated into each of the three groups
Allocation concealment (selection bias)	Unclear risk	No detail provided on process.
Blinding of participants and personnel (performance bias) All outcomes	High risk	There was no blinding of participants and study personnel, which may have had an impact on outcomes
Blinding of outcome assessment (detection bias) All outcomes	High risk	Research nurses were involved in intervention delivery as well as data collection
Incomplete outcome data (attrition bias) All outcomes	High risk	There was a 25% attrition rate at 24 weeks follow-up.
Selective reporting (reporting bias)	Low risk	The protocol was unavailable. However, the study authors reported all the primary outcome variables in the results section
Other bias	High risk	High risk of performance bias. In this trial, it is likely that exposure to a wide range of other additional elements

Methods	<p><b>Study design:</b> randomised controlled trial (RCT) with 2 groups.</p> <p><b>Data collection timepoints:</b> 3 data collection timepoints: Time 1, baseline, on entry to the intervention; Time 2, one month after completing the intervention; Time 3, 4 months after completing the intervention</p>
Participants	<p><b>Setting:</b> cardiac rehabilitation programme within a medical centre in Jerusalem, Israel</p> <p><b>Inclusion criteria</b></p> <ul style="list-style-type: none"> <li>• Patient underwent recent myocardial infarction or coronary artery bypass grafting and admitted to Phase 2 cardiac rehabilitation programme.</li> <li>• Under 71 years of age.</li> </ul> <p><b>Exclusion criteria:</b> women.</p> <p><b>Participants randomised:</b> 92 participants in total; all men. 47 patients were assigned to the intervention group and 45 were assigned to the control group</p>
Interventions	<p><b>Control:</b> usual care, which was a multidisciplinary phase 2 cardiac rehabilitation programme</p> <p><b>Intervention:</b> usual care plus sexual treatment and counselling. The sexual counselling involved three meetings (total 5 hours) between the therapist(s) and the patient. The intervention was delivered by a clinical social worker and medical doctor who specialised in sexual cotherapy. Participants were given the option of inviting their partners to participate. Partners were involved through the 'homework' assignments and exercises. The counselling sessions involved the following content:</p> <p>Session 1: Therapists interviewed patients and introduced themselves and the programme. Patients received a presentation on education around issues related to sexual activity in general and after Myocardial Infarction and coronary artery bypass grafting in particular, including a review of current, effective interventions. Instructions, assignments, and sensate focusing exercises were administered</p> <p>Session 2: Discussion of experience with the exercises, cognitive behavioural techniques, additional medical checks where necessary, and where necessary, prescription of Sildenafil. 37% of those in intervention and 6.7% of those in the control were prescribed this drug during the study</p> <p>Session 3: Cognitive behavioural interventions, assessment of progress, and instruction around future sexual activities</p>
Outcomes	<p><b>Outcomes relevant to this review</b></p> <ul style="list-style-type: none"> <li>• Return to regular sexual activity.</li> <li>• Sexual function for cardiac patient questionnaire, to assess sexual function and problems. Compilation of items from several sources, including the International Index of Erectile Dysfunction. Includes items: fear to have sex; desire; confidence in maintaining an erection; satisfactory sexual relationship; sexual pleasure; frequency of erection; erection solid enough for penetration; satisfaction in frequency of sex; premature ejaculation; achieving orgasm; frequency of satisfaction in sexual intercourse; health problems during sexual relations.</li> <li>• Anxiety: Spielberger's Anxiety Scale to measure state anxiety.</li> <li>• Marital satisfaction: Olson's Enrich Marital Satisfaction.</li> </ul>
Notes	<p>Limitations included: significant differences in intervention and controls in relation to proportion with coronary artery bypass grafting and previous myocardial infarction. More intervention patients were post- coronary artery bypass grafting (44% versus 27%, <math>P &lt; 0.001</math>) and more patients in the control group were post-myocardial infarction (82%</p>

Klein 2007 (Continued)

	versus 60%, $P < 0.05$ )	
<b>Risk of bias</b>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The trial gave no information on how participants were assigned to groups
Allocation concealment (selection bias)	Unclear risk	No detail given on the process.
Blinding of participants and personnel (performance bias) All outcomes	High risk	There was no blinding of participants and study personnel, which may have had an impact on outcomes
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The trial gave limited details about how data were collected: "measurements were based on self-report questionnaires, in addition to information from the patient's medical file"
Incomplete outcome data (attrition bias) All outcomes	High risk	Unclear number of participants that completed the range of indices of questionnaire. For all reported variables, there was at least 20% missing data
Selective reporting (reporting bias)	Low risk	The protocol was unavailable. However, the study authors reported all the primary outcome variables in the results section
Other bias	High risk	The study authors reported significant differences between the treatment and control groups regarding the proportions of patients with coronary artery bypass grafting and previous myocardial infarction. They suggested that future studies should stratify for these pre-existing characteristics

Steinke 2004

Methods	<p><b>Study design:</b> randomised controlled trial (RCT) with 2 groups.</p> <p><b>Data collection timepoints:</b> 4 data collection timepoints: Time 1, Pretest, during patients' hospital stay; Time 2, 1 month post myocardial infarction; Time 3, 3 months post myocardial infarction; T4 5 months post myocardial infarction</p>
Participants	<p><b>Setting:</b> cardiac rehabilitation programme which is part of a large medical centre in the Midwest USA</p> <p><b>Inclusion criteria:</b> patients were identified and referred for inclusion by manager of</p>

	cardiac rehabilitation. Inclusion criteria included a diagnosis of myocardial infarction; ability to read, write and speak English; over 30 years of age; sexually active <b>Exclusion criteria:</b> previous psychiatric problems; discharged to a nursing home; complex, multiple problems <b>Participants randomised:</b> 115 participants in total; 92 men and 23 women. 64 assigned to intervention condition and 51 assigned to the control condition	
Interventions	<p><b>Control:</b> usual care, which involved receiving standard verbal and written instructions provided by the cardiac rehabilitation staff about resuming sexual activity following a myocardial infarction. This contained brief guidelines about resuming sexual activity. "Verbal discussion on resuming sexual activities varied depending on time constraints and comfort with the topic by the cardiac rehabilitation nurse"</p> <p><b>Intervention:</b> usual care, plus a 15-minute video. The video was developed by Steinke and reviewed by clinical experts. The intervention contained content on: the effect of the heart attack on sexuality and sexual function, communicating with the partner, the impact of cardiac risk factors on sexual function, specific suggestions on when and how to resume sexual activity, and the effects of various medications on sexual function</p>	
Outcomes	<p><b>Outcomes relevant to this review</b></p> <ul style="list-style-type: none"> <li>• Anxiety: Spielbergers State Trait Anxiety Inventory.</li> <li>• Quality of Life: Ferrans &amp; Powers Quality of Life Index (QLI) - Cardiac Version III.</li> <li>• Knowledge: 25-item Sex After myocardial infarction Knowledge Test.</li> <li>• Sexual function: The Watts Sexual Function Questionnaire (WSFQ) with 4 subscales: sexual desire; arousal; orgasm; and satisfaction.</li> <li>• Return to sexual activity: 2 questions: was the patient sexually active and when they had returned to sexual activity.</li> </ul>	
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	Random assignment to groups was accomplished by a coin toss.
Allocation concealment (selection bias)	Unclear risk	The trial gave no details on the process.
Blinding of participants and personnel (performance bias) All outcomes	High risk	There was no blinding of participants and study personnel, which may have had an impact on outcomes
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The trial gave no details.
Incomplete outcome data (attrition bias) All outcomes	High risk	45% attrition rate in intervention group, and 27% in the control group

**Steinke 2004** (Continued)

Selective reporting (reporting bias)	Low risk	The trial authors reported all variables in the results section
Other bias	High risk	Threat to external validity. The manager of cardiac rehabilitation identified and referred participants. Therefore participants are unlikely to be representative of the general population. It was largely a white, married, educated sample

Abbreviations: CABG: coronary artery bypass grafting; RCT: randomised controlled trials; MI: myocardial infarction.

**Characteristics of excluded studies** [ordered by study ID]

Study	Reason for exclusion
Begot 2013	The intervention did not match the inclusion criteria of this Cochrane review
Begot 2015	The intervention did not match the inclusion criteria of this Cochrane review
Belardinelli 2005	The intervention did not match the inclusion criteria of this Cochrane review
Berg 2011	Not a randomised controlled trial (RCT) of an intervention (protocol only, study ongoing)
Cohen 1986	Not a RCT of an intervention.
de Araújo 2009	Not a RCT of an intervention.
Dougherty 2012	Not a RCT of an intervention.
Fisher 1997	Not a RCT of an intervention.
Johansen 2013	Not a RCT of an intervention (protocol only, study ongoing).
Kalka 2009	The intervention did not match the inclusion criteria of this Cochrane review
Kohn 2000	The intervention did not match the inclusion criteria of this Cochrane review
Kushnir 1976	Not a RCT of an intervention.
Lie 2010	The intervention does not appear to match the inclusion criteria. We were only able to obtain the abstract and were unable to obtain full information despite contacting the study author
Lindau 2011	Not a RCT of an intervention.

*(Continued)*

Mittag 2006	The intervention did not match the inclusion criteria of this Cochrane review
Moore 2001	The intervention did not match the inclusion criteria of this Cochrane review
Ross 2000	The intervention did not match the inclusion criteria of this Cochrane review
Roviaro 1984	The intervention did not match the inclusion criteria of this Cochrane review
Steinke 1998	Not a RCT of an intervention.
Steinke 2012	Not a RCT of an intervention.
Sumanen 2005	Not a RCT of an intervention.
Whipple 1987	Not a RCT of an intervention.

Abbreviations: RCT: randomised controlled trial.

## DATA AND ANALYSES

This review has no analyses.

## APPENDICES

### Appendix I. Electronic database search strategies

#### CENTRAL

- #1 MeSH descriptor: [Sex Counseling] this term only
- #2 MeSH descriptor: [Sexual Behavior] this term only
- #3 MeSH descriptor: [Sexual Dysfunctions, Psychological] explode all trees
- #4 MeSH descriptor: [Sexual Dysfunction, Physiological] explode all trees
- #5 MeSH descriptor: [Libido] this term only
- #6 sex\* near/4 (counsel\* or psycholog\* or therap\*)
- #7 sex\* near/4 (help\* or advi\* or inform\* or guid\* or skill\*)
- #8 sex\* near/4 (problem\* or concern\* or difficult\*)
- #9 sex\* near/4 (interest\* or wish\* or activ\* or behav\* or libido)
- #10 (sex\* or erect\* or libido) near/2 (function\* or dysfunction\* or disorder\*)
- #11 (sex\* or intima\*) near/4 (relation\* or spouse\* or partner\*)
- #12 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
- #13 MeSH descriptor: [Cardiovascular Diseases] explode all trees
- #14 cardio\*
- #15 cardia\*
- #16 heart\*
- #17 coronary\*
- #18 angina\*
- #19 myocard\*
- #20 isch?em\*
- #21 arrhythmi\*
- #22 tachycardi\*
- #23 fibrillat\*
- #24 #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23
- #25 #12 and #24

#### MEDLINE OVID

1. Sex Counseling/
2. Sexual Behavior/
3. exp Sexual Dysfunctions, Psychological/
4. exp Sexual Dysfunction, Physiological/
5. Libido/
6. (sex\* adj4 (counsel\* or psycholog\* or therap\*)).tw.
7. (sex\* adj4 (help\* or advi\* or inform\* or guid\* or skill\*)).tw.
8. (sex\* adj4 (problem\* or concern\* or difficult\*)).tw.
9. (sex\* adj4 (interest\* or wish\* or activ\* or behav\* or libido)).tw.
10. ((sex\* or erect\* or libido) adj2 (function\* or dysfunction\* or disorder\*)).tw.
11. ((sex\* or intima\*) adj4 (relation\* or spouse\* or partner\*)).tw.

12. or/1-11
13. exp Cardiovascular Diseases/
14. cardio\*.tw.
15. cardia\*.tw.
16. heart\*.tw.
17. coronary\*.tw.
18. angina\*.tw.
19. myocard\*.tw.
20. isch?em\*.tw.
21. arrhythmi\*.tw.
22. tachycardi\*.tw.
23. fibrillat\*.tw.
24. or/13-23
25. 12 and 24
26. randomized controlled trial.pt.
27. controlled clinical trial.pt.
28. randomized.ab.
29. placebo.ab.
30. clinical trials as topic.sh.
31. randomly.ab.
32. trial.ti.
33. 26 or 27 or 28 or 29 or 30 or 31 or 32
34. exp animals/ not humans.sh.
35. 33 not 34
36. 25 and 35

#### **EMBASE OVID**

1. sexual counseling/
2. sexual behavior/
3. exp psychosexual disorder/
4. exp sexual dysfunction/
5. (sex\* adj4 (counsel\* or psycholog\* or therap\*)).tw.
6. (sex\* adj4 (help\* or advi\* or inform\* or guid\* or skill\*)).tw.
7. (sex\* adj4 (problem\* or concern\* or difficult\*)).tw.
8. (sex\* adj4 (interest\* or wish\* or activ\* or behav\* or libido)).tw.
9. ((sex\* or erect\* or libido) adj2 (function\* or dysfunction\* or disorder\*)).tw.
10. ((sex\* or intima\*) adj4 (relation\* or spouse\* or partner\*)).tw.
11. or/1-10
12. exp cardiovascular disease/
13. cardio\*.tw.
14. cardia\*.tw.
15. heart\*.tw.
16. coronary\*.tw.
17. angina\*.tw.
18. myocard\*.tw.
19. isch?em\*.tw.
20. arrhythmi\*.tw.
21. tachycardi\*.tw.
22. fibrillat\*.tw.
23. or/12-22
24. 11 and 23
25. random\$.tw.

26. factorial\$.tw.
27. crossover\$.tw.
28. cross over\$.tw.
29. cross-over\$.tw.
30. placebo\$.tw.
31. (doubl\$ adj blind\$).tw.
32. (singl\$ adj blind\$).tw.
33. assign\$.tw.
34. allocat\$.tw.
35. volunteer\$.tw.
36. crossover procedure/
37. double blind procedure/
38. randomized controlled trial/
39. single blind procedure/
40. 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39
41. (animal/ or nonhuman/) not human/
42. 40 not 41
43. 24 and 42
44. limit 43 to embase

## CINAHL

- S27 S14 AND S26  
 S26 S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25  
 S25 TX allocat\* random\*  
 S24 (MH "Quantitative Studies")  
 S23 (MH "Placebos")  
 S22 TX placebo\*  
 S21 TX random\* allocat\*  
 S20 (MH "Random Assignment")  
 S19 TX randomi\* control\* trial\*  
 S18 TX ( (singl\* n1 blind\*) or (singl\* n1 mask\*) ) or TX ( (doubl\* n1 blind\*) or (doubl\* n1 mask\*) ) or TX ( (tripl\* n1 blind\*) or (tripl\* n1 mask\*) ) or TX ( (trebl\* n1 blind\*) or (trebl\* n1 mask\*) )  
 S17 TX clinic\* n1 trial\*  
 S16 PT Clinical trial  
 S15 (MH "Clinical Trials+")  
 S14 S10 AND S13  
 S13 S11 OR S12  
 S12 (cardio\* or cardia\* or heart\* or coronary\* or angina\* or myocard\* or ischem\* or ischaem\* or arrhythmi\* or tachycardi\* or fibrillat\*)  
 S11 (MH "Cardiovascular Diseases+")  
 S10 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9  
 S9 ((sex\* or intima\*) N4 (relation\* or spouse\* or partner\*))  
 S8 ((sex\* or erect\* or libido) N2 (function\* or dysfunction\* or disorder\*))  
 S7 (sex\* N4 (interest\* or wish\* or activ\* or behav\* or libido))  
 S6 (sex\* N4 (problem\* or concern\* or difficult\*))  
 S5 (sex\* N4 (help\* or advi\* or inform\* or guid\* or skill\*))  
 S4 (sex\* N4 (counsel\* or psycholog\* or therap\*))  
 S3 (MH "Sexual Dysfunction, Male+") OR (MH "Sexual Dysfunction, Female+")  
 S2 (MH "Psychosexual Disorders+")  
 S1 (MH "Sexual Counseling")

## PsycINFO OVID

1. sex therapy/
2. exp psychosexual behavior/
3. exp sexual function disturbances/
4. libido/
5. sex drive/
6. (sex\* adj4 (counsel\* or psycholog\* or therap\*)).tw.
7. (sex\* adj4 (help\* or advi\* or inform\* or guid\* or skill\*)).tw.
8. (sex\* adj4 (problem\* or concern\* or difficult\*)).tw.
9. (sex\* adj4 (interest\* or wish\* or activ\* or behav\* or libido)).tw.
10. ((sex\* or erect\* or libido) adj2 (function\* or dysfunction\* or disorder\*)).tw.
11. ((sex\* or intima\*) adj4 (relation\* or spouse\* or partner\*)).tw.
12. or/1-11
13. exp Cardiovascular Disorders/
14. cardio\*.tw.
15. cardia\*.tw.
16. heart\*.tw.
17. coronary\*.tw.
18. angina\*.tw.
19. myocard\*.tw.
20. isch?em\*.tw.
21. arrhythmi\*.tw.
22. tachycardi\*.tw.
23. fibrillat\*.tw.
24. or/13-23
25. 12 and 24
26. random\$.tw.
27. factorial\$.tw.
28. crossover\$.tw.
29. cross-over\$.tw.
30. placebo\$.tw.
31. (doubl\$ adj blind\$).tw.
32. (singl\$ adj blind\$).tw.
33. assign\$.tw.
34. allocat\$.tw.
35. volunteer\$.tw.
36. control\*.tw.
37. "2000".md.
38. or/26-37
39. 25 and 38

## **CPCI-S**

- # 11 #10 AND #9
- # 10 TS=(random\* or blind\* or allocat\* or assign\* or trial\* or placebo\* or crossover\* or cross-over\*)
- # 9 #8 AND #7
- # 8 TS=(cardio\* or cardia\* or heart\* or coronary\* or angina\* or myocard\* or isch?em\* or ischaem\* or arrhythmi\* or tachycardi\* or fibrillat\*)
- # 7 #6 OR #5 OR #4 OR #3 OR #2 OR #1
- # 6 TS=((sex\* or intima\*) near/4 (relation\* or spouse\* or partner\*))
- # 5 TS=((sex\* or erect\* or libido) near/2 (function\* or dysfunction\* or disorder\*))
- # 4 TS=(sex\* near/4 (interest\* or wish\* or activ\* or behav\* or libido))
- # 3 TS=(sex\* near/4 (problem\* or concern\* or difficult\*))
- # 2 TS=(sex\* near/4 (help\* or advi\* or inform\* or guid\* or skill\*))

# 1 TS=(sex\* near/4 (counsel\* or psycholog\* or therap\*))

## CONTRIBUTIONS OF AUTHORS

MB had the original idea for this Cochrane review and was the lead author of the Cochrane protocol, [Byrne 2014](#), and review. MB is the primary contact author and guarantor for this Cochrane review.

MB and SD screened the literature search results and extracted data from the included trials.

DD contributed review methodology expertise to the design, conduct, and reporting of the protocol and review. DD acted as a third review author where needed.

All review authors contributed important intellectual content throughout the review process, and contributed to writing and editing the final protocol and review.

## DECLARATIONS OF INTEREST

MB, SD, BF, JM, TJ and DD have no known conflicts of interest.

All review authors, except DD, are published researchers in the area of sexual counselling and cardiovascular disease.

One review author, ES, authored one of the included studies ([Steinke 2004](#)). We paid special attention to ensure accurate assessment of eligibility and risk of bias of this study and DD, who was not involved in the study, reviewed the process. ES has no other known conflicts of interest.

## SOURCES OF SUPPORT

### Internal sources

- No sources of support supplied

### External sources

- This project was supported by the National Institute for Health Research via Cochrane Infrastructure funding to the Cochrane Heart Group. The views and opinions expressed therein are those of the review authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, the NHS, or the Department of Health, UK.
- The Cochrane Heart Group US Satellite is supported by intramural support from the Northwestern University Feinberg School of Medicine and the Northwestern University Clinical and Translational Science (NUCATS) Institute (UL1TR000150), USA.

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the Cochrane protocol, under the heading of 'Searching other resources', we proposed that we would "search reference lists of eligible papers and reviews" and "contact the principal investigators of identified studies to ascertain if they are aware of any other relevant published or unpublished studies in the area" ([Byrne 2014](#)). We did not conduct these additional searches of other resources as part of the review process. We, as review authors who are internationally experienced in this field, considered it highly likely that we had captured all ongoing intervention research activity via the core search strategies.

We reported one outcome (knowledge about sex after a MI) in the review that we had not included in the protocol. In addition, we expanded the secondary outcome stated in the Cochrane protocol as 'Quality of life or psychological well-being' within the review to include two separate outcomes: 'quality of life' and 'psychological well-being, including depression and anxiety'. Also we added an additional example of a psychological well-being tool to the outcomes list, namely Spielberger's State-Trait Anxiety Inventory ([Spielberger 1983](#)). Anxiety is a core component of psychological well-being and we should have specified it in the Cochrane protocol.

We included a 'Summary of findings' table and performed GRADE assessments in this Cochrane review, which we had not stated in the protocol.

## **INDEX TERMS**

### **Medical Subject Headings (MeSH)**

\*Sex Counseling; Cardiovascular Diseases [\*complications; rehabilitation]; Coronary Artery Bypass; Myocardial Infarction [complications; rehabilitation]; Patient Satisfaction; Randomized Controlled Trials as Topic; Sexual Dysfunction, Physiological [psychology; \*rehabilitation]; Sexual Partners

### **MeSH check words**

Female; Humans; Male