

## Systematic Review – Protocol

### Title

#### **A systematic review on the effectiveness of nurse-led cardiac clinics for adult patients with coronary heart disease**

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### Background

Coronary Heart Disease (CHD) is the leading cause of death worldwide<sup>1</sup>. The latest available global data from 2004 indicate that 7.2 million people worldwide die of CHD every year<sup>1</sup>. Additionally, 12.1 million people live with a reduced quality of life due to insufficient blood supply to the coronary arteries<sup>1</sup>. The reduced flow of oxygen and nutrition to the heart muscle is mainly caused by a constriction in the coronary arteries due to atherosclerosis<sup>2</sup>. Sufferers are confronted with a constant threat of the two major clinical forms of CHD: angina pectoris (chest pain caused by inadequate blood flow through the coronary blood vessels), or much worse, a myocardial infarction (heart attack).

Modifiable well-known risk factors for CHD are overweight and obesity, diabetes, tobacco smoking and physical inactivity. These may lead to high blood pressure and abnormal blood lipids<sup>3</sup>. Men, people aged over 55 years and those with a hereditary history are at greatest risk of CHD<sup>1</sup>. Treatment for CHD varies according to the severity of the symptoms. Most important is the reduction of risk factors by lifestyle changes including diet, exercise and smoking cessation, as well as medication intake for lowering blood pressure and balancing blood lipids. Stent implantations and bypass surgery are more invasive surgical treatments<sup>3</sup>.

The above-mentioned major risk factors offer great potential for preventive interventions and non-medical treatment. Nurses in nurse-led clinics can provide such preventive interventions. In the 1980s those clinics were first established in the United Kingdom and the United States in the primary care setting to guarantee continuity in care after patient discharge while attempting to contain costs at the same time<sup>4,5</sup>. Nurse-led clinics are mainly run by nurses independently or supported by a multidisciplinary team and have had advanced training. The major interventions in such clinics are assessment, evaluation and monitoring of patients' health status, as well as health counselling and education prior to therapy, diagnosing and case

management<sup>4,6</sup>. A nurse-led cardiac clinic can be defined as a “drop in service”<sup>7</sup> (p. 50) for patients with CHD which takes place in a separate hospital unit<sup>5</sup>, in rooms of a general practitioner or community practice<sup>8</sup> or in the outpatient department of a hospital<sup>6</sup>. The differentiation between a nurse-led clinic and other forms of clinics like physician clinics or hospital clinics lies in the fact that nurse-led clinics are run independently by nurses and that their focus is more holistic, preventive and educative than therapeutic and/or medicinal<sup>4</sup>.

The establishment of nurse-led clinics enhances the professional approach of the nursing profession, particularly the increase of autonomy in the nursing role with the responsibility for their own patient case load, the power to decide about admissions, referrals or discharges<sup>6</sup>. Several studies have demonstrated that cardiac care delivered by nurses in a clinic is effective, but there are still contrary results. A follow-up of a randomised controlled trial after four years in patients with CHD who attended a nurse-led secondary prevention clinic established in a general practice showed significantly lower deaths and coronary event rates compared to the usual care (not described) in a general practice<sup>9</sup>. Components of the secondary prevention program included: aspirin intake, blood pressure and lipid management, exercise, low fat diet and non-smoking. All of these outcomes, with the exception of smoking, were significantly improved in the nurse-led clinic after one-year follow-up. Improvements in these outcomes after four years were no longer significantly different<sup>9</sup>.

Another study, a case-control design, found that mortality could not be reduced by visits to a nurse-led clinic set up next to a family physician practice but that the risk of re-infarction decreased by 52%. They suggest that this result derives from the nurse’s influence by counselling on healthier lifestyle and on smoking cessation<sup>10</sup>. In contrast to this study a randomised controlled trial comparing the effectiveness of a nurse-led cardiac rehabilitation program on health behaviours and physiological risk parameters initiated in the hospital and continued by home visits and phone calls with routine care (not described) did not find a difference in smoking cessation rates<sup>11</sup>. The nurse-led interventions, however, led to significant improvements in a range of outcomes such as the amount of walking exercise, diet and medication adherence and on cardiac physiological risk parameters like blood pressure and certain blood lipids<sup>11</sup>.

By providing psychosocial support, promoting secondary prevention strategies and a holistic approach to patients’ needs, nurse-led clinics may represent one way of tackling the problem regarding the rising number of older and chronically ill patients<sup>6</sup> and addressing issues of consumer satisfaction with their care. For example, qualitative studies on patients’ and nurses’ perceptions about nurse-led clinics report patient satisfaction with the cardiac care. Nurses felt confident in giving reassurance and taking the assessment, but deficits were recognised in discussing the patients’ understanding of the disease and the medication<sup>12</sup>.

As described above, the findings of studies on the effectiveness of nurse-led clinics compared to other clinic types are variable. However, a systematic review published on the topic in 2005 concluded that nurse-led clinics led to general improvements in clinical outcomes concerning lifestyle changes and reduced risk factors<sup>13</sup>. Whether this is still true in 2008 is unclear. Therefore this review will update the existing review and summarise the best available evidence on the effectiveness of nurse-led clinics, compared to any other form of clinic that does not take place in a solely nurse-led setting. Non nurse-led interventions include those delivered by any other health care professional or by information sheets, manuals or web-based learning programs. Some outcomes will be modified from the 2005 review, adapted to the outcomes that

were found in studies considered in the previous review. Unlike the initial review, this update will not include cost effectiveness as an outcome.

### **Review Question/Objectives**

The review question is: What is the effectiveness of nurse-led cardiac clinics concerning nurse-delivered care for adults with coronary heart disease compared to interventions given in other clinics?

The quantitative objective is to identify the effectiveness of nurse-led cardiac clinics on adult patients with coronary heart disease. More specifically, the objectives are to identify what interventions given by cardiac nurses are most effective concerning:

- readmission and admission rates
- exacerbation of CHD symptoms
- reduction of risk factors
- patient satisfaction and compliance related to risk factor reduction and lifestyle changes.

### **Inclusion criteria**

#### **Types of participants**

This review will consider studies that include adults (aged > 18 years), presenting to a cardiac nurse-led clinic with new or existing CHD.

#### **Types of intervention(s)**

The review will consider nurse-led cardiac clinics, defined as clinics providing a service for the customer that is managed and staffed solely by nurses, with the ability to assess or treat and consult or refer the consumer to other health disciplines as required<sup>13</sup>. Interventions of interest are those related to the common role of staff in a nurse-run cardiac clinic, including education, assessment and monitoring, consultation, referral and administrative duties. Nurse-led clinics will be compared to any other form of a clinic that does not take place in a solely nurse-led setting, eg. care delivered in a hospital, in a practice or a health care centre where health care professionals other than nurses deliver care.

#### **Types of outcomes**

The primary outcomes to be considered in this review are:

- exacerbation of CHD symptoms or angina attacks,
- readmission and admission rates,
- reduction of risk factors (blood lipids, blood pressure, general health status),
- consumer satisfaction and
- compliance (such as with recommended management of CHD medications, risk factor management and compliance with interventions or modified behaviours related to cigarette smoking, weight management, exercise and diet).

For example the outcomes can be measured by questionnaires on lifestyle changes, smoking and exercise behaviour, with assessment instruments on nutrition, quality of life by survey or by audit of medical records. If possible they will be subdivided in a short time period (up to 6 month) and a long-time period (from 7 month and more).

### **Types of studies**

This review will consider any randomised controlled trials (RCTs) that evaluate nurse-led cardiac clinics. In the absence of RCTs other research designs such as quasi-experimental designs, cohort and case-control studies, before and after studies as well as time series studies will be considered. The results of those study designs will be presented in a narrative report to give an overview of current approaches concerning cardiac nurse-led clinics.

### **Search strategy**

The search strategy aims to find both published and unpublished literature and includes some grey literature sources. The search will be limited to the English and German language for the period September 2002 to March 2008, as this review updates one that ended at August 2002.

A three-step search will be utilised in each component of this review. An initial search of Medline and CINAHL will be undertaken to refresh optimal search terms and include possible changes in the databases. The search terms to be used will be double checked before starting the main search. In a second step all identified keywords will be used for searching all below mentioned databases. A third search will be undertaken by searching the reference lists of identified articles and by hand-searching the following journals: *Journal of Clinical Nursing*, *Heart*, *BMJ* and *Nursing Clinics of North America* because they proved to be relevant in the previous review.

Initial keywords to be used are:

- nurse-led OR nurse-managed OR nurse(s)
- cardiac OR cardio\*
- Coronary Heart Disease OR CHD
- clinic

The databases for published literature to be searched are:

AustHealth  
BioMed Central  
CINAHL and Pre-CINAHL  
Clinical Practice Guidelines Australia  
CRD (Centre for Reviews and Dissemination)  
Cochrane Library  
Current Contents  
EBM Reviews  
EMBASE  
Guidelines Finder  
Health Source: Nursing/Academic Edition  
Joanna Briggs Institute  
Medline (1996 - present) and Pre-Medline  
National Health and Medical Research Council  
National Institute for Clinical Excellence (NICE)  
National Library for Health  
NLM Gateway

PsycInfo  
PubMed  
PubMed Clinical Queries  
Scopus  
Scirus  
TRIP (Turning Research Into Practice)

Databases containing unpublished literature include:

AHRQ (Agency for Healthcare Research and Quality), Evidence Reports  
ANA (American Nurses Association)  
Australian Digital Theses Program  
Digital Dissertations  
GoogleScholar  
IHSCR (Institute for Health & Social Care)  
Index to Theses  
SIGLE (System for Information on Grey Literature in Europe)  
Subject Resources for Canadian Sources of Grey Literature  
The New York Academy of Medicine, Grey Literature Report  
WHO (World Health Organisation)

#### **Assessment of methodological quality**

Quantitative papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using the standardised Assessment and Review Instrument (JBI-MAStARI) (Appendix I). Any disagreement that arises between the reviewers will be resolved through discussion or by including a third reviewer.

#### **Data extraction**

Quantitative data will be extracted from papers included in the review using the standardised data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

#### **Data synthesis**

Quantitative papers will, where possible, be pooled in statistical meta-analysis using the Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI). All results will be subject to double data entry to minimise the risk of error during the data entry. Where appropriate, Relative Risks and/or Odds Ratios and their associated 95% confidence interval will be calculated for analysis of categorical data. For continuous data that are collected using the same scale the weighted mean differences and standard deviation will be calculated; for data collected using different scales, the standardised mean differences will be calculated. Significant heterogeneity will be assumed at  $p < 0.1$  using the Chi Square test for homogeneity. The causes of any heterogeneity found will be investigated prior to any further analysis. Where statistical pooling is not possible the findings will be presented in narrative form.

#### **References**

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8. McHugh F, Lindsay, G., Hanlon, P. et al. Nurse led shared care for patients on a waiting list for coronary bypass surgery: a randomised controlled trial. *Heart*. 2001;86:317-23.
9. Murchie P, Campbell NC, Ritchie LD, Simpson JA, Thain J. Secondary prevention clinics for coronary heart disease: four year follow up of a randomised controlled trial in primary care. *BMJ (Clinical research ed)*; 2003;326(7380):84.
10. Serrano-Martinez M, Sanjulian-Aranguren B, Ezpeleta-Iturralde I, Madoz-Zubillaga E, Urbina Goni MJ, de Irala-Estevéz J. Primary care nursing of coronary patients and reduction of re-infarction risk: a nested case-control study. *Public Health*. 2005 Feb;119(2):112-7.
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12. Wright FL. Patients' and practice nurses' perceptions of secondary preventive care for established ischaemic heart disease: A qualitative study. *Journal of Clinical Nursing*. 2001;10(2):180-8.
13. Page T, Lockwood C, Conroy-Hiller T. Effectiveness of nurse-led cardiac clinics in adult patients with a diagnosis of coronary heart disease. *International Journal of Evidence Based Healthcare*. 2005;3(1):2-26.

## Appendices

### I. Assessment and Review Instrument (JBI – MASTARI)

#### JBI Critical Appraisal Checklist for Experimental Studies

Reviewer \_\_\_\_\_ Date \_\_\_\_\_

Author \_\_\_\_\_ Year \_\_\_\_\_ Record Number \_\_\_\_\_

	Yes	No	Unclear
1. Was the assignment to treatment groups truly random?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were participants blinded to treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Was allocation to treatment groups concealed from the allocator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were those assessing outcomes blind to the treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were the control and treatment groups comparable at entry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were groups treated identically other than for the named interventions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in the same way for all groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal:                      Include                       Exclude                       Seek further info.

Comments (Including reasons for exclusion)

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## JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

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Reviewer \_\_\_\_\_ Date \_\_\_\_\_  
Author \_\_\_\_\_ Year \_\_\_\_\_ Record Number \_\_\_\_\_

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	Yes	No	Unclear
1. Is sample representative of patients in the population as a whole?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are the patients at a similar point in the course of their condition/illness?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has bias been minimised in relation to selection of cases and of controls?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are confounding factors identified and strategies to deal with them stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are outcomes assessed using objective criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up carried out over a sufficient time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Overall appraisal: Include  Exclude  Seek further info

Comments (Including reason for exclusion)

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## JBI Critical Appraisal Checklist for Descriptive/ Case Series

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Reviewer \_\_\_\_\_ Date \_\_\_\_\_  
Author \_\_\_\_\_ Year \_\_\_\_\_ Record Number \_\_\_\_\_

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- |   | Yes                      | No                       | Unclear                  |
|---|--------------------------|--------------------------|--------------------------|
| 1. Was study based on a random or pseudo-random sample?                             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Were the criteria for inclusion in the sample clearly defined?                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Were confounding factors identified and strategies to deal with them stated?     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Were outcomes assessed using objective criteria?                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. If comparisons are being made, was there sufficient descriptions of the groups?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Was follow up carried out over a sufficient time period?                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Were the outcomes of people who withdrew described and included in the analysis? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Were outcomes measured in a reliable way?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Was appropriate statistical analysis used?                                       | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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Overall appraisal: Include  Exclude  Seek further info

Comments (Including reason for exclusion)

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## II. Data Extraction Tool (JBI – MASTARI)

### JBI Data Extraction Form for Experimental/Observational Studies

Reviewer \_\_\_\_\_ Date \_\_\_\_\_  
Author \_\_\_\_\_ Year \_\_\_\_\_  
Journal \_\_\_\_\_ Record Number \_\_\_\_\_

**Study Method**    RCT                       Quasi-RCT                       Longitudinal   
                         Retrospective                       Observational                       Other

#### Participants

Setting \_\_\_\_\_

Population \_\_\_\_\_

Sample size \_\_\_\_\_

Intervention 1 \_\_\_\_\_                      Intervention 2 \_\_\_\_\_                      Intervention 3 \_\_\_\_\_

#### Interventions

**Intervention 1** \_\_\_\_\_  
\_\_\_\_\_

**Intervention 2** \_\_\_\_\_  
\_\_\_\_\_

**Intervention 3** \_\_\_\_\_  
\_\_\_\_\_

#### Clinical outcome measures

Outcome Description	Scale/measure

**Study results**

Dichotomous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

Continuous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

**Authors' conclusions**

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**Comments**

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