Abstract of thesis entitled

“An evidence-based protocol:

Exercise training for patients with coronary heart disease”

Submitted by

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Background

Coronary heart disease deprives millions of lives in the world annually and this number has increased steadily in recent years. In Hong Kong, coronary heart disease claimed 4360 lives in 2009 and it is one of the major burdens of the healthcare system. In order to reduce cardiac mortality and morbidity and to enhance patients’ quality of life, cardiac rehabilitation program is developed. Exercise training is a pivotal part of the cardiac rehabilitation program.

Objective

The main objective of this translational nursing research is to translate quality
research evidences regarding the effects of exercise training in improving quality of life of patients with coronary heart disease to the local setting. This is achieved by developing an evidence-based protocol.

**Methods**

A systematic search of literature was conducted in 5 electronic databases. 8 relevant randomized controlled trials were eventually obtained. Then, the 8 identified studies were summarized to form a table of evidence and the critical appraisal was performed using the Scottish Intercollegiate Guidelines Network (SIGN) checklist. After performing the quality assessment, evidences were assembled for synthesis and recommendations are made for developing the evidence-based protocol. Since the implementation potential of the proposed exercise training program is considered to be high, an evidence-based protocol is developed for the local context. In order to implement the evidence-based protocol smoothly, implementation plan is developed in which a communication plan and a pilot test are included. Lastly, evaluation plan is established to assess the effectiveness of the program in fulfilling its objectives.

**Results**

In total, 7 recommendations are made based on the 8 appraised studies. According to
the SIGN’s “Grades of recommendation”, all the recommendations in the protocol are graded with “A”. The significance of this evidence-based protocol is that it adds a symptom-limited exercise test for evaluating participant’s level of exercise tolerance before the start of exercise training, so that exercise intensity can be tailored. It is relatively safer than the current practice.

**Conclusion**

A 6-week exercise training program for patients with coronary heart disease is effective in improving their quality of life and increasing their level of physical activity. Since the program has a high implementation potential in the local context and is safer than the current practice, the evidence-based exercise training protocol is worthwhile to be introduced to the cardiac units in Hong Kong.
An evidence-based protocol:

Exercise training for patients with coronary heart disease

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Declaration

I declare that this thesis represents my own work, except where due
acknowledgement is made, and that it has not been previously included in a thesis,
dissertation or report submitted to this University or to any other institution for a
degree, diploma or other qualifications.

Signed _____________________________

Shum Jannie Gem
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CHAPTER 1

INTRODUCTION

1.1 Background

Cardiovascular diseases are the leading cause of death in the world (World Health Organization, 2011). According to the figures from the World Health Organization (WHO) in 2008, 7.3 million of people worldwide are estimated to die from coronary heart disease (WHO, 2011). In Hong Kong, heart diseases were the second leading cause of death in the past decade. In 2009, 33,363 patients were admitted to hospitals due to coronary heart diseases. Of which, 4360 died and this accounted for 11% of all registered deaths in Hong Kong (Department of Health, HKSAR, 2011). Moreover, this number is continuously increasing in recent years (Department of Health, HKSAR, 2011). Coronary heart disease is indeed one of the major burdens of the healthcare system in Hong Kong.

Coronary heart disease, also known as coronary artery disease or ischemic heart disease, is a condition when there is insufficient delivery of oxygenated blood to the myocardium due to atherosclerosis of the coronary arteries. (Widmaier, Raff, & Strang, 2006). The formation of atherosclerotic plaques causes progressive narrowing of the arterial lumen and makes the coronary arteries vulnerable to blockage. As blood
flow to the myocardium decreases, it becomes ischemic and leads to dysfunction in cardiac pumping. If the ischemic episode is severe or prolonged, it may lead to acute coronary syndrome, which includes myocardial infarction and unstable angina.

Coronary heart disease does not only increase mortality and morbidity, it also has a negative impact on the physiological, psychological, and social aspects of individuals (Benetti, Araujo, & Santos, 2010; Thompson et al., 2002). These factors would greatly impair individuals’ quality of life (Sandstrom & Stahle, 2005). As a result, cardiac rehabilitation programs are designed to reduce cardiac mortality and morbidity, and enhance quality of life of patients with coronary heart disease (Izawa et al., 2004). Nowadays, cardiac rehabilitation becomes a pivotal part of cardiac care globally.

1.2 Affirming the Needs

Cardiac rehabilitation is a program of therapeutic intervention and secondary prevention for patients with coronary heart disease (Choo, Burke, & Pyo Hong, 2007). It is defined as “the coordinated sum of interventions required to ensure the best physical, psychological and social conditions so that patients with chronic or post-acute cardiovascular disease may, by their own efforts, preserve or resume optimal functioning in society and, through improved health behaviours, slow or
reverse progression of disease” (Fletcher et al., 2001, as cited in Taylor et al., 2004). A comprehensive cardiac rehabilitation program should comprise continuous clinical evaluation, optimization of pharmacotherapy, exercise training, psychological counseling, health education, risk factors reduction, and lifestyle modification (Heran et al., 2011; Piotrowicz & Wolszakiewicz, 2008). In view of the importance of exercise training in a cardiac rehabilitation program, benefits of exercise training for patients with coronary heart disease are examined in this translational research paper.

Since the effectiveness of exercise training on improving mortality and morbidity of patients with coronary heart disease has been well studied and documented, it would not be discussed in details in this translational research paper. Details regarding the effect of exercise training on mortality and morbidity can be found in these papers (Heran et al., 2011; Marchionni et al., 2003; Yu et al., 2004). Furthermore, as nowadays the life expectancy of people is getting longer, mortality and morbidity rates alone cannot thoroughly measure the effectiveness of an intervention in the contemporary complex healthcare system (Oldridge, 2003). As a consequence, quality of life has become one of the most crucial measurements in the assessment of patients with coronary heart disease (Yonezawa et al., 2009). Therefore, this paper attempts to address this important question particularly by investigating the effect of exercise
training on quality of life for patients with an acute coronary event.

Quality of life is a comprehensive parameter representing patients’ own perceptions on various domains in their lives. According to Staniūtė & Brožaitienė (2010), quality of life is “multifaceted, based on the subjective perception of patient’s health, and includes not only physical but also psychological and social functioning”. Interestingly, recent research has shown that exercise-based cardiac rehabilitation programs significantly improve the psychosocial well-being of patients with coronary heart disease, regardless of the improvement in physical functioning (Bettencourt et al., 2005; Choo et al., 2007). Therefore, it is believed that the major benefit of the exercise-based cardiac rehabilitation program is acquired through an optimistic attitude towards the disease rather than through the improvement of physical capacity alone (Bettencourt et al., 2005). In this translational research paper, the author would focus on the effectiveness of the exercise training on improving the quality of life of patients with coronary heart disease.

1.3 Significance of the Translational Nursing Research

In 1985, cardiac rehabilitation program was initiated in the cardiac unit of public hospitals in Kowloon Central Cluster, Hong Kong. The existing protocol of the
cardiac rehabilitation program includes lifestyle modification educational sessions and exercise training sessions. However, the protocol was not developed based on the best available evidence. Consequently, it is not clear that whether the length of the program, the frequency, duration, and mode of the exercise sessions of the existing protocol are optimal for the patients with coronary heart disease. Also, its impact on improving patients’ quality of life is not known. Therefore, a translational nursing research is needed to establish the modes of exercise training and to investigate the effectiveness of the exercise training program in improving the quality of life for patients with coronary heart disease. Moreover, this translational nursing research would be essential for developing an evidence-based cardiac rehabilitation protocol for the cardiac unit in Kowloon Central Cluster.

1.4 Translational Nursing Research Question

Since the quality of life of patients with coronary heart disease has received increasing attention nowadays, the research question for this translational nursing research is “What is the effectiveness of the exercise training program in promoting quality of life when compared with the usual care (without exercise training) in patients with coronary heart disease?”
The PICO of research question is identified:

P (Population): Patients with coronary heart disease

I (Intervention): Exercise training

C (Control): Usual medical and nursing care (without exercise training)

O (Outcome): Quality of life

1.5 Objectives of this Translational Nursing Research

The objectives of this translational nursing research are:

1. To conduct a systematic search for literature examining the effect of exercise training on improving quality of life for patients with coronary heart disease;

2. To critically appraise the identified research studies;

3. To translate quality research evidences through the development of an evidence-based exercise training protocol;

4. To assess the implementation potential of the proposed exercise training protocol;

5. To design the implementation plan for the proposed exercise training protocol; and

6. To develop an evaluation plan for the proposed exercise training protocol.
CHAPTER 2
CRITICAL APPRAISAL

2.1 Search Strategy

After formulating the translational research question, a systematic search for relevant research studies was conducted (Appendix A). Five electronic databases, including Cochrane Central Register of Controlled Trials (The Cochrane Library, 2011 Issue 3), PubMed, CINAHL Plus (EBSCOhost), British Nursing Index (Ovid) (1994-September, 2011), and EMBASE (Ovid) (1947-September, 2011), were used. The databases were searched using a strategy combining the 3 groups of search terms. The first group of search terms is related to the keywords for the target population: “coronary artery disease” OR “coronary heart disease” OR “ischemic heart disease” OR “acute coronary syndrome” OR “myocardial infarction” OR “myocardial ischemia” OR “unstable angina”. Since coronary heart disease is also known as coronary artery disease and ischemic heart disease, and it is presented as acute coronary syndrome in acute phase which includes myocardial infarction (myocardial ischemia) and unstable angina, these medical terms were all included as keywords. The second group is related to the keywords for the intervention: “exercise” OR “sport” OR “physical training” OR “physical activity” OR “cardiac rehabilitation”. The third group is related to the keyword for the outcome measure: “quality of life”.
Initially, the search combining the 3 groups of keywords yielded a total of 3830 research studies from the 5 databases. Then, in order to obtain more updated research evidences, the search was limited to papers publishing in the recent 10 years (from 2002 till current). The search was further limited to papers in English language as it is an international language which can be understood by the author and most scholars. Then, the search result was limited to those with full text available. After that, the remaining research papers were screened manually and irrelevant studies were eliminated according to the following inclusion and exclusion criteria.

**Inclusion criteria:**

1. Study type was randomized controlled trial
2. Study subjects were aged 18 years or above
3. Study subjects were patients with coronary heart disease (regardless of the medical treatments that they received)
4. Intervention group received supervised exercise training sessions
5. Control group received usual medical and nursing care (without exercise training)
6. The outcome measures included quality of life (regardless of the type of
measurement tool used)

**Exclusion criteria:**

1. Intervention group received home-based cardiac rehabilitation program

2. Study subjects had cardiac diseases other than coronary heart disease

Basically, the inclusion and exclusion criteria are set according to the population, intervention, control, and outcome measure of the translational research question. Study type was restricted to randomized controlled trials because randomized controlled trials are regarded as the “gold standard” of evidence. Collecting and analyzing the empirical information from randomized controlled trials only can help to ensure the quality of the evidences. Moreover, home-based cardiac rehabilitation programs were particularly excluded because it is difficult to confirm whether the study subjects fully comply with the prescribed exercise training, and therefore the exercise prescription could not be quantified.

Finally, a total of 8 relevant randomized controlled trials were identified. They are:


2.2 Data Extraction

Details of the 8 identified randomized controlled trials were extracted and were then summarized to form a table of evidence, as illustrated in Appendix B. The extracted items include: bibliographic citation, study type, level of evidence, sample characteristics, intervention, comparison, time of data collection, outcome measures, and effect size. Only data that are relevant to this translational research question were extracted and are shown in the table of evidence.

2.3 Appraisal Strategy

The quality of the research studies were assessed using the Scottish Intercollegiate Guidelines Network (SIGN) checklists (SIGN, 2008). Since all the identified studies are randomized controlled trials, the methodology checklist 2, which is specifically designed for assessing the methodological quality of randomized controlled trials, is adopted.

The SIGN checklist is divided into 3 sections. Section 1 includes 10 questions in which the reviewer is asked to consider various aspects of a randomized controlled trial design and to decide how well the study meets the criteria in order to maximize
internal validity. For each question, the reviewer has to judge how well the aspect is
addressed in the study and to indicate it as “well covered”, “adequately addressed”,
“poorly addressed”, “not addressed” (which means not mentioned, or indicates that
this aspect of study design was ignored), “not reported” (which means mentioned, but
there is insufficient detail to make the assessment), or “not applicable”.

In section 2, the reviewer has to make an overall assessment of the study based on the
answers obtained in section 1, and to rate the study using the following coding
system:

| ++ | All or most of the criteria have been fulfilled. Where they have not
been fulfilled the conclusions of the study or review are thought
very unlikely to alter. |
|---|---|
| +  | Some of the criteria have been fulfilled. Those criteria that have not
been fulfilled or not adequately described are thought unlikely to
alter the conclusions. |
| -  | Few or no criteria fulfilled. The conclusions of the study are thought
likely or very likely to alter. |

In section 3, the reviewer is asked to summarize the details of the study. However,
since data extraction and summarization were already done in the form of table of evidence, section 3 is not performed.

The quality assessment process and appraisal result for each of the 8 identified studies are illustrated in Appendix C. In summary, 1 study is rated as “++” (Briffa et al., 2005), 4 studies are rated as “+” (Bettencourt et al., 2005; Marchionni et al., 2003; Sandstrom & Stahle, 2005; Seki et al., 2003), and 3 studies are graded as “-” (Hage, Mattsson, & Ståhle, 2003; Yu et al., 2004; Yu et al., 2003), based on the above coding system.

2.4 Summary

Study Design

All of the 8 identified studies were randomized controlled trials. According to the study protocols of the 8 studies, all of them reported that the study subjects were randomly assigned to either intervention group or control group. However, only 1 study described sufficient details of the randomization process (Briffa et al., 2005), which allows the author to confirm the appropriateness of the randomization. Two studies provided brief description of the randomization method (Hage et al., 2003; Seki et al., 2003), but there is insufficient information for the author to determine
whether the randomization was appropriate. For the other 5 identified studies (Bettencourt et al., 2005; Marchionni et al., 2003; Sandstrom & Stahle, 2005; Yu et al., 2004; Yu, Li, Ho & Lau, 2003), they just simply mentioned that study subjects were randomized into groups but no details of the randomization process were provided. As a result, the assessment could not be made.

Regarding blinding for treatment allocation, none of the study subjects were “blinded” in the 8 identified studies. Since all of the study subjects know whether they would receive intervention (exercise training) or not, blinding to study subjects was not possible. On the other hand, 3 studies applied blinding to the investigators (Marchionni et al., 2003; Sandstrom & Stahle, 2005; Yu et al., 2004), so that the evaluation of the outcome measures by those investigators was not biased.

**Level of evidence**

The level of evidence of the identified studies was determined based on the SIGN rating scheme for the strength of evidence (SIGN, 2008). The key to evidence statements is attached in Appendix D. One study is graded as “1++” (Briffa et al., 2005). It indicates that the randomized controlled trial has high quality so its evidence should be highly valued. Four studies are graded as “1+”, which indicates that they
were well-conducted randomized controlled trials and their evidences are of high value for reference (Bettencourt et al., 2005; Marchionni et al., 2003; Sandstrom & Stahle, 2005; Seki et al., 2003). However, 3 studies are graded as “1-”, which indicates that these studies have high risk of bias (Hage et al., 2003; Yu et al., 2004; Yu et al., 2003). Therefore, these evidences should be used with caution.

**Study objectives**

All of the studies defined their research questions and objectives clearly. All these 8 studies examined the effect of exercise training on quality of life in patients with coronary heart disease. In addition, 2 studies evaluated the impact of the exercise training on depression level (Bettencourt et al., 2005; Seki et al., 2003). Three studies also investigated its impact on exercise capacity (Hage et al., 2003; Marchionni et al., 2003; Yu et al., 2003). Three studies evaluated the cost-effectiveness of the program as well (Briffa et al., 2005; Sandstrom & Stahle, 2005; Yu et al., 2004).

**Sample characteristics**

Study subjects from the 8 identified studies were patients with coronary heart disease. To be more specific, 4 studies focused on patients with acute coronary syndrome (Bettencourt et al., 2005; Briffa et al., 2005; Hage et al., 2003; Sandstrom & Stahle,
2005), and 3 studies targeted on patients with recent myocardial infarction or with percutaneous coronary intervention (Marchionni et al., 2003; Yu et al., 2004; Yu et al., 2003).

The age of the study subjects ranged from 31 to 86 years old. 4 studies specifically investigated the impact of exercise training on the elderly population (Hage et al., 2003; Marchionni et al., 2003; Sandstrom & Stahle, 2005; Seki et al., 2003).

Moreover, 4 studies were conducted with European population (Bettencourt et al., 2005; Hage et al., 2003; Marchionni et al., 2003; Sandstrom & Stahle, 2005), 3 studies were conducted with Asian population (Seki et al., 2003; Yu et al., 2004; Yu et al., 2003), and 1 study was conducted with Australian population (Briffa et al., 2005).

**Drop-out rate**

Only 4 studies explicitly reported the number of study subjects dropping out from the study (Briffa et al., 2005; Hage et al., 2003; Marchionni et al., 2003; Yu et al., 2004). The overall drop-out rate of 3 of the studies was lower than 20%, which is generally regarded as acceptable (Briffa et al., 2005; Hage et al., 2003; Marchionni et al., 2003). However for the study conducted by Yu et al. (2004), the drop-out rate of the
intervention group was 27.1%, which is unacceptably high and decreases the quality of the evidence. For the other 4 studies, they did not mention the drop-out rate (Bettencourt et al., 2005; Sandstrom & Stahle, 2005; Seki et al., 2003; Yu et al., 2003), so that it is not sure whether there was no study subject dropping out or they just simply neglected the data from the study subjects who dropped out.

**Intervention**

All the 8 identified studies had supervised exercise training sessions as the intervention. However, the length of the program, frequency and duration of exercise training sessions, and types of exercise practiced by the study subjects varied from study to study. This would be further discussed in the synthesis section later. Moreover, 5 studies combined exercise training and educational and/or counseling as the intervention, while the control groups only received conventional medical and nursing care (Briffa et al., 2005; Marchionni et al., 2003; Seki et al., 2003; Yu et al., 2004; Yu et al., 2003).

**Time of data collection**

Baseline measurements were collected in all of the 8 identified studies. In addition, 2 studies measured the outcome data immediately after the program (Bettencourt et al.,
2005; Seki et al., 2003), and 2 studies measured the outcome data a period of time after the program (Briffa et al., 2005; Marchionni et al., 2003). 4 studies measured both the immediate effect and the long term effect of the exercise training program (Hage et al., 2003; Sandstrom & Stahle, 2005; Yu et al., 2004; Yu et al., 2003).

**Outcome measures**

For assessing quality of life of the study subjects, different measurement tools were adopted in the studies. The Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) is one of the most commonly used measurement tools in assessing quality of life. Among the 8 studies, 5 studies employed SF-36 as the outcome measurement tool (Bettencourt et al., 2005; Briffa et al., 2005; Seki et al., 2003; Yu et al., 2004; Yu et al., 2003). 3 studies adopted Time Trade Off (TTO) (Sandstrom & Stahle, 2005; Yu et al., 2004; Yu et al., 2003) and 2 studies adopted European Quality of Life Scale (EuroQol) (Hage et al., 2003; Sandstrom & Stahle, 2005). Only the study conducted by Briffa et al. (2005) used Utility-Based Quality of life-Heart questionnaire (UBQ-H) and only the study conducted by Marchionni et al. (2003) used Sickness Impact Profile (SIP) as the outcome measurement tool. The Symptom Questionnaire was adopted only in the study conducted by Yu et al. (2004).
**Results**

Among the 8 identified studies, 7 studies showed there was significant improvement in quality of life among study subjects who received exercise training, although in various aspects (Bettencourt et al., 2005; Briffa et al., 2005; Marchionni et al., 2003; Sandstrom & Stahle, 2005; Seki et al., 2003; Yu et al., 2004; Yu et al., 2003). However, only Hage et al.’s study (2003) reported that there was no statistically significant difference in quality of life between the intervention and control group. In fact, the intervention group in that study also showed improvement in quality of life. Hage et al. (2003) attributed this statistically insignificant result to the low sensitivity of the assessment tool.

**2.5 Synthesis**

After identifying relevant studies and performing quality assessments, the evidences can now be assembled for synthesis and recommendations are made for developing the evidence-based protocol. Tables in appendix E are constructed to clearly illustrate the results of the appraised studies.

**Time to start exercise training (Table 1, Appendix E)**

For patients’ safety, it is essential to recognize the optimal time for the start of the
exercise training for patients experiencing an acute coronary event. 5 studies suggested the time should be accorded to the period after the acute coronary event (Bettencourt et al., 2005; Marchionni et al., 2003; Seki et al., 2003; Yu et al., 2004; Yu et al., 2003), while 2 studies made a suggestion based on the time after discharge (Briffa et al., 2005; Hage et al., 2003). After synthesis of the evidences, it is recommended to commence exercise training within 2 weeks after discharge, or it is also considered safe to commence the program 4 to 6 weeks after an acute coronary event.

**Length of exercise training program** (*Table 2, Appendix E*)

The exercise training program of the study conducted by Briffa et al. (2005) lasted for 6 weeks, while 3 other studies suggested the program should last for 8 weeks (Marchionni et al., 2003; Yu et al., 2004; Yu et al., 2003). Two studies recommended the program should last for 12 weeks (Hage et al., 2003; Sandstrom & Stahle, 2005) and 2 studies recommended the program should last for at least 6 months (Bettencourt et al., 2005; Seki et al., 2003). In conclusion, it is suggested to conduct a 6-week to 8-week exercise training program.

**Frequency of supervised exercise sessions** (*Table 3, Appendix E*)
4 studies recommended the frequency of supervised exercise sessions should be 3 times a week (Bettencourt et al., 2005; Briffa et al., 2005; Hage et al., 2003; Sandstrom & Stahle, 2005). Three studies gave a recommendation of less than 3 times a week (Seki et al., 2003; Yu et al., 2004; Yu et al., 2003) while 1 study recommended more (Marchionni et al., 2003). In addition, Bettencourt et al. (2005) suggested once per month during the maintenance phase. In conclusion, it is recommended to have supervised exercise sessions 3 times a week during the program.

**Duration of each supervised exercise session** *(Table 4, Appendix E)*

Three studies agreed the duration of each exercise session should be 60 to 90 minutes (Bettencourt et al., 2005; Briffa et al., 2005; Seki et al., 2003). Two studies recommended the duration should be 50 minutes (Hage et al., 2003; Sandstrom & Stahle, 2005), while 2 other studies recommended the duration should be 120 minutes (Yu et al., 2004; Yu et al., 2003). For the study conducted by Marchionni et al. (2003), exercise sessions were divided into 2 types: endurance training and stretching and flexibility exercises. Marchionni et al. (2003) suggested 30 minutes for endurance training and 60 minutes for stretching and flexibility exercises. To conclude, the duration for each supervised exercise session should be 60 to 90 minutes.
**Types of exercises recommended** *(Table 5, Appendix E)*

All 8 studies consistently introduced aerobic exercise as a type of exercise for training patients in the cardiac rehabilitation program. Three studies also included warm-up and cool-down exercises in the training session (Bettencourt et al., 2005; Marchionni et al., 2003; Seki et al., 2003), while 1 study included only cool-down exercise (Sandstrom & Stahle, 2005). Only the study conducted by Briffa et al. (2005) included resistance training as well. Therefore, it is recommended to have aerobic exercise for the training sessions. Warm-up and cool-down exercises are also encouraged.

**Recommended exercise intensity** *(Tables 6, Appendix E)*

Only 3 studies explicitly stated the recommended exercise intensity in terms of percentage of maximum heart rate (Marchionni et al., 2003; Yu et al., 2004; Yu et al., 2003). However, in the other 5 studies, researchers did not monitor the heart rate of the study subjects for prescribing exercise intensity (Bettencourt et al., 2005; Briffa et al., 2005; Hage et al., 2003; Sandstrom & Stahle, 2005; Seki et al., 2003). Therefore, it is inconclusive to recommend the exercise intensity in accordance with the maximum heart rate. Instead, exercise intensity should be adjusted according to the tolerance level of the patients with reference to their results of symptom-limited
exercise test. The symptom-limited exercise test is recommended to be performed before the attendance of the exercise training sessions. Details of the test will be further discussed in the following part.

**Tests performed before exercise sessions (Tables 7, Appendix E)**

Among the 8 identified studies, 4 studies performed symptom-limited exercise test for the study subjects before the commencement of the exercise training program (Bettencourt et al., 2005; Marchionni et al., 2003; Sandstrom & Stahle, 2005; Seki et al., 2003). After synthesis of the evidences, it is recommended to perform a symptom-limited exercise test for the participants. The test is preliminarily used for assessing their exercise capacity and it should be performed before the commencement of their exercise training. As a result, it would be safer for the participants to receive exercise training as the exercise intensity is tailored for each of them.

**Exercise training only or combined with educational sessions (Tables 8, Appendix E)**

Five studies combined exercise training with educational sessions in their cardiac rehabilitation program (Briffa et al., 2005; Marchionni et al., 2003; Seki et al., 2003; Yu et al., 2004; Yu et al., 2003). Three studies provided exercise training only in the
cardiac rehabilitation program (Bettencourt et al., 2005; Hage et al., 2003; Sandstrom & Stahle, 2005). Therefore, it is recommended to include educational sessions in the exercise-based cardiac rehabilitation program. The purpose of the educational sessions is to modify patients’ lifestyle and to achieve a greater impact on the quality of life of the patients.
CHAPTER 3
IMPLEMENTATION POTENTIAL

In view of the physical and psychological benefits of exercise training for patients with coronary heart disease, it is worthwhile to implement the exercise training program in the local setting. In order to successfully translate the evidences into practice, the implementation potential is needed to be assessed carefully. In this chapter, the implementation potential is examined. Careful considerations are put on the transferability of the evidences, feasibility of the program in local setting, and the cost-benefit ratio of the program.

3.1 Target Setting

The exercise training program is proposed to be carried out in the cardiac unit of a designated public hospital under Hospital Authority in Hong Kong. The cardiac unit consists of a coronary care unit, 32 cardiac beds in 2 general medical wards, 2 cardiac catheterization laboratories, an echocardiography laboratory, and a cardiac ambulatory care centre. Annually, there are more than 1,500 patients admitted to the mentioned hospital and are under the care of the cardiac unit due to coronary heart disease.

The proposed venue for the exercise training program is the gymnasium of the
hospital. The gymnasium consists of an indoor basketball court and different gym equipments, such as treadmills and exercise bikes.

A cardiac rehabilitation nurse would be appointed to be in charge of the exercise training program. For the recruitment of the program, it is proposed that doctors and nurses in the cardiac unit would be responsible for making referrals according to the eligibility criteria in the protocol. In addition, the cardiac rehabilitation nurse would visit the wards of the cardiac unit and conduct screening for recruitment periodically.

3.2 Target Audience

The target audience of the proposed program is adult patients (aged 18 or above) who are admitted to the hospital due to coronary heart disease. Regardless of the types of treatments the patients would receive (i.e. thrombolytic therapy, percutaneous intervention, coronary artery bypass graft surgery, or conservative medical treatment), they would be invited to participate in the program and start having exercise training within 2 weeks after discharge. However, patients who are complicated with other cardiac diseases or have physical disabilities would be excluded from the program and would receive the usual medical and nursing care.
3.3 Transferability of the Evidences

Although it is recognized that exercise training is beneficial for patients with coronary heart disease in terms of improving their physical capacity and quality of life and the intervention is worthwhile to be implemented, we still need to assess if the evidences can be transferred to the local setting before implementation.

Similarity of target setting

The programs of the 8 identified research studies were all carried out on an outpatient basis and the recruitment of the participants were all performed in the inpatient setting, either by screening from researchers or referral from doctors or nurses. Regarding the venue for exercise training, the programs of 3 identified studies were held in the gymnasium of the hospitals (Bettencourt et al., 2005; Marchionni et al., 2003; Sandstrom & Stahle, 2005), whereas the programs of 3 other studies were held in either outpatient clinics or rehabilitation centers (Seki et al., 2003; Yu et al., 2004; Yu et al., 2003). (Two studies did not mention the venue (Briffa et al., 2005; Hage et al., 2003).) As the proposed program will be held in a gymnasium of the hospital, there are similarities between the proposed program and the identified studies.

Similarity of target audience
All participants of the 8 identified studies were adult patients admitted to hospital for coronary heart disease, while 4 studies specifically recruited elderly patients (Hage et al., 2003; Marchionni et al., 2003; Sandstrom & Stahle, 2005; Seki et al., 2003). Five studies excluded the patients with uncompensated heart failure, uncontrolled arrhythmia, uncontrolled hypertension, significant valvular stenosis, cognitive impairment, or physical disability (Briffa et al., 2005; Marchionni et al., 2003; Sandstrom & Stahle, 2005; Yu et al., 2004; Yu et al., 2003). Therefore, the audiences of the identified studies are similar to that of the proposed program.

Although only 3 studies were conducted with Asian population (Seki et al., 2003; Yu et al., 2004; Yu et al., 2003) and the others were conducted with European or Australian population (Bettencourt et al., 2005; Briffa et al., 2005; Hage et al., 2003; Marchionni et al., 2003; Sandstrom & Stahle, 2005), it is believed that the effect of cultural influence would be minimal because exercise is not cultural-specific.

**Philosophy of care**

The mission of the Hospital Authority is “Helping People Stay Healthy”. She remarks that health care professionals are the partners of patients to “empower them (patients) to regain their health and stay healthy by offering them support in the forms of
diagnosis, medication, exercises, information, encouragement and motivation”. (HA, 2010). Since the proposed program aims to improve the quality of life of patients with coronary heart disease by offering them support in the forms of exercises, information, encouragement and motivation, it has similar philosophy of care with the Hospital Authority.

In addition, one of the missions of the designated hospital is “promoting health and a healthy lifestyle” (Queen Elizabeth Hospital, 2012), while the proposed program aims to promote healthy lifestyle by providing exercise training sessions to the patients with coronary heart disease. Therefore, the philosophy of care underlying the proposed program is fundamentally equivalent to that of the designated hospital.

**Number of patients benefit from the program**

Each year, there are more than 1,500 patients admitted to the designated hospital under the care of the cardiac unit due to coronary heart disease. If 50% of these patients are eligible and willing to participate in the program after hospital discharge, there are already a significant number of patients benefited from the program.

**Schedule for implementation and evaluation**
To decide if the evidences are transferrable, it is important to consider if the program would take too long to implement and evaluate. It is proposed to use 4 months for planning and preparation for the program, which includes developing the evidence-based protocol, establishing implementation and evaluation plan, seeking approval from the managerial level, and applying for funding. Then it would take around 3 months for introducing the program to all the staffs in the cardiac unit and obtaining feedbacks and suggestions from them. Meanwhile, specialized training would be provided to the cardiac rehabilitation nurse who would be responsible for the program, and 4 identical basic training seminars would be held for all the nursing staffs in the cardiac unit. After that, it is proposed to take 3 months for the recruitment of participants and implement the program as a pilot test. After the pilot test, it is proposed to use 1 month for evaluating the effectiveness of the program in improving physical activity level and quality of life of the participants. Therefore, in total, it is estimated to use around 11 months for planning, preparation, implementation and evaluation of the exercise training program, which is a justified and affordable length of time.

After considering the similarity of setting, audience and philosophy of care, number of patients benefit from the program, and the schedule for implementation and
evaluation, it can be concluded that the transferability of the evidences to the cardiac unit of the designated hospital is high.

3.4 Feasibility of the Program in Local Setting

Although it is considered that the evidences are transferrable to the local setting, we still need to assess whether the exercise training program is feasible to be implemented in the local setting. The feasibility is examined in several dimensions: actualization of the program, authority and autonomy of nurses, organization climate and administrative support, support from staff, staff training, resources, anticipated resistance and evaluation tool.

Actualization of the program

In fact, cardiac rehabilitation program has already been implemented in the cardiac unit of the designated hospital for more than 10 years. In the existing cardiac rehabilitation program, it consists of 7 components: physical training, education about the disease, its treatment and prognosis, dietary management, smoking cessation, promotion of psychological adjustment, and help with social problems. A cardiac rehabilitation nurse, who is an advance practicing nurse in the cardiac specialty, is in charge of the existing cardiac rehabilitation program. The recruitment of eligible
patients is either screened by the cardiac rehabilitation nurse or referred by doctors or nurses in the cardiac unit.

This translational research modifies the exercise training protocol of the existing cardiac rehabilitation program with the latest available research evidences. The main difference between the existing program and the proposed program is that the proposed program would introduce a symptom-limited exercise test. Because of the test, the exercise intensity of the proposed program can be tailored according to participant’s tolerance, while the existing program prescribes exercise to all participants with the same intensity. In the proposed program, the test is suggested to be performed by a cardiac rehabilitation nurse (who is a trained registered nurse in the cardiac unit).

The aim of the symptom-limited exercise test is to elicit participants’ body reactions to dynamic exercise and monitor the changes that are not observable when they are at rest. During the test, participants are asked to walk and run on a treadmill, and meanwhile their physiological parameters, such as cardiac rhythm, heart rate, blood pressure, oxygen saturation of blood and respiratory rate, are monitored. When the participant makes a complaint or there is abnormality detected during the test, the test
would be stopped immediately. Through these processes, maximum exercise intensity can be obtained for each participant.

Authority and autonomy of nurses

In the cardiac unit of the designated hospital, there is a cardiac rehabilitation nurse responsible for the existing cardiac rehabilitation program. The cardiac rehabilitation nurse is very knowledgeable in the cardiac specialty and has acquired skills for carrying out the cardiac rehabilitation program. The nurse also has high autonomy to initiate evidence-based innovations. Therefore, the proposed exercise training program would be supervised by the cardiac rehabilitation nurse.

Although the cardiac rehabilitation nurse has high autonomy in practice, the implementation, termination or change of a program still need approval from the managerial level, that is, the ward manager, department operations manager and chief of service.

Organization climate and administrative support

The designated hospital formulated her code of professional ethics, which promises to “maintain the highest standard of professional competence” and to “continue to
update and improve professional knowledge and skill” (Queen Elizabeth Hospital, 2012). Hence it can be seen that the designated hospital encourages evidence-based innovations.

In addition, the administrators of the cardiac unit of the designated hospital are very supportive to the utilization of the best available research evidences. For example, in 2011, the department introduced the transcatheter aortic valve implantation (TAVI) for patients with severe aortic stenosis who are not candidates for open heart surgery. This technique was developed in Europe a few years ago and was first brought to Hong Kong. Moreover, the cardiac nurse specialist regularly reviews and shares updated research findings with nursing staffs. Some of the existing nursing practices in the cardiac unit are developed and validated by research evidences. Therefore, it is believed that the exercise training program would be greatly supported by the department.

Support from staff

The proposed exercise training program differs from the existing one mainly by adding the symptom-limited exercise test for tailoring exercise intensity for participants. As a consequence, another registered nurse, who would be appointed as
the cardiac rehabilitation nurse, is needed for the implementation of the new program.

In fact, most of the staffs in the cardiac unit would not be affected by the change and the new program would not add much workload to them. Therefore, it is expected that all staffs in the cardiac unit would welcome the new program.

**Staff training**

Although the nursing staffs in the cardiac unit are all familiar with electrocardiogram (ECG) and other physiological measures which would be used for monitoring during the symptom-limited exercise test, the designated cardiac rehabilitation nurse who would perform the test for the participants still need training about the details of the test and the points for attention. Therefore, the registered nurse, who would be appointed as the cardiac rehabilitation nurse for performing the symptom-limited exercise test, would receive specialized training from a cardiologist.

Moreover, 4 identical basic training seminars would be held for disseminating the most updated research findings of the importance of exercise training to patients with coronary heart disease and to point out the differences between the existing protocol and the new protocol. In addition, all nursing staffs who attend the seminar would receive basic training to perform the symptom-limited exercise test. As a result, all the
nursing staffs in the cardiac unit would gain a better understanding of the proposed exercise training program and hence they would become supportive towards the implementation of the program.

**Resources**

Regarding the issue of manpower, one extra nursing staff (a registered nurse) would be needed to be in charge of the exercise training program. The nurse would be responsible for performing the symptom-limited exercise test for the participants.

Regarding the issue of equipment, a treadmill, a 12-lead electrocardiogram monitor, a blood pressure monitor, and a pulse oximeter are needed for performing the symptom-limited exercise test.

Regarding the venue, a small room is needed for performing the symptom-limited exercise test and planning for individualized exercise intensity. Moreover, a gymnasium is needed for providing exercise training to the participants.

**Anticipated resistance**

Since there is a shortage of manpower in the cardiac unit of the designated hospital, it
would be difficult for the managerial level to arrange nursing manpower and assign a nursing staff to the new post. However, since more nursing graduates would be recruited in the late July, the shortage of manpower may be relieved at that time. Therefore, it is believed that one nursing staff can be assigned to take up the new post and receive training.

In addition, the shortage of manpower will also pose difficulty for all the nursing staffs in the cardiac unit to attend the seminars. However, this can be resolved by distributing the learning materials to the staffs who cannot attend the seminar, so that they can learn about the changes by reading the materials in their own time.

**Evaluation tool**

The main outcome measure of the effectiveness of the exercise training program is quality of life. It would be assessed by the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36). The SF-36 is a widely used generic questionnaire, measuring 8 dimensions of health: physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. The highest score for each subscale is 100 and the lowest score is 0. A higher score suggests a higher quality of life. The Chinese version of SF-36 would be provided for
Chinese patients and the English version would be available for those patients who can read English, instead of Chinese. It has been proven that the Chinese version of SF-36 is a valid and reliable instrument for assessing quality of life among Chinese patients with coronary heart disease (Wang, Lopez, Ying, & Thompson, 2006). The SF-36 scores of the participants would be obtained before they participate in the program and 4 months after they complete the program.

Since quality of life is a relatively long term outcome measure, level of physical activity would be included as a short-term outcome measure of the effectiveness of the exercise training program. In particular, participants’ level of physical activity would be estimated by the long format of the International Physical Activity Questionnaire (IPAQ-LC). A higher score suggests a more strenuous exercise level. IPAQ-LC has been shown to be adequately valid and reliable for assessing level of physical activity (Macfarlane, Chan, & Cerin, 2010). In addition, the Chinese version of IPAQ-LC is verified by Macfarlane et al. (2010) to be reliable and valid for measuring the overall level of physical activity for Hong Kong adults. Therefore, both Chinese version and English version of IPAQ-LC would be available for the assessment. The level of physical activity of participants would be compared before they participate in the program and 1 week after they complete the program.
After considering the above dimensions, it can be concluded that the feasibility of implementation of the program in the cardiac unit of the designated hospital is high.

3.5 Cost-benefit Ratio of the Program

In order to justify the new exercise training program, the expected costs and benefits of the program should be analyzed and compared. Cost-benefit ratio is an indicator which summarizes the overall value of the program.

Risks of maintaining current practice

Although cardiac rehabilitation program is launched in the cardiac unit of the designated hospital for more than 10 years, the existing exercise training program was developed not based on the best available evidence. Consequently, it is not known whether the program is optimal for the patients with coronary heart disease in improving their quality of life and level of physical activity. In addition, under the existing program, participants do not perform the symptom-limited exercise test before receiving training and therefore exercise intensity cannot be tailored for participants individually. As a result, inappropriate exercise training may elicit cardiovascular abnormalities for these participants and may even cause cardiac arrest.
Therefore, maintaining the current practice bears risks to the participants.

**Potential benefits of implementing new protocol**

Since the protocol of new exercise training program is developed based on the best available evidences, the length of the program, the frequency, duration, and mode of the exercise sessions are formulated for the greatest benefits of patients. Moreover, the effectiveness of the program in improving quality of life and level of physical activity for patients with coronary heart disease is well supported. Furthermore, since the most significant change of program is adding the symptom-limited exercise test for evaluating participant’s level of exercise tolerance and tailoring exercise intensity for them, it would be safer for participants to receive exercise training.

**Potential risks of implementing new protocol**

The aim of the symptom-limited exercise test is to elicit participants’ body reactions to dynamic exercise and monitor the changes that are not observable when they are at rest. Therefore, the test may elicit cardiovascular abnormalities and there is a risk of causing cardiac arrest. However, physiological parameters, such as cardiac rhythm, heart rate, blood pressure, oxygen saturation of blood, respiratory rate, are closely monitored during the test. Whenever the participant makes a complaint or there is
abnormality detected during the test, it would be stopped immediately. As screening for participants’ exercise tolerance is not provided in the current practice, the proposed program, which provides screening for participants’ physical capacity before the exercise training, would definitely be safer than the current practice.

**Material cost**

The material cost of implementation of the proposed exercise training program would be divided into 2 parts: one-off cost and running cost.

The one-off cost includes the cost for the official release of staffs for training. It includes the specific training for the cardiac rehabilitation nurse and the seminars introducing the new exercise training program for all the nursing staffs in the cardiac unit. The mean monthly salary of a registered nurse is HK$28,380 (point 20) (Civil Service Bureau, 2011). Hence, the estimated hourly salary is HK$28,380 / 4 weeks / 44 hours = HK$161. Therefore, the cost of official release for training the cardiac rehabilitation nurse for 8 hours would be around HKD$1,288 and the cost for official release for 60 nursing staffs in the cardiac unit to attend a 2-hour seminar would be HKD$19,320. The one-off cost also includes the purchase of equipments for the symptom-limited exercise test: a treadmill (HK$15,000), a 12-lead electrocardiogram
monitoring machine (HK$80,000), a blood pressure monitor (HK$1,000) and a pulse oximeter (HK$800). In total, the one-off cost would be HK$117,408.

The running cost comprises of the cost for the manpower in charge of the program, printing materials, and the venue for performing the symptom-limited exercise test and exercise training. For manpower, since a registered nurse in the cardiac unit would be appointed as the cardiac rehabilitation nurse to hold the program, the monthly salary of the nurse would be around HK$28,380. For printing materials for exercise assessment and training records, papers, ink cartilages and stationery are needed, which cost around HK$500/month. For the venue to perform the symptom-limited exercise test, a small room in the cardiac unit would be spared for the installation of the equipments. For the venue for the exercise training, the gymnasium of the hospital can be used. Therefore, there is no cost associated with the venue. In total, the monthly running cost of the program would be HK$28,880.

**Non-material cost**

Since the proposed exercise training program emphasizes individualized advice for exercise intensity, it increases the time and workload of the cardiac rehabilitation nurse for performing the symptom-limited exercise test and tailoring exercise
intensity for participants.

**Saving in cost**

According to Yu et al.’s study (2004) which evaluated the cost effectiveness of an exercise training program in Hong Kong for patients with coronary heart disease, patients who received exercise training would save US$650 (HK$5,047) per the quality-adjusted life-year (QALY) gained. That is, the health care expenses were reduced for patients who received exercise training. This is mainly related to the decrease in recurrent admissions and subsequent needs for percutaneous interventions (Yu et al., 2004).

After balancing the costs and benefits of the implementation of the new exercise training program, the benefits outweigh the costs. It can be concluded that the proposed program is highly cost effective.

In conclusion, in view of the high transferability of the evidences, high feasibility of the program in the local setting and high cost effectiveness, the implementation potential of the proposed program is considered as high.
CHAPTER 4

EVIDENCE-BASED PRACTICE PROTOCOL

This evidence-based practice protocol is developed in order to guide healthcare professionals in the cardiac unit of the designated hospital to execute the exercise training program in a safe and effective way.

4.1 Title of the Protocol

The title of the protocol is “Evidence-based Protocol: Exercise Training for Patients with Coronary Heart Disease”.

4.2 Aim

The aim of the protocol is to enhance the quality of life and level of physical activity of patients with coronary heart disease.

4.3 Objectives

The objectives of the protocol are:

1. To provide information and guideline for healthcare professionals to conduct an effective exercise training program for patients with coronary heart disease.

2. To improve the quality of life of patients with coronary heart disease 6 months
after an acute coronary event.

3. To increase the level of physical activity of patients with coronary heart disease after an acute coronary event.

4.4 Intended Users

The intended users of the protocol are the cardiac rehabilitation nurses, doctors and all the nursing staffs who work in the cardiac unit. They include nursing officers, advance practicing nurses and registered nurses. The cardiac rehabilitation nurses are the personnel who would be in charge of the program. Other nursing staffs and doctors are responsible for promoting the program and referring eligible patients to participate in the program.

4.5 Target Group

The target group of the protocol is the adult patients (aged 18 or above) admitted for coronary heart disease, regardless of the treatments they receive. However, patients who are complicated with other cardiac diseases or have physical disabilities would be excluded.

4.6 Outcome Measures
The outcome measures of the protocol are the quality of life and level of physical activity. Participants’ quality of life would be assessed by the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) before their participations in the exercise training and 4 months after the completion of their training. Their level of physical activity would be evaluated by the long format of the International Physical Activity Questionnaire (IPAQ-LC) before their participations in the exercise training and 1 week after the completion of their training.

4.7 Grades of Recommendation

In this protocol, SIGN’s “Grades of Recommendation” (SIGN, 2008) is employed to indicate the strength of the evidence for each recommendation. However, it is remarked by SIGN (2008) that the grading of the recommendation does not demonstrate its clinical significance. Detailed description of the grading is shown in Appendix F.

4.8 Recommendations

In total, there are 7 recommendations in this protocol based on the 8 identified studies.

All the recommendations in this protocol are graded “A” according to SIGN’s “Grades of Recommendation”.
**Recommendation 1: Test performed before exercise training sessions (Grade A)**

Patients are recommended to perform a symptom-limited exercise test for assessment of their physical capacity before the commencement of the exercise training sessions.

[Bettencourt et al., 2005 (1+); Marchionni et al., 2003 (1+); Sandstrom et al., 2005 (1+); Seki et al., 2003 (1+)]

**Recommendation 2: Time to start exercise training (Grade A)**

Eligible patients with coronary heart disease should commence the program within 2 weeks after discharge.

[Briffa et al., 2005 (1++)]

**Recommendation 3: Length of exercise training program (Grade A)**

The program which lasts around 6 weeks would be beneficial to patients for enhancing their quality of life.

[Briffa et al., 2005 (1++)]

**Recommendation 4: Frequency of supervised exercise sessions (Grade A)**

The supervised exercise training sessions should be 3 times a week in order to obtain
its optimal effectiveness.

[Bettencourt et al., 2005 (1+); Briffa et al., 2005 (1++); Hage et al., 2003 (1-);
Sandstrom et al., 2005 (1+)]

**Recommendation 5: Duration of each supervised exercise session (Grade A)**

The duration for each supervised exercise session should last 60 to 90 minutes.

[Bettencourt et al., 2005 (1+); Briffa et al., 2005 (1++); Marchionni et al., 2003 (1+);
Seki et al., 2003 (1+)]

**Recommendation 6: Type of exercises (Grade A)**

Aerobic exercise, such as running on treadmill or riding ergometric bicycle, should be
the major type of exercise for training patients with coronary heart disease.

[Bettencourt et al., 2005 (1+); Briffa et al., 2005 (1++); Hage et al., 2003 (1-);
Marchionni et al., 2003 (1+); Sandstrom et al., 2005 (1+); Seki et al., 2003 (1+); Yu et
al., 2004 (1-); Yu et al., 2003 (1-)]

Each training session should consist of a 5-minute warm-up period at the beginning,
and a 5-minute cool-down period at the end.

[Bettencourt et al., 2005 (1+); Marchionni et al., 2003 (1+); Sandstrom et al., 2005
(1+); Seki et al., 2003 (1+)

**Recommendation 7: Exercise intensity (Grade A)**

Exercise intensity should be adjusted according to individual participant’s tolerance.

Although the evidence suggesting the adjustment of exercise intensity should accord to participant’s maximum heart rate is yet to be conclusive, it is advised to adjust exercise intensity according to the result of the symptom-limited exercise test.

[Bettencourt et al., 2005 (1+); Marchionni et al., 2003 (1+); Sandstrom et al., 2005 (1+); Seki et al., 2003 (1+)]
CHAPTER 5

IMPLEMENTATION PLAN

Now, having the evidence-based protocol developed, it is important to design the implementation plan in order to move the innovation from the phase of development to service provision. The implementation plan consists of two main components: communication plan and pilot test.

5.1 Communication Plan

Ongoing effective communication with stakeholders at all levels is essential to ascertain a smooth implementation of the innovation. The aims of the communication activities are:

1. To disseminate information about the proposed evidence-based protocol to all stakeholders;

2. To obtain approval from the administrators; and

3. To gain support from all stakeholders.

Stakeholders

Stakeholders are the people who are affected by the proposed protocol or anticipated results of the proposed protocol. The stakeholders of this evidence-based protocol are
the Chief of Service (COS), Department Operation Manager (DOM), Ward Manager (WM), nurses of all ranks (nursing officers/ advanced practice nurses/ a nurse specialist/ registered nurses/ enrolled nurses), doctors, health care assistants (HCA) of the cardiac unit of the designated public hospital, and also the patients admitted for coronary heart disease. Different strategies would be adopted to communicate with these stakeholders.

**Communication Activities**

The communication activities can be divided into 3 phases: the initiation phase, the facilitation phase, and the sustaining phase. The initiation phase begins with the idea of making a change and ends with obtaining approval and funding from the administrators to carry out the change. The facilitation phase starts when the proposed protocol is approved and ends when the proposed protocol is put into practice. The sustaining phase starts when the proposed protocol is implemented and this phase is kept going as long as the protocol is still in use.

**Initiation Phase**

It is estimated that the initiation phase would take around 16 weeks in total. It starts with an open discussion among nursing staffs of the designated cardiac unit. It would
be an informal discussion regarding the existing cardiac rehabilitation program. The cardiac nurses are encouraged to express their opinions freely on any issues of the existing cardiac rehabilitation program, such as its effectiveness in improving physical fitness and quality of life of patients with coronary heart disease, the attendance of the program, participants’ compliance, the safety issues, etc. During the discussion, the evidence supporting the changes and the advantages of developing an evidence-based protocol would be brought up. After the discussion, three to four cardiac nurses, preferably more experienced, who show supportive attitude towards the changes would be invited to form a group of innovators to lead the change.

Then the innovators would spend approximately 4 weeks to gather the best evidence supporting the change, draft the evidence-based protocol, and have a preliminary meeting with the ward manager. During the meeting, the innovators would discuss the identified problems of the existing program with the ward manager, emphasize the needs and benefits of making changes, estimate the cost of making changes and obtain feedbacks from the ward manager. The innovators need to be well prepared and convincing at this stage. Otherwise, the ward manager may reject the innovation and so it will not proceed to the higher level of administrators.
After revising the evidence-based protocol, it would be presented to the higher level of administrators (i.e. COS and DOM). The contents of the presentation are: 1) identified problems of the existing program; 2) the advantages of the proposed protocol over the existing one, as supported by evidences; 3) summary of the protocol; and 4) feasibility and transferability of the protocol. The communication activity at this stage is very critical. In order to obtain approval and funding from the administrators, the innovators need to emphasize on the significance of the changes during the presentation. Moreover, the presentation has to be precise and concise.

*Facilitation Phase*

Facilitation phase starts when the proposed protocol is approved by the administrators. It is estimated that the facilitation phase would take around 12 weeks.

In order to enhance the knowledge and the competence of the nursing staffs in the designated cardiac unit to implement the proposed protocol, a seminar would be held to share the most updated research evidence regarding the exercise training for patients with coronary heart disease. The differences between the current protocol and the new protocol would be highlighted. In addition, all nursing staffs who attend the seminar would receive basic training to perform the symptom-limited exercise test. In
total, 4 identical sessions would be held so all nursing staffs in the designated cardiac unit can attend the seminar.

Besides holding seminar, detailed information about the proposed protocol would be disseminated to all nursing staffs, doctors, and health care assistants of the designated cardiac unit by internal mass emails. In addition, information sheets would also be posted up on the department website, and at nursing stations and pantries of the cardiac wards. As a result, convenient access to the information is available to all the staffs.

Meanwhile, all the nursing staffs, doctors and health care assistants are encouraged to give feedbacks and suggestions to improve the proposed protocol. Feedbacks and suggestions are mainly obtained by two means: interview and collection box. Staffs who are supportive towards the innovation and eager to give constructive opinions would be interviewed by the innovators. It would be an unstructured interview, so the staffs can express their opinions and ideas freely. On the other hand, collection boxes would be set up in the wards of the designated cardiac unit. Opinions and questions from all the staffs of the designated cardiac unit are welcomed. Innovators would be responsible for answering the questions. Communication activities at this stage not
only allow the staffs to express their opinions on the proposed protocol freely, but also provide a platform for the innovators to clarify any ambiguities and answer the enquiries. The mode of communication is expected to be interactive.

Last but not least, the new exercise training program would be introduced to the potential participants (patients with coronary heart disease who are eligible to join the proposed program) and their families. The mode of the exercise training program and the benefits of the exercise training would be explained by the nurses of the designated cardiac unit. Moreover, pamphlets would be given to the potential participants for reference. In addition, posters promoting the exercise training program would be posted up in the wards of the designated cardiac unit to draw the attention of the potential participants and their relatives.

Sustaining Phase

The sustaining phase starts when the proposed protocol is implemented and it keeps going as long as the protocol is still in use. At the beginning of the sustaining phase, a pilot test would be conducted to assess the feasibility of the protocol and the protocol would be revised if necessary. It is planned to take about 16 weeks for conducting the pilot test. The details of the pilot test would be discussed in the following section
(Section 5.2). After the pilot test, the innovators would obtain feedbacks from all the stakeholders and further revisions would be made if necessary. Furthermore, the results of the pilot test would be shared with all the stakeholders. It is expected that the inspiring results would gain greater support from all the stakeholders to sustain the innovation.

5.2 Pilot Test

Pilot test is a small scale, preliminary actualization of the proposed protocol. The aims of the pilot test are:

1. To assess the feasibility of the proposed protocol;
2. To assess the compliance of cardiac nurses;
3. To monitor patient outcomes;
4. To identify difficulties in implementing the protocol; and
5. To determine whether revisions of the protocol are needed.

Participants

Participants of the pilot test are the providers and the recipients of the intervention.

Three voluntary nurses from the designated cardiac unit, who have attended the
training seminar, would be recruited to be the intervention providers. They would be responsible for the assessment of eligibility of patients and the recruitment of eligible patients. A cardiac rehabilitation nurse would be responsible for conducting the symptom-limited exercise test and the exercise training sessions in accordance with the proposed protocol.

Twelve eligible patients would be recruited to be the recipients of the intervention. Their eligibility would be the same as the inclusion and exclusion criteria of the proposed protocol. Therefore, adult patients (aged 18 or above) admitted for coronary heart disease, regardless of the treatments they receive, would be included in the pilot test. However, patients who are complicated with other cardiac diseases or have physical disabilities would be excluded.

All the participants would be recruited by convenience sampling, based on their availability and voluntariness.

Procedure

The pilot test would be conducted in the designated cardiac unit. It is proposed to take about 16 weeks for conducting the pilot test.
For the first 6 weeks, voluntary cardiac nurses and eligible patients would be recruited.

In addition, baseline assessments of the quality of life and level of physical activity of the eligible patients would be conducted. The symptom-limited exercise test would also be performed for patients individually.

Then, for the next 6 weeks, exercise training sessions that are supervised by the cardiac rehabilitation nurse would be conducted. He/she would arrange training sessions for the eligible patients according to the proposed protocol.

The last 4 weeks would be the evaluation period. Process and outcome evaluations would be performed in order to refine the protocol. Details of the evaluation would be discussed in the following part.

**Evaluation**

For the sake of assessing the feasibility of the proposed protocol, 2 methods of evaluation would be employed: Process evaluation and Outcome evaluation. However, in this pilot test, process evaluation would be emphasized as it can provide more valuable information for refining the program.
Process Evaluation

Process evaluation focuses on the implementation and operation of the program. It obtains information for verifying whether the program is being implemented as designed. Therefore, the compliance of the voluntary cardiac nurses and the cardiac rehabilitation nurse with the protocol would be reviewed. The innovators would assess their compliance with reference to their documentations.

Meanwhile, individual interviews would be conducted by the innovators, inviting the voluntary cardiac nurses, the cardiac rehabilitation nurse, and eligible patients who participated in the pilot test to express their opinions and level of satisfaction on the program. It would be a semi-structured interview. The participants are welcomed to point out the strengths and weaknesses of the program, to comment on the logistic arrangement and resource availability of the program, and to bring up the difficulties they encountered. Each interview would last around 10 minutes. The gathered information would be used for improving the program.

Outcome Evaluation

Outcome evaluation focuses on the success and accomplishments of the program. It
assesses whether the program has achieved its objectives. Two categories of outcomes would be evaluated in the pilot test: Patient outcomes and Healthcare provider outcomes.

For the patient outcomes, quality of life and level of physical activity of the participants would be assessed before the participants receive their exercise training and 1 week after they complete the exercise training program. Quality of life would be assessed by the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36). Level of physical activity would be assessed by the long format of the International Physical Activity Questionnaire (IPAQ-LC). Although quality of life is regarded as a relatively long term outcome measure, it is still assessed in the pilot test for reference.

For the healthcare provider outcomes, cardiac nurses’ knowledge concerning the exercise training for patients with coronary heart disease would be examined after their attendance of the training seminar. It would be assessed by a quiz which consists of 15 multiple choice questions. The quiz would be constructed by the innovators, according to the content of the seminar. The cardiac nurse would get a pass if he/she can answer more than 80% of the multiple choice questions correctly.
After the evaluation of pilot test is done, the innovators would gather the results and decide whether further revisions of the protocol are needed.
Finally, it comes to the last yet crucial part of this translational research – Evaluation. Systematic process and outcome evaluations are very important for the stakeholders to understand the effectiveness of the program in fulfilling its objectives. Furthermore, it provides invaluable information for the administrators to decide whether to allot funds to sustain the program in view of limited resource. The evaluation plan for the program is therefore developed as below.

6.1 Aims and Objectives

Aim

The aim of the evaluation plan is to determine the effectiveness of the evidence-based exercise training protocol in improving quality of life and level of physical activity for patients with coronary heart disease.

Objectives

The objectives of the evaluation plan are:

1. To decide the characteristics and number of patients to be involved;

2. To identify outcomes to be achieved by the protocol;
3. To determine the time and frequency of taking measurements;

4. To specify method of data analysis; and

5. To establish basis for determining the effectiveness of the protocol.

6.2 Characteristics and Number of Patients to be involved

Characteristics of Patients

The characteristics of the patients to be involved in the evaluation are identical to the eligibility of patients to be recruited in the program. As stated in the earlier chapter, the adult patients (aged 18 or above) admitted for coronary heart disease, regardless of the treatments they receive, would be included. However, patients who are complicated with other cardiac diseases or have physical disabilities would be excluded.

Number of Patients

The number of patients needed to be included for evaluation is estimated by the Java Applets for Power and Sample Size (Lenth, 2006-9). Since the primary patient outcome is the quality of life of the patients, which is measured by the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36), the method employed for data analysis would be a two-tailed paired t-test. The standard deviation (sigma) of
SF-36 scores is estimated to be around 33, with reference to Yu et al.’s study (2003). The minimal significant difference in scores of each subscale is 15 (Wyrwich et al., 2004). The level of significance (alpha) and the power are taken as 0.05 and 0.8 respectively, as conventional practice. Based on the above calculation, the sample size required for the evaluation would be 40 and the estimated recruitment time would be 6 weeks.

6.3 Process Evaluation

As mentioned in the previous chapter, process evaluation focuses on the implementation and operation of the program. The items for process evaluation are categorized into healthcare provider outcome and system outcomes.

Healthcare Provider Outcome

Compliance with the Protocol

Nurses’ compliance with the protocol would be examined. Nurses in the designated cardiac unit are expected to assess the eligibility of each patient admitted for coronary heart disease in their wards for receiving the exercise training. They are also responsible for referring eligible patients to the cardiac rehabilitation nurses. Nurses who have made the assessments and referrals should document their actions in the
Nursing Kardex. The innovators would assess their compliance with reference to their documentations.

The cardiac rehabilitation nurse, who conducts the exercise training program, is expected to follow the protocol and hold the exercise training sessions. The cardiac rehabilitation nurse also needs to have full documentations regarding the details of each training session. As a result, innovators can verify to what extent he/she complies with the protocol.

The documentations would be checked every 2 months after the program is implemented. If more than 80% of the patients admitted for coronary heart disease in their wards are being assessed for eligibility to join the exercise training program and are referred if appropriate, the compliance of the nurses in the designated cardiac unit would be considered as good. The compliance of the cardiac rehabilitation nurse would be considered as good if more than 80% of the items in the protocol in conducting exercise training sessions are followed.

**System Outcomes**

**Adverse Events**
Since the proposed protocol emphasizes patient safety, the number of participants experiencing major adverse events during the exercise training would be documented for evaluation. Major adverse events include cardiovascular abnormalities, such as symptomatic arrhythmia, and cardiac arrest. Once the participants experience discomfort during the exercise training, they would be advised to stop their training immediately and would be assessed and taken care by the cardiac rehabilitation nurse in charge. The cardiac rehabilitation nurse would document the incident and classify whether it is a major adverse event.

The number of participants experiencing major adverse events during exercise training would be evaluated 4 months after the implementation of the protocol. The program would be considered as effective if less than 5% of participants experience major adverse events during the exercise training.

Cost

In view of the limited resource allocated to the public sector of healthcare system in Hong Kong, the program has to be cost effective in order to sustain. Therefore, the costs for the implementation of the protocol would be evaluated. The actual one-off cost for purchasing equipments and providing training for nursing staff, and the actual
monthly-running cost would be recorded.

The cost effectiveness of the program would be evaluated 1 year after the implementation of the program. The program would be regarded as cost effective if the total cost (including the one-off cost and running cost) for running the program in the first year is less than HKD 2,000,000. This estimate is based on Yu et al.’s study (2004) in which they evaluated the cost effectiveness of an exercise training program in Hong Kong for patients with coronary heart disease. According to Yu et al. (2004), patients who received exercise training can save US$650 (HK$5,047) per quality-adjusted life-year (QALY). It is thought to be related to the decrease in recurrent admissions and subsequent needs for percutaneous interventions. So, for the proposed program, if 400 patients are recruited each year and approximately HKD 5000 is saved for each patient, the overall amount that can be saved in each year would be HKD 2,000,000. Therefore, if the actual cost of the program is less than HKD 2,000,000 in the first year of the implementation, the program would be considered as cost effective.

6.4 Outcome Evaluation

As mentioned in the previous chapter, outcome evaluation focuses on the success and
accomplishments of the program. The items for outcome evaluation are categorized into patient outcomes and healthcare provider outcomes.

**Patient Outcomes**

Since patient outcomes are the primary objectives of the protocol, they are the prime factors determining the success of the program.

**Primary Patient Outcome**

The primary patient outcome is the quality of life of the patients, which is assessed by the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36). The Chinese version of SF-36 is proven to be a valid and reliable instrument for assessing quality of life of Chinese patients with coronary heart disease (Wang, Lopez, Ying, & Thompson, 2006).

The SF-36 scores of participants would be obtained before the patients participate in the program and 4 months after they complete the program. Two-tailed paired t-test would be adopted for data analysis with the level of significance set at 0.05.

According to Wyrwich et al. (2004), the minimal clinically important difference for
SF-36 scores are established by the expert panel as the following:

<table>
<thead>
<tr>
<th>SF-36 Items</th>
<th>Minimal clinically important difference in score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>15</td>
</tr>
<tr>
<td>Physical role</td>
<td>18.75</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>20</td>
</tr>
<tr>
<td>General health</td>
<td>15</td>
</tr>
<tr>
<td>Vitality</td>
<td>18.75</td>
</tr>
<tr>
<td>Social functioning</td>
<td>25</td>
</tr>
<tr>
<td>Emotional role</td>
<td>16.7</td>
</tr>
<tr>
<td>Mental health</td>
<td>15</td>
</tr>
</tbody>
</table>

Therefore, the program would be considered as effective if there is a statistically significant increase in each score of the SF-36 subscale, and such increase should be more than the minimal clinically important difference as reported by Wyrwich et al. (2004).

Secondary Patient Outcome

The secondary patient outcome is the level of physical activity of patients, which is
evaluated by the long format of the International Physical Activity Questionnaire (IPAQ-LC). IPAQ-LC is verified by Macfarlane et al. (2010) to be reliable and valid for measuring overall levels of physical activity of Hong Kong adults.

Participants’ score on IPAQ, expressed as MET-minutes per week, would be obtained before their participation in the training and 1 week after the completion of their training. Two-tailed paired t-test would be adopted for data analysis with the level of significance set at 0.05. The program would be considered as effective if the mean score of IPAQ of the participants increases significantly.

**Healthcare Provider Outcomes**

**Knowledge**

One of the healthcare provider outcomes is the nurses’ knowledge concerning the exercise training for patients with coronary heart disease. It would be assessed by a quiz which consists of 15 multiple choice questions. The quiz would be constructed by the innovators, according to the content of the training seminar. The cardiac nurse would get a pass if he/she could answer more than 80% of the multiple choice questions correctly.
The knowledge of the cardiac nurses would be evaluated immediately after they attend the training seminar. The program would be regarded as effective if more than 80% of cardiac nurses could get a pass (answer more than 80% of the multiple choice questions correctly) in the quiz at their first attempt.

*Attitude towards the Protocol*

The attitude of the nurses in the designated cardiac unit towards the protocol is an essential element in determining the accomplishment of the program. A focus group interview would be conducted to evaluate the overall attitude of the cardiac nurses. Four cardiac nurses would be randomly selected to attend the interview. It would last about 30 minutes. One of the innovators would be the facilitator of the discussion and guide the nurses to express their impressions and opinions on the program with regard to 4 areas: 1) Effectiveness of the program in promoting quality of life of patients; 2) Effectiveness of the program in promoting level of physical activity of patients; 3) Change in workload; and 4) Confidence in implementation of the protocol. The focus group interview would be audio-taped. The innovators would perform content analysis afterwards to make inferences.

The focus group interview would be conducted 4 months after the implementation of
the protocol. The program would be considered as effective if the overall content shows positive attitude.
CHAPTER 7
SUMMARY AND CONCLUSION

7.1 Summary

Background

Coronary heart disease deprives millions of lives in the world annually and the number has increased steadily in recent years. In Hong Kong, coronary heart disease claimed 4360 lives in 2009, which accounted for 11% of all registered deaths in the respective year. It is one of the major healthcare burdens in Hong Kong. Therefore, cardiac rehabilitation program, a program of therapeutic intervention and secondary prevention for patients with coronary heart disease, is developed to reduce cardiac mortality and morbidity, and enhance patients’ quality of life. Since exercise training is a pivotal part of the cardiac rehabilitation program, its benefits for patients with coronary heart disease are examined in this translational research paper.

Translational Nursing Research Question

The research question for this translational nursing research is “What is the effectiveness of exercise training when compared with the usual care (without exercise training) in promoting quality of life for patients with coronary heart disease?”
**Objective**

The main objective of this translational nursing research is to translate quality research evidences about exercise training in improving quality of life for patients with coronary heart disease to the local setting. This is achieved by developing an evidence-based protocol.

**Methods**

A systematic search of literature was conducted in 5 electronic databases. Eventually, 8 relevant randomized controlled trials were obtained. Then the 8 identified studies were summarized to form a table of evidence and critical appraisal was conducted using the Scottish Intercollegiate Guidelines Network (SIGN) checklist. After performing the quality assessment, evidences were assembled for synthesis and recommendations are made for developing the evidence-based protocol.

In order to successfully translate the appraised evidences into practice, implementation potential is assessed based on the consideration of the transferability of the evidences, feasibility of the program in local setting and the cost-benefit ratio of the program. Since the implementation potential of the proposed exercise training
program is considered as high, the evidence-based protocol is developed for the local context. For the sake of a smooth implementation of the evidence-based protocol, comprehensive implementation plan is developed in which a communication plan and a pilot test are designed. Lastly, evaluation plan, including process evaluation and outcome evaluation, is established to assess the effectiveness of the program in fulfilling its objectives.

**Results**

Among the 8 identified studies, 1 study is rated as “1++”, 4 studies are rated as “1+”, and 3 studies are rated as “1-”, based on the SIGN coding system. Regarding the results of the 8 reviewed studies, 7 of them found there is significant improvement in the quality of life of the study subjects who received exercise training, although in various aspects.

In total, 7 recommendations are made based on the 8 appraised studies. All the recommendations in the protocol are graded with an “A”, according to SIGN’s “Grades of recommendation”. The significance of the evidence-based protocol is that it adds a symptom-limited exercise test for evaluating participant’s level of exercise tolerance before the start of the exercise training, so that exercise intensity can be
tailored. It is relatively safer than the current practice.

7.2 Conclusion

A 6-week exercise training program for patients with coronary heart disease is effective in improving their quality of life and increasing their level of physical activity. In addition, cardiac mortality and morbidity can be reduced. Therefore, the program can help to ease the burden of the healthcare system in Hong Kong, which is mainly related to the decrease in recurrent admissions and subsequent needs for percutaneous interventions. Since the program has a high implementation potential in the local context and an emphasis on patients’ safety, the evidence-based exercise training protocol is worthwhile to be introduced in all the cardiac units in Hong Kong.
### Appendix A: Search Strategy

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<tr>
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</thead>
<tbody>
<tr>
<td>Cochrane Central Register of Controlled Trials (The Cochrane Library, 2011 Issue 3)</td>
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<td>(1) Coronary artery disease/ Coronary heart disease/ Ischemic heart disease/ Acute coronary syndrome/ Myocardial infarction/ Myocardial ischemia/ Unstable angina</td>
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<td>497314</td>
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<tr>
<td>(3) Quality of life</td>
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Search date: 27th September, 2011
## Appendix B: Table of Evidence

<table>
<thead>
<tr>
<th>Bibliographic Citation</th>
<th>Study Type (Level of Evidence)</th>
<th>Sample Characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Time of data collection</th>
<th>Outcome Measures</th>
<th>Effect Size Pretest → Posttest (Intervention Vs Control)</th>
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</thead>
<tbody>
<tr>
<td>Bettencourt et al., 2005</td>
<td>Randomized controlled trial (1+)</td>
<td>Patients admitted for ACS in Portugal</td>
<td>12-month CRP: Supervised exercise: First 3 months: 60min/ session, 3 times/ week; Following 9 months: 60min/ session, 1 time/ month (n=31)</td>
<td>No exercise training (Standard cardiology follow up)</td>
<td>Baseline and at 12 months</td>
<td>1. QOL (Portuguese version of SF-36)</td>
<td>1. QOL (SF-36): Physical functioning 63 → 70 Vs 64 → 62 Physical performance 68 → 66 Vs 64 → 57 Bodily pain 51 → 73 Vs 52 → 65 General health 57 → 57 Vs 53 → 46** Vitality 55 → 62 Vs 52 → 47** Social functioning 72 → 73 Vs 66 → 66 Emotional performance 69 → 65 Vs 66 → 58 Mental health 66 → 87 Vs 63 → 75</td>
</tr>
<tr>
<td>Briffa et al., 2005</td>
<td>Randomized controlled trial (1++)</td>
<td>Patients admitted for ACS in Australia</td>
<td>6-week CRP: Supervised exercise: 60-90min/ session, 3 times/ week Plus 12 education sessions and 6 psychosocial counseling sessions (n=57)</td>
<td>No exercise training nor education/ counseling sessions (Conventional care by doctor)</td>
<td>Baseline, at 6 months and 12 months</td>
<td>1. QOL (SF-36, UBQ-H)</td>
<td>1. QOL (SF-36): Physical functioning 61.9 → 77.8 → 79.5* Vs 61.9 → 69 → 68.7 Role physical 0.0 → 75 → 100 Vs 0.0 → 75 → 75 Bodily pain 48.9 → 75.5 → 79.1 Vs 48.9 → 68.1 → 69.8</td>
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<tr>
<td>Study</td>
<td>Design</td>
<td>Participants</td>
<td>Methods</td>
<td>Outcomes</td>
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<tr>
<td>Hage et al., 2003</td>
<td>Randomized controlled trial</td>
<td>Patients older than 65 years old, admitted for ACS in Sweden</td>
<td>12-week CRP: Supervised exercise: 50min/session, 3 times/week (n=44)</td>
<td>General health: 59.6 → 59.7 → 62.3 Vs 59.6 → 59.0 → 61.8</td>
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<tr>
<td></td>
<td>(1-)</td>
<td>Mean age: 76</td>
<td>No exercise training (n=44)</td>
<td>Vitality: 50.9 → 58 → 62.8 Vs 50.9 → 54.6 → 57.8</td>
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<td>Social functioning: 59.2 → 78.8 → 82.8 Vs 59.2 → 73.3 → 75.6</td>
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<td>Role emotional: 66.7 → 100 → 100 Vs 66.7 → 100 → 100</td>
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<td>Mental health: 70.8 → 71.3 → 74.4 Vs 70.8 → 72.2 → 74.7</td>
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<td></td>
<td>QOL (UBQ-H): 0.9593 → 0.9753 → 0.9853* Vs 0.9599 → 0.9719 → 0.9699</td>
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<td>Marchionni et al., 2003</td>
<td>Randomized controlled trial</td>
<td>Patients older than 45 years old, 4-6 weeks after MI in Italy</td>
<td>1. 8-week Hosp-CR: Endurance training: 30min/session, 3 times/week; and</td>
<td>1. QOL (EuroQol): 1. QOL (EuroQol): 0.80 → 0.85 → 0.88 → 0.85 Vs 0.83 → 0.84 → 0.84 → 0.82</td>
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<td></td>
<td>(1+)</td>
<td>Mean age: Middle-aged: 57±0.6 Elderly: 70±0.3</td>
<td>stretching and flexibility exercises: 60min/session, 2 times/week; and</td>
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</table>
### Sandstrom et al., 2005

<table>
<thead>
<tr>
<th>Patients older than 65 years old, admitted for ACS in Sweden</th>
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</thead>
<tbody>
<tr>
<td>Median age (range): CRP: 71 (64-84) Control: 71 (65-83)</td>
</tr>
</tbody>
</table>

#### 2. 8-week Home-CR:
- 4-8 supervised instruction sessions; and then self-directed exercise sessions at home similar to hospital CRP (n=74)
- Both groups received risk factor management counseling and joined support group (n=79)

<table>
<thead>
<tr>
<th>12-week CRP: Supervised exercise: 50min/session, 3 times/week (n=50)</th>
<th>No exercise training (n=51)</th>
<th>Baseline, at 3 months, and 12 months</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>1. QOL (TTO, EuroQol)</th>
<th>2. QOL TTO</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.78±0.23→0.84±0.24→0.86±0.23 Vs 0.77±0.26→0.85±0.21→0.85±0.21</td>
<td></td>
</tr>
<tr>
<td>0.79±0.24→0.85±0.17→0.87±0.15 Vs 0.81±0.2→0.84±0.17→0.86±0.16</td>
<td></td>
</tr>
<tr>
<td>6.52±1.56→7.72±1.61→7.6±1.46 Vs 6.8±1.61→7.51±1.71→7.43±1.4</td>
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</tbody>
</table>

### Very old: 80±0.3 (n=79)

2. 8-week Home-CR:
- 4-8 supervised instruction sessions; and then self-directed exercise sessions at home similar to hospital CRP

<table>
<thead>
<tr>
<th>Median age (range): CRP: 71 (64-84) Control: 71 (65-83)</th>
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</thead>
</table>

#### Baseline, at 3 months, and 12 months

<table>
<thead>
<tr>
<th>1. QOL (TTO, EuroQol)</th>
<th>2. QOL TTO</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.78±0.23→0.84±0.24→0.86±0.23 Vs 0.77±0.26→0.85±0.21→0.85±0.21</td>
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<tr>
<td>0.79±0.24→0.85±0.17→0.87±0.15 Vs 0.81±0.2→0.84±0.17→0.86±0.16</td>
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<tr>
<td>6.52±1.56→7.72±1.61→7.6±1.46 Vs 6.8±1.61→7.51±1.71→7.43±1.4</td>
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</tr>
</tbody>
</table>
### Seki et al., 2003

**Randomized controlled trial**

**1+**

**Participants:** Male patients older than 65 years old, with CAD in Japan

**Mean age:**
- CRP: 69.3±2.9
- Control: 70.1±3.7

**6-month CRP:**
- Supervised exercise: 60-80min/session, 1 time/week
- Plus dietary and educational sessions

**Control:**
- No exercise training nor dietary or educational sessions

**Follow-up:**
- Doctor as usual

**Baseline and at 6 months**

**1. QOL (SF-36)**

Only reported in graphs but no exact figures for each item reported. (In CRP group, 4 domains (bodily pain, general health, vitality, mental health) showed significant increase for improvement. In control group, none of the scores for any domain were significantly changed.)

### Yu et al., 2004

**Randomized controlled trial**

**1-**

**Participants:** Patients with recent AMI or PCI performed in Hong Kong

**Mean age:**
- CRP: 64±11
- Control: 64±11

**8-week CRP:**
- Supervised exercise: 120min/session, 2 times/week
- Plus educational sessions

**Control:**
- No exercise training

**Follow-up:**
- Attended a 2-hour educational talk

**Baseline, at 2 months, 8 months, and 2 year**

**1. QOL (SF-36, the Symptom Questionnaire, TTO)**

Only reported in graphs but no exact figures for each item reported. (In CRP group, 6 domains (physical functioning, physical role, vitality, social functioning, emotional role, mental health) improved significantly at 2 months, and were maintained at 8 months and 2 years.)

The Symptom Questionnaire

Only reported in graphs but no exact figures for each item reported. (Patients in CRP group were more contented and relaxed at 2 months and were less anxious and depressed throughout the study period. In control group, no psychologic improvements were observed.)

**TTO (Net change of TTO)**

0 $\rightarrow$ 0.03±0.03 $\rightarrow$ 0.05±0.03 $\rightarrow$ 0.04±0.03 Vs
Yu et al., 2003
Randomized controlled trial (1-)

Obese patients with recent AMI or PCI performed in Hong Kong
Mean age: CRP: 62.3±11.2
Control: 61.2±10.2

8-week CRP: Supervised exercise: 120min/ session, 2 times/ week
Plus educational sessions
(n=72)

No exercise training (Attended a 2-hour educational talk)
(n=40)

Baseline, at 2 months, 8 months, and 2 year

1. QOL (SF-36, TTO)

1. QOL
SF-36
Physical functioning
79±19 87±12* 88±12* 88±13* Vs
80±16 82±14 82±17 87±9
Physical role
47±40 81±28* 73±33* 80±32* Vs
36±37 59±38* 66±35* 79±30*
Bodily pain
73±29 85±22 80±25 81±21 Vs
65±30 88±18* 80±25* 85±20*
General health
61±21 66±22* 64±26 64±20 Vs
64±24 61±27 60±28 61±18
Vitality
66±22 75±16* 79±18* 73±21 Vs
63±23 69±20 65±17 73±17
Social functioning
81±24 91±17* 89±27* 79±30 Vs
73±24 83±29 82±28 90±18
Emotional role
78±39 88±28 93±18 89±25 Vs
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<th>77±20</th>
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<tr>
<td>TTO</td>
<td>0.72±0.23</td>
<td>0.80±0.21*</td>
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<td>0.76±0.22</td>
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<td>0.79±0.19</td>
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</tbody>
</table>
Remarks:

a. Level of evidence is graded based on the Scottish Intercollegiate Guidelines Network (SIGN) rating scheme for the strength of evidence. (SIGN, 2008) (Refer to Appendix C)

b. ACS: Acute coronary syndrome; CRP: Cardiac rehabilitation program; MI: Myocardial infarction; CAD: Coronary artery disease; AMI: Acute myocardial infarction; PCI: Percutaneous coronary intervention.

c. Hosp-CR: Hospital based cardiac rehabilitation program; Home-CR: Home based cardiac rehabilitation program.

d. QOL: Quality of life; SF-36: The Medical Outcomes Study 36-Item Short Form Health Survey; UBQ-H: Utility-Based Quality of life-Heart questionnaire; EuroQol: European Quality of Life Scale; SIP: Sickness Impact Profile; TTO: Time Trade Off.

* There is significant difference between the pretest and posttest values within the group, p<0.05.

** There is significant difference between the intervention and control group for the posttest values, p<0.05.

Data are expressed as mean ± SD (if not specified)
Appendix C: Critical Appraisal
Methodology Checklist (Controlled Trials) by Scottish Intercollegiate Guidelines Network (SIGN), March, 2004

<table>
<thead>
<tr>
<th>SECTION 1: INTERNAL VALIDITY</th>
<th>Bettencourt et al., 2005</th>
<th>Briffa et al., 2005</th>
<th>Hage et al., 2003</th>
<th>Marchionni et al., 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Not reported</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not reported</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Not addressed</td>
<td>Adequately addressed</td>
<td>Not reported</td>
<td>Not addressed</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept “blind” about treatment allocation.</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Subjects: Not applicable Investigators: Kept “blind”</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Poorly addressed</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Adequately addressed</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
</tr>
</tbody>
</table>
1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? Not addressed

| CRP: \( \frac{2}{37} = 3.51\% \) |
| Control: \( \frac{5}{56} = 8.93\% \) |

| CRP: \( \frac{6}{50} = 12\% \) |
| Control: \( \frac{7}{51} = 13.7\% \) |

Hosp-CR: \( \frac{11}{90} = 12.2\% \)

Home-CR: \( \frac{16}{90} = 17.8\% \)

No CR: \( \frac{11}{90} = 12.2\% \)

1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)

Adequately addressed

Well covered

Not addressed

Adequately addressed

1.10 Where the study is carried out at more than one site, results are comparable for all sites.

Not applicable

Not applicable

Not applicable

Not applicable

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimize bias? Code ++, +, or -

+  ++  -  +

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

Yes  Yes  No  Yes

2.3 Are the results of this study directly

Yes  Yes  Yes  Yes
<p>| 2.4 | Summarise the authors conclusions. | After one-year follow-up, patients referred to CRP have a better BDI score; the vitality and general health parameters, as well as the mental health component evaluated by SF-36, are significantly improved after CRP. | The effects on QOL tend to reinforce treatment advantages on survival for patients having post-discharge rehabilitation after an acute coronary syndrome. | Even a short period of supervised exercise training has the potential to positively influence physical activity level of elderly coronary patients for as long as 3 to 6 years. | Post-MI Hosp-CR and Home-CR are similarly effective in short term in improving TWC and HRQOL in each age group. However, in long term, the improvement was better preserved with Home-CR. |</p>
<table>
<thead>
<tr>
<th></th>
<th>Sandstrom et al., 2005</th>
<th>Seki et al., 2003</th>
<th>Yu et al., 2004</th>
<th>Yu et al., 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SECTION 1: INTERNAL VALIDITY</strong></td>
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<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
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<td>Well covered</td>
<td>Well covered</td>
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<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomised.</td>
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<td>Poorly addressed</td>
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<td>An adequate concealment method is used.</td>
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<td>Not addressed</td>
<td>Not addressed</td>
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<tr>
<td>1.4</td>
<td>Subjects and investigators are kept “blind” about treatment allocation.</td>
<td>Subjects: Not applicable Investigators: Kept “blind”</td>
<td>Not applicable</td>
<td>Subjects: Not applicable Investigators: Kept “blind”</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
<td>Well covered</td>
<td>Well covered</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Adequately addressed</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Adequately addressed</td>
<td>Well covered</td>
<td>Adequately addressed</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm</td>
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<td>Not addressed</td>
<td>CRP: ( \frac{49}{181} = 27.1% ) Control: ( \frac{16}{88} = 18.2% )</td>
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</tbody>
</table>
of the study dropped out before the study was completed?

<table>
<thead>
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<th>1.9</th>
<th>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</th>
<th>Adequately addressed</th>
<th>Adequately addressed</th>
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<th>Not addressed</th>
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</thead>
<tbody>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 | How well was the study done to minimize bias? Code ++, +, or - | + | + | - | - |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Yes | Yes | No | No |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by your guideline? | Yes | Yes | Yes | Yes |
| 2.4 | Summarise the authors conclusions. | The CRP group | Phase III CRP for | An 8-week course of | CRP was effective in |
increased their level of physical activity and scored a higher QOL than the control group.

intervention group significantly improved some aspects of QOL and state anxiety.

CRP was highly cost effective in providing better QOL to patients with recent AMI or after elective PCI. And, the improvement of QOL was quick and sustained for at least 2 years after CRP.

promoting an early improvement in exercise capacity and QOL in obese patients with CHD after a recent AMI or PCI.
Appendix D: Key to Evidence Statements

Levels of evidence (SIGN, 2004):

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta-analyses, systematic reviews, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High quality systematic reviews of case control or cohort or studies with a very low risk of confounding or bias and a high probability that the relationship is causal</td>
</tr>
<tr>
<td>2+</td>
<td>Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2-</td>
<td>Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
</tr>
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</table>
Appendix E: Tables of Summarized Data

Table 1: Time to start exercise training

<table>
<thead>
<tr>
<th></th>
<th>Within 6 weeks of ACS</th>
<th>4-6 weeks after ACS</th>
<th>6 months after ACS</th>
<th>After discharge</th>
<th>Within 2 weeks after discharge</th>
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<tbody>
<tr>
<td>Bettencourt et al., 2005 (1+)</td>
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<td>Hage et al., 2003 (1-)</td>
<td></td>
<td>✓</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Marchionni et al., 2003 (1+)</td>
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<td></td>
</tr>
<tr>
<td>Sandstrom et al., 2005 (1+)</td>
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<td></td>
<td>✓</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Yu et al., 2004 (1-)</td>
<td>✓</td>
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<td></td>
<td></td>
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<tr>
<td>Yu et al., 2003 (1-)</td>
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Table 2: Length of exercise training program

<table>
<thead>
<tr>
<th></th>
<th>6 weeks</th>
<th>8 weeks</th>
<th>12 weeks</th>
<th>6 months</th>
<th>12 months</th>
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<tr>
<td>Bettencourt et al., 2005 (1+)</td>
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<td></td>
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<tr>
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<tr>
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<tr>
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<tr>
<td>Sandstrom et al., 2005 (1+)</td>
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<tr>
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<tr>
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</table>
Table 3: Frequency of supervised exercise sessions

<table>
<thead>
<tr>
<th>Study</th>
<th>1 time/week</th>
<th>2 times/week</th>
<th>3 times/week</th>
<th>5 times/week</th>
<th>1 time/month</th>
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<tr>
<td>Bettencourt et al., 2005 (1+)</td>
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<td></td>
<td></td>
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<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(First 3 months)</td>
<td>(Following 9 months)</td>
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<td></td>
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<td>✓</td>
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<tr>
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Table 4: Duration of each supervised exercise session

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<th>Study</th>
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<th>50min.</th>
<th>60min.</th>
<th>60-90min.</th>
<th>120min.</th>
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<tr>
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<tr>
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<td>✓ (stretches and flexibility exercises)</td>
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<td></td>
<td></td>
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<td>✓</td>
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<tr>
<td>Yu et al., 2004 (1-)</td>
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<tr>
<td>Yu et al., 2003 (1-)</td>
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</table>
Table 5: Types of exercises recommended

<table>
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<tr>
<th></th>
<th>Warm-up</th>
<th>Cool-down</th>
<th>Aerobic exercise</th>
<th>Resistance training</th>
<th>Stretching/flexibility exercises</th>
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<tbody>
<tr>
<td>Bettencourt et al., 2005 (1+)</td>
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<td>✓</td>
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<td>✓</td>
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Table 6: Recommended exercise intensity

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<tr>
<th></th>
<th>65-85% of max. heart rate</th>
<th>70-85% of max. heart rate</th>
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<tr>
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<tr>
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<td>✓</td>
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<tr>
<td>Seki et al., 2003 (1+)</td>
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<td>Yu et al., 2004 (1-)</td>
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<tr>
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Table 7: Tests performed before exercise sessions

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<tr>
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</tr>
<tr>
<td>Briffa et al., 2005 (1++)</td>
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<td>Hage et al., 2003 (1-)</td>
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<tr>
<td>Marchionni et al., 2003 (1+)</td>
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<tr>
<td>Sandstrom et al., 2005 (1+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seki et al., 2003 (1+)</td>
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<tr>
<td>Yu et al., 2004 (1-)</td>
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<td>✓</td>
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<tr>
<td>Yu et al., 2003 (1-)</td>
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Table 8: Exercise training only or combined with educational sessions

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<tr>
<th></th>
<th>Exercise only</th>
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<tr>
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<td>Hage et al., 2003 (1-)</td>
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<td></td>
</tr>
<tr>
<td>Marchionni et al., 2003 (1+)</td>
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### Appendix F: Grades of Recommendation

Grades of Recommendation (SIGN, 2008)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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</table>
| A     | At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or  
       | A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results |
| B     | A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or  
       | Extrapolated evidence from studies rated as 1++ or 1+ |
| C     | A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or  
       | Extrapolated evidence from studies rated as 2++ |
| D     | Evidence level 3 or 4; or  
       | Extrapolated evidence from studies rated as 2+ |
| ✓     | Recommended best practice based on the clinical experience of the guideline development group |
REFERENCES


http://www.csb.gov.hk/english/admin/pay/42.html


Effects of phase II cardiac rehabilitation on job stress and health-related quality of life after return to work in middle-aged patients with acute myocardial infarction.

