

# Physical Therapy Program Improves the Physiological Impact Towards Better Quality of Life and Low Cardiac Risk Factors in Patients Following Coronary Artery Bypass Grafting. Systematic Review

Rawan Aldahash<sup>1</sup>, Hussain Al Dera<sup>1,2</sup>

<sup>1</sup>College of Medicine, King Saud bin Abdulaziz University for Health Science (KSAU-HS), <sup>2</sup>Kind Abdullah International Medical Research Center (KAIMRC)

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## ABSTRACT

**Introduction:** Studies suggest that exercise therapy may enhance heart rate variability in myocardial infarction, chronic heart failure and revascularization patients by increasing vagal tone and decreasing sympathetic activity. This review addressed the impact of cardiac rehabilitation programs (CRPs) in post CABG patients on the quality of life, in terms of physical function and cardiac risk factors.

**Methods:** OVID, Science direct, Embase, AMED and Cochrane controlled Trial Register were searched for studies published from 2005 up to 2015. Two reviewers assessed the eligibility of each study based on predefined inclusion criteria.

**Results:** Of 35 abstracts reviewed, 9 studies met the inclusion criteria. All studies compared CRPs of different interventions to a control (non-intervention) group. From the selected 9 studies, 6 studies included interventions compared with control groups (usual or standard care) while 3 studies compared two different intervention strategies with groups and included a no-intervention control group.

**Conclusion:** This systematic review concludes that all types of CRPs lead to improvements in the quality of life and reduction of cardiac risk factors in post CABG patients. However, these improvements were quite varied between the 9 studies according to variations in the components of CRPs.

## BACKGROUND

Coronary heart disease (CHD) is a disease affecting the arteries supplying the heart, it can be manifested in different forms including; myocardial infarction (MI), angina pectoris, heart failure, and coronary death. In the Framingham heart study conducted on 7733 participants who were initially free of CHD, aged 40 to 94, to measure the lifetime risk of CHD.<sup>1</sup> It was found that for individuals at age 40, the lifetime risk of CHD

reaches 49 percent in men and 32 percent in women. Myocardial infarction (MI), commonly known as a heart attack is characterized by irreversible necrosis of the heart muscle as a result of prolonged ischemia. The basic etiology is an imbalance in oxygen supply and demand, which is a result of plaque rupture with thrombus formation in a coronary vessel; as a consequence blood supply will be reduced acutely to a portion of the myocardium.<sup>2</sup> MI is one of the leading causes of morbidity and mortality in the adult population and is most frequently associated with atherosclerotic disease of the coronary arteries.<sup>3</sup>

## The Development of Coronary Heart Disease and Myocardial Infarction.

Different risk factors are attributed to MI and CHD. Some are modifiable, that can be adjusted by an individual, including elevated serum cholesterol levels,

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## Corresponding Author:

Hussain Saad Al Dera, Kind Abdullah International Medical Research Center (KAIMRC). Tel: +966114295275. E-mail: dera1444@hotmail.com

A serum cholesterol level greater than 200 mg/dl or a fasting triglyceride level more than 200 mg/dl is accredited to an increased incidence of coronary artery disease. Obesity is a strongly related risk factor with a higher incidence of mortality from CHD. Physical inactivity hastens the development of CHD as much as smoking, consuming a diet high in saturated fats and cholesterol, hypertension, and alcohol use.<sup>4</sup> Other nonmodifiable risk factors, those risk factors that an individual cannot adjust, include age, gender, ethnicity, and heredity. As people age incidence of CHD increases.<sup>4</sup>

Diabetes mellitus and a stressful lifestyle are examples of contributing factors, those factors that put individuals at higher risk for developing cardiovascular disease. In addition to the fact that diabetics are more likely than the general population to experience CHD, they are exposed to the risk of developing coronary heart disease at an earlier age than the nondiabetic individual. Two-thirds of diabetic individuals die from some form of heart or blood vessel disease.<sup>4</sup>

### Management for Coronary Heart Disease and Myocardial Infarction

Management of a patient with coronary artery ischemia differs according to the extent of injury, starting with controlling the risk factors and medical therapy, as well as the more advanced management interventions such as coronary artery stenting and Coronary Artery Bypass Grafting (CABG) surgery.<sup>5</sup> CABG is defined as "open-heart surgery in which the blocked section of the coronary artery is bypassed by a section of a blood vessel that is grafted from the aorta to improve the blood supply to the heart".<sup>6</sup> In 1910, Alexis Carrel was the first to describe CABG.<sup>6</sup> In the late 1930s, with the development of the heart-lung machine which enabled cardiopulmonary bypass (CPB) by Dr. John Gibbon cardiac surgery became more feasible.<sup>7</sup> The first coronary artery bypass surgery was performed on May 2, 1960 at the Albert Einstein College of Medicine – Bronx Municipal Hospital Center-New York, in the United States of America.<sup>8</sup> However, others including Kolesov have cited Goetz,<sup>9</sup> as the first successful human coronary artery bypass.<sup>10</sup> Since the thorax is opened and the sternum wired, thus the recovery is painful. A period of hospitalization of eight to ten days is required post CABG. Fortunately, the duration of hospitalization can be decreased and associated cardiopulmonary complications can also be minimized helping patients recover more quickly with the involvement of various muscular and breathing exercises.<sup>11</sup> Therefore, it is now standard practice that medical and physical therapy is initiated in post CABG patients to aid faster recovery and restore their cardiac capacity leading to a better performance of daily activities and exercise.

### Rehabilitation Programs after Coronary Artery Bypass Surgery

In healthy individuals and in subjects with cardiovascular disease it has been shown that exercise capacity is the best predictor of survival.<sup>12,13</sup> Therefore, the initiation of a rehabilitation program post-operatively for CABG patients' was suggested as an essential part of the management plan, cardiac rehabilitation programs (CRP) is a professionally supervised program in heart attacks, heart surgery and percutaneous coronary intervention (PCI) procedures such as stenting and angioplasty to help improving recovery. CRP constitutes several exercises such as graded exercises, respiratory exercises, bed mobilization and gradual ambulation. Another part of the CRP is the involvement of education and counseling services to assist heart patients in reducing their risk of future heart problems, including heart attack by increasing physical fitness, and improving general health.<sup>14</sup>

Early 20<sup>th</sup> century bed rest was the usual prescription for heart disease recovery, which became a poorly substantiated dogma of cardiac rehab. In the 1950s, Herman Hellerstein used a multidisciplinary team to set forth his ideas for the comprehensive rehabilitation of patients recovering from acute cardiac events.<sup>15</sup> In 1963, Hellerstein was able to prove his ideas and publish a study about the benefits of aerobic conditioning for patients diagnosed with heart disease (myocardial infarction, angina, or both).<sup>16</sup> These programs play an important role in the restoration of cardiopulmonary function, reduction of symptoms, increase in exercise tolerance and physical work capacity, normalization of blood lipid levels, alleviation of psychological stress and reduced hospitalization period.<sup>17</sup> Thus, the integration of physiotherapy rehabilitation programs as part of postoperative CABG care is now a main principal.

While it is well documented in the literature that cardiac rehabilitation in patients with cardiovascular disease is beneficial, the structure and content of these programs is widely varied. One way of exercise training is the combination of aerobic and resistance muscle training sessions. With a continuous or interval aerobic exercise training that includes; ambulation, stationary cycling exercises, strengthening exercises, endurance exercises or any prescribed aerobic exercises. Some encourage group exercising by similar patients, as patients motivate and inspire each other. In addition, resistance training of arm, leg and trunk exercises has also become popular in CRPs. High intensity continuous exercise training may not be feasible for CAD patients who are unable to sustain high intensities for long periods of time due to the fact that intensity of the exercise-training stimulus is a determinant of the magnitude of physiological adaptations that occur in response to training and this might not be achievable due

to symptom limitations. Accordingly, it has been proven that intermittent exercising (i.e. alternating periods of high intensity exercise by resting periods or periods of lower-intensity exercise) can be tolerated by CAD patients (100% of peak work rate) with lower metabolic and cardiorespiratory demands.<sup>18</sup> Achieving the proven benefits of improving physical health, and decreasing subsequent morbidity and mortality.<sup>19</sup>

Not only the heart and coronary vasculature will benefit of exercise training, endothelial function, autonomic tone, coagulation and clotting factors and inflammatory markers will also benefit of exercise training.<sup>20</sup> The results of four studies<sup>21-24</sup> that investigated the effects of exercise on BP revealed that regular physical activity lowers BP in hypertensive patients. All studies found consistent overall reductions in BP with the adoption of physical activity regimens.<sup>25</sup> A direct relation between physical inactivity and cardiovascular mortality was found, and physical inactivity being an independent risk factor for the development of coronary artery disease. Although cardiovascular disease mortality can be affected by moderate-intensity activity (40- 60% of maximal oxygen uptake, depending on age).<sup>26</sup> Despite the fact that most of the supporting data are men-based studies, more recent findings show indistinguishable results for women.<sup>27</sup> Results of pooled studies shows that people who change their practices after myocardial infarction to involve regular exercise have better survival rates. Intensive multiple interventions such as smoking cessation, blood lipid reduction, weight reduction, and physical activity significantly minimizes the rate of progression and, in some cases, reduces the severity of atherosclerotic lesions in persons with coronary disease.<sup>25</sup> Focusing on excitation-contraction coupling, exercise training has proved to improve cardiac function, especially after infarction by reversing many of the abnormal Ca<sup>2+</sup> regulatory pathways observed in post-MI myocytes. At present, it is undetermined which of the excitation-contraction regulatory pathways probably is the primary responsible for the exercise-induced enhancement in myocyte contractile function.<sup>28</sup>

Cardiac rehabilitation programs (CRP) have also clinically showed to effectively improve exercise capacity i.e. patient can perform exercise for a longer time without fatigue, while decreasing plasma lipid values, increasing quality of life parameters and eventually minimizing cardiac risk factors in patients with CAD and post coronary artery bypass grafting surgery.<sup>29</sup>

Quality of life is the individual's perceptions of their life position in regard to the cultural values in which they live and in parallel to their goals, expectations, standards and concerns. It is a wide-ranging conception influenced in a

complex way by the person's physical health, psychological state, degree of independence, social relationships, and their relationship to notable features of their environment.<sup>29</sup> Physical function as an essential aspect of the quality of life includes three main concepts: firstly, muscular strength which is the amount of power that a muscle can utilize, being essential for activities that comprise lifting, pushing or jumping. An individual with superb muscular strength is competent to perform daily tasks more efficiently.<sup>30</sup> Secondly, flexibility that is defined as the capacity to move body parts or extremities through a full range of motions. Flexibility has the critical role of regressing muscle strain and back disorders.<sup>31</sup> Thirdly, muscular endurance which is the ability of the muscles to execute different physical functions over a period of time without causing fatigue. Muscular endurance is the aspect that enhances posture and halt back problems.<sup>32</sup> Because of the positive effects on quality of life factors these concepts of exercising are all incorporated in CPSs.

CRPs play a critical role in minimizing the danger of cardiac risk factors such as obesity, cholesterol levels or cardiac rate variability that may produce serious harm or even death post CABG.<sup>33</sup> Most recent studies concluded that CRPs involving walking and stationary cycling post revascularization causes a remarkable reduction of total cholesterol reaches 6.3%, 10.1% in LDL cholesterol, and 13.4% in cholesterol/HDL cholesterol and 5% increase in HDL cholesterol.<sup>34</sup> As obesity is an identifiable risk factor for coronary artery disease and obese patients have a high chance of recurrent angina and increased preoperative morbidity and myocardial Infarction (MI), CRPs should focus on achieving weight reduction and associated reduction of the comorbidities.<sup>34</sup>

Studies propose that exercise therapy may enhance heart rate variability in myocardial infarction, chronic heart failure and revascularization patients by augmenting vagal tone and restrict sympathetic activity.<sup>35</sup> This is due the stability of autonomic system activity that regulates cardiovascular activities including heart rate (HR). Increased sympathetic nervous system activity is associated with an increased risk of cardiac events, especially in patients with documented cardiac disease such as MI, CAD or cardiac myopathy.<sup>34</sup> Different experimental methods of study have been conducted to evaluate the value of CRPs post MI, one such method is the randomized control trial.

### Randomized Control Trials

The randomized controlled trial (RCT) is one of the easy, but the most influential tools of research. Basically, the RCT is a study in which people are randomly allocated to receive one of several clinical interventions. RCTs is a powerful method of experimenting the effect of interventions on particular outcomes such as death or the recurrence of disease.<sup>36</sup>

Randomized controlled trials, when perfectly designed, performed, and reported, typify the gold standard in evaluating healthcare interventions. However, biased results can result if randomized trials lack methodological diligence.<sup>37</sup> The randomization step is the core of the randomized controlled trial's strength. Random allocation means that all participants have equal chance of being a part of each of the study groups. Therefore, the investigators, the clinicians, or the study participants do not determine allocation. The aim of random allocation of participants is to ensure that the characteristics of participants are as likely to be identical as possible in each group at the beginning of the comparison, also called the baseline.<sup>36</sup>

## 2. Objective of the review

The aim of this project is to conduct a systematic review of randomized control trails published during the period from 2005 to 2015 in an attempt to answer the following question: "Which cardiac rehabilitation program best improves quality of life and minimizes cardiac risk factor profile in patients post CABG surgery?"

## MATERIAL AND METHODS OF SYSTEMATIC REVIEW

This project was performed to answer the study question and also to identify areas for further studies on the value and attributes of quality CRPs.

Therefore a number of important tools required in order to provide a valuable systematic review. These include:

- Access to databases of King Saud bin Abdulaziz University (KSAU-HS) Library, and NGHHA Library, Riyadh-Saudi Arabia; in order to browse global databases, discussed in stage 1 of study design and phases listed below.
- Data Extraction sheet: It consists of questions which were set from the Journal of the American Medical Association (JAMA) users' guide to the medical literature and Cochrane collaboration to facilitate the process of systematic review (see appendix A).

This systematic review was conducted with guidance of an academic supervisor at KSAU-HS.

### Study Design and Phases

This project used systematic review of published RCTs which fulfilled specific criteria (listed below) in an attempt to answer the research question stated above. This study was segregated into two (2) stages. The first stage focused on conducting the data search and reading the research papers. In the second stage the data from included studies was sorted and stored in an extraction sheet to finally collect them in the systematic review.

### Stage 1

Computerized searches using standardized search strategies were conducted. Databases utilized include OVID (2005 to 2015), Science direct (2005 to 2015), Embase (2005 to 2015), AMED (2005 to 2015) and Cochrane controlled Trial Register. Key words that were searched included revascularization, coronary bypass graft surgery, coronary bypass grafting, randomized control trials post CABG, all RCTs after revascularization, aerobic exercise after coronary artery bypass grafting, body flexibility after revascularization, endurance exercise, strength exercise post CABG, CABG surgery, protocols post open heart surgery, cardiac rehabilitation, physiotherapy after open heart surgery and general body flexibility. Papers identified from the searches were then selected for inclusion using a list of seven inclusion and exclusion criteria. Studies were included if they fulfilled the following criteria:

1. Randomized Control Trials (RCTs).
2. Adult male and female participants (18+ years).
3. All patients were in the post CABG period i.e. period of hospitalization (8 to 10 days) and period of follow up.
4. One of the following outcomes had to be reported; pain reduction reported by the patient, walking distance, muscle power, endurance, body flexibility or return to work.
5. Each trial or study had to discuss a specific type of cardiac rehabilitation program i.e. they had to specify the type of exercise used within the program.
6. At least 30 participants were included in each study.
7. Studies were written and published in English.
8. Studies were published from 2005 until 2015.

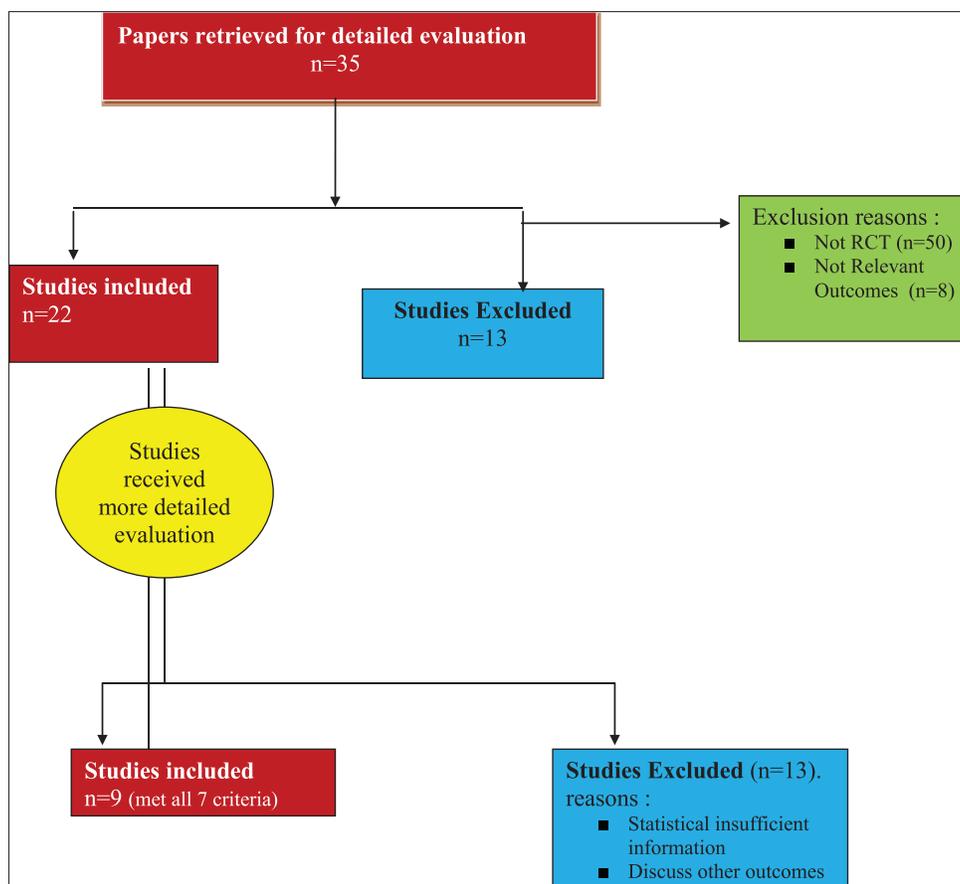
These criteria were set according to the importance of cardiac rehabilitation or exercise training post CABG as discussed in the introduction. Thus, this systematic review study emphasizes the role of different cardiac rehabilitation programs provided after cardiac revascularization or CABG surgery.

### Stage 2

Data from included studies meeting the inclusion criteria was placed into an extraction spreadsheet to allow comparison of the variables under study. Then, comprehensive analysis of the data from these studies is reported and discussed.

### Results of Literature Search

Using the search terms and electronic databases previously mentioned 35 potential studies were identified. Upon inspection of these studies 13 were excluded as they were not RCTs or had outcomes irrelevant to the aims of this study. The 22 remaining RCTs were evaluated, 13 contained insufficient statistical information or patient outcomes other than those to be investigated in this project. Hence out of the original 35 studies there were 9 which could be included for further analysis in this project (Figure 1).



**Figure 1:** This diagram outlines the steps in the justification process taken in the analysis process reducing the number of studies from 35 articles to 9

### Tabulation of Collected Data

A summary of the data extracted from the 9 included RCTs including sample size, comparison groups, exercise therapy given including dose, duration and outcomes measured are itemized in Tables 1a & 1b. Not all data was provided by the authors of the publications and therefore could not be obtained from all studies.

RCTs selected for inclusion in this study were further analysed to determine their accuracy and possible sources of error and bias.

### Identification of Study as Randomized

Although a variety of keywords were used in the original literature search to specifically identify studies which were randomized, the electronic databases may not have explicitly reported this information or identified or classified it clearly as a RCT study. This could be a consequence of the publishing authors failing to state this in the abstract or within the contents and therefore it may not have produced a positive search. Of the nine studies analyzed, only 4 studies indicated randomization in the title and 5 studies mentioned randomization in their abstracts or contents.

### Evaluation of the Type of Randomization

In some of the publications reading the title and the material and methods of the article it was unclear as to the type of the randomization process used i.e. random allocation, random assignment.

### Interventions Description and Effectiveness in Specific Population Groups

Most studies investigated their interventions among people aged between 30 and 85 years, which is a wide range. Interestingly there was no information describing participant ethnicities or populations from different cultures or countries, important information which might lead to understanding if intervention results are different for different peoples.

### Selection Methods of Samples Size of the 9 RCTs

After the completion of reviewing the 9 selected studies, there were no studies that clearly described by the authors the method they neither used to select participants nor stated the approaches to determining sample size of participants or using power of testing of hypothesis (Power calculation). It is prudent to utilize the skills of a statistician to help with power calculations prior to embarking upon

costly and time-consuming research. Power calculations provide guidance for sample sizes large enough to ensure results are statistically significant.

### Withdrawal of Subjects in the RCTs

Review of the 9 RCTs reveals that withdrawal of participants was more common in the intervention groups. The reasons for withdrawal were not specified and may have been voluntary withdrawal or due to protocol breach such as compliance issues or loss to follow-up or due to adverse events. As the reasons for withdrawal were not clear this may create withdrawal bias. The rate of clinical trial withdrawal was less in the control groups.

### Discussion of Data Search and Identification of RCTs Meeting the Inclusion Criteria Defined

Using the parameters listed in the methodology section and from the databases detailed in the previous section 35 references were initially identified but only 9 studies met the selection criteria allowing them to be included for analysis in this study (Table 1a & b). Other reasons for the exclusion of studies from this review were: non-randomized study

design, written in a language other than English, studies with low participant numbers (<30), studies not relevant to the research question and poorly defined or inadequate statistical analysis.

Evaluation of the experimental design and results of the 9 RCTs reveals they collectively investigated 10 intervention strategies to improve or assess 11 major patient outcomes, as shown in Table 2. All these outcomes are extremely important as measuring methods to assess the efficacy of cardiac rehabilitation programs post CABG surgery; the more benefits or outcomes, the more effectiveness of the rehabilitation protocol used. These outcomes may appear directly; such as increased distance walked over a short period of time (per minute); or may appear indirectly; such as blood tests to measure cholesterol level, lipids level or to measure lung function, (Functional residual capacity (FRC), Vital Capacity (VC), or Functional Expiratory Volume (FEV)). Both direct and indirect outcomes indicate effects on the Quality of Life (QoL) and cardiac risk factors.

The nine studies assessed the outcomes from intervention components of CRPs such as combined comprehensive

**Table 1a: This table describes the author's name, date of study, sample size and number of participants in each of the 9 studies included in this project**

S. no	Authors	Date	Sample size	Age	Intervention	Study type	Groups	Exercise	Control
1	Busch JC et al	2012	173	>75 y	Special balance training/ resistance training	RCT	n=84	n=89	Participated in inpatient CR program
2	Ann-Dorth Olsen et al	2005	770	63.4 y	Combined comprehensive cardiac rehabilitation including training exercise	RCT	n=385	n=385	Usual cardiac care
3	Andrew D. Hirschhorn et al	2007	93	>18 y	Walking exercise, walking/ breathing exercise	RCT	n=31 Walking exercise	n=30 Walking/ breathing exercise	n=32 Standard treatment
4	Smith KM et al	2011	144	70±9.5 y	6 months of home or hospital-based exercise training during CR	RCT	n=70 home	n=74 Hospital	
5	Sen-Wei Tsai et al	2005	30	>18 y	Phase II cardiac rehabilitation 30-40 min aerobic exercise. 3 times a week	RCT	n=15	n=15	
6	Johan Bringeman et al	2006	173	18-70 y	2 h teaching sessions about heart function+physical training 3sessions/w+relaxation therapy+psycho-education 1 session/a week	RCT	n=70 Fit plus program	n=76 Fit program	
7	Wu s-k et al	2006	53	60+7-62+6	Aerobic exercise. 30-60-min training session	RCT	n=18	n=18	n=18 Normal levels of daily activity
8	C Edstrom Pluss et al	2007	224	Under 75 y	Usual cardiac protocol+stress management+5 day stay at patients' hotel+cooking session	RCT	n=111	n=113	Usual cardiac protocol
9	Konstantions A volaklis et al	2007	34		2 sessions of aerobic exercise, 2 sessions of resistance training a week on land and water	RCT	n=12 Land exercise. Group	n=12 Water exercise. Group	n=10

RCT: Randomized controlled trial

**Table 1b: Allocation, duration of intervention and follow up, with draws, outcomes measures, method of measuring and statistical analysis used in each study**

S. no	Authors	Allocation		Duration of intervention	Length of follow up	Withdrawals	Loss to follow up	Outcomes measured	Method of measuring	Statistical analysis	Validity of instruments used
		Concealed	Randomized								
1	Busch JC et al	-	✓	A mean of 20.4±3.2 days	-	-	-	Functional capacity and health-related quality of life (HRQL)	Six-minute walk test, cardiopulmonary exercise testing, Timed-up-and-go test (TUG), and a maximal isometric strength test/ the MacNew questionnaire		Not stated
2	Ann-Dorth Olsen et al	-	✓	6 weeks	3-12 months	-	-	Mortality-MI and readmission	Interview, clinical examination, blood test, self administration questionnaire	Multi variant random effect modeling maintoba-drat mouth modification the charisan index	Not stated
3	Andrew D. Hirschhorn et al	-	✓	During the hospitalization period and at discharge	4 weeks	1 patient died on the third day post op	-	Walking capacity-vital capacity	6 min walk assistant	Two tailed test	Not stated
4	Smith KM et al	-	✓	6 months	6 years	52 patients	-	Habitual activity, vital status, physical activity	Peak oxygen uptake, physical activity scale in the elderly (PASE), semi-structured interviews	-	Not stated
5	Sen-Weitsai et al	-	✓	3 months	12 weeks	-	-	Heart rate (HR)	-O <sub>2</sub> pro - cycle ergometer - ECG	ANOVA - paired t test	Not stated
6	Johan Bringeman et al	-	✓	6-8 weeks	2 years	18 patients	-	QOL., Blood lipids Exercise capacity	Questionnaire Rand Scl - 90 blood test Exercise capacity	Analysis of Chi square	Not stated
7	Wu s-k et al	-	✓	12 weeks	-	-	-	Heart rate recovery	O <sub>2</sub> pro Cycle ergometer ECG BB	χ <sup>2</sup> MSD Paired student t test	Not stated
8	C. Edstrom Pluss et al	-	✓	1 year	1 year	13 patients	-	Metabolic and inflammatory markers exercise performance	Blood sample exercise test	MSD ANOVA Chi square	Not stated
9	Konstantions A volaklis et al	-	✓	4 months	-	-	-	Combined resistance and aerobic training	Exercise stress test, ECG and Blood sample	Analysis of co-variance	Not stated

NS: Not stated by the author, ECG: Electrocardiogram, ANOVA: Analysis of variance, MSD: Mean standard deviation, QoL: Quality of life, FRC: Functional residual capacity, VC: Vital capacity, FVC: Forced vital capacity, FEV: Forced expiratory volume

**Table 2: This table classifies how many of the 9 selected articles address each of the 11 outcomes being evaluated in post CABG exercise rehabilitation programs**

S. no	The outcome	Number of studies out of 10 included
1.	Exercise capacity	4
2.	Quality of life (QoL) and risk factors	2
3.	Metabolic and inflammatory markers	1
4.	Blood lipids	1
5.	Heart rate (HR)	2
6.	Physical activity	1
7.	Combined resistive and aerobic exercise tolerance	1
8.	Vital capacity	2
9.	Mortality	1
10.	MI and readmission	1
11.	Habitual activity	1

programs or cardiac programs including training exercises. All studies compared cardiac rehabilitation of different interventions to a control (non-intervention) group. From the selected 9 studies, 6 studies included interventions compared with control groups (usual or standard care) while 3 studies<sup>40,42,44</sup> compared two different intervention strategies with groups and included a no-intervention control group as shown in Tables 1 a & b.

### Outline of the Main Findings of Each of the Selected 9 RCTs

It is important to focus on the main findings not only as a part of systematic review process, but also to identify clusters of similar studies. The main findings of the RCTs included in this project are summarised below.

The Ann-Dorth et al<sup>38</sup> study had good follow up after 12 months and contained a good mixture of several interventions which produced good outcomes. In this systematic review, there were 10 studies included combining comprehensive cardiac rehabilitation programs.

The effect of a cardiac rehabilitation program over a three month duration as described by Sen-Wei Tsai et al<sup>39</sup> resulted in improvement in recovery on heart rate over 7 minutes i.e. the heart rate returned to its normal level at first minute after 7 minutes performing exercise. The authors recommended the increase in the study sample size to figure out better outcomes.

Wu S-K et al<sup>40</sup> compared home exercises with cardiac centre rehabilitation programs after 12 weeks interventions and concluded that the sample size should increase and significant result in resting cardiac rate.

The study by Brugman et al<sup>41</sup> concluded that post CABG patients benefited from a simple exercise rehabilitation program, improving quality of life and cardiac risk factors such as cholesterol level. And the result was not significantly positive.

Andrew D et al<sup>42</sup> study showed that walking and walking/breathing exercise groups had a significantly improved six-minute validity assessment (6MVA) distance compared with the standard intervention group at discharge. Although there were no statistically significant results after 4 weeks, there was either no clear evidence if this was the case with long-term effectiveness.

The study reported by Edstrom et al<sup>43</sup> had 224 participants under the age of 57. Participants were followed during 12 months intervention classified into one of 3 groups: light, modest or heavy training. Despite the long intervention period of 12 months, the study resulted in no significant benefit in between treatment groups after one year. However, there was a modest significant improvement on cholesterol level and resting heart rate.

Konstantanos et al<sup>44</sup> clearly described a well-structured study in which the exercise program combined resistance and aerobic training, on land or in water, capable of producing an improvement in exercise tolerance, muscle strength, cholesterol level and weight reduction in patients post CABG. The study only lasted four months but resulted in these positive outcomes.

The study by Smith KM et al<sup>45</sup> investigated the long-term effectiveness of hospital versus telephone-monitored home-based exercise training during cardiac rehabilitation (CR) on exercise capacity and habitual physical activity which showed that home and hospital-based exercise training maintained exercise capacity above pre-CR levels 6 years after CR. Exercise training initiated in the home environment in low-risk patients undergoing coronary artery bypass graft surgery conferred greater long-term benefit on  $VO_2$  and persistent physical activity compared with traditional hospital-based CR.

Study with 173 participants conducted by Busch JC et al<sup>46</sup> used a resistance training and special balance training (5 d/wk) duration which proved that There were significant improvements in all measured variables in very old adults participating in CR soon after CABG. With additional functional exercise training, participants randomized to intervention group improved significantly more than those randomized to control group on 6-MWD, TUG time, and relative workload.

Review of the selected 9 RCTs showed that there were 7 studies with positive outcomes i.e. the interventions

**Table 3: A table of summarizing the significance of result of the 9 selected RCTs**

Study	Sample size	Age (year)	Intervention	Duration of intervention	Significance of results		
					Positive	Negative	Unclear
Bush JC et al	173	>75	Resistance training/special balance training	20.4±3.2 days	✓		
Ann-Dorth Olsen et al	770	63.4	Combined comprehensive cardiac rehabilitation including training exercise	6 weeks	✓		
Andrew D Hirschhorn et al	93	>18	Walking exercise, walking/breathing exercise	During hospitalization	✓		
Sen-Weitsai et al	30	>18	Phase II cardiac rehabilitation 30-40 min aerobic exercise. 3 times a week	3 months	✓		
Johan Bringeman et al	173	18-70	2 h teaching sessions about heart function+physical training 3 sessions/w+relaxation therapy+psycho-education 1 session/a week	6-8 weeks			✓
Wu s-k et al	53	60.7-62.6	Aerobic exercise. 30-60-min training session	12 weeks	✓		
C Edstrom pluss et al	224	Under 57	usual cardiac protocol+stress management+5 day stay at patients' hotel+cooking session	1 year			✓
Konstantions A Volaklis et al	34	Adults	2 sessions of aerobic exercise, 2 sessions of resistance training a week on land and water	4 months	✓		
Smith KM et al	144	70±9.5	6 months of home or hospital based exercise training during CR	144	✓		

were considered successful and resulted in better patient outcomes. However, two studies by Bringeman et al<sup>41</sup> and Edstrom et al<sup>43</sup> reported results having negative outcomes (Table 3).

From analyzing the selected 9 studies it became obvious there were frequent methodological limitations within some of the studies. Some of these were differences in baseline characteristics between intervention groups and high attrition rates or inadequate presentation of investigated outcome parameters. Detailed descriptions of study characteristics, intervention components and outcomes are presented in Tables 1a & b.

#### A Summary of the Characteristics and Quality of the 9 selected RCTs

Six published RCTs were judged to be comprehensive cardiac rehabilitation trials while 6 studies were discussing different types of exercises as shown in Table 4. The majority of trials as single center studies i.e. each one of them was conducted at single hospital. Trial sample sizes varied widely from 30 to 770 patients (mean, 188 patients). Patients with CABG and other patients with heart disease were recruited in all trials. The ages of patients in the RCTs ranged from 18 to 85 years. The 6 comprehensive cardiac rehabilitation trials had a combination of education or risk factor modification and psychological intervention plus exercise. The publication dates of selected studies ranged from 2005: 2 studies, 2006-2007: 5 studies and 2011-2012: 2 studies.

#### Validity of the Nine Selected RCTs Findings

There is no definite guarantee that the validity of selected RCTs is accurate despite the efforts made by their authors to maintain appropriate randomization and blinding procedures. In general there were appropriate and legitimate efforts made

**Table 4: A summary of the types of interventions or treatment and the number of studies shared these**

Serial number	Interventions types	Studies shared same interventions
1	• Combined comprehensive cardiac rehabilitation including training exercises	6
2	• Education and life counseling	1
3	• Walking	1
4	• Stress management	1
5	• Relaxation	1
6	• Aerobic exercises	4
7	• Breathing exercises	1
8	• Resistance training	2
9	• Special balance training	1

by the RCTs researchers to maintain satisfactory and accurate measurement of outcomes. This was not unanimously the case however as some studies did not, thus increasing the likelihood of the reported results being due to chance. Ideally researchers should devote considerable effort to the developmental stage of their research methodology in an attempt to establish their hypotheses and perform hypothesis testing and estimation of random variation on an adequate sample size. Intrinsic in the quest for answers to the unknown, research does incorporate unexpected and uncontrollable influences, which when they occur affect the results obtained. Biases due to these affects are possible in the 9 RCTs selected for analysis in this project, in regard to parameters such as patient selection, measure of outcomes, or even analysis of data. During the analysis of the selected 9 RCTs, it was observed that some studies had unequal sample allocation between groups, or a sample that was small and probably not big enough to represent the target population. There is also missing information regarding the 'follow-up' status in some studies and no information when some studies were stopped. There is the possibility that 'analysis' bias could occur due to lack of this information,

thus generalisability of the reported findings to the larger population can be somewhat limited.

### Conclusions on the Quality of the 9 RCTs and Reported Patient Outcomes

Review and analysis of these 9 publications addressing the use of CRPs in post CABG patients has focused on different Cardiac rehabilitation programs given post CABG surgery and their impacts on the quality of life, in terms of physical function (muscular strength, endurance and body flexibility) and cardiac risk factors. This systematic review concludes that all types of cardiac rehabilitation programs (CRPs) lead to improvements in the quality of life and reduction of cardiac risk factors such as cholesterol level, resting heart rate or weight reduction in post CABG patients. However, these improvements were quite varied between the 9 studies according to variations in the components of CRPs.

Each study of the selected 9 studies was extensively reviewed including the author's name, date of publication, allocations, sample size, arms of trial, duration of intervention, numbers of withdrawals and loss to follow-up, outcomes measured, method of measuring and statistical tools that were used to measure the effectiveness of a specified CRP as an intervention in each of the trials. Additionally, of the 9 studies, 6 were considered comprehensive cardiac rehabilitation trials supporting the effectiveness of such programs focusing on a holistic approach.

Three types of interventions including a combined comprehensive program, walking and breathing exercises that were shown to be useful in the promotion or enhancement of cardiac ability to perform exercise for a longer time without fatigue or symptoms. When delivered in combination mode consisting of more than one intervention there were no differences for gender with respect to these outcomes. A considerable observation is that cardiac rehabilitation programs delivered more than 6 weeks intervention in general post CABG periods have shown to be effective in improving physical strength as well as reducing cardiac risk factors.

The results of these studies were dissimilar in terms of interventions, participants and outcomes measures. The studies that discussed one or merely a few interventions such as breathing exercises or preoperative educational sessions appear to have results with limited impact on the desired outcomes. On the other hand, small group interventions delivered their interventions over a short period of time.

Interestingly there was no information that was clearly described by the authors the method they either used to select participants or stated the approaches to determining sample size in each trial. It might be that the investigators

had some idea of the minimum clinically significant differences that they were interested in, but did not calculate the size of improvement should be that would improve the new intervention or treatment.

In conclusion, there is evidence for the long-term effectiveness of combined comprehensive cardiac rehabilitation programs in patients post CABG as the most efficient and highly recommended program to improve quality of life and minimize cardiac risk factors.

### Implications for Practice

This review of the 9 RCTs on CRPs in post CABG patients concludes that there is sufficient evidence for the effectiveness of CRPs especially when combined with other support programs after CABG. Thus, therapists, practitioners and policy-makers should consider the following points:

- An internal review of existing cardiac rehabilitation programs and education programs to increase the availability of good clinical practice and health education programs.
- Increased implementation of peer support programs, particularly targeting patients in need of cardiac rehabilitation programs after CABG.
- Implementation of a 'package' or set of interventions of cardiac rehabilitation programs after CABG at national and local institutes.

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