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# Psychosocial Outcomes in Home-Based Cardiovascular Rehabilitation Programmes

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## Abstract

Exercise-based cardiac rehabilitation has been introduced in medical practice many years ago, initially only as center-based rehabilitation. It is part of the activities for the secondary prevention of cardiovascular diseases and has been effective in reducing cardiovascular morbidity and mortality. Cardiac rehabilitation programs are commonly used in patients who have had an ischemic event or a myocardial revascularization procedure and in patients with heart failure of various etiologies. However, participation rate in center-based rehabilitation programs is low, especially by the elderly or women, and depending on the variability of the symptoms of cardiovascular disease. Alternative models are mainly based on telerehabilitation techniques and are grouped under the name of home-based rehabilitation. Our study aimed at reviewing the main randomized clinical trials published from January 2012 to December 2016, selected from the MEDLINE, Web of Science and Science Direct databases that compared home-based with center-based rehabilitation or usual care, and were focused on psychosocial outcomes. In the studied articles, the mental and social components were assessed by completing upon enrollment and at various times during reassessment quality of life questionnaires, questionnaires for depression and anxiety and self-perceived stress. Several studies highlight the superiority of home-based rehabilitation in hemodynamically stable patients who wanted to resume their social and professional activities. The outcomes are generally similar in terms of increasing exercise capacity and superior in terms of quality of life, reducing anxiety and depression, or socio-professional reintegration.

*Keywords:* psychosocial outcomes, home-based cardiac rehabilitation, centre-based cardiac rehabilitation, quality of life, self-perceived stress.

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## Introduction

Exercise-based cardiovascular rehabilitation is effective in reducing mortality and morbidity (Aamot *et al*., 2014). Aerobic exercise is an important component of most of the programs that have been implemented. Aerobic capacity that can be determined in healthy individuals or cardiovascular patients has been associated with total cardiovascular risk (Myers *et al.*, 2002). Exercise programs have been initially implemented in specialized clinics, as the basic component of center-based cardiovascular rehabilitation. Cardiovascular rehabilitation generally aims to support patients with cardiovascular disease, especially those with ischemic heart disease, after myocardial infarction or revascularization procedures in order to adopt a healthy lifestyle and return to social and professional activity, being part of the activities aimed at the secondary prevention of cardiovascular diseases. Medical education and therapy optimization begin during phase I cardiac rehabilitation and also during phase II, which starts after patient discharge, when exercise programs are continued in association with personalized education lectures for the control of risk factors and lifestyle change (Abell *et al.*, 2016). Center-based rehabilitation programs also have an important psychosocial and educational component. An overview that included six systematic reviews of cardiovascular rehabilitation (148 randomized clinical trials, 98,093 patients) demonstrated the effectiveness of these programs: after entering rehabilitation programs patients with moderate or low-risk heart failure after myocardial infarction or revascularization procedures had fewer hospitalizations, improved health-related quality of life, and reduced long-term mortality (Anderson & Taylor, 2014; Piepoli *et al*., 2016). The evaluation of such programs is still limited due to the variety of the types of interventions, with variable working methods and inclusion criteria.

Physical exercise has direct physiological effects, and rehabilitation programs have resulted in the reduction of risk factors and lifestyle improvement. Referral and level of inclusion in center-based rehabilitation programs vary from one area to another depending on the development of specialized centers and other factors. Patients with greater severity of cardiovascular disease, the elderly and women have lower participation rates in traditional programs. To improve the participation rate in rehabilitation programs, alternative models that have been grouped under the name home-based cardiac rehabilitation have been developed. Some alternative models have been developed to provide nurse-led intervention. This category included the EUROACTION program, which allowed lifestyle improvement over a 16-week period, with patients and their families being trained directly at home (Ofori & Kotseva, 2015, Piepoli *et al*., 2016). Similarly, the Randomized Evaluation of Secondary Prevention by Outpatient Nurses Specialists (RESPONSE) trial evaluated at 1 year the patients who have sustained an acute coronary syndrome and who were randomized to a control group and a group who

benefited from nurse-coordinated rehabilitation activities. In this group, a better control of risk factors, fewer rehospitalizations, and a 17% decrease in relative mortality risk, calculated according to SCORE risk charts were recorded (Jorstad *et al*., 2013, Piepoli *et al*., 2016). Home-based rehabilitation with or without telemonitoring appears to be an effective solution for increasing patient participation in complex rehabilitation programs. An important component of home-based rehabilitation will be telerehabilitation, which uses electronic communication systems and computer technology to achieve practical applications of rehabilitation programs (Piepoli *et al*., 2016).

Psychosocial outcomes have been pursued in the two main types of programs. An important feature of home-based rehabilitation is that it is patient-centered, offering him/her more intervention options but also more responsibilities. The evaluation of the two main types of cardiovascular rehabilitation has not been completed. Several randomized trials and ongoing meta-analyzes are currently ongoing. Along with the psychosocial outcomes, the effects on symptoms and exercise capacity, changes in cardiovascular risk factors, decrease in the number of cardiovascular events and mortality are followed. The goal is to identify which of the many used programs are the most efficient ones and that can be maintained in the long run. An example is the Global Secondary Prevention Strategies to Limit Event Recurrence After Myocardial Infarction (GOSPEL) trial in which 3241 patients who completed a center-based rehabilitation program were randomized to a 3-year usual care (control group) or intensive, multifactorial program (intervention group). In the intervention group, exercise types and counseling sessions were reassessed every 6 months for 3 years. This type of intervention resulted in an over 30% reduction in stroke or myocardial infarction and cardiovascular mortality (Giannuzzi *et al*., 2008; Piepoli *et al*., 2016). The results so far foresee an evolution toward home-based models, emphasizing their stronger points. Using quality of life, patient satisfaction or stress assessment questionnaires, and other psychosocial outcomes, several studies noted the potential for superior acceptability of home-based rehabilitation, especially in stable patients who want to resume their social and professional activities. More recent studies, some ongoing, aim at developing more complex programs for patients with comorbidities; one example is the patients who associate chronic obstructive pulmonary disease and heart failure (Bernocchi *et al*., 2016). On the other hand, in the randomized studies and review-type analyses published so far the psychosocial data obtained from patients attending the two types of cardiovascular rehabilitation programs were not subject to separate analysis.

## Methods

Our study aimed at reviewing the main clinical trials published over the past five years that compared home-based with center-based cardiac rehabilitation and usual care, primarily focused on the psychological and social outcomes. Eligible studies were the randomized clinical trials published in specialized journals from January 2012 to December 2016; they have been selected from the MEDLINE, Web of Science and Science Direct databases. The analysis included human randomized cardiac rehabilitation studies centered on the home-based rehabilitation model, reporting data on accessibility, adherence, and improvement in quality of life, mental and social well-being. To access the databases, the following keywords were used: home-based cardiac rehabilitation and center-based cardiac rehabilitation, being paired with psychosocial outcomes and quality of life. In total, 454 titles have been selected. After reviewing the titles, the duplicate references were removed. The analysis continued with the screening of the abstracts of the 240 remaining articles and the removal of those irrelevant to the literature review topic, or of the non-randomized clinical trials. Finally, 8 full-text articles were selected as relevant for the type of questionnaires used and analysis of psychosocial outcomes in home-based rehabilitation. The steps in the selection of the studied articles are summarized in *Figure 1*.

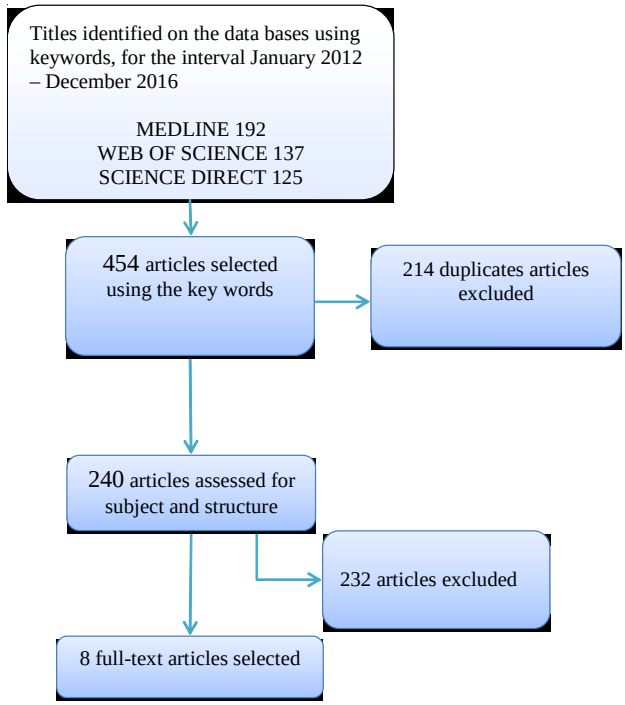


*Figure 1.* Selection process of the studied articles

## Results

### *Methods for the evaluation of psychosocial outcomes in cardiac rehabilitation studies*

Most randomized studies and meta-analyzes were dealing with the changes in risk factors, exercise capacity and readmission rate, but also evaluated some psychological or social components at entry and at completion of cardiac rehabilitation programs. Studies were primarily conducted in patients who had a myocardial infarction or myocardial revascularization procedure, but, more recently, studies have also been conducted in patients with heart failure of various etiologies, not only by ischemic heart disease. The evaluation of the mental and social components was made by completing at enrollment and at various times during reassessment of quality of life, depression and anxiety questionnaires and the perceived stress scale.

The quality of life questionnaires used in these studies were adapted to the patient's type of cardiovascular disease but also to the chosen rehabilitation program. For studies enrolling patients with heart failure, the Minnesota Living with Heart Failure Questionnaire (MLWHFQ) was first used. This is a validated 21-item questionnaire that measures physical, socioeconomic and psychological impairments related to heart failure. The responses are rated on a 6-point Likert scale from 0 to 5, the total score ranging between 0 and 105 points (Safiyari-Hafizi *et al.,* 2016). A second questionnaire used to assess the quality of life in patients with heart failure is the Chronic Heart Failure Questionnaire (CHFQ). Less used, and measuring general quality of life is Dartmouth COOP with scores from 1 to 5, a score of 1-3 being categorized normal and 4- 5 abnormal. Another quality of life questionnaire is the MacNew Heart Disease Health-related Quality of Life Instrument which assesses the emotional, social and physical quality of life, the score ranging from 1 to 7 (Dixon, Lim, & Oldridge, 2002).

A more comprehensive questionnaire for measuring health status is the MOS 36-item Short Form Health Survey (SF-36). The questionnaire assesses 8 health concepts (physical functioning, physical role limitation, bodily pain, mental health, social functioning, mental role limitation, vitality and general health) and is used in studies evaluating the psychosocial outcome because it measures both mental health and social functioning. It was mostly used in patients with ischemic heart disease attending cardiac rehabilitation programs (Pinto *et al.*, 2013), being considered a complex quality of life assessment questionnaire.

Depression and anxiety are recognized as predictive factors that accompany cardiovascular disease from onset, but also during rehabilitation. Aggravation of anxiety and depression is also associated with an unfavorable prognosis of cardiovascular disease progression. If the prevalence of anxiety in the U.S. adult population is estimated to be 18%, this percentage doubles to 36% when we refer to adults diagnosed with cardiovascular disease (Clark *et al.*, 2016). Beck Anxiety Inventory (BAI) is a questionnaire specifically developed to assess the symptoms of anxiety in a complex manner; it is a 21-item, multiple-choice, self-report inventory that measures the cognitive and somatic symptoms of anxiety; each item is rated from *0* to *3* points, the maximum score being 63. In a group of 208 patients in phase II of cardiac rehabilitation, 25% described mild anxiety (BAI score 8-15), 11% moderate anxiety (BAI between 16-25), and 5% severe anxiety symptoms (BAI greater than 26) (Clark *et al.*, 2016). For anxiety assessment, the State and Trait Anxiety Questionnaire was also used, and the 14-item Perceived Stress Questionnaire (PSQ-14) was used as a self-report measure of perceived stress.

In other studies Hamilton Depression Scale (HDS) and Hamilton Anxiety Scale (HAS) were used; Generalized Anxiety Disorder (GAD-7) is a 7-item scale validated for anxiety, and PHQ-9 is a 10-item questionnaire for screening and measuring the severity of depression (Brouwers *et al.*, 2017). Cardiac Depression Scale is a 26-item scale, each item rated from 0 to 7, validated for the assessment of depression in cardiac patients. The total score ranges from 26 to 182, scores above 95 indicating severe depression (Pinto *et al.*, 2013).

In the study published by Shanmugasegaram and colaborators the assessment was complex and included an important social component. The initial assessment included questions related to marital status and ethnocultural background, residence and distance to the center-based rehabilitation site. Socioeconomic status was measured by applying the MacArthur Scale of Subjective Social Status. After a follow-up period of 12 months, the percentage of participation in cardiac rehabilitation sessions was calculated. The assessment was completed by administering the Cardiac Rehabilitation Barrier Scale (CRBS) questionnaire, which may depend on patient, chosen rehabilitation method or certain components of the health insurance system (Shanmugasegaram *et al.*, 2013). The main presented questionnaires are summarized in *Table 1*.

*Table 1.* Psychosocial outcomes assessment questionnaires in cardiac rehabilitation studies

| Domaine | Assessment questionnaires |
|---|---|
| Health-related quality of life | Minnesota Living with Heart Failure Questionnaire (MLWHFQ)<br>Chronic Heart Failure Questionnaire (CHFQ)<br>Dartmouth COOP<br>MacNew Heart Disease Health-related Quality of Life Instrument<br>MOS 36-Item Short Form Health Survey (SF-36) |
| Anxiety and depression | Beck Anxiety Inventory (BAI)<br>State and Trait Anxiety questionnaire<br>Hamilton Anxiety Scale (HAS)<br>Generalized Anxiety Disorder (GAD-7)<br>Hamilton Depression Scale (HDS)<br>PHQ-9 Depression Scale<br>Cardiac Depression Scale<br>Depression, Anxiety and Stress Scale 21 (DASS21) |
| Stress level perception | 14-item Perceived Stress Questionnaire (PSQ-14)<br>Kessler 10 (K10) Psychological Distress Scale |
| Socio-economic status | The MacArthur Scale of Subjective Social Status<br>The Cardiac Rehabilitation Barriers Scale (CRBS) |

## *Psychosocial outcomes in home-based cardiac rehabilitation randomized trials*

The psychosocial outcomes assessed by home-based cardiac rehabilitation randomized trials are presented in *Table 2.*

*Table 2.* Psychosocial outcomes in the main randomized trials of home-based cardiac rehabilitation

| Study | Population (n)/ Diagnosis | Follow-up/ Intervention | Gender Male/ Women (n) | Mean age (y) | Psychosocial outcomes |
|---|---|---|---|---|---|
| 1. Safiyari-Hafizi, Taunton, Ignaszewski, & Warburton, 2016 | 40/HF | 12 weeks/20 patients control group and 20 home-based CR | 40/0 | Not mentioned | Home-based CR improved quality of life in patients with HF |
| 2.Vahedian-Azimi *et al*., 2016 | 70/post MI | 3 years/randomized in standard home-based CR or Family-Centered Empowerment Model of CR | 46/24 | 61.40 ± 12.83 | HRQoL questionnaire, SF-36 questionnaire, The 14-item Perceived Stress Questionnaire, The State and Trait Anxiety questionnaire were used Quality of life, perceived stress and state anxiety showed significant improvement in both groups |

| | | | | | |
|---|---|---|---|---|---|
| 3. Aamot *et al.*, 2014 | 90/CAD | 12 weeks/ 3 patient group (control group, treadmill or home exercise) | 80/10 | 57 ± 8 | HRQoL did not differ significantly among groups |
| 4. Varnfield M, *et al.*, 2014 | 120/post MI | 6 months/60 patients in a centre-based CR and 60 in a smatphone-based home CR | 82/38 | 56.2 ± 10.1 in centre-based CR and 54·9 ± 9.6 in home CR | HRQoL improved more in patients randomized to home-based CR improved 6 weeks psychological distress, and significantly decrease DASS – depression and DASS – anxiety score in home-based CR |
| 5. Pinto, Dunsiger, Farrell, Marcus & Todaro, 2013 | 130/CAD | 12 months/64 patients Maintenance Counseling group and 66 patients Contact Control group | 104/26 | 63.6 ± 9.7 | Higher quality of life and less depressive symptoms at 12 months for Maintenance Counseling group |
| 6.Shanmugasegaram, Oh, Reid, McCumber & Grace, 2013 | 939/CAD | 12 months/843 centre and 96 home-based rehabilitation | 718/221 | 64.1 ± 9.9 | Home-based participants reported significantly grater barriers for cardiovascular rehabilitation |
| 7. Oerkild, Frederiksen, Hansen & Prescott, 2012 | 40/CAD | 12 months/21 patients usual care and 19 patients home care | 23/17 | 76.5 ± 7.7 (usual care) 77.3±6 (home-based CR) | HRQoL and anxiety (HAS), depression (HDS) did not differ significantly at 3 and 12 months |
| 8. Wang, Chair, Thompson, & Twin, 2012 | 133/post MI | 6 months/65 patients in control group and 68 patients in home-based CR | 111/22 | 58.3 ± 10.4 (control group) 57.3 ± 8.6 (home-based CR) | Home-based CR improves HRQoL and reduces anxiety |

*CAD – coronary artery disease; CR – cardiac rehabilitation; HAS – Hamilton anxiety score; HDS – Hamilton Depression Score; HF – heart failure; HRQoL – health-related quality of life; MI – myocardial infarction*

## Discussion

Patients with heart failure were enrolled in randomized trials including home-based cardiac rehabilitation more recently, due to the higher potential for heart disease destabilization; in the study published by Safiyari-Hafizi and colaborators (Safiyari-Hafizi *et al.*, 2016), one of the most important cardiovascular outcomes was the increase in maximal oxygen consumption, and therefore in exercise capacity following home-based combination of interval and resistance training, all with implications for overall quality of life, and with a potential for increasing life expectancy in heart failure patients, reducing the number of hospital admissions and the associated costs. Also published in 2016 was a meta-analysis that assessed home-based cardiac rehabilitation in heart failure from its initiation to December 2015 (Zwisler *et al*., 2016). Cardiac rehabilitation has been proven to be effective in heart failure. However, access to center-based cardiac rehabilitation is limited. A 2011-2012 *UK*-based survey found that *only 16%* of *cardiac rehabilitation* centers *provided* a *program* specifically designed for people with *heart failure*. In the meta-analysis published by Zwisler and colaborators (Zwisler *et al*., 2016), most of the included studies dealt with home-based physical exercise, and only four trials combined physical exercise with medical education and psychological intervention. In this meta-analysis, 13 trials evaluated the quality of life of patients with heart failure. The Minnesota Living with Heart Failure score demonstrated a significantly improved quality of life by home-based cardiac rehabilitation compared to usual care. In this meta-analysis no significant difference was found between home and center-based cardiac rehabilitation in terms of quality of life in heart failure patients. Comparable psychosocial outcomes were also reported in the study by Safiyari-Hafizi and colaborators (Safiyari-Hafizi *et al.*, 2016), presented in *Table 2*.

However, adherence to the various types of cardiac rehabilitation programs remains generally suboptimal. In general, a 20% dropout rate is reported during cardiac rehabilitation programs and only 50% of patients maintained exercise routine at 6 months after the completion of phase I cardiac rehabilitation. The risk factors for low adherence are: insufficient awareness of the consequences of cardiovascular disease, patients with significant functional deficits, intensely symptomatic, difficulty traveling to the rehabilitation center, financial constraints, advanced age, precarious socioeconomic status, depression and anxiety. For these reasons, the alternative model of home-based cardiac rehabilitation programs is very important and some authors discuss the learning and coping strategies that help improve patient adherence. Lynggaard and colaborators talk about developing patient involvement strategies. Patients should be informed in order to be well aware of the disease and its risks. Individual interviews with patients can help build a plan aimed at improving their health and establishing the phases of rehabilitation (Lynggaard *et al.*, 2017). In 2017, Lynggard and colaborators

published the LC-REHAB trial in which the effectiveness of the addition of learning and coping strategies to improving adherence to cardiac rehabilitation programs, lowering morbidity and mortality, and improving quality of life was evaluated. The study showed that after 8 weeks of education sessions adherence to cardiac rehabilitation was improved; better results were recorded in patients with heart failure and in those with a lower initial education level (Lynggaard, *et al*., 2017). Sustained patient education will improve their adherence to various types of cardiac rehabilitation programs.

Adherence to cardiac rehabilitation programs also depends on patients'age and gender. Of the studies presented in Table 2, the study by Oerkild and colaborators included the patients with the highest mean age, comparing home-based rehabilitation with usual care (Oerkild *et al.*, 2012). This may be one of the explanations for the comparable results in terms of quality of life, depression, anxiety at 3 and 12 months follow-up. Also, participation in rehabilitation programs is lower in women. In the study by Midence and colaborators developed a woman-only cardiac rehabilitation program. This kind of cardiac rehabilitation program had cardiovascular and quality of life outcomes similar to other mixed-gender programs; only anxiety and depression symptoms were significantly less in the model imagined by Midence and colaborators (Midence *et al.*, 2016). In most of the here discussed studies, patients were assessed with quality of life questionnaires at study entry, intermediate time point and at the completion of the rehabilitation program. As to the psychosocial outcome, assessment of quality of life is very important and should be highlighted in most cardiac rehabilitation studies. This aspect is also emphasized by Wang and colaborators who analyzed several randomized trails and meta-analyzes and noted that a sufficiently small number of randomized studies evaluating the rehabilitation programs appreciate the changes in the quality of life during their course (Wang *et al.*, 2012).

## Conclusions

Home-based cardiac rehabilitation is increasingly used and has been documented to be effective and convenient. From the point of view of social interest, there will be a greater demand for home-based rehabilitation because it offers more autonomy to the patient; although the patient has to face more complex responsibilities, he is made more accountable and able to maintain rehabilitation activities for a longer period of time. The analyzed studies report similar results in terms of increased exercise capacity, but with generally superior outcomes in terms of quality of life, fighting anxiety and depression, or socio-professional reintegration. The psychosocial outcomes of home-based cardiac rehabilitation are at least equal to those of center-based cardiac rehabilitation and certainly superior to usual care.

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