KNGF Guideline on Cardiac Rehabilitation

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All sections of the guideline, including the summary, are available at kngf.nl/kennisplatform





Vereniging van Oefentherapeuten

The KNGF guideline on 'Cardiac Rehabilitation' is a publication of the Royal Dutch Society for Physical Therapy (Koninklijk Nederlands Genootschap voor Fysiotherapie – KNGF) and the Association of Cesar and Mensendieck Exercise Therapists (Vereniging van Oefentherapeuten Cesar en Mensendieck – VvOCM).

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Authors | Development

Involvement of stakeholders (authors)

The project group of the KNGF (Royal Dutch Society for Physical Therapy) guideline on Cardiac Rehabilitation for coronary artery disease and chronic heart failure consists of the core group, the guideline panel and the review panel. The core group consists of guideline advisers and subject-matter expert scientists. The guideline panel and review panel of the guideline on Cardiac Rehabilitation for coronary artery disease and chronic heart failure consists of a delegation of subject-matter expert scientists, representatives from the professional field of physical and exercise therapy, (para)medical professionals, patient representatives and healthcare insurance companies. The roles and tasks of stakeholders in the guideline are described in the KNGF guideline methodology 2022 (Koninklijk Nederlands Genootschap voor Fysiotherapie 2022).

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KNGF = Koninklijk Nederlands Genootschap Fysiotherapie (Royal Dutch Society for Physical Therapy); Radboudumc = Radboud Universitair Medisch Centrum (Radboud University Medical Centre); VvOCM = Vereniging van Oefentherapeuten Cesar en Mensendieck (Association of Cesar and Mensendieck Exercise Therapists).

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HartVaatHAG = Hart- en Vaatziekten Huisartsen Advies Groep (General Practitioners Advisory Group on Cardiovascular Diseases); KNGF = Koninklijk Nederlands Genootschap voor Fysiotherapie (Royal Dutch Society for Physical Therapy); NVVC = Nederlandse Vereniging voor Cardiologie (Dutch Society for Cardiology); NVZF = Nederlandse Vereniging voor Ziekenhuisfysiotherapie (Dutch Society for Hospital Physical Therapy); VHVL = Vereniging voor Hart-, Vaat- en Longfysiotherapie (Society for Cardiovascular and Pulmonary Rehabilitation); VSG = Vereniging voor Sportgeneeskunde (Society for Sports Medicine); VvOCM = Vereniging van Oefentherapeuten Cesar en Mensendieck (Association of Cesar and Mensendieck Exercise Therapists).

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EN = Ergotherapie Nederland (Occupational Therapy Netherlands); KNGF = Koninklijk Nederlands Genootschap voor Fysiotherapie (Royal Dutch Society for Physical Therapy); M PT. = Masters in Physical Therapy; NIP = Nederlands Instituut van Psychologen (Dutch Institute of Psychologists); NVAB = Nederlandse Vereniging voor Arbeids- en Bedrijfsgeneeskunde (Dutch Society of Occupational Medicine); NVHVV = Nederlandse Vereniging voor Hart- en Vaatverpleegkundigen (Dutch Society for Cardiovascular Nurses); NVRF = Nederlandse Vereniging voor Revalidatiefysiotherapeuten (Dutch Society for Rehabilitation Physiotherapists); VRA = Nederlandse Vereniging van Revalidatieartsen (Dutch Society of Rehabilitation Physicians); VvOCM = Vereniging van Oefentherapeuten Cesar en Mensendieck (Association of Cesar and Mensendieck Exercise Therapists); WVVK = Wetenschappelijke Vereniging van Vlaamse Kinesitherapeuten (Scientific Association of Flemish Physiotherapists); ZiN = Zorginstituut Nederland (Healthcare Institute of the Netherlands).

Patient perspective and preferences

During the guideline project, the perspective, experience, expectations and preferences of patients are carefully and repeatedly verified and taken into account.

In the preparatory phase, Harteraad (Heart Council) indicated barriers from previous research (Harteraad 2020). These barriers have been included and taken into account in the barrier analysis and in the drafting of the framework. Other information from Harteraad was also included in the further development of the guideline, for instance in determining the most significant outcome measures, describing and weighing up the various considerations and formulating recommendations.

The national expertise centre on health inequities at Pharos is also involved in the guideline panel to ensure that attention is given to health inequities in cardiac rehabilitation. Both parties actively contributed to the development of modules (and accompanying recommendations) and are participating in all of the guideline development phases.

Conflict of interest

Prior to and upon completion of the project, all guideline panel and review panel members provided a declaration of interest. The declarations of interest were assessed by the guideline advisers and, where necessary (if there was a conflict of interest), measures were taken during the guideline project (for example not participating in the 'from evidence to recommendation' process in the guideline panel or review panel) to limit any (impression of) undue influence through conflict of interest in as far as possible, in accordance with the 'KNGF guideline methodology 2022' (Koninklijk Nederlands Genootschap voor Fysiotherapie 2022).

The declarations of interest state the affiliations (the organisation or institution and location of work activities) of the project group's members. These declarations of interest are available on request through KNGF. Since declarations of interest include personal information, these are not made public.

Development

The subject-matter experts involved (Dr R.J. Achttien and Dr T.M.H. Eijsvogels and KNGF) evaluate on a yearly basis whether the subject-matter and/or policy developments necessitate a revision of this guideline. A revision of the KNGF guideline on Cardiac Rehabilitation from 2011 was necessary. This guideline replaces the KNGF guideline on Cardiac Rehabilitation from 2011. The present guideline was developed modularly, in accordance with the 'KNGF guideline methodology 2022' (Koninklijk Nederlands Genootschap voor Fysiotherapie 2022).

Preparatory phase (including barrier analysis)

The first step in the development of the revision was to set up the core group, guideline panel and review panel with representation from the relevant stakeholders. The core group members and all guideline panel and review panel members signed a declaration of interests at the start and at the completion of the project.

The barrier analysis was given shape by consulting with physical and exercise therapists; patients and stakeholders that are relevant for the guideline, by regularly putting questions to the guideline and review panel and by gathering (aggregated) information on the topic of the guideline in the literature, in order to do a barrier analysis based on all this information. Based on this information, barriers were listed, drawn up and analysed, which will form the basis for the prioritised clinical questions in the guideline.

The activities and methods that the core group selected for this purpose in the KNGF guideline on Cardiac Rehabilitation for coronary artery disease and chronic heart failure were aligned with the relevant guideline and the availability of the parties for the duration of the preparatory phase and consisted of: 1) drawing up a written barrier analysis, 2) conducting a patient consultation, 3) organising an invitational conference, 4) doing surveys, 5) setting up a focus group of physical and exercise therapists, 6) organising a guideline panel meeting, 7) organising a review panel meeting and 9) conducting an orienting literature review.

The preparatory phase, in which the barrier analysis was done, took place between 1 March 2022 and 1 June 2022.

Development phase

During the development phase, three guideline panel meetings took place in which the considerations were discussed and recommendations were formulated. The review panel also provided feedback on the draft modules.

External review and authorisation phase

In the external review phase, in which all modules were combined, the concept guideline was sent for comments to the physical and exercise therapists concerned and to all parties that contributed to the development of the guideline or that indicated before the process that they would like to become involved in the commentary phase. During a work field round, the guideline was submitted to physical therapists and exercise therapists who are involved in care for the patient group at which the guideline is aimed and was discussed during a focus group meeting. The collected comments were assembled in a comments table, which was presented to the guideline panel. The guideline panel determined which changes and/or additions were required or desired to be made to the draft guideline. The review panel advised on this as well. After being adopted by the guideline panel and the review panel, the guideline was presented to all involved stakeholders for authorisation.

Dissemination and implementation phase

After publication of the guideline, various dissemination and implementation products were delivered, including:

- patient information;
- summary card;
- knowledge gaps (see Appendix A.o-1);
- training (including an e-learning module);
- articles in magazines (both within and outside the fields of physical therapy and exercise therapy, both nationally and internationally);
- lectures at congresses and symposia.

Implementation activities are aimed in particular at the following four core topics:

- 1. Doing the exercise programme of phase II cardiac rehabilitation in a primary care setting
- 2. Personalised care
- 3. Telerehabilitation
- 4. Complex casuistry

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A General information

A.1 Introduction

A.1.1 Initiative

Royal Dutch Society for Physical Therapy (Koninklijk Nederlands Genootschap voor Fysiotherapie – KNGF) / Association of Cesar and Mensendieck Exercise Therapists (Vereniging van Oefentherapeuten Cesar en Mensendieck – VvOCM).

A.1.2 Financing

The guideline development was financed by ZonMw with the resources of the 'System Advice on physical and exercise therapy – A new balance between access to and the affordability of good healthcare' (Zorginstituut Nederland 2016).

In 2016 the Healthcare Institute of the Netherlands (Zorginstituut Nederland [ZiN]) issued the 'System Advice on physical and exercise therapy – A new balance between access to and the affordability of good healthcare' to the Minister of Health, Welfare and Sport to change the way of determining physical therapy and exercise therapy claims within the fee structure (Zorginstituut Nederland 2016). The most important reason for this was that current claims result in patients/ insured parties opting for more expensive types of healthcare that are fully reimbursed. The Minister adopted this advice in part and stresses that experimentation should take place in particular with regard to conditions where physical therapy and exercise therapy offer a good chance of substitution (replacing expensive care with inexpensive care with comparable effectiveness). The ZiN determined priorities within the framework of the advice implementation, whereby the subject of 'cardiac rehabilitation' was prioritised for a guideline. Based on the System Advice, the development of this guideline was co-financed by the Ministry of Health, Welfare and Sport. The guideline was also financed by KNGF and Vv0CM.

A.1.3 Reason

Since the publication of the 'KNGF Guideline on Cardiac Rehabilitation' in 2011, new (scientific) insights have been obtained with regard to diagnosing and treating patients with coronary artery disease or chronic heart failure. In order to offer patients with coronary artery disease or chronic heart failure the right therapeutic intervention(s) for the right treatment goals – at the right place within the healthcare process – and to decrease variations in practice, a revision was needed of the existing guideline on physical therapy for patients with coronary artery disease or chronic heart failure. This revision forms part of the agreements stemming from the 'System Advice on physical and exercise therapy – A new balance between access to and the affordability of good healthcare' (Zorginstituut Nederland 2016). The close correlation between physical therapy and exercise therapy was the impetus for VvOCM and KNGF to revise the KNGF guideline from 2011 together.

A.1.4 Goal of the guideline

The aim of this guideline is to provide guidance for the daily practice of physical and exercise therapists in diagnosing and treating patients with coronary artery disease or chronic heart failure. The guideline aims to describe the most effective treatment and support for patients with coronary artery disease or chronic heart failure. Based on a systematic evaluation of scientific research and by weighing up patient preferences and professional expertise, the 'KNGF Guideline on Cardiac Rehabilitation for coronary artery disease and chronic heart failure' supports therapists and patients in the clinical decision-making process and also offers transparency for other healthcare providers and stakeholders.

A.1.5 Target group

Patient group

This guideline describes the treatment of adult patients with coronary artery disease or chronic heart failure with an absolute or relative indication for cardiac rehabilitation. Patients can also be referred to cardiac rehabilitation with another indication, but such indications fall outside the scope of this guideline. The absolute and relative indications for cardiac rehabilitation are described in B.7 'Indication'.

Intended users of the guideline

This guideline is primarily aimed at physical therapists and exercise therapists who treat and guide the patient group defined in this regard, regardless of the setting (primary care, a hospital or rehabilitation institute; or in a mono or multidisciplinary setting).

These professional groups are described in the '<u>Physical Therapist Professional Profile</u>' and the '<u>Exercise Therapist Professional Profile</u>' (Koninklijk Nederlands Genootschap Fysiotherapie 2021; Vereniging van Oefentherapeuten Cesar en Mensendieck 2019).

Other users of the guideline

The guideline is also relevant for other healthcare providers who are involved in guiding and treating patients with coronary artery disease or chronic heart failure such as general practitioners, cardiologists, sports physicians, copany doctors, rehabilitation physicians, psychologists, nurses, social workers, dieticians, and occupational therapists. This guideline is further relevant for patients, policy-makers and organisations involved in healthcare for patients with coronary artery disease or chronic heart failure The guideline provides a clear picture of what one can expect from physical therapists and exercise therapists with regard to cardiac rehabilitation.

A.1.6 Scope

This guideline is aimed at the profession-specific diagnostic and therapeutic process of the physical and exercise therapist for patients with coronary artery disease or chronic heart failure. These patient groups were prioritised during the barrier analysis; see '<u>Authors | Development</u>'. Topics that were not prioritised in the barrier analysis can be found in Appendix A.1.2 'Barrier analysis'; see 'Appendices to the Practice Guideline'.

The guideline describes the entire care process (all phases of cardiac rehabilitation) of patients with coronary artery disease or chronic heart failure; however, the recommendations that provide answers to the prioritised clinical questions focus on phase II of cardiac rehabilitation.

The guideline applies to all the different settings where cardiac rehabilitation is offered; however, the setting to which the recommendations apply will differ for each module.

The specific clinical questions that are answered in these guidelines are indicated for each module.

A.1.7 Methodology

KNGF guideline methodology

The present guideline was developed in accordance with the 'KNGF guideline methodology 2022' (Koninklijk Nederlands Genootschap voor Fysiotherapie 2022). The way in which this methodology was applied and the manner in which stakeholders were involved in the development are described in 'Authors | Development'.

Alignment with the NVVC guideline

This guideline aligns with the 'Multidisciplinary guideline on cardiac rehabilitation of 2024' of the Dutch Society for Cardiology (Nederlandse Vereniging voor Cardiologie or NVVC). The guideline is currently being revised at the behest of the NVVC. Throughout the guideline process, consultations took place between the two parties to ensure that the guideline would be complementary.

Status of the guideline

Recommendations in a guideline are not laws or mandatory regulations. In principle, therapists should adhere to the recommendations, but substantiated deviation is legitimate or even necessary if the deviation is commensurate with the individual patient's situation and wishes (Zorginstituut Nederland 2021).

A.1.8 Reading guide and structure of the guideline

This guideline consists of three sections. The general information in Section A contains the general introduction, background information on cardiac rehabilitation and information on how the healthcare is organised. Section B looks at the diagnostic process and indication as well as facilitating and limiting factors that pertain to the continuation and completion of cardiac rehabilitation. Section C has to do with the therapeutic process and looks at various forms of personalised care and start and stop criteria for treatment.

The various topics within a section are dealt with in separate, stand-alone modules. In each module, the information is subsequently divided into three levels, which each level going more in-depth into the respective topic:

- The practical tips, the recommendations, are included in the Practice Guideline (the first level).
 Information on the topic being addressed and the considerations of the most important arguments that lead to the recommendation or description are contained in the Substantiation (second level).
- The Justification (the third level) provides details about how this information was collected (including the search strategy, summary of results, evaluation of the evidentiary value and description of considerations), the process with which this consideration came about and the references of the (scientific) literature used.

Where this document refers to 'he', this can also mean 'she'. Where this document uses 'therapist', this can mean 'physical therapist' or 'exercise therapist'. Where this document uses 'therapy', this can mean 'physical therapy' or 'exercise therapy'. Where this document uses 'patient', this can also be read as 'client'.

In Appendix A.1.1 – see 'Appendix to the Practice Guideline' – the most important definitions, terms and abbreviations used in this guideline are described.

А

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A.2 Background

A.2.1 Epidemiology and pathophysiology

Coronary artery disease

Coronary heart diseases, or ischaemic heart diseases, are cardiac conditions caused by calcification (atherosclerosis) or defects in the coronary arteries. Coronary artery disease is a chronic disease and is also referred to as chronic coronary syndrome (CCS). CCS comes in various forms. The acute form is called acute coronary syndrome (ACS). It is mostly caused by an unstable atherosclerotic plaque. ACS can further be divided into acute myocardial infarction (AMI; with or without ST elevation) and unstable angina pectoris (IAP). The distinction between these is whether or not there is myocardial damage, using the release of troponin (a heart-muscle marker) in the blood as a measurement unit. The more stable form of CCS is stable angina pectoris. In this case patients will, as the name indicates, have stable symptoms of chest pain.

Chronic heart failure

Heart failure mostly implies chronic heart failure. Acute heart failure is referred to if the symptoms and phenomena occur within a few hours or days. Heart failure is a clinical syndrome that occurs through structural or functional defects in the heart whereby the pumping function can only be maintained with increased intracardiac pressure. Symptoms of chronic heart failure include dyspnoea, reduced exertion tolerance and fatigue. The diagnostic classification of heart failure according to international guidelines is based on left ventricular ejection fraction (LVEF), which is defined as the fraction of left chamber volume ejected by the left ventricle in systole, commonly determined through echocardiography.

- HFpEF: heart failure with preserved ejection fraction LVEF (\geq 50%)
- HFmrEF: heart failure with mid-range ejection fraction LVEF (40-49%)
- HFrEF: heart failure with reduced ejection fraction LVEF (< 40%)

To describe the severity of heart failure, the classification system of the New York Heart Association (NYHA) is often used. This classification system is based on limitations of physical activity.

Class	Symptoms
Class I	no clear clinical symptoms, no limitation of activities
Class II	light; some symptoms during physical exercise, little/no symptoms during rest
Class III	moderate-severe; symptoms already with minimal (everyday) physical effort
Class IV	severe; symptoms (fatigue and/or dyspnoea) at rest

A.2.2 Cardiovascular risk factors

Cardiovascular risk factors are: smoking, high blood pressure, heredity and high cholesterol. Age, overweight, little exercise, alcohol, diabetes and long-term stress also lead to a greater risk of cardiovascular disease.

In the Netherlands, general practitioners play an important role in detecting people with a increased risk of cardiovascular disease and in determining whether they should be considered for interventions.

A.2.3 Cardiac rehabilitation

Cardiac rehabilitation is care that is offered as a follow-up to acute treatment for patients who have suffered a cardiac incident. The American Public Health Services use an extended definition for heart rehabilitation, which also encompasses the definition of the World Health Organisation (WHO): 'Cardiac rehabilitation services are comprehensive, long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counselling. These programs are designed to limit the physiological and psychological effects of cardiac illness, reduce the risk for sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients. Services commence during hospitalisation and are followed up with an outpatient program in the next 3 to 6 months, followed by a lifetime maintenance phase which consists of exercise with the goal of reducing risk factors in a setting without or with minimal supervision' (Feigenbaum 1987). The four phases are:

Preoperative phase. In this phase, patients who are scheduled for a heart operation can be screened for the risk of postoperative pulmonary complications and, based on that risk, receive preoperative therapy.

Phase I or clinical phase (hospitalisation). This phase starts immediately after the acute cardiological event such as an ACS (for example an acute myocardial infarction (AMI) or a manifestation of unstable angina pectoris (IAP)), acute heart failure or acute hospitalisation due to any other heart disease.

hase II or rehabilitation phase. This phase aligns with the clinical phase and starts after discharge from the hospital on an (almost exclusively) outpatient basis.

Phase III or post-rehabilitation phase. This phase aligns with the rehabilitation phase. The focus in this phase is in particular to maintain the lifestyle changes implemented in phase II.

SUBSTANTIATION

A.2.1 Epidemiology and pathophysiology

In the Netherlands, the number of cases of coronary artery disease (coronary heart disease) is rising steadily, as is the number of hospitalisations (57,000 in 2020). This progression is largely influenced by cardiovascular risk factors such as smoking, hypertension, hypercholesterolaemia, lack of exercise, stress and obesity, which are intensifying year by year. As the number of people with these risk factors has been growing since 1980, the incidence of coronary heart disease has also been increasing. Through improved treatment opportunities, the number of deaths due toe coronary heart disease has been decreasing since 1980: reaching about 8,000 in 2020. The drop in the number of deaths does, however, mean that more and more people in the Netherlands have a form of CCS. An estimated 786,600 people in the Netherlands were diagnosed with a coronary heart disease in 2021. Healthcare costs due to coronary artery disease is estimated at EUR 1.4 billion (figures in 2019).

In 2021 an estimated 241,300 people in the Netherlands suffered from heart failure. In most age groups, relatively more men than women suffer from heart failure. Yet many more women than men suffer from heart failure (in 2021 respectively 125,000 and 116,300), because women strongly outnumber men in the highest age categories. In 2020, there were 28,000 hospital intakes due to heart failure. Heart failure is not one of the top ten diseases that are responsible for the largest disease burden. Healthcare expenses in the Netherlands are estimated at EUR 527.4 million (figures in 2019) (Rijksinstituut voor Volksgezondheid en Milieu).

For the latest information on the prevalence, incidence, disease burden and healthcare expenses of coronary artery disease and chronic heart failure, see the information from the <u>Dutch National</u> Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu).

Coronary artery disease

Acute coronary syndrome (ACS) can cause a combination of symptoms and phenomena:

- The most characteristic symptom of an ACS is chest pressure (in 75% of all patients), both for men and women. The sensation appears acutely and does not disappear at rest or within 5 minutes of administering nitrate under the tongue. The pressure can be accompanied by a feeling of impending disaster/the 'feeling that this is serious'.
- Other frequently occurring symptoms (30–50%) are dyspnoea/a sensation of not breathing deep enough, perspiring, nausea or vomiting, tiredness, looking pale or sickly and pain that spreads to the left shoulder or arm.

- The following symptoms occur less frequently (< 30%): pain between the shoulder blades, dizziness or feeling faint, neck pain, palpitations, pain in the right shoulder or arm, jaw pain or dyspepsia. Those that occur the least frequently are pain in the middle of the stomach or fainting (both occurring in only 10% of patients).
- Sometimes the pain is less obvious than other symptoms, such as suddenly occurring dyspnoea, whether or not in combination with vegetative phenomena, fatigue, dizziness, an overall feeling of weakness or anxiety. This less specific presentation is seen more often at a higher age (> 65 years). (Nederlands Huisartsen Genootschap 2022).

In women, the signals are often less clear and different than in men, for example sleeping problems, extreme fatigue, dyspnoea, dizziness and an unpleasant sensation in the stomach. But pain between the shoulder blades or in the arms or jaw can also be a warning sign of a heart attack in women (Hartstichting).

Chronic heart failure

The heart can be seen as a suction pump. With heart failure, the heart pumps an insufficient amount of blood to supply in all the needs of the body. In the case of HFrEF and HFmrEF, the pumping power of the left ventricle is insufficient, which reduces the ejection fraction (systolic dysfunction). With HFpEF the ejection fraction is not reduced, but the left ventricle fills up more slowly and less due to the increases stiffness of the heart tissue, causing insufficient pump volume during exercise or higher heart frequency (diastolic dysfunction). Heart failure is a chronic, progressive disease. Patients can remain stable for a while with appropriate therapy, but eventually the damage to and malfunctioning of the heart muscle will increase (Nederlands Huisartsen Genootschap 2021).

Heart failure leads to non-specific symptoms (dyspnoea, reduced exercise capacity, fatigue) that limit day-to-day functioning and that increase over time. The more specific signs of heart failure detected under physical examination are mostly due to fluid volume overload (Nederlands Huisartsen Genootschap 2021):

- lungs: pulmonary crackles, attenuation at heartbeat and diminished breath sounds, sometimes rhonchi and wheeze;
- increased central venous pressure (swollen neck veins);
- oedema in ankles and/or sacrum;
- increased waist circumference (enlarged liver, ascites).

Symptoms increase as heart failure exacerbates. Sometimes also night-time symptoms:

dyspnoea when lying horizontally, more pillows needed when sleeping (orthopnoea); nocturia.

To describe the severity of heart failure, the classification system of the New York Heart Association (NYHA) is often used (McDonagh 2021).

A.2.2 Cardiovascular risk factors

The main recommendations with regard to cardiovascular risk management (CVRM) are described in the 'FMS guideline on cardiovascular risk management'. In this guideline, the main risk factors

for coronary artery disease and chronic heart failure are mentioned, as well as how these are identified and which interventions (including lifestyle recommendations) apply (Federatie Medisch Specialisten 2019).

A.2.3 Cardiac rehabilitation

The guideline focuses in particular on multidisciplinary outpatient rehabilitation (phase II). The guideline panel made this choice based on barriers that they had identified as priorities during the preparatory phase of the guideline.

For absolute and relative indications for cardiac rehabilitation in the Netherlands, as well as a description of the definition of cardiac rehabilitation, the 'Multidisciplinary guideline on cardiac rehabilitation of 2024' is maintained (Nederlandse Verenging voor Cardiologie).

See <u>B.5 'Physical examination and treatment plan'</u> for the goals of cardiac rehabilitation. The diagnosis categories are described in <u>B.7</u> 'Indication'.

See for a more in-depth description of the preoperative phase (Hulzebos 2006; Valkenet 2011).

JUSTIFICATION

The efficacy of cardiac rehabilitation (with an exercise programme) has been studied extensively (Savage 2019).

Efficacy of cardiac rehabilitation for patients with coronary artery disease

The efficacy of cardiac rehabilitation compared to no exercise for patients with coronary artery disease was described according to the following outcome measures in the short (6–12 months), medium (13–36 months) and long (> 36 months) term (Dibben 2023):

- mortality (due to all causes and cardiovascular mortality);
- fatal and/or non-fatal myocardial infarction;
- revascularisation and the chances of CABG;
- revascularisation and the chances of PCI;
- hospitalisation (due to all causes and cardiovascular-related intakes);
- quality of life;
- cost-effectiveness.

Efficacy of cardiac rehabilitation for patients with heart failure

The efficacy of cardiac rehabilitation compared to usual care for patients with heart failure was described according to the following outcome measures in the short (6–12 months), medium (13–36 months) and long (> 36 months) term (Long 2019):

- mortality;
- hospitalisation (due to all causes and intakes related to heart failure);
- quality of life;
- cost-effectiveness.

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Cost-effectiveness

Cardiac rehabilitation is seen as a cost-effective intervention (Dibben 2021; Dibben 2023; Frederix 2018; Long 2019; Shields 2018).

Developments, trends and challenges

Important developments, trends and challenges in cardiac rehabilitation that are described in the literature are (Gevaert 2020; Savage 2019; Taylor 2023; Vromen 2021):

- There is an increase in the number of absolute indications where the positive effects of cardiac rehabilitation has been demonstrated (e.g. atrial fibrillation).
- There is an under-representation of specific sub-populations in cardiac rehabilitation that have participated (e.g. women, obese patients, older adults, frail people).
- There is an increase in new cardiac rehabilitation models to promote participation (e.g. telerehabilitation, home-based rehabilitation).
- Only half of all countries worldwide have cardiac rehabilitation programmes.

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A.3 Organisation of healthcare

Amass knowledge of and insight into the expertise of the (para)medical professionals involved in coronary artery disease or chronic heart failure and the treatment that is offered, including (specialised) physical and exercise therapists.

Determine with the involved (para)medical professionals how multidisciplinary collaboration for patients with coronary artery disease or chronic heart failure will be organised at the local or regional level in phase II.

The process of cardiac rehabilitation is a multidisciplinary matter par excellence. Many healthcareproviding experts are involved in cardiac rehabilitation, such as the cardiologist, cardiothoracic surgeon, (supervising) general practitioner, rehabilitation physician, sports physician, company doctor, doctors affiliated with insurance companies, psychiatrist, (neuro)psychologist, psychotherapist, exercise physiologist, cardiac rehabilitation coordinator, general practice-based nurse, physical therapist, exercise therapist, social worker, dietitian, occupational therapist, lifestyle coach, (cardiovascular) nurse, sex therapist and occupational expert. The composition, roles and tasks of the multidisciplinary treatment team varies (at a local and a regional level) and also depends on the individual rehabilitation goals of the patient.

SUBSTANTIATION

All KNGF guidelines include an 'Organisation of healthcare' module. This module has therefore not been included on the basis of a prioritised barrier, but has been aligned with the subject of the guideline.

Reason

In the treatment process of cardiac rehabilitation, cooperation takes place with many experts in the field of healthcare. It must be made clear which expert is involved and how the cooperation is organised. Based on this, the following clinical question was drawn up.

Clinical question

How is multidisciplinary healthcare for patients with an indication for cardiac rehabilitation organised?

Rationale of the recommendation

In consultation with the guideline panel it was decided not to carry out any systematic search action in order to answer this clinical question, but to gather the information needed for answering this clinical question in a non-systematic way and work it out narratively using the knowledge and clinical expertise of the guideline panel.

A.3.1 Organisation of multidisciplinary collaboration

The process of cardiac rehabilitation is a multidisciplinary matter par excellence. Many healthcareproviding experts are involved in cardiac rehabilitation, such as the cardiologist, cardiothoracic surgeon, (supervising) general practitioner, rehabilitation physician, sports physician, company doctor, doctors affiliated with insurance companies, psychiatrist, (neuro)psychologist, psychotherapist, exercise physiologist, cardiac rehabilitation coordinator, general practice-based nurse, physical therapist, exercise therapist, social worker, dietitian, occupational therapist, lifestyle coach, (cardiovascular) nurse, sex therapist and occupational expert (Nederlandse Vereniging voor Cardiologie 2011).

As described in A.2 'Background', cardiac rehabilitation consists of four phases.

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The composition of the multidisciplinary treatment team varies for each phase and a local and regional level, and also depends on the individual rehabilitation goals of the patient (cf. module B.5 'Physical examination and treatment plan').

Preoperative phase. In the preoperative phase, patients who are scheduled for cardiac surgery can be screened for the risk of developing postoperative pulmonary complications and receive preoperative physical or exercise therapy (Hulzebos 2006; Valkenet 2011). The preoperative phase is coordinated from the hospital, where the cardiologist is ultimately responsible for the treatment process. During hospitalisation, the cardiologist will call on other healthcare providers such as the hospital physical or exercise therapist, depending on the patient's situation. The cardiologist will often work with the cardiothoracic surgeon in this process. Phase I or clinical phase. This starts immediately after the acute cardiological event such as an acute coronary syndrome (ACS, which includes an acute myocardial infarction (AMI) or a manifestation of unstable angina pectoris (IAP)), acute heart failure or acute hospitalisation due to any other heart disease. Patients who are scheduled for surgery are subsequently taken up. Phase I takes place in the hospital, where the cardiologist is ultimately responsible for the treatment process. During hospitalisation, the cardiologist will call on other healthcare providers such as the hospital physical or exercise therapist, depending on the patient's situation. In addition, the cardiologist is responsible for referring the patient for cardiac rehabilitation phase II (NVVC/NHS rehabilitation commission and PAAHR project group). Phase II or rehabilitation phase. This phase aligns with the clinical phase and starts after discharge from the hospital on a mainly outpatient basis. In module C.2 'Continuation and completion of cardiac rehabilitation' it is furthermore stated that this rehabilitation can also take place in a home situation (with or without e-health support), in a hybrid form or as part of the rehabilitation programme in a physical or exercise therapy practice in a primary care setting in order to encourage participation in cardiac rehabilitation. It is important here also to take account of the specific preconditions that have been established in this regard, such as the indication that it must take place in a cardiac centre in a secondary care setting and that the responsibility for the treatment will remain with the cardiologist. During this phase, the cardiologist will also include other healthcare providers, as described in module B.7 'Indication'. The cardiologist is furthermore responsible for referring the patient to healthcare providers in the post-rehabilitation phase (if applicable) as well as transfer to the general practitioner. Phase III or post-rehabilitation phase. This phase aligns with the rehabilitation phase. The focus in this phase is in particular to maintain the lifestyle changes implemented in phase II. The patient can receive support here from healthcare providers, often situated in the primary care setting. The responsibility and monitoring of the treatment in this phase resides with the patient's general practitioner.

The description above applies to the phasing of a regular cardiac rehabilitation process. The patient may, however, also have extended health issues, which means that the process will be deviated from. In this regard, see the 'Multidisciplinary guideline on cardiac rehabilitation of 2024' of the Dutch Society for Cardiology or NVVC (Nederlandse Vereniging voor Cardiologie).

As stated previously, many (para)medical professionals and experts are involved in the cardiac rehabilitation process. The involvement of these healthcare providers and experts is the (ultimate) responsibility of the cardiologist or the general practitioner. Attention is paid here to individual

cardiac rehabilitation goals, (relative) contraindications, comorbidities, complexity of the disease profile, healthcare needs, and the patient's individual characteristics, possibilities, wishes, needs, learning strategy and (social) set-up. Tips for implementing this multidisciplinary cooperation are described in <u>disease-specific guidelines</u> for cardiologists and <u>general practitioners</u>.

The '<u>Tool for responsibility distribution in healthcare cooperation</u>' has established the prerequisite for the clear division of tasks and responsibilities, effective mutual communication and coordination about activities and information (Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst 2022).

Aligning the care provided by the various healthcare providers in the treatment of a patient with coronary artery disease or chronic heart failure is important for being able to signal possible barriers in the treatment in a timely manner and to facilitate participation in cardiac rehabilitation. This is done through multidisciplinary dialogue (NVVC/NHS rehabilitation commission and PAAHR project group). During this dialogue, agreement is also reached on the indication and monitoring of the treatment.

A.3.2 Role of the physical or exercise therapist

The physical or exercise therapist screens the patient for contraindications, determines whether there are dysfunctions or recovery-impeding factors at play and documents the degree of limitations experienced and participation problems. Based on the findings, it is decided whether treatment is indicated and the treatment plan is determined (see <u>B.4 'Medical history taking'</u>, <u>B.5 'Physical examination and treatment plan'</u>, and <u>B.7 'Indication'</u>). If there is no indication for treatment, then the therapist considers – in consultation with the patient – whether to refer the patient (back) to the general practitioner or cardiologist.

The therapist is (potentially) involved in the drafting (of the goals) and the supervision of the exercise programme, coordinating the relaxation programme (in consultation with a psychologist and/or social worker) and the information programme (the therapist informs and advises the patient on the physical functioning and development of an active lifestyle).

The physical or occupational therapist assesses and indicates (e.g. psychosocial, cognitive or occupation-related complaints) which support a patient with coronary artery disease or chronic heart failure will need and weighs the care need against their own knowledge and expertise. Based on this, the physical therapist decides whether they feel competent and qualified to offer the patient in question physical or exercise therapy, or whether to involve other healthcare providers for this purpose.

The physical or exercise therapist will discuss this with the cardiologist who is (ultimately) responsible as well as other healthcare providers during the multidisciplinary dialogue (phase I, II) or with the general practitioner (phase III) (Koninklijk Nederlands Genootschap Fysiotherapie 2021; Vereniging van Oefentherapeuten Cesar en Mensendieck 2019).

The role and position of the physical therapist and the exercise therapist in healthcare, i.e. the domain description, can be found in the professional profile of the physical therapist and the exercise therapist (Koninklijk Nederlands Genootschap Fysiotherapie 2021; Vereniging van Oefentherapeuten Cesar en Mensendieck 2019).

The way in which information is shared with the referrer is described in $\frac{C.7}{Evaluation, stop}$ criteria and closure of the treatment'.

Below the specialisations within physical therapy and exercise therapy are described for which specific expertise is recognised by the KNGF or the VvOCM, as described in the 'Professional Code for Physical Therapists 2022' (Beroepscode voor de Fysiotherapeut 2022) (Koninklijk Nederlands

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Genootschap Fysiotherapie 2022) and the '<u>Professional Code for Exercise Therapists</u>, June 2018 version' (Beroepscode voor oefentherapeuten, versie juni 2018) (Vereniging van Oefentherapeuten Cesar en Mensendieck 2018).

These specialisations feature in the Dutch Quality Register for Physical Therapy (Kwaliteitsregister Fysiotherapie NL or KRF NL) of the Kwaliteitshuis Fysiotherapie (www.kwaliteitshuisfysiotherapie. nl), which guarantees that the knowledge and skills of these healthcare professionals are raised to and maintained at a good level. This includes the following specialisation fields within physical therapy that have their own professional associations and professional profiles:

- Society for Cardiovascular and Pulmonary Rehabilitation (Vereniging voor Hart-, Vaat- en Longfysiotherapie VHVL);
- Dutch Society for Hospital Physical Therapy (Nederlandse Vereniging voor Ziekenhuis Fysiotherapie NVZF);
- Dutch Society of Rehabilitation Physical Therapists (Nederlandse Vereniging van Revalidatie Fysiotherapeuten – NVRF);
- Dutch Association for Company and Occupational Health Physical Therapists (Nederlandse Vereniging voor Bedrijfs- en Arbeidsfysiotherapeuten NVBF);
- Dutch Association for Physical Therapy in Geriatrics (Nederlandse Vereniging voor Fysiotherapie in de Geriatrie NVFG);
- Dutch Association for Physical Therapy according to Psychosomatics (Nederlandse Vereniging voor Fysiotherapie volgens de Psychosomatiek NFP);
- Dutch Association for Physical Therapy in Sports Medicine (Nederlandse Vereniging voor Fysiotherapie in de Sportgezondheidszorg (NVFS);
- Dutch Society of Physical Therapists for the Mentally Handicapped (Nederlandse Vereniging van Fysiotherapeuten voor Verstandelijk Gehandicapten NVFVG);
- Dutch Association for Paediatric Physical Therapy (Nederlandse Vereniging voor Kinderfysiotherapie – NVFK);
- Dutch Society for Manual Therapy (Nederlandse Vereniging voor Manuele Therapie NVMT);
- Dutch Association for Orofacial Physiotherapy (Nederlandse Vereniging voor Orofaciale Fysiotherapie – NVOF);
- Dutch Association for Pelvic Physiotherapy (Nederlandse Vereniging voor Bekkenfysiotherapie NVFB);
- Dutch Association for Physiotherapy in Lymphology and Oncology (Nederlandse Vereniging voor Fysiotherapie binnen de Lymfologie en Oncologie NVFL);

The following specialisations exist within exercise therapy:

- pelvic exercise therapist;
- geriatric exercise therapist;
- paediatric exercise therapist:
- psychosomatic exercise therapist.

The <u>KNGF Professional Profile of the Physical Therapist</u> and the <u>VvOCM Professional Profile of the</u> <u>exercise therapist</u> give a description of the activities of the specialisation fields in physical and exercise therapy respectively, the set-up in which these activities take place and the competencies that are required for therefor.

A.3.3 Expertise of other healthcare providers

Healthcare providers who are also involved as advisory, head or co-treatment providers for patients with coronary artery disease or chronic heart failure include: the cardiologist, cardiothoracic surgeon, (supervising) general practitioner, rehabilitation physician, sports physician, company doctor, doctors affiliated with insurance companies, psychiatrist, (neuro)psychologist, psychical therapist, exercise physiologist, cardiac rehabilitation coordinator, social worker, dietitian, occupational therapist, lifestyle coach, (cardiovascular) nurse, sex therapist and occupational expert. The various (expert) healthcare providers are shortly described below.

Cardiologist

The cardiologist works on the prevention, diagnosis and treatment of cardiovascular diseases in the broadest sense of the word, such as coronary artery disease, arrhythmia and conduction disorders, heart-valve defects, heart-muscle diseases and congenital heart defects. For this, the cardiologist has access to a wide panoply of diagnostic possibilities, both invasive (cardiac catheterisation) and non-invasive (echocardiography, nuclear techniques, cardiac magnetic resonance imaging (MRI) and computed tomography (CT)). The cardiologist can also choose from a range of therapeutic possibilities. The treatment of cardiovascular disease will mostly involve medication, but it can also take place through an intervention, such as coronary-artery Dottering or the implantation of a pacemaker, an internal defibrillator or an artificial valve. The cardiologist can also indicate heart surgery and is thus intensely involved in the preparation and after-treatment of patients who underwent heart surgery. Cardiologists therefore often work together with surgeons in a heart team (Artsenfederatie KNMG 2023). The cardiologist also does cardiovascular risk management, where the patient's health is monitored and interventions like cardiac rehabilitation are performed. The cardiologist is ultimately responsible for the cardiac rehabilitation but can choose to delegate certain tasks (such as coordination) to the cardiac rehabilitation coordinator. Lastly there are emerging professional fields like preventative cardiology and sports cardiology, where interventions may also focus on lifestyle changes and sport practice.

Recommendations for diagnosis and treatment of coronary artery disease and chronic heart failure by the cardiologist are described in condition-specific guidelines for the cardiologist.

Cardiothoracic surgeon

A cardiothoracic surgeon operatically treats patients with defects in organs in the chest cavity such as the heart, lungs and big vessels, with the exception of the oesophagus. Operations to correct defects in the chest wall also fall under cardiothoracic surgery. These operations are performed on children as well as adults. The most frequently occurring disorders are defects of the coronary arteries and heart valves, congenital heart defects, arrhythmia, heart failure, and aneurysms and/ or tears in the thoracic aorta. Patients are mostly referred to the cardiothoracic surgeon by a lung specialist or a cardiologist (Artsenfederatie KNMG 2023).

Recommendations for diagnosis and treatment of coronary artery disease or chronic heart failure by the cardiothoracic surgeon are described in <u>condition-specific guidelines for the cardiothoracic</u> surgeon.

General practitioner

The (overseeing) general practitioner screens the patient for warning signs and diagnoses, informs and coordinates the healthcare. The general practitioner can refer the patient for additional diagnostics or treatment to a wide range of healthcare providers (e.g. the cardiologist) in the

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primary, secondary and tertiary care setting. Referral takes place based on the nature of problems, the need for assistance, the patient's preference and the local availability and expertise of healthcare providers. The work of the general practitioner, as well as the context within which it takes place and the competencies required for this, are described in the professional profile of the general practitioner (van de Vijver 2016).

Recommendations for diagnosis and treatment of coronary artery disease and chronic heart failure by the general practitioner are described in <u>condition-specific guidelines for the general</u> practitioner.

Rehabilitation physician

The rehabilitation physician is concerned with preventing and reducing the lasting effects of disease, physical injury and congenital defects. This does not only include bodily functions (e.g. muscle strength), but also the impact that a disease has on activities (e.g. walking and self-sufficiency) and participation (e.g. working or relationships). Significant diagnosis categories are cerebrovascular accidents (CVA), non-congenital brain injury, amputation, paraplegia, chronic pain, cerebral palsy, cardiac or organ rehabilitation and post-intensive care rehabilitation, and neuromuscular disorders in children and adults (Artsenfederatie KNMG 2023).

The rehabilitation physician can also take over ultimate responsibility for the treatment of the patient from the cardiologist. This often happens in extended rehabilitation care.

Recommendations for diagnosis and treatment of coronary artery disease and chronic heart failure by the rehabilitation physician are described in <u>condition-specific guidelines for the rehabilitation</u> specialist.

Sports physician

Sports medicine is a professional field that focuses on the advancement, maintenance and recovery of the health of people who participate in sports activities, where sport-specific load and capacity are taken into account. The sports physician is therefore occupied in (injury) consultations, preventative sports-medicine examinations, exercise testing and giving advice on sports practice. Another task of the sports physician is to provide sports medicine support to teams and individual players. The testing and rehabilitation of people with chronic disorders, for example with heart, lung or oncological disorders, is also part of the work of the sports physician (Artsenfederatie KNMG 2023).

Recommendations for diagnosis and treatment by the sports physician in the event of coronary artery disease or chronic heart failure are described in <u>condition-specific guidelines for the sports</u> physician.

Company doctor

The company doctor is a medical specialist in the field of work conditions and health. Company doctors focus on improving the sustainable employability of workers and the prevention of occupational diseases and profession-related disorders. The company doctor provides preventative and curative occupational medicine care from a professionally independent position with the aim to maintain and/or restore the health of workers and to advise employers on what is needed for this at an executive and policy level.

The work of the company doctor, as well as the context within which it takes place and the competencies required for this, are described in the professional profile of the company doctor (Nederlandse Vereniging voor Arbeids– en Bedrijfsgeneeskunde 2004).

Recommendations for diagnosis and treatment by the company doctor for coronary artery disease or chronic heart failure are described in condition-specific guidelines for company doctors.

Doctors affiliated with insurance companies

The doctor affiliated with an insurance company determines whether there is a disorder that can be determined with medical objectivity and that is the result of a disease or deficiency, which limits a person in their functioning. The framework in which this is established refers to a broad spectrum of legislation and regulations. The doctor affiliated with an insurance company is also involved in the support and reintegration of employees with an incapacity to work. The vast majority of doctors affiliated with insurance companies work at UWV. They focus on the prevention, identification, diagnosis and treatment of the causes of incapacity in an insured worker who is sick. This includes actively monitoring and supporting the insured party towards recovery of their employability (Artsenfederatie KNMG 2023).

Psychiatrist

A psychiatrist is a medical specialist who focuses primarily on mental health issues. Mental health issues are referred to when someone suffers from problems with their thoughts or feelings. In practice, this often involves patients who are confused or suffering (in the long term) from feelings like anxiety and depression. The psychiatrist mainly looks at the integration of biological, social and emotional problems. The psychiatrist determines whether there is a psychosomatic disorder, a personality disorder or a relationship or contact disorder (Artsenfederatie KNMG 2023). Recommendations for diagnosis and treatment by psychiatrists in the case of coronary artery disease or chronic heart failure are described in condition–specific guidelines for psychiatrists.

Psychologist, neuropsychologist, psychotherapist

The psychologist diagnoses and treats people with psychological problems. BIG-registered psychologists include healthcare psychologists, clinical psychologists and psychologists who are BIG-registered psychotherapists. The clinical neuropsychologist specialises in the brain and the effect of brain functions on behaviour.

The work of healthcare psychologists, clinical (neuro)psychologists and BIG-registered psychotherapists, as well as the context within which it takes place and the competencies required for this, are described in the professional profiles of the healthcare psychologist, the clinical psychologist, the clinical neuropsychologist and the physical therapist respectively (De Nederlandse Vereniging voor Gezondheidszorgpsychologie en het Nederlands Instituut van Psychologen 2015; Nederlandse Vereniging voor Gezondheidszorgpsychologie 2017; Nederlandse Vereniging voor Gezondheidszorgpsychologie 2015, herdruk 2020; Nederlandse Vereniging voor Psychotherapie 2007)

Exercise physiologist

An exercise physiologist is someone who looks at the effects of physical exercise on the body and who has specialised knowledge and skills with regard to exercise physiology and training methods. The work of an exercise physiologist consists of assessing and preserving the vital functions of the patient, measuring heart rate and oxygen consumption, performing stress and fitness tests and developing training programmes to maintain good health. They create exercise programmes for chronically ill patients, as well as activities to help improve flexibility, body composition and cardiovascular functioning. This includes exercises or physical activities that are designed to improve heart function, breathing, body composition, muscle strength, muscle stamina or flexibility.

General practice-based nurse

A general practice-based nurse assists the general practitioner in their work. The general practitioner remains ultimately responsible for the healthcare.

The work of the general practice-based nurse, as well as the context within which it takes place and the competencies required for this, are described in the professional profile of the general practice-based nurse (Nederlandse Vereniging van Praktijkondersteuners en Praktijkverpleegkundigen).

Social worker

The social worker focuses on improving a person's social functioning by working both with the patient and with their environment. The work of social workers, as well as the context within which it takes place and the competencies required for this, are described in the professional profile of the social worker (Beroepsvereniging van professionals in sociaal werk 2011)

Dietitian

The dietician is a (healthcare) professional who assists with nutritional issues. In a preventative, curative as well as palliative capacity, the dietitian can have a positive impact on the patient's health thanks to their specific knowledge of and experience in the field of nutrition. The principle is to find an optimal nutritional status that can differ from one person and situation to another. The work of the dietician, as well as the context within which it takes place and the competencies required for this, are described in the professional profile of the dietician (Nederlandse Vereniging van Diëtisten 2013).

Occupational therapist

The occupational therapist focuses on improving execution of everyday activities, with the healthcare primarily being aimed at the patient's need for assistance. The need for assistance can be in the area of self-reliance, productivity, leisure activity, work situation, living situation and mobility. The occupational therapist evaluates the distribution between exertion and capacity and whether postures and movements can be performed in an ergonomic and efficient manner. The work of the occupational therapist, as well as the context within which it takes place and the competencies required for this, are described in the professional profile of the occupational therapist and the accompanying competency profile (Van Hartingsveldt, Kammerer, de Langen 2023)

Lifestyle coach

The lifestyle coach guides people in (re)taking control of their health and well-being. The lifestyle coach applies a biopsychosocial model and explicitly uses the definition of positive health. In positive health the focus is on resilience and personal empowerment and not on the illness. The approach of a lifestyle coach is based on guiding people in making their own choices. Lifestyle coaches are not healthcare professionals; they help everyone who wants to change their daily habits so they can (continue to) feel good. The work of the lifestyle coach, as well as the context within which it takes place and the competencies required for this, are described in the professional profile of the lifestyle coach (Beroepsvereniging voor Leefstijlcoaches Nederland 2016)

Cardiovascular nurses

Support and treatment of patients with coronary artery disease and chronic heart failure are provided by a nurse with specialised knowledge, who is referred to as a cardiovascular nurse. The cardiovascular nurse mainly works in the cardiology unit and takes care of patients who are

hospitalised in this unit when this nurse is on shift. A cardiovascular nurse can also work in an outpatient unit. The work of the cardiovascular nurse, as well as the context within which it takes place and the competencies required for this, are described in the professional profile of the cardiovascular nurse (Flint 2017).

Nursing specialist

A nursing specialist is often involved in cardiac rehabilitation. Nursing specialists are originally BIG-registered nurses with an HBO qualification (Bachelor of Nursing) who have also completed a two-year or sometimes three-year NVAO-accredited Master's programme in Advanced Nursing Practice (M ANP). The nursing specialist is an independent practitioner who is authorised to work autonomously. The core of their professional field is to offer integral treatment to people who require healthcare based on clinical reasons in complex care settings, where they ensure the continuity and quality of the treatment, support the patient's autonomy, personal control and self-management and improve the empowerment of healthcare recipients within the 'patient journey'. The treatment includes both medical and nursing interventions. The nursing specialist works from a holistic perspective. This means that they focus on the disease and the fact of being ill, where the central focus is on the person within their context. In addition, they focus on the consequences of disease and on prevention.

The work of the nursing specialist, as well as the context within which it takes place and the competencies required for this, are described in the professional profile of the nursing specialist (Beroepsvereniging Verzorgende en Verpleegkundigen 2019).

Sex therapist

A sex therapist is usually a psychologist, a doctor or a social worker who is specialised in sexual problems. A sex therapist therefore helps with sexual problems.

Occupational experts

The occupational expert specialises in people, work and income and weighs the burden that work puts on a person against their capacity to tolerate such a burden. Where possible, the occupational expert offers support for the prevention and recovery of occupational incapacity and actively looks at opportunities in work and the work capacity of the person (Nederlandse Vereniging van Arbeidsdeskundigen).

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B Diagnostic process

B.1 Personalised care

B.1.1 Personalised care

Make personalised care part of the exercise programme of cardiac rehabilitation phase II for patients with coronary artery disease or chronic heart failure to facilitate starting, completion and continuation.

Take the following into consideration here:

The indication (including an intake interview, screening and identifying goals for the cardiac rehabilitation) and formulation of the physical and exercise therapy treatment plan are established and started up by a multidisciplinary cardiac rehabilitation team in a cardiac rehabilitation centre/hospital in a secondary or tertiary care setting.

When drawing up the treatment plan, the following principles apply:

- the healthcare needs, individual characteristics, capabilities, wishes, needs, learning strategy and context of the patient;
- (relative) contraindications and comorbidities of the patient (see B.7 'Indication');
- the complexity of the disease profile;
- the cardiac rehabilitation goals that were chosen by the multidisciplinary cardiac rehabilitation team together with the patient (see B.5 'Physical examination and treatment plan').

The indication and formulation of the treatment plan take place upon referral and under the ultimate responsibility of the cardiologist.

Throughout the cardiac rehabilitation programme, the therapist will assess together with the patient whether the implemented exercise programme is still sufficiently suited to the patient. Consult with the multidisciplinary cardiac rehabilitation team about whether it is necessary to adapt the cardiac rehabilitation programme. In this regard also see <u>C.7 'Evaluation, stop criteria</u> and closure of the treatment'.

Actively involve the patient with coronary artery disease or chronic heart failure in any decisionmaking regarding their diagnosis, treatment, accompaniment and after-care in order to choose the most suitable treatment during the exercise programme of cardiac rehabilitation phase II, and consider using the i3s model in this regard.

B.1.2 Models to reach a decision on treatment together with the patient

Consider using the 'Samen Beslissen' (shared decision-making) and the '3 goede vragen' (3 good questions) models.

The first model was written from the healthcare provider's perspective and the second from the patient's perspective.

The 'shared decision-making' (Samen beslissen) model

In this model, the therapist actively involves the patient in making decisions about diagnosis, treatment, accompaniment and after-care and together with the patient chooses the most suitable treatment. In doing so, the therapist goes through the following steps:

В

Step 1: Choice

Indicate that the patient has more than one option and that they have a say in it.

Step 2: Options

Discuss the various options with the patient, while paying attention to:

pros and cons as well as risks of the options;

expected outcomes of the options;

the potential impact that the options might have on the patient's personal situation.

Step 3: Preference

Discuss the patient's preferences, needs and circumstances, with the therapist supporting the patient in the process. Together, see which treatment is the most suitable.

Step 4: Decision

Talk about the making of a decision. Together, reach a decision on the policy that will be followed.

A successful application of the 'Samen beslissen' (shared decision-making) model requires the following competencies of the therapist:

awareness;

- the time needed to make a decision.

The therapist:

- acknowledges that shared decision-making leads to a higher quality of care;
- accompanies the shared decision-making process;
- has the necessary interviewing techniques and skills to facilitate the shared decision-making process;
- keeps the patient's situation in mind;
- supports the patient and actively encourages the patient to take part in the shared decisionmaking process ('empowerment');
- ensures the clear transfer of knowledge and sharing of information and makes use of tools that support shared decision-making;
- is a reliable and professional dialogue partner;
- acknowledges the importance of cooperation and communication with other healthcare professionals and (social) factors from the patient's network and knows when to integrate these.

The '3 good questions' (3 goede vragen) model

Here, the therapist supports the patient in considering the following questions:

Question 1	What possibilities do I have?
Question 2	What are the pros and cons of these possibilities?
Question 3	What does this mean in my situation?

В

By means of support, the therapist can mention the following to the patient:

- 'Tell me if there is anything you don't quite understand.'
- 'Tell me if you have doubts about anything.'
- 'Next time, bring your questions on a piece of paper and feel free to write down the answers. That way you can read them again at home in your own time.'
- 'Now that we have finished our discussion, would you like to summarise it in your own words? We can then check together whether you have understood everything.'

SUBSTANTIATION

Reason

Healthcare in the Netherlands is changing fast. The Ministry of Health, Welfare and Sport in 2018 published a report on 'The right care in the right place' to make healthcare in the Netherlands future-proof. In this report, the way people function is taken as a starting point, where the term 'functioning' refers to physical, psychological and social functioning. The ownership of the functioning thereby lies primarily with the people themselves, where the environment, as well as healthcare providers, can help ('Zorg op de juiste plek' (care in the right place) Task Force 2018). Terms such as 'personalised care', 'shared decision-making' and 'tailored care' are in line with the central position that the patient has in healthcare. Concepts like 'self-management', 'own control' and 'patient empowerment' are also frequently used in this regard. These terms have a long-standing history in policy and research reports (Ouwens 2012).

Shared decision-making also plays a prominent role in healthcare today. The term is mentioned both in the 'Administrative agreement on medical-specialist care for 2019-2022' (Bestuurlijk akkoord medisch-specialistische zorg 2019-2022) and in the 'Administrative agreements in paramedical care for 2019-2022' (Bestuurlijke afspraken paramedische zorg 2019-2022) (Ministerie van Volksgezondheid Welzijn en Sport 2018; Ministerie van Volksgezondheid Welzijn en Sport 2019). A large-scale campaign was also launched in 2021 by the government and the Dutch patient federation for shared decision-making or Patiëntenfederatie Nederland 'Samen Beslissen' (Patiëntenfederatie Nederland 2021).

In order to offer the right care in the right place to patients with coronary artery disease or chronic heart failure, it is important to be able to interpret these terms. Ouwens (2012) conducted a literature review on the definitions of these concepts and the interrelatedness of the concepts, which are described in this module (Ouwens 2012). The following clinical question was formulated for this:

Clinical question

KNGF Guideline on Cardiac Rehabilitation

How are the concepts of 'personalised care', 'shared decision-making' and 'tailored care' applied in clinical reasoning within the exercise programme as part of the diagnostic, therapeutic and closure process for patients with coronary artery disease or chronic heart failure?

Rationale of the recommendations

In coordination with the guideline panel it was decided not to carry out any systematic search action, but to gather the information needed for answering this clinical question in a non-systematic way and work it out narratively using the knowledge and clinical expertise of the guideline panel.

B.1.1 Personalised care

'Personalised care' is considered as a synonym for the following terms that are found in the international scientific literature: *personalised*, *tailored* or *patient-centred care*. These terms originated in psychology or psychotherapy but have spread to (para)medical care. Ouwens (2012) uses patient-centred care as an overarching term and considers 'shared decision-making', 'self-management' and 'patient empowerment' (or 'self-management support') to be part of it. He sometimes indicates the healthcare provider to be the player, sometimes the patient and sometimes both. The meaning of personalised care is multi-interpretable and is likely to keep changing over time.

In this guideline on Cardiac Rehabilitation for coronary artery disease and chronic heart failure, personalised care is described as follows: *Personalised care is a way of providing tailored care to people with a need for care*.

The following aspects form part of personalised care:

- healthcare in which the entire person is the focus and not their illness or impairment: one of the fundamental attitudes of the physical therapist and exercise therapist is to apply all aspects of the biopsychosocial model (Engel 1977);
- care that is tailored to the patient's individual characteristics, capabilities, wishes, needs, learning strategy and context;
- care that is based on *shared decision-making*. Here it is evaluated which healthcare is needed and is most suited to the person, with the basic principle that the therapist and the patient will together consider the diagnosis, treatment, accompaniment and after-care of the patient and then make a decision;
- care with continuity, so that a relationship of trust can be built.



(Nederlands Huisartsen Genootschap 2021).

The concepts of 'self-management' and 'self-management support' are described and explained in the KNGF guideline on Self-management (Koninklijk Nederlands Genootschap voor Fysiotherapie 2022).

B.1.2 Shared decision-making

'Shared decision-making' (Stiggelbout 2015) is based on the idea that patients and therapists have different but equally important expertise to contribute to the making of medical decisions. Shared decision-making takes place during one or more discussions. The patient and the therapist talk about all the possibilities and what these mean for somebody's life. Shared decision-making implies for the therapist that they can focus better on the needs and preferences of the patient. For the patient, shared decision-making means that they can choose what is most suited to their own situation and personal preferences. The 'Shared decision-making' model has been included in the guidelines of the Dutch federation of medical specialists (Federatie Medisch Specialisten 2019) and the Dutch patient federation (Patiëntenfederatie Nederland 2021).

'Shared decision-making' and 'joint decision-making' are both terms that are used for the concept of deciding together. Both the patient and the therapist are players in shared decision-making, which means that it is a two-way process. This is the opposite of condescending or informed decision-making, where the patient is merely informed. The meaning of shared decision-making is multi-interpretable and will change over time (Ouwens 2012).

In this guideline on Cardiac Rehabilitation for coronary artery disease and chronic heart failure, *shared decision-making* is described as follows:

In shared decision-making, patients are actively involved in making decisions regarding their diagnosis, treatment, accompaniment and after-care in order to choose the most suitable treatment together. It is therefore important for the patient to be well informed by the therapist. *Shared decision-making* is based on the idea that patients and therapists have different but equally important expertise to contribute to the making of medical decisions. *Shared decision-making* takes place during one or more discussions. In these, the patient and the therapist talk together about all the possibilities and what these mean for somebody's life. *Shared decision-making* implies for the therapist that they can focus better on the needs and preferences of the patient. For the patient, *shared decision-making* means making the choice that is best suited to their own situation and personal preferences (Federatie Medisch Specialisten 2019; Patiëntenfederatie Nederland 2021).

Shared decision-making can ensure that the patient is better informed and more satisfied with the decision and that they will trust the therapy more, experience less choice stress and will make other choices. For healthcare providers, shared decision-making brings more job satisfaction (Nederlandse Federatie van Kankerpatiëntenorganisaties 2018). Healthcare providers have the impression that they are already making a lot of decisions together with the patient (46%). However, in a survey by Kantar (2020) only 37% of all patients indicate that they make decisions together with their healthcare provider. 11 to 15% of the patients furthermore state that they find it difficult to participate actively in the discussion with the therapist, and 30% say that they do not prepare for discussions with the therapist. This shows a mismatch between the experienced degree of shared decision-making between patients and healthcare providers (Kantar 2020).

Various models are available to support the process of shared decision-making. Dutch healthcare mainly uses the models of Elwyn (2012) and Stiggelbout (2015) and the '3 good questions' (Patiëntenfederatie Nederland 2021). The model of Stiggelbout (2015) is written from the healthcare provider's perspective and is based on that of Elwyn (2015). The '3 good questions' model is written from the patient's perspective.

Various other tools are available that can support the process of shared decision-making. Decision-aid tools are available, as well as patient information. The patient and the therapist can also write down the decisions that have been made (regarding feedback and monitoring), preferably in an individual care plan. It is, however, important to use these tools as a support and not to replace a good dialogue between the patient and the therapist (Koninklijk Nederlands Genootschap Fysiotherapie; Patiëntenfederatie Nederland).

B.1.3 Personalised care and shared decision-making in cardiac rehabilitation

The patient and their specific need for assistance in their own living environment are the focus of any therapeutic actions. Together with the patient, the therapist determines the treatment goals that are suited to the patient's healthcare needs, capabilities and skills, and health literacy (Koninklijk Nederlands Genootschap Fysiotherapie 2021; Vereniging van Oefentherapeuten Cesar en Mensendieck 2019). All of this also applies to therapeutic actions within cardiac rehabilitation.

The number of patients with coronary artery disease and chronic heart failure who start with phase II of cardiac rehabilitation is suboptimal (Conijn 2022; van Engen-Verheul 2013), as is the number of patients who continue and complete their cardiac rehabilitation. From the number of patients who report in certain sub-populations, 80% complete their cardiac rehabilitation (Sunamura 2017; Vonk 2021). An important solution for starting, continuing and completing phase II of cardiac rehabilitation is seen in offering personalised care (see <u>C.2</u> 'Continuation and completion of cardiac rehabilitation') (Gevaert 2020).

B.1.4 Clinical reasoning

In order to offer personalised care, the therapist must, through clinical reasoning and a continuous dialogue with the patient, decide which treatment suits the patient and also assess this treatment. This is important during the diagnostic process (medical history taking, physical examination and establishment of the treatment plan), the therapeutic process and the closure process. A strategy that can help in this regard is the i3 strategy.

The i3 strategy

The strategy consists of: 1) taking an inventory of comorbidity; 2) taking an inventory of (contra) indications and restrictions; 3) taking an inventory of possible adjustments to the treatment goals and 4) a synthesis (Dekker 2016).

These steps were elaborated by the guideline panel for the treatment of patients with coronary artery disease and chronic heart failure.

Step 1. Inventory of comorbidity and risk factors

In this step, stock is taken of comorbidity and risk factors of the patient.

For this patient group, these might include CVA, peripheral arterial disease, high blood pressure, valve defects, arrhythmia and conduction disorders, diabetes mellitus, obesity, cachexia, cognitive
disorders, cancer and psychological or sleep-related respiratory disorders (McDonagh 2021; Nederlands Huisartsen Genootschap 2021, 2022).

Step 2. Inventory of (contra)indications and restrictions

In this step, the therapist takes stock of the main (contra)indications and restrictions regarding the patient. See **B.7** 'Indication' for the most important ones.

Step 3. Inventory of possible adjustments to the treatment goals

In this step, the therapist takes stock of possible adjustments to the treatment goals. For treatment goals, see **B.5** 'Physical examination and treatment plan'.

Step 4. Synthesis

It is important to align all the information from the previous steps with the healthcare needs, preferences and capabilities of the patient, through dialogue with the patient. For determining the treatment goals, see <u>B.5 'Physical examination and treatment plan'</u>. The treatment goals will always be the starting point of the synthesis. A decision will also have to be made regarding the way in which the chosen treatment goals should be reached. For recommendations regarding interventions that will facilitate the continuation and completion of cardiac rehabilitation, see **C.2 'Continuation and completion of cardiac rehabilitation'**.

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B.2 Inhibiting and facilitating factors

Recommendations

It is important to know about factors that might inhibit the continuation and completion of phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure. The way in which these factors are defined is described in <u>B.4 'Medical history taking'</u>, <u>B.5</u> 'Physical examination and treatment plan' and B.6 'Measurement instruments'.

The way in which the exercise programme in phase II of cardiac rehabilitation is aligned with the described factors is found in C.2 'Continuation and completion of cardiac rehabilitation'.

Factor	Predictive value
cardiovascular risk factors and/or comorbidityª	Having cardiovascular risk factors and/or comorbidity can be related to not being able to continue and complete cardiac rehabilitation.
living situation	Being single, divorced or widowed can be related to not being able to continue and complete cardiac rehabilitation.
physical functioning ^b	Reduced physical functioning can be related to not being able to continue and complete cardiac rehabilitation.
accessibility	Reduced access to a cardiac rehabilitation programme can be related to not being able to continue and complete cardiac rehabilitation.
socio-economic status (SES) and/ or health literacy	A low SES and/or limited health literacy can be related to not being able to continue and complete cardiac rehabilitation.

activities/way of spending the day ^c	Having a job can be related to not being able to continue and complete cardiac rehabilitation.
psychosocial factors	Suffering from anxiety, depression or stress can be related to not being able to continue and complete cardiac rehabilitation.
being a foreign-language speaker, deaf or hearing- impaired	Being a foreign-language speaker, deaf or hearing-impaired can be related to not being able to continue and complete cardiac rehabilitation.

 a. 'Cardiovascular risk factors and/or comorbidity' is understood to include factors that increase the risk of cardiovascular disease according to the guideline on Cardiovascular risk management of the Dutch federation of medical specialists (Federatie Medisch Specialisten).

b. The term 'physical functioning' refers to maximum exercise capacity, physical capacity, subjective exercise capacity and physical activity as described in B.6 'Measurement instruments'.

c. 'Activities/way of spending the day' is understood to include activities of daily living such as working, hobbies, being unemployed, receiving an allowance, going to school or being a pensioner.

SUBSTANTIATION

Reason

The number of patients with coronary artery disease or chronic heart failure who start, continue with and complete phase II of cardiac rehabilitation in the Netherlands is suboptimal (Sunamura 2017; Vonk 2021; Conijn 2022; Van Engen-Verheul 2013). The variations in practice with regard to the implementation of cardiac rehabilitation can be one of the reasons for this. Aligning with the needs of the patient can increase compliance with the therapy and the percentage of patients who complete phase II of cardiac rehabilitation. It is therefore crucial to identify factors that facilitate or inhibit compliance (continuation) and the completion of phase II of cardiac rehabilitation.

Clinical question

Which inhibiting and facilitating factors affect compliance (continuation) and the completion of phase II of cardiac rehabilitation and have at least been identified in patients with coronary artery disease or chronic heart failure?

Conclusions based on the literature

Based on the search, seven cohort studies were identified that describe inhibiting and facilitating factors for the continuation and completion of phase II of cardiac rehabilitation. In these prognostic studies, several inhibiting and facilitating factors were identified. Due to the heterogeneous nature observed in the prognostic factors and crucial outcomes, a meta-analysis was not justified and instead a narrative synthesis was carried out.

The prognostic factors were categorised, from which the following relevant factors emerged: age, diagnosis, cardiovascular risk factors and/or comorbidity, living situation, physical functioning, accessibility, SES and/or health literacy, gender, factors related to the cardiac rehabilitation programme, activities/way of spending the day and lastly, psychosocial factors. The table below summarises the evidentiary value of these factors.

Factor	Evidentiary value	Direction in which the evidence points
age	very low	contrary
diagnosis	very low	contrary
cardiovascular risk factors and/or comorbidity	very low	Having cardiovascular risk factors and/or comorbidity is negatively associated with being able to continue and complete cardiac rehabilitation.
living situation	very low	Being single, divorced or widowed is negatively associated with being able to continue and complete cardiac rehabilitation.
physical functioning	very low	Reduced physical functioning is negatively associated with being able to continue and complete cardiac rehabilitation.
accessibility	very low	contrary
SES and/or limited health literacy	very low	Having a low SES is negatively associated with being able to continue and complete cardiac rehabilitation.
gender	very low	Being male is negatively associated with being able to continue and complete cardiac rehabilitation.
related to cardiac reha- bilitation programme	very low	A waiting time of > 18 days before starting with cardiac rehabilitation is negatively associated with being able to continue and complete the cardiac rehabilitation.
activities/way of spending the day	very low	Having a job is negatively associated with being able to continue and complete cardiac rehabilitation.
psychosocial factors	very low	Having self-reported mild to extremely severe depression is negatively associated with being able to continue and complete cardiac rehabilitation.

Summary of the conclusion from the literature for each factor

Rationale of the recommendations

The guideline panel has chosen not to formulate a general recommendation with regard to diagnostic factors. Such a recommendation would require an action from the therapist, and considering the limited scientific substantiation of these factors, the guideline panel finds that it would be inappropriate.

It was therefore decided to formulate recommendations for the <u>medical history</u> taking, <u>physical</u> <u>examination and treatment plan</u>, <u>measurement instruments</u> and interventions to facilitate the continuation and completion of cardiac rehabilitation.

The guideline panel did, however, for each factor weigh up the relationship between the identified factors and the continuation or completion of cardiac rehabilitation. The factor 'being a foreign–language speaker, deaf or hearing–impaired' was added in the evidence to decision and was not found in the literature.

JUSTIFICATION

Literature

To answer the clinical question, a systematic literature review was performed on the following research question:

Which inhibiting and facilitating factors play an important role in influencing compliance (continuation) and the completion of phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure?

Relevant outcome measures

The guideline panel considers the continuation and completion of phase II of cardiac rehabilitation to be a crucial outcome measure for decision-making. Per outcome measure:

Continuation of phase II of cardiac rehabilitation: The guideline panel defines compliance (continuation) as following \geq 75% of the exercise programme of phase II of cardiac rehabilitation. Continuation and completion of phase II of cardiac rehabilitation: The guideline panel defines an odds ratio (OR) \neq 1 (the value of 1 is not in the reliability interval) as an important effect (clinically relevant difference).

Systematic literature review

On 22 June 2022 and 24 June 2022, an information specialist Ms H.W.J. Deurenberg conducted a systematic search in MEDLINE, Embase and CINAHL. A blinded screening on titles and abstracts and potential inclusion based on the full article was conducted by two researchers (DC and RA). A further search was then conducted to add literature where the study design was unknown (see Appendix B.2–1 for the search justification). The systematic search produced 1,012 unique hits. After screening of the title and the abstract based on the inclusion criteria, 963 articles were excluded. The inclusion criteria are shown in the following table.

Inclusion criteria		
Type of studies	 cohort studies: n ≥ 500 patients multivariate analysis, where links are determined representative for the entire cardiac rehabilitation population (no subpopulations, for example studies that only looked at women or older adults) Articles written in Dutch or in English the intervention is comparable to phase II of cardiac rehabilitation as de- scribed in the 'Multidisciplinary guideline on Cardiac Rehabilitation of 2011' (Revalidatiecommissie NVVC/NHS en projectgroep PAAHR) 	
Type of patients	patients with coronary artery disease or chronic heart failure	
Type of index test	inhibiting and facilitating factors	
Type of comparison	no comparison	

Type of outcome	 crucial: compliance (continuation) with phase II of cardiac rehabilitation: completion of phase II of cardiac rehabilitation 	
Type of timeline	 the moment at which the factors are evaluated is the diagnostic process. the moment for which the factors are predictive is phase II of cardiac rehabilitation 	
Setting	phase II of cardiac rehabilitation carried out in a heart centre (secondary/tertiary care setting)	

To be able to decide which factors have an impact on the entire population, it is important that the factors should be corrected with regard to each other. The pragmatic choice was made to include cohorts with \geq 500 patients and only studies in which multivariate analyses were carried out. Studies in which only subpopulations (e.g. women) were described, were also excluded on the basis of general applicability. 49 full-text articles were screened, and after consensus was reached between DC and RA, seven studies were eventually included (Brouwers 2021; Gaalema 2017; González-Salvado 2021; Nakayama 2020; Rao 2021; Sunamura 2017; en Wittmer 2012). See appendix B.2-2 for the flowchart of the inclusion process.

The articles that were excluded on the basis of the full text and the reasons for exclusion are listed in Appendix B.2–3 (Armstrong 2015; Bostrom 2020; Colbert 2015; De Jong 2012; De Melo Ghisi 2013; Farah 2019; Frechette 2019; Gaalema 2015; Gardiner 2018; Gobeil 2021; Goldstein 2022; Grace 2015; Grace 2021; Heald 2022; Hwang 2022; Keteyian 2022; Laddu 2018; Lee 2013; Lemstra 2013; Martin 2012, 2013; Marzolini 2015; McDonall 2013; Mikkelsen 2014; Minges 2017; Nakanishi 2022; Olsen 2018; Parashar 2012; Pardaens 2017; Park 2017; Poh 2015; Redfern 2014; Ritchey 2020; Rubin 2019; Sanchez-Delgado 2016; Tang 2022; Turk-Adawi 2013; Vonk 2021; Wallert 2019; Weeger 2017; Wu 2022; Zullo 2017).

Characteristics of the included studies

The characteristics of the included studies are provided in Appendix B.2–4 and B.2–5. In total, 23,596 patients (average age 57–71, 15–50% women) with a diagnosis of coronary artery disease or chronic heart failure were included in the seven studies. The population consisted of the following sub-diagnoses: patients with acute coronary syndrome (ACS), an aorta disease, coronary artery bypass graft surgery (CABG), chronic heart failure, coronary revascularisation, surgical or percutaneous treatment, documented coronary artery disease without revascularisation, valve replacement or repair, myocardial infarction without ST elevation (NSTEMI), a change in risk factors, acute myocardial infarction (AMI), stable angina pectoris (SAP) or myocardial infarction with ST evaluation (STEMI).

Individual study quality (RoB)

The risk of bias of the individual studies (RoB) was scored by DC and RA using the QUIPS tool (Hayden 2006, 2013). The assessment of the various items was discussed by DC and RA, after which consensus was reached. An overview of the assessment of the study quality of each study is provided in Appendix B.2–6.

Effectiveness and evidentiary value of the prognostic factors

An overview table of the effectiveness and evidentiary value of the studies for each factor is provided in Appendix B.2–7.

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Due to the heterogeneous nature observed in the prognostic factors and crucial outcomes, a meta-analysis was not justified and instead a narrative synthesis was carried out. The prognostic factors were thus categorised as follows.

Age

This factor was included as a continuous, dichotomous and categorical measure. In five studies, it appears from the multivariate analysis that age is linked in a clinically significant way with continuing and completing cardiac rehabilitation (Brouwers 2021; Gaalema 2017; González-Salvado 2021; Nakayama 2020; Rao 2021).

The direction in which the links point differs between the studies, as does the observed effect size:

In the multi-centre study of González-Salvado (2021), only in one location (Bern) was age in multivariate analysis significantly linked to the continuation or completion of cardiac rehabilitation, whereas it was not the case in other locations (Copenhagen, Zwolle and Santiago). In two studies age was linked in a non-significant way in the univariate analysis, which is why this factor was not included in the multivariate model (Sunamura 2017; Wittmer 2012). In two studies, a higher age was linked in a clinically relevant way with not continuing or completing cardiac rehabilitation (OR 0.9-1.05) (Brouwers 2021; González-Salvado 2021). In three studies, a higher age was linked in a clinically relevant way with continuing or completing cardiac rehabilitation (OR 0.57-1.58) (Gaalema 2017; Nakayama 2020; Rao 2021).

The evidentiary value was lowered by three levels from high to very low considering: 1) the inconsistency both in the factor and in the outcome measure, 2) the heterogeneous nature of the described populations and interventions and 3) the opposite effects of the factors on the outcome measures.

Diagnosis

This factor for instance includes: CABG, percutaneous coronary intervention (PCI), STEMI, NSTEMI or diagnosis groups (whether or not surgical). The factor was included as a dichotomous and categorical variable.

In three studies, it appears from the multivariate analysis that diagnosis is significantly linked with continuing and completing cardiac rehabilitation (Gaalema 2017; González–Salvado 2021; Nakayama 2020).

The direction in which the links point differs between the studies, as does the observed effect size:

- In the multicentre study of González–Salvado (2021), having ACS varies between locations as a significant factor in the multivariate analysis. In two locations (Zwolle en Santiago), ACS was included in the model but did not appear to be significant, although it did in the model of the Bern location.
- In three studies, the factor was included in the multivariate model but was non-significantly linked with continuing and completing cardiac rehabilitation (Brouwers 2021; Nakayama 2020; Rao 2021).
- In two studies, diagnosis as a factor was linked in a non-significant way in the univariate analysis, which is why this factor was not included in the multivariate model (Sunamura 2017; Wittmer 2012).

CABG was linked in a clinically relevant way with continuing or completing cardiac rehabilitation (OR 2.6-94) compared to not continuing or completing cardiac rehabilitation with a clinically relevant link (OR 1.24) (González-Salvado 2021; Nakayama 2020).

- In two studies, a PCI was linked in a clinically relevant way with continuing or completing cardiac rehabilitation (OR 0.69-3.6) (González-Salvado 2021; Nakayama 2020).
- The other studies also point in opposite directions. It is, for example, described that having ACS, chronic heart failure (CHF) and an aorta aneurysm are linked in a clinically relevant way with continuing or completing cardiac rehabilitation (OR 0.58–3.9), while on the other hand, a non-surgical diagnosis, valvulopathy and a valve operation were linked with not continuing or completing cardiac rehabilitation with a small to moderate (clinically) relevant link (OR range 0.11–1.54).

The evidentiary value was lowered by three levels from high to very low considering: 1) the inconsistency both in the factor and in the outcome measure, 2) the heterogeneous nature of the described populations and interventions and 3) the opposite effects of the factors on the outcome measures.

Cardiovascular risk factors and/or comorbidity

This factor for instance includes: smoking (history), body mass index (BMI), related previous history or associated diagnoses, diabetes mellitus or inactivity/exercise behaviour. This pertains to factors that increase the risk of cardiovascular disease according to the guideline on Cardiovascular risk management (CVRM) of the Dutch federation of medical specialists (Federatie Medisch Specialisten) (2019). The factor was included as a continuous, dichotomous and categorical variable. In six studies, it appears from the multivariate analysis that cardiovascular risk factors and/ or comorbidity are significantly linked with continuing and completing cardiac rehabilitation (Gaalema 2017; González–Salvado 2021; Nakayama 2020; Rao 2021; Sunamura 2017; Wittmer 2012). The direction in which the links point differs between the studies, as does the observed effect size:

- In five studies, the factor in the multivariate analysis was non-significantly linked (body mass index (BMI), chronic obstructive pulmonary disease (COPD), cardiovascular disease (CVD) or coronary arterial disease (CAD) in the patient's medical history, hypercholesterolemia, previously suffered PCI) with the continuation and completion of cardiac rehabilitation (Brouwers 2021; Gaalema 2017; González-Salvado 2021; Rao 2021; Sunamura 2017). In four studies, in a univariate analysis the factor (hypercholesterolemia, high blood pressure, smoking, positive family history, BMI, previously suffered CABG) was non-significantly linked with the continuation and completion of cardiac rehabilitation, which is why the factor was not included in the multivariate model (Brouwers 2021; Rao 2021; Sunamura 2017; Wittmer 2012). Smoking is associated with not continuing or completing cardiac rehabilitation with a clinically
- relevant link (OR 0.00-2.40) (Gaalema 2017; Rao 2021; Sunamura 2017; Wittmer 2012). A higher BMI is associated with not continuing or completing cardiac rehabilitation with a
- clinically relevant link (OR 1.03–1.60) (Rao 2021; Wittmer 2012).
- Diabetes is associated with not continuing or completing cardiac rehabilitation with a clinically relevant link (OR 0.59–1.63) (Rao 2021; Sunamura 2017; Wittmer 2012).
- Having \geq 3 forms of comorbidity, an albumin level of \leq 3.8 g/dl, PAD, ACS, a previously suffered myocardial infarction (MI) and sedentary behaviour is associated with not continuing or completing cardiac rehabilitation with a clinically relevant link (OR 0.02–11.13) (Gaalema 2017; González–Salvado 2021; Nakayama 2020; Rao 2021; Sunamura 2017).

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Having one or more cardiovascular risk factors is negatively associated with being able to continue or complete cardiac rehabilitation with a clinically relevant link in six studies (OR 0.00–11.13) (Gaalema 2017; González–Salvado 2021; Nakayama 2020; Rao 2021; Sunamura 2017; Wittmer 2012).

The evidentiary value was lowered by three levels from high to very low considering: 1) the risk of bias in the results, 2) the inconsistency both in the factor and in the outcome measure and 3) the heterogeneous nature of the described populations and interventions.

Living situation

This factor includes all dichotomous and categorical variables, such as being married/unmarried/ engaged or not, being divorced or separated, being single or being widowed. In three studies, it appears from the multivariate analysis that living situation is significantly linked with continuing and completing cardiac rehabilitation (Rao 2021; Wittmer 2012). The direction in which the links point differs between the studies, as does the observed effect size:

- In the multicentre study of González–Salvado (2021), living situation was included for only one location (out of five) in the model, and the factor was non–significantly linked in the multivariate analysis.
- In only study was living situation non-significantly linked according to the univariate analysis, which is why this factor was not included in the multivariate model (Brouwers 2021).
- In the remaining studies, this factor was not included as a variable.
- In two studies, being single, divorced or widowed was linked in a clinically relevant way with not continuing or completing cardiac rehabilitation (OR 1.99–2.01) (Rao 2021; Wittmer 2012).

The evidentiary value was lowered by three levels from high to very low considering: 1) the inconsistency in the factor and 2) the heterogeneous nature of the described populations and interventions.

Physical functioning

This factor includes: physical functioning in questionnaires, exercise capacity (expressed in wattage and potentially in relation to the set goal in an exertion test), maximal capacity and the estimated METs. 'Physical functioning' includes maximum exercise capacity, physical capacity, subjective exercise capacity and physical activity as described in <u>B.6 'Measurement instruments'</u>. The factor has been included as a continuous variable.

In two studies, it appears from the multivariate analysis that physical functioning is significantly linked with the continuation and completion of cardiac rehabilitation (Brouwers 2021; Wittmer 2012). The direction in which the links point differs between the studies, as does the observed effect size:

- In two studies, the factor was non-significantly linked (physical functioning on MOS-SF-36 and estimated METs) with the continuation and completion of cardiac rehabilitation in the multivariate model (Gaalema 2017; Rao 2021).
- In only study was physical functioning, expressed in METs, non-significantly linked according to the univariate analysis, which is why this factor was not included in the multivariate model (Rao 2021).

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- In the remaining studies, this factor was not included as a variable.
- In two studies, higher physical functioning (maximal physical load or wattage of the exertion goal) was linked in a clinically relevant way with the continuation or completion of cardiac rehabilitation with a (clinically) relevant link (OR 0.81–0.99) (Brouwers 2021; Wittmer 2012).

The evidentiary value was lowered by three levels from high to very low considering: 1) the inconsistency both in the factor and in the outcome measure and 2) the heterogeneous nature of the described populations.

Accessibility

This factor includes: distance to the rehabilitation centre and living in a city. The factor was included as a continuous, dichotomous and categorical variable.

In two studies, it appears from the multivariate analysis that accessibility is significantly linked with continuing and completing cardiac rehabilitation (González–Salvado 2021; Nakayama 2020). The direction in which the links point differs between the studies, as does the observed effect size:

- In only one study did it emerge from the multivariate model as a non-significantly linked factor for the continuation and completion of cardiac rehabilitation (Brouwers 2021).
- In the remaining studies, this factor was not included as a variable.
- In only one study, a distance of > 20 km was linked in a clinically relevant way with not continuing or completing cardiac rehabilitation (OR 1.85–3.55) (Nakayama 2020).
- In this study, living in a city was associated with not continuing or completing cardiac rehabilitation with a clinically relevant link (OR 0.2) (González-Salvado 2021).

The evidentiary value was lowered by three levels from high to very low considering: 1) the inconsistency both in the factor and in the outcome measure and 2) the heterogeneous nature of the described interventions.

SES and/or health literacy

The factor was included as a continuous, dichotomous and categorical variable. In one study, it appears from the multivariate analysis that there is a significant link between SES and/or health literacy and the continuation and completion of cardiac rehabilitation (Gaalema 2017). The following outcomes were reported:

- In three studies, the factor was included in the multivariate analysis, from which a nonsignificant link appeared (Rao 2021; Sunamura 2017; Wittmer 2012).
- In only one study, a low SES was linked in a clinically relevant way with not continuing or completing cardiac rehabilitation (OR 0.02) (Gaalema 2017).

The evidentiary value was lowered by three levels from high to very low, since only one study identified the factor and there was moreover an unknown risk of bias in the results of this study.

Gender

This factor was included as a dichotomous variable in the analyses (male/female). In one study, it appears from the multivariate analysis that gender is significantly linked with continuing and completing cardiac rehabilitation (Nakayama 2020). The following outcomes were reported:

- In the study of Brouwers, gender was non-significantly linked in a multivariate analysis with the continuation and completion of cardiac rehabilitation (Brouwers 2021).
- In four other studies, the factor was non-significantly linked in the univariate analysis, which is why this factor was not included in the multivariate model (Gaalema 2017; Rao 2021; Sunamura 2017; Wittmer 2012).
- In the remaining studies, this factor was not included as a variable.
- In only one study, male gender was linked in a clinically relevant way with not continuing or completing cardiac rehabilitation (OR-1.48) (Nakayama 2020).

The evidentiary value was lowered by three levels from high to very low, since only one study identified the factor and there was moreover an unknown risk of bias in the results of this study.

Related to the cardiac rehabilitation programme

This factor includes: waiting time before starting with rehabilitation and previous participation in cardiac rehabilitation. The factor was included as a continuous and categorical variable. In one study, it appears from the multivariate analysis that waiting time until the start of cardiac rehabilitation and previous participation in cardiac rehabilitation is significantly linked with the continuation and completion of cardiac rehabilitation (Rao 2021). The following outcomes were reported:

- In only one study does the factor, expressed in the number of days of waiting to the start of the cardiac rehabilitation or previous participation in cardiac rehabilitation, emerge from the univariate analysis as being non-significantly linked, which is why it was not included in the multivariate model (Brouwers 2021).
- In the remaining studies, this factor was not included as a variable.
- In only one study, a waiting time of > 18 days until the start of cardiac rehabilitation was linked in a clinically relevant way with not continuing or completing cardiac rehabilitation (OR 1.32–1.72) (Rao 2021).

The evidentiary value was lowered by three levels from high to very low, since only one study identified the factor and there was, moreover, an unknown risk of bias in the results of this study.

Activity/way of spending the day

This factor includes all variables that are related to the person's activities/way of spending the day, such as: having a job, being unemployed, receiving an allowance, going to school or being a pensioner. The factor was included as a dichotomous or categorical variable.

In one study it appears from the multivariate analysis that activities or ways of spending the day is significantly linked with continuing and completing cardiac rehabilitation (González–Salvado 2021). The following outcomes were reported:

In two studies, activities/way of spending the day were included in the multivariate analysis, but the factor appears to be non-significantly linked with continuing and completing cardiac rehabilitation (Rao 2021; Wittmer 2012).

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- In only study did it emerge from the univariate analysis as a non-significantly linked factor,
- which is why it was not included in the multivariate model (Brouwers 2021).
- In the remaining studies, this factor was not included as a variable.
- In only one study was the fact of having a job linked with not continuing or completing cardiac rehabilitation with a clinically relevant link (OR-0.2) (González-Salvado 2021).

The evidentiary value was lowered by three levels from high to very low, since only one study identified the factor and there was, moreover, an unknown risk of bias in the results of this study.

Psychosocial factors

This factor includes: all variables that are related to the person's psychosocial status, such as suffering from anxiety, depression or stress (and deduced scores) and their mental and social health. The factor was included as a dichotomous or categorical variable.

In one study, psychosocial factors emerged from the multivariate model as a significantly linked factor for the continuation and completion of cardiac rehabilitation (Rao 2021). The following outcomes were reported:

- In one study, it appears from the multivariate model that self-reported anxiety and stress or the related sub-scales (scored on MOS SF-36) are non-significantly linked with the continuation and completion of cardiac rehabilitation (Rao 2021).
- In two studies, the factor (GAD score, depression score) emerged from the univariate analysis as a non-significantly linked factor, which is why it was not included in the multivariate model (Brouwers 2021; Gaalema 2017).
- In the remaining studies, this factor was not included as a variable.
- In only one study, having self-reported mild to extremely severe depression was associated with not continuing or completing cardiac rehabilitation with a (clinically) relevant link (0R-1.33) (Rao 2021).

The evidentiary value was lowered by three levels from high to very low, since only one study identified the factor and there was, moreover, an unknown risk of bias in the results of this study.

Cardiac-related

The factor 'cardiac-related' includes: all variables that are related to the person's cardiac status, such as cardiac-related blood levels, ejection fraction, blood pressure and heart rhythm. The factor was included as a continuous, dichotomous or categorical value. The following outcomes were reported:

- In two studies, the factor (expressed in terms of rest diastolic, resting heart rate or atrial fibrillation) did not emerge from the multivariate analysis as a significantly linked factor (González–Salvado 2021; Rao 2021).
- In two studies, the factor (systolic blood pressure, ejection fraction and LVEF \leq 40%) emerged from the univariate analysis as a non-significantly linked factor, which is why it was not included in the multivariate model (Rao 2021; Wittmer 2012).
- In the remaining studies, this factor was not included as a variable.

The evidentiary value and RoB were therefore not described.

В

Quality of life

The factor 'Quality of life' includes: all variables that relate to the person's quality of life, such as specific measurement instruments (MOS–SF–36, PLC). The factor was included as a categorical variable. The following outcomes were reported:

In two studies, the factor (on the MOS SF-36 and PLC scale) did not emerge from the multivariate analysis as a significantly linked factor (Rao 2021; Wittmer 2012). In only study did it emerge from the univariate analysis as a non-significantly linked factor, which is why it was not included in the multivariate model (Brouwers 2021).

The evidentiary value and RoB were therefore not described.

Medication

The factor 'Medication' includes: all variables that are related to cardiac mediation.

Only one study looked at the link between mediation and the continuation and completion of cardiac rehabilitation. Antiarrhythmic medication emerged here as a significant factor from the univariate analysis, but beta blockers and nitrates were also included in the multivariate analysis. No single type of medication appeared from the multivariate analysis to be significantly linked (Rao 2021).

The evidentiary value and RoB were therefore not described.

Other factors

No other factors or related topics were described in the studies.

Criteria for formulating the recommendations

From evidence to recommendation

Internationally recognised criteria were used to assess the evidence on which the recommendations are based. These criteria, as well as the remaining considerations formulated by the guideline panel, determine the strength of the recommendation.

Effects (desirable and undesirable)

Due to the heterogeneous nature observed in the prognostic factors and crucial outcomes, a meta-analysis is not justified and instead a narrative synthesis has been carried out. It is therefore not possible to indicate the effect size with an absolute figure, but only to determine it with a range of effect sizes from the included studies. This limits the interpretation of the range and the indication of a direction in which the evidence points. The guideline panel has clustered factors (or subgroups of the factor) for which the direction and relevance correlate as far as possible in order to assess the effects of the prognostic factor.

Quality of evidence

Due to the heterogeneous nature observed in the prognostic factors, the crucial outcomes and the fact of not being able to compare the populations and interventions, a large number of included studies were devalued by at least two levels and appeared to have a very low evidentiary value.

If evidence is based on only one study, the quality of evidence is per definition very low due to 'selection of measurement bias'.

Patient values and preferences

The guideline panel believes that patients attach great value to having their values identified and that there is little variation among patients in this regard. These are in fact already identified during the diagnostic process. Identifying the values and preferences that can predict the continuation and completion of cardiac rehabilitation therefore does not require any additional effort from the patient. This is in line with the study of the Dutch Heart Council (Harteraad) of 2022, which investigated why people with heart failure do not participate in or adhere to a cardiac rehabilitation programme.

Balance between desirable and undesirable effects

Cardiovascular risk factors and/or comorbidity. Despite the very low evidentiary value of studies in which the presence of cardiovascular risk factors and/or comorbidity is negatively linked with being able to continue or complete cardiac rehabilitation, the guideline panel considers that it is important to identify the factor of 'cardiovascular risk factors and/or comorbidity' in order to predict whether the patient will be able to continue and complete the cardiac rehabilitation. The guideline panel offered the following motivation for this:

 The clinical experience of the guideline panel shows that patients with several cardiac risk factors and/or comorbidity (such as diabetes mellitus, COPD or peripheral artery disease (PAV)) in practice are less able to continue and complete cardiac rehabilitation.

Living situation. Despite the very low evidentiary value of studies in which the fact of being single, divorced or widowed is negatively linked with being able to continue or complete cardiac rehabilitation, the guideline panel considers that it is important to identify the factor of 'living situation' in order to predict whether the patient will be able to continue and complete the cardiac rehabilitation.

The guideline panel offered the following motivation for this:

The clinical experience of the guideline panel shows that single patients in practice are less able to continue and complete the cardiac rehabilitation programme than those who are not single. An explanation could be that single patients experience less social support for continuing or completing cardiac rehabilitation than those who are not single, which is supported by the study of Wittmer (2012). Another explanation could be that single patients are less likely to have a means of transport and are therefore dependent on their social network. These explanations are developed further for the factor 'accessibility' and 'psychosocial factors'.

Physical functioning. Despite the very low evidentiary value of studies in which reduced physical functioning is negatively linked with being able to continue or complete cardiac rehabilitation, the guideline panel considers that it is important to identify the factor of 'physical functioning' in order to predict whether the patient will be able to continue and complete the cardiac rehabilitation.

The guideline panel offered the following motivation for this:

Identifying physical functioning forms part of the diagnostic process, as does determining, together with the patient, what the goals of the physical or exercise therapy will be. If there is a change in the patient's motivation during the treatment process, it can be supportive at that point to go over the goals with the patient once again and to talk about the progress in physical functioning.

Accessibility. The factor of 'accessibility' is linked both positively and negatively with being able to continue and complete cardiac rehabilitation. Despite the very low evidentiary value of these studies, the guideline panel considers that it is important to identify the factor of 'accessibility' in order to predict whether the patient will be able to continue and complete the cardiac rehabilitation.

The guideline panel offered the following motivation for this:

The clinical experience of the guideline panel shows that patients who live further away from the heart centre are more likely to stop with cardiac rehabilitation than patients who live close by.

The guideline panel indicates that the fact of not having a means of transport to overcome the distance to the heart centre or not being able to find the way to the heart centre can play an inhibiting role.

SES and/or limited health literacy. Although only one study describes a clinically relevant link, where the fact of having a low socio-economic status (SES) is negatively associated with being able to continue or complete cardiac rehabilitation, the guideline panel considers that it is important to identify the factor of 'SES and/or health literacy' in order to predict whether the patient will be able to continue and complete the cardiac rehabilitation.

The guideline panel offered the following motivation for this:

The clinical experience of the guideline panel shows that patients with a low SES or limited health literacy are more likely to stop with their cardiac rehabilitation. This experience is supported by the literature (Gaalema 2017).

Activities/way of spending the day. Although only one study describes the fact of having a lob as being negatively linked with being able to continue or complete cardiac rehabilitation, the guideline panel considers that it is important to identify the factor of 'activities/way of spending the day' in order to predict whether the patient will be able to continue and complete the cardiac rehabilitation.

The guideline panel offered the following motivation for this:

The clinical experience of the guideline panel shows that patients who have a job are more likely to stop with cardiac rehabilitation if they return to work during the cardiac rehabilitation programme. A seriously limiting factor here is the fact that heart centres are invariably only open during office hours. Patients who return to work fast are therefore limited in following the cardiac rehabilitation programme. This experience is supported by the literature (Gaalema 2017). В

Psychosocial factors. Although only one study describes a clinically relevant link, where the fact of suffering from self-reported mild to extremely severe depression is negatively associated with being able to continue or complete cardiac rehabilitation, the guideline panel considers that it is important to identify the factor of 'psychosocial factors' in order to predict whether the patient will be able to continue and complete the cardiac rehabilitation. The guideline panel offered the following motivation for this:

- The clinical experience of the guideline panel shows that patients for whom (more complex) psychosocial issues play a role are more likely to stop their cardiac rehabilitation. This is supported by a systematic review of the link between depression and the completion of cardiac rehabilitation (Edwards 2019).
- The ESC Clinical Practice Guidelines confirms that psychosocial stress, depression and anxiety are negatively linked with the continuation and completion of cardiac rehabilitation and that it is difficult for patients with psychosocial stress, depression and anxiety to make positive changes to their lifestyle or to adhere to a therapeutic programme (Knuuti 2020).

Socio-economic considerations and cost-effectiveness

The guideline panel considers that the resources or costs needed to identify the factors that predict the continuation and completion of cardiac rehabilitation are negligible. This is because the factors identified in the included studies in current practice are already identified during the diagnostic process. Identifying the factors therefore requires no additional resources or costs compared to current practice. The guideline panel further considers that if increased inflow in cardiac rehabilitation and the completion of cardiac rehabilitation by the patient decreases the (future) healthcare burden, this reduced care burden will directly translate into benefits for society and for the economy (De Gruyter 2016; Frederix 2018).

Health equality

The guideline panel expects that the identification of factors that predict whether a patient can continue and complete cardiac rehabilitation will not have any impact on health equality. The factors identified in the included studies in current practice are already identified during the diagnostic process. Based on clinical expertise, the guideline panel considers that the continuation and completion or not of cardiac rehabilitation has no impact on health equality.

Acceptability

The guideline panel expects that the identification of factors that predict whether a patient can continue and complete cardiac rehabilitation will be accepted by all the main stakeholders. This is because the factors identified in the included studies in current practice are already identified during the diagnostic process. No additional effort is required, which makes identification feasible.

Feasibility

The guideline panel considers that the identification of factors that predict whether a patient can continue and complete cardiac rehabilitation is realistic. This is because the factors identified in the included studies in current practice are already identified during the diagnostic process. No additional effort is required, which makes identification feasible.

Other considerations

Age and gender. The guideline panel believes that the factors of age and gender do not need to be identified, since these factors are not important for being able to predict whether the patient will be able to maintain the cardiac rehabilitation. It is, however, known that women and older adults are taken in less frequently in cardiac rehabilitation. This is supported by studies that were carried out in the situation of the Netherlands, where female gender and a higher age are predictive of a lower influx (Brouwers 2021; Conijn 2022; González–Salvado 2021; Sunamura 2017; Van Engen–Verheul 2013; Vonk 2021). The guideline panel believes, however, that these sub–populations, once they have started with cardiac rehabilitation, are well motivated for it.

Diagnosis. The guideline panel believes that the factor of diagnosis does not need to be identified, since this factor is not important for being able to predict whether the patient will be able to maintain or complete cardiac rehabilitation. The guideline panel indicates that the factor of diagnosis is important in particular with regard to the influx in cardiac rehabilitation.

Related to cardiac rehabilitation programme. The guideline panel believes that the factor of being related to the cardiac rehabilitation programme does not need to be identified, since this factor is not important for being able to predict whether the patient will be able to maintain or complete cardiac rehabilitation. The guideline panel indicates that the factor of being related to the cardiac rehabilitation programme is important in particular with regard to the influx in cardiac rehabilitation.

Cognitive skills. The guideline panel believes that the factor of cognitive skills does not need to be identified. Cognitive skills was not analysed in the included studies and therefore no conclusion could be linked to this opinion based on the literature. The identification of cognitive factors is, however, described in the European guideline for post-reanimation care (Nolan 2021). The guideline panel is of the opinion that identifying cognitive status should not be done primarily by the physical or exercise therapist. It is, however, important during the exercise programme of phase II of cardiac rehabilitation to keep the patient's cognitive status in mind.

Being a foreign-language speaker, deaf or hearing-impaired. The guideline panel believes that the fact of the patient being a foreign-language speaker, deaf or hearing-impaired can be related to whether or not they will be able to continue and complete the cardiac rehabilitation programme. This factor was not identified in the literature, however, but was added based on the clinical expertise of the guideline panel members.

Focus areas for implementation

See the description of 'Feasibility' in this regard.

Knowledge gaps

From the systematic literature review it emerged that there was a large degree of heterogeneousness in the way in which prognostic factors were defined and that this also applied to the notions of 'continuation' and 'completion' of cardiac rehabilitation. The latter has in fact already been pointed out in the literature (Brouwers 2021; Sunamura 2017). Another point is that cardiac rehabilitation programmes are not mutually comparable between the various countries. It is therefore important to identify inhibiting and facilitating factors that apply specifically to the situation in the Netherlands. Based on this, the guideline panel considers that the following research question is important: Which inhibiting and facilitating factors that are related to the exercise programme in phase II of cardiac rehabilitation play an important role in influencing compliance (continuation) and the completion of phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure in the Netherlands?

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B.3 Low SES/limited health literacy

Recommendations

For all patients with coronary artery disease or chronic heart failure, but in particular those with a low socio-economic status (SES) and/or limited health literacy, apply the following advice to facilitate compliance and the completion of the exercise programme in phase II of cardiac rehabilitation.

1. Communicate with clarity

During a conversation

- Normalise low literacy. For example: 'We know that many people find it difficult to fill in forms. How about you?'
- Assume that they lack basic knowledge of the body. People with limited health literacy find it difficult to get hold of, understand and apply medical information. After explaining, use <u>the</u> <u>teach-back method</u>: 'I've told you quite a lot. What will you tell people at home?'
- Let people demonstrate their exercises. 'Let's see if I showed you the exercises properly last time.'
- Use <u>supporting informational material</u> that is suited to the person's language and digital abilities.
 Use short sentences and use simple words.
- Do not 'make excursions' in your story: stick to the core of the message.
- Be as concrete as possible, and avoid jargon and figurative speech.
- Repeat the main points (and limited these to three at the most).
- Write instructions and advice down for them to take away.

In written communication

- Use short films or informational material with drawings that has been tested with or on the target group.
- Use vocabulary of level A2-B1.
- Limit the amount of information to three main points at most. If necessary, refer them to relevant sources of information to learn more.
- A clear layout and headings will facilitate comprehension.
- Only use material that has been tested for clarity. And always <u>test the material you assemble</u> yourself to make sure it is understandable before using it in practice.

Source: Landelijk Expertisecentrum Pharos (Pharos National Expertise Centre)

2. Support the person's belief in their own abilities

Make use of the recommendations formulated in the '<u>KNGF guideline on Self-Management</u>' (Koninklijk Nederlands Genootschap voor Fysiotherapie 2022).

3. Ask about practical, social and/or economic barriers

At the start of the cardiac rehabilitation programme, talk with the patient about any possible practical, social and/or economic barriers to the starting and successful completion of cardiac rehabilitation.

Interventions related to health and lifestyle

During medical history taking, ask, for instance, about the following inhibiting factors (see <u>B.4</u> 'Medical history taking'):

- The exercise location must be easy to find an accessible (advise, for example, to have someone accompany the person the first time they go there).
- The therapy must be affordable.
- Talk about other possible practical barriers: for example, no-one to look after their children. In the case of group therapy, talk individually with the participant beforehand to find out what their preferences are in terms of set-up and methods. In the case of sporting activities, also talk about whether they prefer to do it indoors or outdoors and whether they need to wear any specific clothing. Take cultural differences into account.
- Unknown situation: it is important to explain in a warm tone. Find out who can make the first contact and/or let a family member or neighbour come along the first time.
- Presence of psychosocial factors (stress, anxiety, depression). The presence of these can be an obstacle to developing or maintaining an active lifestyle.

Source: Landelijk Expertisecentrum Pharos (Pharos National Expertise Centre)

4. Try to form an idea of the person's health, language and digital literacy

5. Be aware of your own therapeutic attitude

Therapeutic attitude in phase II of cardiac rehabilitation

- Make personal contact.
- Make it clear how the participant may benefit.
- Ensure that there is a sociable, safe atmosphere in the group.
- Make sure that the counsellor and the participant get along.
- Do not start to quickly with the intervention.
- Invest in a relationship of trust.
- Be empathetic.

Source: Landelijk Expertisecentrum Pharos (Pharos National Expertise Centre)

6. Consult with the entire cardiac rehabilitation team

- Discuss the focus areas. It might be necessary to consider adjusting the cardiac rehabilitation programme (including the exercise programme). For this, see <u>C.2 'Continuation and completion</u> of cardiac rehabilitation'.
- Continue monitoring during the entire cardiac rehabilitation programme. In this regard see C.7 'Evaluation, stop criteria and closure of the treatment'.

SUBSTANTIATION

Reason

One in three Dutch people has limited health literacy. This means that they find it difficult to get hold of, understand, assess and make use of health information. A part of this group has low literacy (Landelijk expertisecentrum Pharos).

In the Netherlands, people with a low SES and/or limited health literacy have an average life expectancy that is four years shorter, and as much as 15 years with lower perceived health, than people with higher vocational training (HBO) or a university education (Landelijk expertisecentrum Pharos). Cardiovascular diseases occur significantly more frequently among people with limited health literacy (Landelijk expertisecentrum Pharos). Cardiovascular diseases by making changes to a person's lifestyle and reducing risk factors; patients with a low SES are, however, less able to complete cardiac rehabilitation (see <u>B.2</u> 'Inhibiting and facilitating factors').

In order to still achieve the positive effects of cardiac rehabilitation, it is important to adapt to the inhibiting factors and needs of a patient with a low SES and/or limited health literacy.

Clinical question

How do you facilitate compliance and the completion of the exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure with a low SES and/or limited health literacy?

Conclusions based on the literature

In coordination with the guideline panel it was decided not to carry out any systematic search action, but to gather the information needed for answering this clinical question in a non-systematic way and work it out narratively using the knowledge and clinical expertise of the guideline panel.

Rationale of the recommendations

It is highly uncertain whether the use of recommendations during phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure with a low SES and/or limited health literacy has any impact. The guideline panel believes, however, that the potentially beneficial effects of using recommendations is preponderant, which has led to the formulation of a conditional recommendation.

JUSTIFICATION

Literature

For the non-systematic gathering of information, the guideline panel selected the systematic literature review of Gaalema (2017). He concludes that for patients with a low SES, the implemented intervention aimed at behavioural changes appears to be less successful. In the Netherlands, Pharos is the national expertise centre for health inequities. The guideline panel decided to include the recommendations of Pharos to answer the clinical question (De Been 2018; Landelijk expertisecentrum Pharos). The guideline panel considers that it is the responsibility of the therapist to implement an intervention in such a way that it will align in the closest possible way with the patient's needs and capabilities.

From evidence to recommendation

From evidence to recommendation

Internationally recognised criteria were used to assess the evidence on which the recommendations are based. These criteria, as well as the remaining considerations formulated by the guideline panel, determine the strength of the recommendation.

Desirable and undesirable effects

No literature was selected that provides an answer to the clinical question. Because of this the guideline panel did not formulate a balance between desirable effects and undesirable effects.

Quality of evidence

No literature was selected that provides an answer to the clinical question. Because of this the guideline panel did not formulate a balance of quality of evidence.

Patient values and preferences

The guideline panel considers that patients attach great value to the facilitation of compliance and completion of cardiac rehabilitation that is specifically aimed at the individual patient and that there is little variation between patients in this regard.

This is supported by the report 'Quality criteria for cardiac rehabilitation. Formulated from the patient perspective', which was drawn up by De Hart&Vaatgroep in the scope of the 'Kwaliteit in Zicht' (Quality in Sight) programme. The report explains that patient-centred care, aligned with the preferences, capabilities and needs of the individual patient, is an important quality criterion (formulated from the patient's perspective) (Harteraad 2012).

Balance between desirable and undesirable effects

No literature was selected to provide an answer to the clinical question. Because of this, the guideline panel did not establish a balance between desirable and undesirable effects.

Socio-economic considerations and cost-effectiveness

The guideline panel considers that the resources needed for the intervention to be negligible. The intervention is probably cost-effective, even though there are no specific studies to support this assessment.

Health equality

The guideline panel expects that the intervention will lead to an increase in health equality.

Acceptability

The guideline panel expects that the intervention will be accepted by all key stakeholders.

Feasibility

The guideline panel considers the implementation of effective components to be 'probably realistic'. The guideline panel indicates that organising specific (transmural) care journeys or training groups for subpopulations within the current heart centres is a challenge, particularly for smaller establishments. See also <u>C.6 'Telerehabilitation'</u> and <u>C.4 'The exercise programme in a primary care setting'</u>.

Other considerations

The guideline panel considers that the following recommendations are also important to give shape to an exercise programme in phase II of cardiac rehabilitation in order to facilitate compliance and the completion of the exercise programme among patients with coronary artery disease or chronic heart failure with a low SES/limited health literacy.

The guideline panel considers that the study of Nielsen (2013) is a good example of a cardiac rehabilitation programme in which effective components for people with a low socio-economic status (SES) are applied. The guideline panel does, however, believe that there are several ways in which these effective components can be applied within the exercise programme in phase II of cardiac rehabilitation.

In this study, an extended cardiac rehabilitation programme over five years with 508 patients (of whom 303 had a low SES) led to higher participation (97.7 vs. 75% in standard cardiac rehabilitation; p < 0.0001). The extended cardiac rehabilitation programme included the following components:

- an extra individual consultation with a nurse, where the patient defines a plan for their post-rehabilitation phase;
- a prevention discussion with the general practitioner after completion of the cardiac rehabilitation, for which the general practitioner will have received a patient plan beforehand, so that they can take over the rehabilitation programme; half an hour is recommended for the prevention discussion;
- a telephone call to the patient at the nurse's initiative four months after release from hospital, which is two months before the end of the cardiac rehabilitation, to find out how the cardiac rehabilitation is going and what progress has been made on the goals that the patient has set for themselves;
- ensuring action-oriented components and skill training with regard to nutrition, exercise, relaxation and giving up smoking up to 1.5 year after hospitalisation.
- the recommendation to let pensioner patients take part in non-cardiac-specific activities in local community centres;
- use of motivating dialogue by nurses;
- encouraging patients to define goals and motivating action routes based on the principles of agreement rather than compliance.
- providing interpreters for patients who do not speak Danish.

The guideline panel believes that the conditions as described in <u>C.2 'Continuation and</u> <u>completion of cardiac rehabilitation'</u> should be included when establishing a treatment plan for patients.

The guideline panel believes that it is important to keep monitoring the treatment during the execution of the cardiac rehabilitation programme. In this regard see <u>C.7 'Evaluation, stop</u> criteria and closure of the treatment'.

The guideline panel is of the opinion that the therapist has a signalling function in the identification of patients with a low SES/limited health literacy so that these suspicions can subsequently be discussed in the multidisciplinary dialogue with the cardiac rehabilitation team in order to consider adjusting the cardiac rehabilitation programme.

Focus areas for implementation

The guideline panel indicates that implementation of the recommendations formulated in this module does not require any further attention. It is, however, important that the therapist should be capable of recognising patients with a low SES and/or limited health literacy. This requires a certain degree of awareness-raising.

Knowledge gaps

No systematic search was conducted, which is why the guideline panel is unsure of whether literature is available on this topic. The guideline panel does, however, have the impression that literature is available on how to facilitate compliance and completion of the exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure with a low SES and/or limited health literacy.

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B.4 Medical history taking

Recommendations

During the medical history taking, ask about relevant information, but first of all take note of the relevant referral details sent by the cardiologist with regard to the patient in question.

Relevant referral details from the cardiologist

- (medical) diagnosis;
- cardiac-rhythm and conduction disorders;
- presence or not of an implantable cardioverter defibrillator (ICD)* or pacemaker (type, settings); data on maximum or symptom-limited exertion test (if applicable with a breath gas analysis). See B.6 'Measurement instruments';

relevant comorbidity;

- history (cardiac/non-cardiac);
- medication (type and dosage);
- details on operations, if applicable;
- cardiology information considered relevant by the cardiologist.

* See B.7 'Indication' for limitations and contraindications regarding exercise.

For coronary artery disease

details regarding haemodynamic stability during and after the treatment of the event, size and location of the infarct, potential complications, left ventricular ejection fraction (LVEF), potential ischaemia during rest intervals and the status of (untreated) coronary arteries; percutaneous coronary intervention (PCI): number and location; presence or not of stent; coronary artery bypass graft surgery (CABG) (number of bypasses during CABG; method of bypass operation (sternotomy*, endocab, opcab); types of bypass (venous/arterial graft)); valve surgery (type of valve, valve location, surgery method*)

For chronic heart failure

details regarding the severity of the chronic heart failure (expressed in terms of left ventricular ejection fraction (LVEF), New York Heart Association (NYHA) classification), the cause of the chronic heart failure (for example ischaemic cardiac disease, high blood pressure, valve defects, heart rhythm problems) and treatment;

type of chronic heart failure: patients with reduced ejection fraction (HFrEF; LVEF < 40%), patients with moderate ejection fraction (HFmREF; LVEF 41-49%) and patients with preserved ejection fraction (HFpEF; LVEF > 50%).

Relevant data from maximum or symptom-limited exertion test (with breath gas analysis if applicable)

- current (physical) capacity of the patient based on the maximum or symptom-limited exertion test expressed in absolute value and threshold value (V0₂-max/METs/wattage);
- protocol used for the exertion test;
- assessment by the doctor of the electrocardiogram (ECG) before, during and after exertion (criteria for cardiac ischaemia, rhythm and conduction disorders, and related practical consequences);
- resting heart rate, maximum heart rate reached, predicted maximum heart rate, predictable maximum V0,-max or wattage;
- blood pressure sequence during rest intervals and during exertion and recovery;
- reasons for ending the test (also think of exercise anxiety);
- use of medication (e.g. beta blocker, including type and dosage);
- (subjective) symptoms of the patient during the test (angina pectoris/dyspnoea) and preferably the Borg score (6-20);

spiro-ergometry: gas exchange parameters such as maximum oxygen uptake (VO₂-max), percentage of the predicted VO₂-max, O₂ pulse, maximum respiratory minute volume (VE) (tidal volume (VT) X breathing rate), respiratory exchange rate (RER), anaerobic or ventilatory threshold, VE/VCO₂ ratio, saturation and other relevant parameters that may be present (e.g. VO₂ oxygen uptake efficiency slope and whether or not respiratory oscillations occur); maximum voluntary ventilation (MVV) that might be deduced from the generated data.

* See <u>B.6 'Measurement instruments'</u> for further explanations of the maximum or symptom-limited exertion test (if applicable with <u>breath gas analysis</u>)

Identify the following information.

General

What is the healthcare need?

Inventory of the health conditions that led to the cardiac incident or the deterioration of chronic heart failure

How did the symptoms start, how long have they been going on and what is their course?
 What is the prognosis and what are the (cardiovascular) risk factors (e.g. inactive lifestyle, smoking, stress, problems with falling asleep or continuing to sleep)?

Inventory of current status

- Is there any comorbidity (such as diabetes mellitus, peripheral artery disease or chronic obstructive pulmonary disease (COPD))?
- What does the current treatment consist of (medication (type and dosage)/concomitant treatment) and to what extent would the treatment impact the exercise programme?
- What is patient's living situation (marital status/social support)?
- What is their social status (daily activities, role in household)?
- Are any problems expected with returning to work? Also see the screening questions in the 'Multidisciplinary guideline on cardiac rehabilitation of 2024'.
- How accessible is the cardiac rehabilitation programme for the patient?
- What is the patient's need for information?

Functions and anatomical characteristics

Inventory of functional disorders (nature and severity) before the onset of the cardiac incident or the deterioration of chronic heart failure

What functional disorders (nature and severity) were there before the onset of the cardiac incident or the deterioration of chronic heart failure?

Inventory of current status

What current functional disorders is the patient experiencing as a result of the coronary artery disease or chronic heart failure?

Activities

Inventory of limitations in activities (nature and severity) before the onset of the cardiac incident or the deterioration of chronic heart failure

- What activity limitations (nature and severity) were there before the onset of the cardiac incident or the deterioration of chronic heart failure?
- What was the patient's activity level before the onset of the cardiac disease?
- What is their exercise behaviour (present, past and future)?

Inventory of current status

- What current limitations is the patient experiencing in their activities as a result of the coronary artery disease or chronic heart failure?
- Are their any problems related to sexuality?
- The patient-specific goal setting (PSK) method includes the following components:

Step 1 'Make an inventory'

What do you find important but challenging to do as a result of your symptoms?

Step 2 'Set priorities'

Note which activities from step 1 are most important to you.

Step 3 'Score' How capable are you of performing these activities? Circle the number (follow the PSG format).

Step 4 'Fix goals' What do you want to achieve with the therapy?

Participation

Inventory of participation problems (nature and severity) before the onset of the cardiac incident or the deterioration of chronic heart failure

What were the limitations for participation (nature and severity) before the onset of the cardiac incident or the deterioration of chronic heart failure?

Was the patient involved in the work process before the onset of the cardiac disease?

Inventory of current status

What current participation problems is the patient experiencing as a result of the coronary artery disease or chronic heart failure?

External factors

Inventory of external factors before the onset of the cardiac incident or the deterioration of chronic heart failure

What challenges did the environment pose to the patient before the onset of the cardiac disease?

Inventory of current status

- What physical exertion does the patient's job require (if applicable)?
- Are there any external thresholds or barriers for developing/maintaining/resuming an active lifestyle?

Personal factors

Inventory of personal factors before the onset of the cardiac incident or the deterioration of chronic heart failure

What did the patient demand from themselves before the onset of the cardiac disease?

Inventory of current status

- How is the patient experiencing the cardiac disease?
- Try to get an idea of the patient's socio-economic status. Ask about their educational level and professional level.
- Try to get an idea of the patient's health literacy.
- Try to get an idea of the patient's cognitive status.
- What consequences does the disease have for their psychosocial functioning (e.g. burn-out, (exercise) anxiety, panic disorders, stress, depression)?
- What illness beliefs does the patient have? (What ails me? Why is that? Personal consequences? How can I influence this myself?)
- Are there any thresholds or barriers to developing/maintaining/resuming an active lifestyle (for example psychosocial factors)?
- What is the patient's motivation for following the exercise programme and for developing/ maintaining/resuming an active lifestyle?
- Try to get an idea of the patient's digital literacy, for example with the help of a <u>QuickScan</u> (Pharos. Landelijk expertisecentrum sociaaleconomische en etnische gezondheidsverschillen).

SUBSTANTIATION

This module was not included in the guideline on the basis of a prioritised barrier. Every guideline of the Royal Dutch Society for Physical Therapy (Koninklijk Nederlands Genootschap voor Fysiotherapie – KNGF) includes a module on 'Medical history taking'.

Reason

Medical history taking starts during the diagnostic process of the exercise programme in phase II of cardiac rehabilitation. This module describes what the medical history taking consists of for patients with coronary artery disease and/or chronic heart failure, on the basis of which the following clinical question was formulated.

Clinical question

What does medical history taking consist of for patients with coronary artery disease and chronic heart failure with an indication for the exercise programme in phase II of Cardiac Rehabilitation?

Rationale of the recommendation

In consultation with the guideline panel it was decided not to carry out any systematic search action, but to gather the information needed for answering this clinical question in a non-systematic way and work it out narratively with the use of the International Classification of Functioning, Disability and Health (ICF) and with the help of the knowledge and clinical expertise of the guideline panel.

This was furthermore aligned with the '<u>Multidisciplinary guideline on Cardiac Rehabilitation</u>' (Multidisciplinaire richtlijn Hartrevalidatie). Based on these screening questions, the cardiac rehabilitation coordinator screens which care offer is indicated. The therapist has a signalling function regarding a number of topics, which can then be discussed in the multidisciplinary cardiac rehabilitation team (NVVC/NHS Rehabilitation Commission and PAAHR 2011 project group).

SOURCES

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B.5 Physical examination and treatment plan

Recommendations

During the physical examination, relevant information should be collected by means of an assessment at rest, a functional assessment and the basic examination.

Through <u>dialogue</u> with the patient, establish a personalised treatment plan based on: 1) the <u>referral details</u> from the cardiologist; 2) information provided by the multidisciplinary team and 3) information that emerges from your own analysis.

Integrate the following treatment goals in this.

For coronary artery disease:

- 1. get to know own physical limits;
- 2. learn to cope with physical limitations;
- 3. optimise exercise capacity;
- 4. overcome fear of physical exertion;
- 5. develop/maintain/resume a physically active lifestyle;
- 6. optimise the back-to-work process (if applicable).

В

For chronic heart failure

Specific goals

- 1. optimise exercise capacity;
- 2. align exertion with capacity;
- 3. reduce fatigue, dyspnoea and inactivity.

General goals

- 1. get to know own physical limits;
- 2. learn to cope with physical limitations;
- 3. overcome fear of physical exertion;
- 4. develop/maintain/resume a physically active lifestyle;
- 5. optimise the back-to-work process (if applicable).

SUBSTANTIATION

This module was not included in the guideline on the basis of a prioritised barrier. Every guideline of the Royal Dutch Society for Physical Therapy (Koninklijk Nederlands Genootschap voor Fysiotherapie – KNGF) includes a module on 'Physical examination and treatment plan'.

Reason

In the diagnostic process of the exercise programme in phase II of cardiac rehabilitation, medical history taking is followed by a physical examination and treatment plan. This module describes what this consists of for patients with coronary artery disease and/or chronic heart failure, on the basis of which the following clinical questions were formulated.

Clinical questions

- What does physical examination consist of for patients with an indication for an exercise programme in phase II of cardiac rehabilitation?
- How are the treatment plan and associated treatment goals established for patients with an indication for an exercise programme in phase II of cardiac rehabilitation?

Rationale of the recommendation

In coordination with the guideline panel it was decided not to carry out any systematic search action, but to gather the information needed for answering this clinical question in a non-systematic way and work it out narratively using the knowledge and clinical expertise of the guideline panel.

Explanation

Physical examination

The aim of the physical examination is to identify functional disorders, activity limitations, participation problems and health issues, which will determine exercise activities in the exercise programme.

The therapist analyses the execution of challenging activities that emerged from the <u>medical</u> <u>history taking</u>. The <u>areas</u> that are essential for the desirable exercise activities are identified, as is the way in which and the level at which these areas can be addressed. The therapist will estimate to what degree performance in an exercise activity is relevant for the particular area.

Treatment plan and treatment goals

The therapist gathers the relevant information by combining the data from the medical history taking and the physical examination. The therapist will then identify the treatment plan. The data needed for establishing the treatment plan will partly come from the multidisciplinary team and referral details from the cardiologist and partly from the therapist's own analysis. Based on the information from the medical history taking and the physical examination, the physical therapist will, through dialogue with the patient, draw up a personalised treatment plan (including treatment goals).

If there is an indication for an exercise programme, various individual cardiac rehabilitation goals will be aimed for. These goals form part of the '<u>Multidisciplinary guideline on cardiac rehabilitation</u> of 2024' (Nederlandse Vereniging voor Cardiologie).

In the following tables, the individual cardiac rehabilitation goals that can be aimed for through an exercise programme are described.

Treatment goals	Description	
1. get to know own physical limits	The patient can cope independently with their own physical limits in everyday life. By confronting the patient with their objective and subjective limits, they learn what their physical capacity is or what their physical limits are.	
2. learn to cope with physical limitations	The patient can cope with their own physical limitations in various exercise situations and during various forms of exertion. By confronting the patient with their physical limitations, they learn how to cope with these. This goal can only be reached if the patient comes to accept the situation. Exercise exertion is dosed in agreement with the patient and may be affected by changes in the type and dosage of medication. Active involvement is desirable in order to translate this dosage into everyday practice.	
3. optimise exercise capacity	The patient reaches the desirable level of physical functioning, or the patient's exercise capacity improves to such an extent that they can function at their desirable or feasible level during activities of daily living, work, sport and/or hobbies.	
4. overcome fear of physical exertion	The patient has a positive or successful exercise experience in the situation that originated after the cardiac event, which reduces their fear of exertion both durir and after cardiac rehabilitation, (which in turn increases the chance of returning to work and resuming sport and/or hobbies).	
5. develop/maintain/ resume a physically active lifestyle	The patient develops pleasure in exercising. The therapist helps the patient to be active at home. The patient learns to integrate exercise activities in their daily lifestyle. This reduces the 'inactive lifestyle' risk factor. The aim is for the patient to start experiencing activities as a fixed habit, so that they will continue with it in the post-rehabilitation phase (phase III).	
6. optimal return to work	The patient reaches their optimal/required capacity, a condition to resume activities (if applicable), whether or not in an adapted work environment.	

For patients with coronary artery disease

Chronic heart failure				
Specific treatment goals	Description			
1. optimise exercise capacity	The patient reaches the desirable level of physical functioning, or the patient's exercise capacity improves to such an extent that they can function at their desirable or feasible level during activities of daily living, work, sport and/or hobby. For New York Heart Association (NYHA) class III patients, training will mainly be aimed at maintaining exercise capacity and teaching the patient to use their limited energy wisely. For NYHA class II patients, the aim is to improve exercise capacity to such an extent that the patient can function at the desirable or feasible level during activities of daily living, at work or when doing sport or hobbies.			
2. align exertion with capacity	The patient learns to strike a balance between exertion and capacity, can spread out exertion and relaxation (work/rest) during the day and recognises signs of overexertion or deterioration of chronic heart failure.			
3. reduce shortness of breath, fatigue and inactivity.	The goal is to recognise, reduce and learn how to cope with shortness of breath, fatigue and inactivity (improved breath control, breathing calmly). Making efficient use of capacities and limited energy is essential to prevent (severe) fatigue. The patient is stimulated as much as possible to remain active (preventing de-conditioning).			
General goals	Description			
 get to know own physical limits 	The patient can cope independently with their own physical limits in everyday life. By confronting the patient with their objective and subjective limits, they learn what their physical capacity is or what their physical limit are.			
2. learn to cope with physical limitations	Confront the patient with their physical limitations in different exercise situations and during various forms of exertion and have them learn how to live with these limitations. For NYHA class III patients, this confrontation can already take place during ADL activities. This goal can only be reached if the patient comes to accept the situation. Exercise exertion is dosed in agreement with the patient and may be affected by changes in the type and dosage of medication. Active involvement is desirable in order to translate this dosage into everyday practice.			
3. overcome fear of physical exertion	The patient has a positive or successful experience of exercise, which reduces their fear of exertion both during and after cardiac rehabilitation. The patient indicates that they feel less uncertain by gaining experience during exercise, by learning and doing, at a continuously higher level.			
4. develop/maintain/ resume a physically active lifestyle	The patient develops or maintains a sense of enjoyment in exercise, so that they will also adopt or keep up an active lifestyle at home, which will reduce risk factors. The patient learns to integrate exercise activities in their lifestyle and to recognise symptoms of deterioration or decompensation in time. The aim is for the patient to start experiencing activities as an established habit, so that they will continue with it in the post- rehabilitation phase (phase III).			
5. optimal return to work	The patient reaches their optimal/required capacity, a condition to resume their activities (if applicable), whether or not in an adapted work environment.			
During the exercise programme (if possible), goals the supported by other disciplines are often pursued as well, such as 'regaining an emotional balance' and 'learning to cope with cardiac disease in a functional manner'.

For nearly all patients, a combination of goals is pursued. If 'improvement of exercise capacity' is not considered feasible (enough), other goals such as 'learning to recognise one's own physical limits' and 'learning to cope with physical limitations' will in any event be taken into account. For these goals, self-management is very important.

If the set goal of 'improving exercise capacity' is feasible, the goals of 'learning to recognise one's own physical limits' and/or 'optimising exercise capacity' are strived for.

To be able to strive for optimisation of exercise capacity, the training intensity must first be established. The therapist will preferably establish this based on the outcomes of the maximum or symptom-limited exertion test (with breath gas analysis if applicable). The 'Multidisciplinary guideline on Cardiac Rehabilitation' describes the considerations on the basis of which a maximum or symptom-limited exertion test (with breath gas analysis if applicable) is taken (NVVC/NHS Rehabilitation Committee and PAAHR project group). When determining the training intensity, the therapist also takes into account physical barriers to increasing capacity, other (internal and external) factors that will negatively impact the natural ability to adjust capacity and personal training goals. If there is any question of a subjective diminishing of exercise capacity, the treatment can be aimed at 'leaning to recognise one's own physical limits', 'overcoming fear of exertion' and 'developing/maintaining a physically active lifestyle'. 'Learning to recognise one's own physical limits' and 'developing/maintaining a physically active lifestyle' are often strived for in the first place. Patients must, after all, overcome their fear of exertion and get to know their limits before they can be trainable.

Stimulating the development of a physically active lifestyle is important for almost all patients. Already during cardiac rehabilitation, the patient will be advised to start doing exercise or sport on their own.

Returning to work is an important goal in cardiac rehabilitation, and during rehabilitation the patient is already encouraged to resume their job gradually in consultation with the company doctor. The therapeutic care is aimed at identifying physical capacity, removing any (physical) limitations that might stand in the way of returning to work and advising on (possible) adaptations that would optimise the return to work.

The treatment goals must be formulated as concretely as possible at the start of the treatment programme. For example, the goal of 'overcoming fear of exertion' could be defined more specifically as 'the patient can once again cycle on their own in the street' or 'the patient has resumed their sex life'.

Specific treatment goals for chronic heart failure

The specific treatment goals for patients with chronic heart failure apply to all chronic heart failure patients. When pursuing specific goals, general goals must be taken into account. General goals 1 and 2 must, for example, lead to the effective alignment of the relationship between burden and capacity.

If the subjective exercise capacity is reduced, the treatment will focus on treatment goal 1 and/ or 3. The challenges indicated in the goals will often be the starting point. To be trainable and to prevent further deconditioning, the patient will, for instance, first have to overcome their fear of exertion and learn to recognise their own limits. Improving exercise capacity is not always feasible for patients with chronic heart failure (especially NYHA class III–IV). Research shows that for a substantial part of heart-failure patients, peak VO₂ does not increase through training (Kemps 2008; Wilson 1996). The goal can also be to improve the maintaining of (sub)maximal exercise capacity, or to maintain the current exercise capacity in order to prevent deconditioning.

Stimulating the development of an active lifestyle is always an important goal. During training, the therapist teaches the patient to recognise symptoms of overexertion and decompensation.

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B.6 Measurement instruments

Recommendations

Use the Patient-Specific 'Goal-setting' method (PSG) with all patients to diagnose, monitor and evaluate the therapeutic treatment, unless there is a patient-specific reason not to do so. If these are not yet in your possession, ask for the results of the maximum or symptom-limited exertion test (with beath gas analysis if applicable) from the cardiologist.

Recommended measurement instruments

Domain	Measurement instrument
maximum exercise capacity ^a	maximum or symptom-limited exertion test (if applicable with a breath gas analysis).
activities and participation during ADL	PSG

 a. This test is performed by a doctor or by a trained professional under the supervision of a doctor and contains essential information for the physical or exercise therapist.
 ADL = activities of daily living; PSG = patient-specific goal-setting.

ADE - activities of daily living, FSG - patient-specific goal-settin

Use the optional measurement instruments if there is a patient-specific reason to identify the domain and/or it is relevant for reaching the patient's individual cardiac rehabilitation goals.

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Domain	Measurement instrument
physical capacity (functional exercise capacity) to evaluate dosage of training	Six Minute Walk Test (6MWT) ^{a,b,c} Steep Ramp Test (SRT)
subjective exercise capacity ^d	Metabolic equivalent of task (MET) method
muscle strength	'One-Repetition' maximum test (1RM)
respiratory muscle function	Maximal Inspiratory Pressure (MIP)
subjectively perceived exertion ^d	Borg Rating of Perceived Exertion (RPE) scale (6–20)
dyspnoea	Dyspnoea scale
angina pectoris	Angina Pectoris (AP) scale
blood pressure	Validated blood pressure monitors
oxygen saturation (at rest and during exercise)	Saturation measurement
daily physical activity	Short Questionnaire to Assess Health-enhancing physical activ- ity (SQUASH) and/or activity monitors
anxiety (cardiac-related)	Cardiac Anxiety Questionnaire (CAQ)
anxiety (kinesiophobia)	Tampa Scale for Kinesiophobia (TSK (NL-heart))

a. If the 6MWT or SRT is too difficult for the patient, the Timed Up and Go (TUG) test can be an alternative.

b. If the 6MWT is too easy for the patient, the Shuttle Walk Test (SWT) can be an alternative. For patients with coronary artery disease use the SWT, and for patients with chronic heart failure use the test protocol of the modified SWT, which starts at three kilometres/hour (Hollywood score list).

c. Based on the clinical expertise of the therapist and the preference of the patient, it will be decided in consultation which test can be used as an alternative for the 6MWT.

d. The subjective exercise capacity, revealed through the MET method, can, for example, be used to determine a discrepancy between the subjective and objective exercise capacity. The subjectively perceived exertion during an exertion performed by the patient can be revealed through the BORG.

SUBSTANTIATION

This module was not included in the guideline on the basis of a prioritised barrier. Every guideline of the Royal Dutch Society for Physical Therapy (Koninklijk Nederlands Genootschap voor Fysiotherapie – KNGF) includes a module on 'Measurement instruments'.

Reason

Medical history taking and physical examination start during the diagnostic process of the exercise programme in phase II of cardiac rehabilitation. For this, measurement instruments are used. This module describes which measurement instruments are used for patients with coronary artery disease and/or chronic heart failure, on the basis of which the following clinical question was formulated.

В

Clinical question

Which measurement instruments will best identify the different domains of the International Classification of Functioning Disability and Health (ICF) (namely: body functions and structures, activities, participation and personal factors) and individual physical rehabilitation goals (recommended and optional measurement instruments) for patients with coronary artery disease or chronic heart failure?

Conclusions based on the literature

To answer the clinical question, current Dutch and European guidelines for cardiac rehabilitation were consulted in a systematic way. A non-systematic literature review was also performed. The guideline panel considers that – divided according to ICF domains – the following domains are important:

body functions and structures: maximum exercise capacity, physical capacity (functional exercise capacity), subjective exercise capacity, muscle strength, respiratory muscle function, subjectively perceived exertion, fatigue, dyspnoea, angina pectoris, blood pressure, oxygen saturation; activities and participation: activities and participation during ADL, physical activities; external factors: none;

personal factors: anxiety.

Rationale of the recommendation

This question was answered by describing the recommended and optional measurement instruments that can be used during the diagnostic and therapeutic process. The Clinimetric Framework for Evidence-based Products was used for this (Swinkels 2016). The information was obtained in a non-systematic manner and developed narratively with the help of the guideline panel's knowledge and clinical expertise.

Maximum exercise capacity

Maximum or symptom-limited exertion test (if applicable with a breath gas analysis). Upon indication from the cardiologist, the maximum or symptom-limited exertion test will be performed, if applicable with a breath gas analysis (spiro-ergometry) (Nederlandse Vereniging voor Cardiologie). This test is performed by a doctor or by a trained professional under the supervision of a doctor and is considered the golden standard for objectively assessing maximum exercise capacity. The exertion test is mostly used diagnostically and ideally combined with a test to evaluate physical capacity (functional exercise capacity). See further down.

The maximum or symptom-limited exertion test will give the maximum exercise tolerance of the patient in terms of maximum exercise capacity (in watt). Exercise capacity can also be expressed as a percentage of the predicted capacity and can, if necessary, be converted into METs (MET stands for 'metabolic equivalent of task').

During the maximum or symptom-limited exertion test, the following physiological parameters are determined: maximum heart rate reached, blood pressure sequence, Borg score (6-20) and the result of the stress electrocardiogram. Upon indication from the cardiologist, the maximum or symptom-limited exertion test will be combined with a breath gas analysis (spiro-ergometry). Based on the breath gas analysis, the peak VO_2 (volume of oxygen) can be determined. In addition, a specific submaximal exercise capacity can be estimated by determining the ventilatory

threshold. An idea can also be formed of the respiratory efficiency and the possible presence of a respiratory inefficiency (VE/VCO₂ slope or 'oxygen uptake efficiency slope' and respiratory oscillations) or indications of a pathology (chronic obstructive pulmonary disease (COPD)). It is also possible from physiological parameters to get an idea of the reasons why a test is stopped or interrupted and what the possible cause (pulmonary, cardiac or peripheral) of the exertion cap might be. It is also possible to get an idea of movement anxiety.

Various protocols exist for the maximum or symptom-limited exertion test, differences in performance (walking or cycling) but also in duration, stress caps, progression of physical load, the way in which intensity is increased, wattage, speed and percentage of the slope.

Physical capacity (functional exercise capacity)

To assess functional exercise capacity objectively, the Six–Minute Walk Test (6MWT), the Shuttle Walk Test (SWT), the Steep Ramp Test (SRT) and the Timed Up & Go (TUG) test were considered. These four tests correlate well with the maximum or symptom–limited exertion test (with breath gas analysis if applicable) and are reproducible and easy to execute for the patient and the therapist. The safety of the SRT was not examined at a large scale.

Subjective exercise capacity

By means of the MET method and/or Specific Activity Scale (SAS), the therapist can estimate whether a discrepancy between actual and desirable performance capacity can be addressed with an adequate exercise programme in phase II of cardiac rehabilitation. The MET method scores well on validity and reliability. The validity of the SAS was not investigated, but its reliability is good for cardiac patients. The patient is classified according to the metabolic equivalent of task.

Muscle strength

For the inventory-taking and evaluation of strength-related limitation, the Hand-held Dynamometer (HDD) and 'One-repetition' maximum test (1RM) were analysed. The validity, including the differentiation between the low and high muscle strength of the 1RM and of the sub-maximal version thereof, is lower than that of the more objective methods such as HHD. Standard values and reference formulas are available for HHD measurement. There are no standard values for 1RM tests, and the measured values are to a large extent dependent on the equipment used, which is why these tests cannot be used for diagnostic purposes.

Respiratory muscle function

A 'Maximal Inspiratory Pressure' (MIP) measurement can reliably be measured with a respiratory muscle function monitor if the difference between three repetitions is less than 10%. This measurement is recommended for patients with coronary artery disease and a ventilatory limitation (for example after a bypass operation or with chronic obstructive pulmonary disease (COPD)) or chronic heart failure.

Subjective rating of exertion

The 'Borg Rating of Perceived Exertion' (RPE) scale (6–20) can be used to monitor the subjectively perceived exertion by a patient when doing an exercise activity. The Borg scale is reliable and can help with estimating the perceived exertion, extent of the physical load and degree of fatigue of the cardiac patient.

Dyspnoea

The Dyspnoea scale can be used to quantify the perception of dyspnoea. Dyspnoea is a frequently heard complaint among patients with chronic heart failure with COPD as a comorbidity. When dyspnoea occurs, the scale can be introduced during training. The patient can indicate in four degrees to what extent they experience the symptom. For each degree, a description is given.

Angina pectoris

The Angina Pectoris (AP) scale appeared to be fit for purpose and can be used to monitor whether there are symptoms as a result of (rest) ischemia of the cardiac muscle.

Blood pressure

To monitor blood pressure, at rest or during exertion, various approved blood pressure monitors are available. Digital blood pressure monitors are easy to use.

Oxygen saturation

For patients with a ventilatory limitation, measuring oxygen saturation (SpO₂) can be indicated, such as for patients with coronary artery disease and COPD or patients with chronic heart failure (with COPD). A fingertip oximeter is reliable and handy to use.

Activities and participation in ADL

For measuring activities and participation in ADL, the Patient-Specific Complaints (PSC) and the Patient-Specific Goal-setting method (PSG) were assessed for manageability and clinimetric quality. The PSC is easy to use. It does not take a lot of time to complete, requires hardly any additional expertise or experience on the part of the therapist and demands minimal effort from the patient. The PSG is the updated version of the PSC. The PSG is especially suitable for setting goals together with the patient. Training is required for correct application of the instrument in practice. No research was done on the validity, responsiveness and reproducibility of the Dutch version of the PSC for cardiac patients. The English version was found to be valid, reliable and responsive for patients with osteoarthritis of the hip or knee. No research on the clinimetric quality of the PSG was found.

Physical activity

For the identification of exercise behaviour, the Dutch Standard for Healthy Exercise (Nederlandse Norm Gezond Bewegen or NNGB) questionnaire, the International Physical Activity Questionnaire (IPAQ), the Short Questionnaire to Assess Health–enhancing physical activity (SQUASH) and an Assessment of Physical Activity and Energy Expenditure (PAEE) were evaluated. Although questionnaires are not the ideal way to assess cardiac patients' exercise behaviour objectively, SQUASH appears to be the most feasible. Research is continuing on the clinimetric quality of activity monitors to identify PAEE, for instance applications on smartphones. Inaccuracy, limited clinical validity, a lack of standardised regulatory policy and concerns over patients' privacy however still seem to limit the widespread use of smart portable technologies in clinical practice. On the other hand, user-friendliness and the social acceptability of activity monitors, such as step counters, is a factor, and these developments have the potential to contribute to cardiac patients' exercise behaviour.

В

(Cardiac and exercise) anxiety

To measure anxiety, the Hospital Anxiety and Depression Scale (HADS), the Cardiac Anxiety Questionnaire (CAQ) and the Tampa Scale for Kinesiophobia (TSK NL-heart) were assessed in terms of manageability and clinimetric quality. The HADS and TSK NL-heart show good validity, reproducibility and responsiveness and are manageable for the patient and the therapist. The CAQ has good validity and reproducibility, but the cut-off value and responsiveness are unknown.

JUSTIFICATION

Literature

To answer the clinical question, current Dutch and European guidelines for cardiac rehabilitation were consulted in a systematic way. The prioritisation of the measurement instruments is described in step 3. A non-systematic literature review was also performed in addition.

The guideline differentiates between (a) recommended measurement instrument(s) and optional measurement instruments.

The literature that was found was analysed according to the method of the Clinimetric Framework for Evidence-based Products (Raamwerk Klinimetrie voor evidence-based products) (Swinkels 2016). The framework describes a step-by-step plan with which measurement instruments can be selected in a goal-oriented manner in eight steps by means of an iterative process. The steps are:

- Step 1 What do you want to measure?
- Step 2 Why do you want to measure?
- Step 3 With what kind of measurement instrument do you want to measure?
- Step 4 How will you find a measurement instrument?
- Step 5 How manageable is it?
- Step 6 What is the clinimetric quality?
- Step 7 Are standard values available?
- Step 8 How do you calculate and interpret the data?

Step 1 'What do you want to measure?'

When choosing measurement instruments in the scope of personalised care, the patient's language comprehension and cognition must be taken into account, but also their physical capacity.

The following relevant domains are formulated and subdivided according to the International Classification of Functioning Disability and Health (ICF):

body functions and structures: maximum exercise capacity, physical capacity (functional exercise capacity), muscle strength, respiratory muscle function, subjectively perceived degree of exertion, dyspnoea, angina pectoris, blood pressure and oxygen saturation; activities and participation: activities and participation during activities of daily living (ADL), physical activities;

external factors: none;
 personal factors: anxiety.

Step 2 'Why do you want to measure?'

All of the domains listed in step 1 can be measured with both a diagnostic goal and an evaluative goal (including monitoring). Evaluation of the individual cardiac rehabilitation goals is central here. There are no domains that can explicitly be measured with a prognostic goal. The maximum or symptom-limited exertion test is mostly used diagnostically and ideally combined with a test to evaluate physical capacity (functional exercise capacity). The therapist can thus adapt the dosage of the training and assess the impact thereof.

Step 3 'With what kind of measurement instrument do you want to measure?'

Appendix B.6–1 lists the measurement instruments from relevant Dutch cardiac rehabilitation guidelines as well as guidelines and position statements from the European Society of Cardiology (ESC). Appendix B.6.–2 contains measurement instruments for each individual rehabilitation goal, described by Achttien and Vromen (2015) (Achttien 2015). These measurement instruments are mostly based on the prioritisation that is described in Appendix B.6–1. The guideline panel decided to analyse the measurement instruments from these appendices and to supplement this with an analysis of measurement instruments that were found through a narrative search per domain in various data banks. From the additional literature search, the following measurement instruments emerged:

- the Patient-Specific Goal-setting (PSG) method;
- the Tampa scale for Kinesiophobia (TSK NL-heart) and the Cardiac Anxiety Questionnaire (CAQ);
 the Steep Ramp Test (SRT);
- the Short Questionnaire to Assess Health-enhancing physical activity (SQUASH).

Maximum exercise capacity

Exercise capacity can objectively be assessed as maximum and functional exercise capacity. For the objective assessment of maximum exercise capacity, the maximum or symptom-limited exertion test (with breath gas analysis if applicable) is recommended. If indicated by the cardiologist, the maximum or symptom-limited exertion test will be performed, if applicable with a breath gas analysis (spiro-ergometry) (Nederlandse Vereniging voor Cardiologie 2024).

Physical capacity (functional exercise capacity)

For the objective assessment of functional exercise capacity, an analysis was made of the Six Minute Walking Test (6MWT) (Du 2009), the (modified) Shuttle Walk Test (SWT) (Morales 1999), the Steep Ramp Test (SRT) (Meyer 1996) and for older adults (Bellet 2013) and low-tolerance patients with chronic heart failure (Hwang 2016), the Timed Up & Go test (TUG).

Subjective exercise capacity

To estimate subjective exercise capacity, the metabolic equivalent of task (MET) method (Ainsworth 2011, 1993) and/or the Specific Activity Scale (SAS) (Goldman 1981) were analysed.

Muscle strength

To assess muscle strength objectively, the Hand-Held Dynamometer (HHD), the One-Repetition maximum test (1RM) and the 6RM or 10RM submaximal test were analysed.

Respiratory muscle function

For an objective assessment of the respiratory muscle function in patients with chronic heart failure, the Maximal Inspiratory Pressure (MIP) was analysed.

Subjective rating of exertion

To render a subjective rating of exertion during training objective, the Borg RPE scale (6–20) for 'Fatigue' was analysed (Borg 1982).

Dyspnoea

To identify dyspnoea, the Dyspnoea scale was analysed (Roitman 2001).

Angina pectoris

To estimate cardiac ischemia (during rest intervals), the Angina Pectoris (AP) scale was analysed (Christensen 2006).

Blood pressure

To measure blood pressure, various blood pressure monitors were analysed.

Oxygen saturation

For patients with a ventilatory limitation, measuring oxygen saturation (SpO_2) can be indicated, such as for patients with coronary artery disease and COPD as a comorbidity or patients with chronic heart failure (with COPD). SpO_2 can be used to determine whether to start the training, adapt the intensity during exertion or stop the exercise. SpO_2 is also measured to determine saturation recovery after exercise. The transcutaneous non-invasive measurement of SpO_2 using a saturation monitor on a finger, earlobe or forehead was analysed (Garvey 2016).

activities and participation in ADL

To assess activities and participation in ADL objectively, the Patient-Specific Complaints (PSC) and the Patient-Specific Goal-setting method (PSG) were analysed.

Physical activity

To assess exercise behaviour objectively, activity monitors and the following questionnaires were analysed: the Dutch Standard for Healthy Exercise (Nederlandse Norm Gezond Bewegen or NNGB) questionnaire/TNO monitor, the International Physical Activity Questionnaire (IPAQ), the Short Questionnaire to Assess Health-enhancing physical activity (SQUASH) and the Assessment of Physical Activity and Energy Expenditure (PAEE).

(Cardiac and exercise) anxiety

To measure anxiety objectively, the Hospital Anxiety and Depression Scale (HADS), the Cardiac Anxiety Questionnaire (CAQ) and the Tampa Scale for Kinesiophobia (TSK NL-heart) were analysed.

Step 4 'How will you find a measurement instrument?'

All of the measurement instruments listed in this guideline are available or can be made available via www.meetinstrumentenzorg.nl.

Step 5 'How manageable is it?'

Maximum exercise capacity

The maximum or symptom-limited exertion test (with breath gas analysis if applicable) is a reliable way to determine maximum exercise capacity. Upon indication from the cardiologist, the maximum or symptom-limited exertion test will be performed, combined with a breath gas analysis (spiro-ergometry) if necessary. These indications are described in the 'Multidisciplinary guideline on Cardiac Rehabilitation of 2024' (Nederlandse Vereniging voor Cardiologie).

Physical capacity (functional exercise capacity)

The 6MWT is a simple test that can be used with cardiac patients to determine sub-maximal exercise capacity (Du 2009; Pollentier 2010). The 6MWT is a self-paced test and is the most commonly used test in practice in the Netherlands. The test is considered to be very manageable. The SWT is a sub-maximal exertion test that can be used to determine cardiac patients' functional capacity or exertion tolerance (Keell 1998; Morales 1999, 2000). The SWT is often preferred for patients who have an inherently faster walking speed. The modified SWT is validated by cardiac patients and starts at a walking speed of 3.0 km/h (kilometres per hour). This take-off speed is not feasible for all patients with chronic heart failure. For this reason, the protocol starting at a walking speed of 1.8 km/h can also be chosen. The choice of take-off speed is made by the patient in consultation with the therapist (but the speed at pre-measurement and post-measurement must be the same).

The SRT is a short maximum exertion test on a calibrated exercise bike to measure aerobic capacity. During the test, the workload is increased rapidly in a short time (standard 25 W/10 sec.) until the patient is exhausted (Meyer 1996). Based on the test result, an estimate can be made of the peak VO₂ (maximum oxygen uptake) and Wmax (maximum exercise capacity) as measured through a regular maximum or symptom-limited exertion test (with breath gas analysis if applicable), by means of a regression equation. This test can be used to determine training intensity. However, it was not examined whether its quality was sufficient in terms of the patient's safety.

The TUG is practical and simple to perform and should be repeated twice (Mesquita 2016). The measurement instrument is ADL-specific and can be used to measure functional exercise capacity if other exercise tests are not possible, for example due to limited workload tolerance in frail older adults (Bellet 2013) and for patients with chronic heart failure (Hwang 2016) or for example at home (Mesquita 2016). The TUG also provides insight into the activities 'standing up from a chair' and 'walking'. The TUG is considered to be very manageable.

Subjective exercise capacity

By means of the MET method (Ainsworth 2011, 1993) and or SAS (Goldman 1981), the therapist can estimate whether a discrepancy between actual and desirable performance capacity can be addressed with an adequate exercise programme in phase II of cardiac rehabilitation. The SAS scores the functional status of patients with cardiac disease based on four questions in order to divide them into four groups. The questionnaire can be taken in 3 minutes. The MET method offers the possibility to indicate the metabolic workload of motor activities, depending on the person's body size. For a person, 1 MET equals basic metabolism during rest for that person. The number of METs for a specific motor activity is the relation between metabolism for the activity and metabolism during rest. Both measurement instruments are easy to handle.

Muscle strength

Measuring the strength endurance of large muscle groups is very important for assessing peripheral muscle strength in patients with coronary artery disease or chronic heart failure. The HDD does not take much time to measure. In daily practice, the HHD is a small, portable instrument that is easy to use for a quick measurement. The instrument is relatively inexpensive compared to isokinetic dynamometers, which are considered to be the golden standard but which require special knowledge, skill and equipment (Schrama 2014). No HHD measurement of the upper extremity (e.g. shoulder abduction) is recommended; this is considered to be less relevant than measurement of the lower extremity. The HDD is considered to be sufficiently manageable. The maximum amount of weight that can correctly be displaced in one repetition maximum (1RM) over a specific movement trajectory is an often-used measure for calculating resistance in strength training. Since a 1RM measurement puts too much strain on cardiac patients, a pyramid curve can be used to estimate the (maximum) muscle strength without requiring the patient to do 1RM. Based on the pyramid curve, the number of repetitions can be correlated with the (maximum) muscle strength. Determining the number of RM depends on the type of exercise, the speed of execution and the age of the patient.

The 1RM maximum test can also be taken in a short time (Kaelin 1999). No additional equipment needs to be acquired for the measurement if the therapist already has strength equipment with precision settings. In contrast to the HHD, the 1RM cannot be used for diagnostic purposes. The 1RM can be used to help determine the training intensity for training on the same strength equipment as is used to conduct the measurement (Morree 2006). The 1RM is considered to be sufficiently practical.

Respiratory muscle function

For an MIP measurement of patients with chronic heart failure, the acquisition of a respiratory muscle function monitor is essential (Basso-Vanelli 2018). A measurement is reliable if three repetitions differ from each other by less than 10%. If the cardiac rehabilitation centre already has a respiratory muscle function monitor, this measurement instrument is considered to be manageable. During inspiratory breath training, which can be indicated for these patients, the threshold device can be used (Dall'Ago 2006; Mello 2012).

Subjective rating of exertion

The RPE scale is a 15-point scale (6-20) that is used to assess subjective experience during physical exertion (Borg 1982). This subjective exertion scale can help to estimate the degree of exertion, the extent of the physical load and the fatigue of the patient. The Borg scale can, for example, support cardiac patients in doing sensible exercise. It is a short, simple scale that is used very often by therapists in the Netherlands. The Borg Scale is considered to be very manageable.

Dyspnoea

Dyspnoea can be identified during training by means of the Dyspnoea scale (Roitman 2001). The patient can indicate in four degrees to what extent they experience the symptom. For each degree, a description is given. The patient can give a score from 1+ up to 4+. The following categories are given: 1) 'mild, noticeable for the patient, but not to an observer', 2) 'mild, slight problems, noticeable to an observer', 3) 'moderate problems, but can continue' and 4) 'severe problems, patients needs to stop'.

Angina pectoris

The AP scale is easy to use in practice (Austen 1975; Campeau 2002, 1976). Angina pectoris is an absolute or in some cases a relative contraindication (for patients with ischemic symptoms during rest intervals) for taking part in exercise activities.

Blood pressure

Various validated blood pressure monitors exist. The Hartstichting (Dutch heart foundation) has published a list on its <u>website</u> of <u>reliable blood pressure monitors</u> (visited on 11–1–2022). Blood pressure monitors with a digital reading are easy to use.

Oxygen saturation

Transcutaneous Sp0₂ can be measured easily and quickly in practice using a finger or earlobe. An oxygen saturation meter must be acquired, but the costs of this are low. The oxygen saturation meter is considered to be very manageable due to this.

Activities and participation in ADL

The PSK is used as a measurement instrument to determine the functional status of the individual patient. The patient selects the three to five most important complaints with regard to physical activities. These activities must be relevant (important), the patient must find them difficult to perform and they must be done regularly (weekly) (Beurskens 1999).

The PSG is the updated version of the PSC. The PSG can be used as a measurement instrument, but at the same time also as a method to set goals together with the patient (Stevens 2013, 2017). With the PSG, the PSC is taken immediately, so that the setting of goals becomes a more integral part of the therapeutic methodical approach (Stevens 2018). All that is needed are the – freely available – questionnaire and a pen. Depending on the target group and the time it takes to select activities, it takes an average 5 to 15 minutes to take the PSG (Beurskens 1999). Because the PSG is part of the methodical approach, taking it does not require additional time, which makes the PSG very manageable (Stevens 2017).

Physical activity

The Nederlandse Norm Gezond Bewegen (NNGB) questionnaire (Douwes 2000) and the International Physical Activity Questionnaire (IPAQ) (Treskes 2017), the Short Questionnaire to Assess Health-enhancing physical activity (SQUASH) (Wendel-Vos 2003) and activity monitors such as exercise monitors, step counters and smartwatches, and the Assessment of Physical Activity and Energy Expenditure (PAEE) (Hills 2014)) can be used to rate exercise activity. The TNO monitor (NNGB) has been included in the decision tree for indication for outpatient cardiac rehabilitation (Nederlandse Vereniging voor Cardiologie 2012). The IPAQ is used to estimate the physical activity level. The questionnaire consists of 31 questions divided into five sub fields and takes about 8 minutes to fill in. The SQUASH is based on the Dutch standard for healthy exercise (Nederlandse Norm Gezond Bewegen). The questionnaire includes 11 items that must be filled in by the respondent themselves. PAEE methods are diverse, which is why the choice will depend on the patient's preferences and rehabilitation goals.

(Cardiac and exercise) anxiety

The HADS can be used to measure depression and anxiety both in a hospital setting and in daily practice for various target groups ((Zigmond 1983). The questionnaire consists of 14 items that are divided equally over the sub-scales 'Anxiety' (HADS-A) and 'Depression' (HADS-D). The HADS

does not adequately detect the presence of specific anxiety or depressive disorders and is not a medical diagnostic tool or a good predictor of specific diagnoses, but does provide indications for generalised symptoms of anxiety and depression (Julian 2011). The HADS is easy to use. It's a short questionnaire that takes 2 to 5 minutes to complete. The HADS is an often used questionnaire for quickly and easily assessing psychological symptoms and is considered to be very manageable. The CAQ is a reliable and valid instrument to assess cardiac anxiety in patients who have been hospitalised with acute coronary artery syndrome (Eifert 2000; Van Beek 2012). The CAQ is a self-reporting measurement tool with 18 items that evaluate anxiety in relation to cardiac symptoms. The TAMPA can be used to identify kinesiophobia (Acar 2016; Kese 2022; Monticone 2015). The TSK NL-heart was specifically designed and validated for the cardiac population (Keessen 2020). This questionnaire can be used to find out if the cardiac patient's activity level is affected by fear of heart injury or tissue damage, which may cause avoidance behaviour. The questionnaire consists of 13 items, where a high score indicates a high degree of exercise anxiety (Keessen 2020).

Step 6 'What is the clinimetric quality?'

Maximum exercise capacity

The maximum or symptom-limited exertion test (with breath gas analysis if applicable) is an instrument that is suitable for measuring maximum exercise capacity and is therefore considered to be the gold standard in this regard (Hansen 2015; Nederlandse Vereniging voor Cardiologie 2024). The test-retest reliability of the maximum or symptom-limited exertion test (with breath gas analysis if applicable) for measuring peak VO₂ in people with coronary artery disease or chronic heart failure is good.

Physical capacity (functional exercise capacity)

Both the 6MWT (Du 2009; Pollentier 2010) and the (modified) SWT (Keell 1998; Morales 1999, 2000) appear to be suitable for measuring sub-maximal exercise capacity and are valid, reliable and responsive measurement instruments. The clinimetric quality of the 6MWT and the (modified) SWT are seen as good.

The SRT is valid and reliable for determining peak VO₂ and training wattage. It correlates well with the maximum or symptom-limited exertion test (with breath gas analysis if applicable) (Chura 2012; Meyer 1996; Takken 2008). However, these studies did not include any cardiac patients. The TUG is suitable for measuring functional tolerance in low-tolerance cardiac patients, patients with chronic heart failure (Hwang 2016) and older patients (Bellet 2013). A significant correlation was demonstrated between the TUG and the 6MWT (Bellet 2013). The test-retest reliability is good.

Subjective exercise capacity

The validity of the SAS was not investigated, but its reliability is good for cardiac patients (Goldman 1981; Lee 1988). The patient is classified according to the metabolic equivalent of task. The MET method scores well on validity and reliability (Ainsworth 1993).

Muscle strength

The validity, including the differentiation between low and high muscle strength of the 1RM and of the sub-maximal version thereof, is lower than that of more objective methods such as HHD (Schrama 2014). The HHD appears to be valid from a systematic literature review (Stark 2011). The inter-rater reliability of the HDD for measuring the upper extremity is good (Schrama 2014).

The indirect determining of 1RM was validated within the cardiac patient population (Barnard 1999; Ellis 2019; Reynolds 2006). 4–6RM is reliable; 1–3RM gives a too heavy physical load and >7RM is less reliable for patients with good tolerance who suffer from coronary artery disease. For low-tolerance patients, such as patients with severe comorbidity, 10RM can be determined reliably.

Respiratory muscle function

The MIP measurement is suitable for determining and evaluating maximal inspiratory muscle strength (Basso-Vanelli 2018). The measurement is reliable in patients when multiple measurements are taken and the measurement is done by an experienced healthcare professional. The reliability can be negatively influenced in the presence of hyperinflation and/or a severe obstruction (for example in patients with COPD). The clinimetric properties of MIP measurement are considered to be sufficient due to this.

Subjective rating of exertion

The Borg RPE Scale (6–20) is valid and correlates well with heart rate (Chen 2002; Scherr 2013). It is not clear what the effect of medication is on the correlation between the Borg RPE scale and heart rate.

Dyspnoea

The Dyspnoea scale shows a significant overlap with the New York Heart Association (NYHA) classification.

Angina pectoris

The inter-rater reliability of the AP scale is good and the validity is adequate (Christensen 2006).

Blood pressure

Various validated blood pressure monitors exist, each with their own specific handling protocol. For the clinimetric properties of blood pressure monitors, please refer to the list of the Dutch heart foundation (Hartstichting website bezocht op 11–11–2022).

Oxygen saturation

At about 4%, the precision of the oxygen saturation monitor (Amalakanti 2016) is sufficient for detecting a significant decrease in oxygen saturation. Although there are signs that the measurement in COPD patients overestimates the SpO_2 value ((Amalakanti 2016), the finger saturation monitor is accepted as a reliable instrument (Hess 2016; Nitzan 2014). The measurement can be unreliable with an abnormal haemoglobin content, during exercise and when wearing nail polish or when the finger is cold (decreased peripheral circulation) (Hess 2016; Nitzan 2014). In this case, the measurement can be repeated elsewhere on the body, for example an earlobe or with an adhesive sensor on the forehead. There are also practical considerations when choosing a specific measurement location. Measuring on the forehead appears to be closer to the arterial oxygen saturation (SaO_2) than on the finger, but both sensors detect exercise–related desaturation (Wilson 2013). The clinimetric quality of the saturation meter is considered to be sufficient.

Activities and participation in ADL and physical exercise

The methodological quality of the PSC was deemed to be good but was studied mostly in target groups other than cardiac patients (Berghmans 2015; Hall 2011; Rollman 2010). The validity and responsiveness of the questionnaire are sufficient (Beurskens 1999). The reliability varies

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depending on the chosen activity (Nijkrake 2009). If the Visual Analogue Scale (VAS) is used in the questionnaire instead of the Numeric Rating Scale (NRS), the reliability of the PSC is adequate (Rollman 2010). Based on the clinimetric properties of the PSC, the clinimetric quality of the PSG is also considered to be sufficient.

Physical activity

The clinimetric quality of questionnaires (TNO-monitor, IPAQ) is too limited to get an understanding of the exercise behaviour of patients. Completing questionnaires or diaries results in an overestimate of most activities, while low-intensity activities are underestimated due to this (Ainsworth 2011; Helmerhorst 2012). The SQUASH, on the other hand, appears to be valid and reliable for the objective assessment of exercise behaviour (Campbell 2016; Makabe 2015; Sorensen 2018; Wagenmakers 2008; Wendel-Vos 2003).

Too little research has so far been done on the clinimetric quality of applications on smartphones, such as activity meters, which could give an understanding of PAEE (Johnston 2021). Studies in which such applications were examined show that their validity varies among cardiac patients, but also among other patient groups (Larsen 2022). More and more research is being done on activity monitors, and an increasing number of activity monitors are seen as valid and reliable (Case 2015; Patel 2020). Recently, however, Bayoumy et al (2020) concluded that inaccuracy, limited clinical validity, a lack of standardised regulatory policy and concerns over patients' privacy still seem to limit the widespread use of smart portable technologies in clinical practice (Bayoumy 2021).

Anxiety

Both the internal consistency of the sub-scales and the test-retest reliability of the HADS is high (Bjelland 2002; Christensen 2020; Hunt-Shanks 2010; Roberts 2001). Compared to other often-used (but longer) questionnaires for identifying depression and anxiety, the validity of the HADS is good to very good (Bjelland 2002; Julian 2011). The discriminatory power of the HADS is moderate to high and comparable to other screening questionnaires (Bjelland 2002; Brennan 2010) The clinimetric quality of the HADS is therefore assessed as good. The CAQ (Eifert 2000; Van Beek 2012) and NL-heart TSK (Keessen 2020) have been validated for cardiac patients. The NL-heart TSK can be used reliably, is sufficiently responsive and can detect changes in time (Ter Hoeve 2022). A direct positive correlation was furthermore found between the NL-heart TSK, the CAQ and the HADS (Keessen 2020). Clinimetric properties of both the CAQ and the NL-heart TSK are considered adequate.

Step 7 and 8 'Are standard values available and how do you calculate and interpret the data?'

For the standard values and interpretation of optional measurement instruments, please refer to www.meetinstrumentenzorg.nl.

Maximum exercise capacity

Standard values are available for the maximum or symptom-limited exertion test (with breath gas analysis if applicable) (Hansen 2015).

Physical capacity (functional exercise capacity)

Standard values are available for the 6MWT (Beekman 2014; Mylius 2016) and various versions of the SWT (Lima 2019; Neves 2015). With regard to the 6MWT, it is important to use standard values that are associated with the way the test was taken, such as route length and the manner of encouragement, and to make sure that the standard values match the country or region where the

tested person comes from (Mylius 2016). For both the SRT (Meyer 1996) and the TUG (Podsiadlo 1991) standard data are available. However, the standard values of the SRT do not specifically apply to cardiac patients.

Subjective exercise capacity

Both the MET method and the SAS (Lee 1988) are expressed as metabolic equivalents. The patient is classified according to the metabolic equivalent, which can be compared to the results of the maximum or symptom–limited exertion test (with breath gas analysis if applicable).

Muscle strength

Standard values and reference formulas are available for HHD measurement (Andrews 1996; Bohannon 1997; McKay 2017; Van der Ploeg 1991). There are no standard values for 1RM tests, and the measured values are to a large extent dependent on the equipment used, which is why these tests cannot be used for diagnostic purposes.

Respiratory muscle function

Standard values are available for the MIP for determining decreased respiratory muscle function in patients (Laveneziana 2019; Rodrigues 2017)

Subjective rating of exertion

The higher the patient scores on the scale, the heavier the physical exertion that they experience (Borg 1982).

Dyspnoea

The higher the patient scores on the scale, the shorter they are of breath during training (Roitman 2001).

Angina pectoris

The higher the patient scores, the more angina pectoris they experience during the exercise activities (Austen 1975; Campeau 2002, 1976).

Blood pressure

The <u>Multidisciplinary guideline on cardiovascular risk management (CVRM)</u> includes standard values for blood pressure (Federatie Medisch Specialisten 2019). Blood pressure can depend on the type and dosage of anti-hypertension medication and the fitness of the cardiac patient and can be affected by, for instance, emotional stress.

Oxygen saturation

With regard to oxygen saturation, recommendations have been formulated for the situation in which the training must (temporarily) be stopped due to desaturation in patients with COPD.

Activities and participation in ADL

Standard data are available for clinically relevant improvement on the PSC and PSG (Beurskens 1999; Stevens 2017).

Physical activity

The total exercise volume is linked to a reduction in (cardiac) mortality. In the WHO guideline it is recommended for cardiac patients to get moderate to intensive exercise at least 150 to 300 minutes per week (World Health Organisation 2020). A lot of research focuses on the counting of steps. There is consensus that 7,500 to 10,000 steps per day can be considered as an active, healthy lifestyle (Del Pozo Cruz 2022; Hancock 2012; Lee 2019; Tudor-Locke 2004, 2009). For patients with cardiovascular disease, a lifelong active lifestyle is associated with a 50% lower chance of premature death compared to an inactive lifestyle. The health benefit was slightly lower for patients who were initially inactive but who later became active (45% reduction) as well as for patients who were initially active but who later became inactive (20% reduction) (Gonzalez-Jaramillo 2022). Another survey study shows that 3,000 and more steps per day reduces the risk of cardiac mortality and that the maximum risk reduction is reached at 10,000 steps per day (Paluch 2022). Although to achieve a health benefit, even a modest increase in steps per day is already relevant (Jayedi 2022), a healthy person walks only 5,500 to 6,000 steps per day and people with a chronic disorder only as little as 3,500 to 5,500 steps per day (Lee 2019; Tudor-Locke 2004, 2009). In a recent study in the Netherlands, the number of steps of over 110,000 people was examined (Stens 2023). The conclusion was that health benefits could be measured starting from about 2,500 steps. Every 500 steps more will reduce the chances of premature death or cardiovascular disease by 8%. The chance of cardiovascular disease is already reduced to the maximum at 7,126 steps and of mortality at 8,763 steps. To prevent the likelihood with other disease profiles (such as preventing inflammation), it is necessary to walk more than 7,126 steps. 8,800 steps are therefore recommended. It is furthermore recommended to build up gradually with 500 steps at a time.

(Cardiac and exercise) anxiety

Standard data of the HADS and NL-heart TSK are available, but not of the CAQ (Eifert 2000; Keessen 2020; Snaith 2003; Van Beek 2012; Zigmond 1983).

From evidence to recommendation

The guideline panel established a few 'other considerations' in this module.

Other considerations

The guideline panel believes that it is important to focus optional measurement instruments on the patient's need for assistance and the monitoring of the treatment.

The guideline panel therefore considers that a combination of questionnaires should ideally be selected to identify the domains and, based on the outcomes of the questionnaires, advises doing an additional (exercise) analysis or functional test.

The guideline panel also believes that a manual blood pressure measurement should be advised for patients with abnormal cardiac rhythm (for example atrial fibrillation), as digital blood pressure monitors are not sufficiently reliable.

As an operational measurement instrument for physical capacity (functional exercise capacity) the guideline panel chooses the 6MWT or SRT. If the 6MWT or SRT is too difficult for the patient, the TUG test can be an alternative. If the 6MWT is too easy for the patient, the SWT can be an alternative.

The therapist estimates the patient's tolerance based on their clinical expertise while taking the patient's preference into account.

As an optional measurement instrument for subjective exercise capacity, the guideline panel chooses the MET method. The guideline panel considers the SAS to be a too global measurement instrument and therefore advises against it.

As an optional measurement instrument for muscle strength, the guideline panel chooses the 1RM method. This is the most frequently used method in clinical practice. Determining the number of RM depends on the type of exercise, the speed of execution of the test and the age of the patient. One direct 1RM measurement is not recommended, as this puts too heavy a burden on the patient. The guideline panel recommends a 4–6RM measurement for coronary artery disease patients with good exercise tolerance. For patients with low exercise tolerance, such as patients with severe comorbidity, the guideline panel recommends a 10RM for safety reasons. Tolerance is estimated on the basis of clinical expertise.

As recommended measurement instrument for activities and participation in ADL, the guideline panel chooses PSG. The guideline panel considers that the additional goal-setting contributes to the patient's motivation to continue with cardiac rehabilitation. The guideline is aware that additional training is needed for the use of PSG, but nevertheless gives their preference to this method.

As an optional measurement instrument for physical activity, the guideline panel chooses the SQUASH as a questionnaire and recommends also using activity monitors such as exercise monitors, step counters and smart watches. The guideline panel indicates that the use of questionnaires is often complex, which reduces the reliability thereof. The SQUASH appears to be the most clinically applicable. Despite the limited scientific substantiation of activity monitors, which is, however, increasing over time, the guideline panel sees the social acceptance and userfriendliness of this technology and therefore its potential to stimulate exercise behaviour (see also the KNGF guideline on remote healthcare ('Zorg op afstand')).

The guideline panel considers that it is highly preferable to take a maximum or symptom-limited exertion test to ensure personalised care in:

- measuring maximum exercise capacity
- measuring blood pressure and heart rate frequency response for cardiac rehabilitation;
- measuring training intensity for cardiac rehabilitation;
- measuring the response to cardiac rehabilitation (start and evaluation measurement).

The purpose of taking a test that focuses on physical activity (functional exercise capacity), such as the 6MWT or SRT, is to enable the therapist to dose the training and to assess its impact by themselves. These indications are further described in the '<u>Multidisciplinary guideline on cardiac rehabilitation</u> of 2024' (Nederlandse Vereniging voor Cardiologie).

As an optional measurement instrument for anxiety, the guideline panel chooses the TSK (NLheart) and CAQ. The guideline panel indicates that the HADS only measures generic anxiety, whereas it is important in particular for physical and exercise therapists to identify the subcategories (cardiac anxiety and exercise anxiety). In addition, in current practice, for generic anxiety, multidisciplinary questions are often asked using HADS or another measurement instrument. The TSK (NL-heart) and CAQ are therefore the preferred methods here.

The guideline panel chose to focus on the primary areas for this module. However, the guideline panel considers that the physical or exercise therapist can also act in other areas, such as depression. The guideline panel indicates that exercise is an important intervention for attenuating depression.

The signalling function (cf. <u>A.3 'Organisation of healthcare'</u>) of the physical or exercise therapist is also important when it comes to signalling, for example, psychosocial, work-related or cognitive complaints.

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B.7 Indication

Recommendation(s)

Based on the referral details, the medical history taking and the physical examination (see <u>B.4</u> <u>'Medical history taking'</u> and <u>B.5 'Physical examination and treatment plan'</u>), determine whether there is a physical or exercise therapy indication for an exercise programme in phase II of cardiac rehabilitation.

There is an indication for an exercise programme in phase II of cardiac rehabilitation when:

- a patient with coronary artery disease or chronic heart failure comes to the physical or exercise therapist with a need for assistance related to limitations in activities of daily living and/or social participation based on movement-related functioning; and
- the essential components, mentioned in <u>B.1 'Personalised care'</u>, have been considered in this regard.

SUBSTANTIATION

This module was not included in the guideline on the basis of a prioritised barrier. Every guideline of the Royal Dutch Society for Physical Therapy (Koninklijk Nederlands Genootschap voor Fysiotherapie – KNGF) contains a module on 'Indication'.

Reason

After phase I of cardiac rehabilitation, the treating cardiologist refers the patient for phase II of cardiac rehabilitation. In this module, the absolute and relative indications, contraindications and restrictions regarding the referral are described, for which the following clinical question was formulated:

Clinical question

What does the physical or exercise therapy indication for the exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure consist of?

Rationale of the recommendation

In consultation with the guideline panel it was decided not to perform a systematic search, but to gather the information needed for answering this clinical question in a non-systematic way and work it out narratively using the knowledge and clinical expertise of the guideline panel and to align it with the 'Multidisciplinary guideline on cardiac rehabilitation 2024 (Nederlandse Vereniging voor Cardiologie 2024).

Screening by the cardiac rehabilitation coordinator

All patients with an indication for cardiac rehabilitation are eligible for screening and an intake interview conducted by a professional from the rehabilitation team, which will often be the cardiac rehabilitation coordinator. This intake and screening constitute the start of phase II of cardiac rehabilitation. Based on this information, it will be decided in consultation with the patient which care offer is indicated.

The outcome of the indication for interventions is discussed during the multidisciplinary dialogue (MDO), after which the patient is referred to the various disciplines, including the exercise programme, which is conducted by a physical or exercise therapist. This is followed by a discipline–specific intake. The process is further explained in the 'Multidisciplinary guideline on cardiac rehabilitation of 2024' (Nederlandse Vereniging voor Cardiologie 2024).

Goals in the cardiac rehabilitation programme

In order to offer personalised cardiac rehabilitation, it is decided together with the patient which individual treatment goals the patient wants to reach and which interventions will be followed in what format. See also Module B.1 'Personalised care'.

There are four types of goals in multidisciplinary cardiac rehabilitation:

- 1. physical goals (see B.5 'Physical examination and treatment');
- 2. psychological goals;
- 3. social goals;
- 4. goals with regard to risk behaviour.

The process is further explained in the 'Multidisciplinary guideline on cardiac rehabilitation of 2024' (Nederlandse Vereniging voor Cardiologie 2024).

Indication, contraindications and restrictions for the exercise programme (discipline-specific intake) Before patients take part in the exercise programme, the physical or exercise therapist will conduct a disciplinary-specific intake, which consists of medical history taking, a physical examination and, based on these, the establishment of a treatment plan. See <u>B.4 'Medical history</u> taking' and B.5 'Physical examination and treatment plan'.

The aim is to put together a treatment plan that is suited to the patient in collaboration with the latter. It will also be considered whether the setting in which the exercise programme in phase II of cardiac rehabilitation will take place is suited to the essential components of personalised care (see B.1 'Personalised care').

General contraindications for physical training are non-cardiac diseases where exercise or exertion is (temporarily) not possible or not desirable. These might include fever, poorly regulated diabetes mellitus, severe anaemia or desaturation. There can also be cardiac contraindications. These cardiac and other contraindications are further explained in the 'Multidisciplinary guideline on cardiac rehabilitation of 2024' (Nederlandse Vereniging voor Cardiologie 2024). The cardiologist is furthermore responsible for transferring the contraindications and restrictions to the patient's therapists.

SOURCES

Nederlandse Vereniging voor Cardiologie. Multidisciplinaire richtlijn Hartrevalidatie 2024. Utrecht: Nederlandse Vereniging voor Cardiologie, 2024. Available at https://richtlijnendatabase.nl/ richtlijn/hartrevalidatie/hartrevalidatie_-_startpagina.html

C Therapeutic process

C.1 Introduction to cardiac rehabilitation programme

Interventions in general

The multidisciplinary cardiac rehabilitation team decides, in dialogue with the patient, when and with what programmes the patient will start.

The individual treatment plan includes the following interventions:

- an information programme, where the patient (and their partner) is given information on the disease and how to deal with it, and the way in which cardiac rehabilitation can lead to physical, mental, and social recovery, as well as information on (legislative) rules for the rehabilitation of social participation;
- an exercise programme;
- a relaxation programme;
- guidance on behavioural change (lifestyle programme, behavioural change programme); psychological programmes, which include psychological education (aimed at informing about heart problems and how to deal with them, for example cardiac anxiety) and a programme for treating mental symptoms (various programmes such as stress management or cognitive behavioural therapy).

Various disciplines are involved in reaching the treatment goals and executing the interventions. The composition, roles and tasks of the multidisciplinary treatment team varies and depends on the individual rehabilitation goals of the patient and knowledge and expertise of the team. See A.3 'Organisation of healthcare'.

For the content and effectiveness of this intervention, please refer to the '<u>Multidisciplinary</u> guideline on cardiac rehabilitation 2024' (Nederlandse Vereniging voor Cardiologie).

The exercise programme

A lot of research has been done on the effectiveness of the exercise programme in phase II of cardiac rehabilitation. For a description of the content and effectiveness of the exercise programme, please refer to <u>A.2</u> 'Background' and the '<u>Multidisciplinary guideline on Cardiac</u> <u>Rehabilitation 2024</u>'. This guideline also looks at complex and non-complex cardiac rehabilitation (Nederlandse Vereniging voor Cardiologie 2024).

Important developments, trends and challenges in cardiac rehabilitation focus on optimising the continuation and completion of cardiac rehabilitation (Savage 2019; Vromen 2021). Being able to offer personalised care (see <u>B.1 'Personalised care'</u>) leads to a variety of interventions. The following aspects are addressed:

- continuation and completion of cardiac rehabilitation (see C.2);
- behavioural changes in the case of low SES/limited health literacy (see C.3);
- the exercise programme in a primary care setting (see <u>C.4</u>);
- FITT factors with chronic heart failure (see C.5);
- telerehabilitation (see C.6).

SUBSTANTIATION

Reason

This module is an introduction to the modules that describe (therapeutic) interventions for phase II of cardiac rehabilitation. The following clinical question was formulated for this:

Clinical question

Which interventions are offered to patients with an indication for phase II cardiac rehabilitation? What is the effectiveness of these interventions?

Rationale of the recommendation

In consultation with the guideline panel, it was decided not to conduct a systematic search to answer this clinical question but only to revise the module. For this, information was gathered in a non-systematic way and worked out narratively relying on the knowledge and expertise of the guideline panel, where it was decided to align with the information from the <u>Multidisciplinary</u> guideline on cardiac rehabilitation 2024 (Nederlandse Vereniging voor Cardiologie 2024).

SOURCES

Nederlandse Vereniging voor Cardiologie. Multidisciplinaire richtlijn Hartrevalidatie 2024. Utrecht: Nederlandse Vereniging voor Cardiologie, 2024. Available at https://richtlijnendatabase.nl/ richtlijn/hartrevalidatie/hartrevalidatie_-_startpagina.html

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Vromen T, Brouwers RWM, Jorstad HT, Kraaijenhagen RA, Spee RF, Wittekoek ME, Cramer MJ, van Hal JMC, Hofstra L, Kuijpers PMJC, de Melker EC, Rodrigo SF, Sunamura M, Uszko–Lencer NHMK, Kemps HM. Novel advances in cardiac rehabilitation: position paper from the Working Group on Preventive Cardiology and Cardiac Rehabilitation of the Netherlands Society of Cardiology. Neth Heart J. 2021;29(10):479–85.

C.2 Continuation and completion of cardiac rehabilitation

Recommendations

The exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure must be adapted to the patient. To do so, take the essential components mentioned in B.1 'Personalised care' into account.

Consider in this regard:

get in touch with the patient at an early stage (upon release from hospital or referral/ registration) to make an inventory of their needs, beliefs and expectations (regarding support and information);

identify the inhibiting factors (see <u>B.2 'Inhibiting and facilitating factors'</u>) at an early stage. See also B.4 'Medical history taking' and B.5 'Physical examination and treatment plan';



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provide the exercise programme in phase II of cardiac rehabilitation at different times (including sessions outside of office hours);

offer different forms and types of exercise (adapted to the patient's daily activities) in the exercise programme of phase II of cardiac rehabilitation;

offer a hybrid form of the exercise programme in phase II of cardiac rehabilitation, such as:

- telerehabilitation, see C.6 'Telerehabilitation';
- the exercise programme in a primary care setting, see <u>C.4 'The exercise programme in a</u> primary care setting';
- at home without supervision/accompaniment during exercises (home-based cardiac rehabilitation), see C.4 'The exercise programme in a primary care setting'.

SUBSTANTIATION

Reason

The number of patients with coronary artery disease or chronic heart failure who start, continue with and complete phase II of cardiac rehabilitation in the Netherlands is suboptimal (Sunamura 2017; Vonk 2021); (Conijn 2022; Van Engen-Verheul 2013). The variations in practice in the performance of cardiac rehabilitation can be one of the causes of reduced compliance and a drop-out rate in cardiac rehabilitation. It is important that the physical and exercise therapy care aligns with the patient's needs in order to increase compliance (continuation) and the percentage that completes phase II and thus be able to achieve the positive effects of cardiac rehabilitation (see <u>A.2 'Background'</u>). In <u>B.2 'Inhibiting and facilitating factors'</u>, the factors have been identified that inhibit the continuation (compliance with) and completion of cardiac rehabilitation.

This module looks at interventions that focus on the factors that inhibit the continuation and completion of phase II of cardiac rehabilitation.

Clinical questions

For this barrier, two clinical questions were formulated.

Clinical question 1

Which interventions effectively facilitate the continuation and completion of phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure?

Clinical question 2

How is the exercise programme in phase II of cardiac rehabilitation organised based on the inhibiting factors for patients with coronary artery disease or chronic heart failure in order to facilitate compliance (continuation) and completion?

The factors identified in B.2 'Inhibiting and facilitating factors' are:

Cardiovascular risk factors and/or comorbidity. The presence of cardiovascular risk factors and/ or comorbidity can be linked to not being able to continue and complete cardiac rehabilitation. *Living situation*. Being single, divorced or widowed can be linked to not being able to continue and complete cardiac rehabilitation.

- *Physical functioning*. Reduced physical functioning can be related to not being able to continue and complete cardiac rehabilitation.
- Accessibility. Reduced access to a cardiac rehabilitation programme can be linked to not being able to continue and complete cardiac rehabilitation.
- Socio-economic status (SES) and/or health literacy. Having a low SES and/or limited health literacy can be linked to not being able to continue and complete cardiac rehabilitation. Activities/way of spending the day. Having a job can be linked to not being able to continue and complete cardiac rehabilitation.
- *Psychosocial factors*. Suffering from anxiety, depression or stress can be linked to not being able to continue and complete cardiac rehabilitation.
- Being a foreign-language speaker, deaf or hearing-impaired. Being a foreign-language speaker, deaf or hearing-impaired can be linked to not being able to continue and complete cardiac rehabilitation.

Conclusions based on the literature and clinical question 1

To answer the first clinical question, a non-systematic literature search was carried out. Based on this orienting search, one systematic literature review was identified that describes the effectiveness of cardiac rehabilitation with regard to the continuation and completion of cardiac rehabilitation.

The assessment was based on the effect size and the evidentiary value, and the results were then formulated in a standardised manner. These standardised formulations are internationally accepted and make a statement about the certainty of the evidence found in a specific study (Langendam 2022).

Crucial outcome measures

- Interventions that focus on an increase in the continuation of cardiac rehabilitation, in particular in home-based rehabilitation interventions, probable lead to only a slight increase in the continuation of cardiac rehabilitation compared to regular cardiac rehabilitation. *Explanation*: There was found to be a clinically non-relevant effect (SMD 0.38) on the continuation of cardiac rehabilitation to the advantage of interventions focusing on the continuation of cardiac rehabilitation, compared to regular cardiac rehabilitation, for patients with coronary artery disease and chronic heart failure in phase II of cardiac rehabilitation, where the evidentiary value of these results is reasonable, so that we are fairly certain of the effect demonstrated in the literature.
- Interventions that focus on an increase in the completion of cardiac rehabilitation, specifically when it is performed and evaluated in only one cardiac rehabilitation location, are likely to result in some increase in the completion of cardiac rehabilitation compared to regular cardiac rehabilitation.

Explanation: There was found to be a clinically non-relevant effect (SMD 1.13) on the continuation of cardiac rehabilitation to the advantage of interventions focusing on the completion of cardiac rehabilitation, compared to regular cardiac rehabilitation, for patients with coronary artery disease and chronic heart failure in phase II of cardiac rehabilitation, where the evidentiary value of these results is reasonable, so that we are fairly certain of the effect demonstrated in the literature.

Important outcome measures No undesirable effects were reported in the studies.

Conclusions based on the literature and clinical question 2

The second clinical question was answered based on the literature collected non-systematically. The results from the selected literature were weighed by the guideline panel and translated in the 'From evidence to recommendation' process.

Rationale of the recommendation

The guideline panel decided to include a conditional recommendation for interventions aimed at the continuation and completion of cardiac rehabilitation in this guideline, in response to both clinical questions.

The results of the selected literature show that interventions focusing on the continuation and completion of cardiac rehabilitation have clinically non-relevant positive effects on the continuation and completion of the exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure. Considering the reasonable evidentiary value, interventions focusing on the continuation and completion of cardiac rehabilitation compared to regular cardiac rehabilitation probably result in an increase in the number of patients who continue or complete cardiac rehabilitation.

The guideline panel is, however, of the opinion that the desirable effects (positive effects on continuation and completion of the exercise programme in phase II of cardiac rehabilitation) outweigh the undesirable effects (the prevention of 'major adverse cardiovascular effects'). The economic considerations and cost-effectiveness, values and preferences of the patient, and health equality also appear to be in favour of these intervention compared to regular cardiac rehabilitation or care. The remaining criteria used to evaluate the evidence-to-recommendation process (acceptability, feasibility, implementation) are found to be non-grievous or in favour of the interventions.

In conclusion, the evidence is fairly certain for the effect of implementing interventions to facilitate the continuation and completion of phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure. The guideline panel considers, however, that the favourable effects outweigh the adverse effects and on this basis formulated a conditional recommendation for interventions, on condition that the intervention meets specific conditions (see B.1 'Personalised care').

JUSTIFICATION

Literature

In order to answer clinical question 1, a non-systematic literature search was done in consultation with the guideline panel by means of the following clinical question (PICO):

 Which other interventions effectively facilitate the continuation and completion of phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure compared to regular cardiac rehabilitation? Based on the answers to this research question, effective interventions could be identified with a possible solution for several inhibiting factors. The literature was furthermore used that was selected to answer the research question in <u>B.2 'Inhibiting and facilitating factors'</u>, with which an answer to clinical question 2 can subsequently be formulated.

The identification process is described in the section 'From evidence to recommendation'.

Relevant outcome measures

The guideline panel considers the continuation and completion of phase II of cardiac rehabilitation to be a crucial outcome measure for decision-making.

The guideline panel considers undesirable effects linked to the intervention to be important outcome measures for decision-making.

Per outcome measure:

- Standardised Mean Difference (SMD). The guideline panel defines an effect > 0.5 as a significant effect (clinically relevant difference) (Sawilowsky 2009).
- *Continuation of phase II of cardiac rehabilitation.* The guideline panel uses the same definition for compliance (continuation) as in the selected literature, namely the percentage of the total number of prescribed sessions completed.
- *Completion of phase II of cardiac rehabilitation.* The guideline panel defines the same definition for the completion of cardiac rehabilitation as in the selected literature, namely that patients complete at least a part of the cardiac rehabilitation intervention components and undergo a formal reassessment by the cardiac rehabilitation team at the end of the programme (dichotomous, yes/no).
- *Completion of phase II of cardiac rehabilitation*. The guideline panel defines an increase of 10 people (per 100 people) who complete cardiac rehabilitation as a significant effect (clinically relevant difference).
- *Undesirable effects.* The guideline panel considers any major cardiac incident that may be linked to the intervention as an adverse incident (Bosco 2021). The guideline panel furthermore considers that any significant difference is also a clinically relevant difference (an increase of, for example, 1 death is already relevant).

Search and selected literature

Based on an orienting search and in consultation with the guideline panel, the systematic literature review of Santiago de Araújo Pio (2019) was chosen to provide an answer to clinical question 1. This systematic literature review was analysed according to the GRADE-ADOLPMENT systematics (Schünemann 2017).

Characteristics of the included study

In this systematic literature review, the following inclusion criteria were described in order to answer clinical question 1.

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Inclusion criteria							
Type of studies	Randomised or quasi-randomised controlled trials (RCTs) at an individual level, cluster level or in a parallel group or cross-over design						
Type of patients	Adults (≥ 18 years old) with myocardial infarction, angina pectoris, angina, cor- onary artery bypass grafting (CABG), percutaneous coronary intervention (PCI) or chronic heart failure who qualify for cardiac rehabilitation						
Type of intervention	All interventions with the aim to increase compliance with or the completion of cardiac rehabilitation						
Type of comparison	Regular cardiac rehabilitation						
Type of outcome	Crucial: • compliance with phase II of cardiac rehabilitation (continuation); • completion of phase II of cardiac rehabilitation. Important: – any major cardiac incidents that might be linked to the intervention.						

The characteristics of the included studies are provided in appendix C.2–1. The 13 included studies in total included 2,406 patients with coronary artery disease or chronic heart failure. The average age of the patients varied between 52 and 68. The number of women varied between 0 and 100%, since some of the studies included only men or only women. The studies were conducted in the United States, Denmark, Canada, Australia and the Netherlands and describe a variety of interventions to increase compliance or completion, such as a preventative intervention focusing on a relapse in motivation, cardiac rehabilitation among people of the same gender, motivational interviewing, the implementation of treatment in a primary care setting, shortened programmes, cognitive exercise behaviour programmes, home-based rehabilitation, telerehabilitation, guidance and dialogue and coping interventions, relaxation techniques, self-management techniques, diaries and making an early appointment to start cardiac rehabilitation (< 10 days). In the systematic literature review, these interventions are compared to giving basic information on exercise, community-based cardiac rehabilitation or regular cardiac rehabilitation.

Individual study quality (RoB)

The risk of bias (RoB) of the systematic literature review was scored by DC and RA using AMSTAR-2 (Shea 2017). The assessment of the various items was discussed with DC and RA, after which consensus was reached. For an overview of the study quality assessment of this systematic literature review, see Appendix C.2–2. The results of the systematic literature review were found to have a low risk of bias.

The RoB of the systematic literature review by Santiago de Araújo Pio (2019) including RCTs was added to Appendix C.2–3 'Risk–of–bias table'. The results of the RTCs were found to have a low risk of bias.

Efficacy and evidentiary value

An overview of the results is shown in the following table.

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GRADE assessment of continuation and completion of cardiac rehabilitation

Assessment of evidentiary value							Number of patients		Effect		Eviden-	Impor-
Num– ber of studies	Study design	Risk of bias	Incon- sistency	Indirect evi- dence	Inaccu- racy	Other factors	Cardiac reha- bilitation interventions aimed at increasing the continuation and comple- tion of cardiac rehabilitation	Regular cardiac rehabil- itation	Relative (95% RI)	Absolute (95% RI)	tiary value	tance

Continuation of cardiac rehabilitation

9	Ran- domised trials	Not severe	Severeª	Not severe	Not severe	Not found	867	787	-	SMD 0.38 SD higher (0.2 lower to 0.55 higher)	●●●○ Reason- able	CRUCIAL
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Completion of cardiac rehabilitation

8	Ran- domised trials	Not severe	Severe ^a	Not severe	Not severe	Not found	573/809 (70.8%)	491/756 (64.9%)	RR 1.13 (1.02 to 1.25)	84 more per 1,000 (from 13 more to 162 more)	●●●○ Reason- able	CRUCIAL
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a. Due to the heterogeneous nature of the given interventions, the effect of the interventions in general is uncertain. The quality of the evidence is therefore lowered by 1 level.

Efficacy and evidentiary value of cardiac rehabilitation interventions to facilitate the continuation of cardiac rehabilitation

The effect of continuing with cardiac rehabilitation programmes compared to regular cardiac rehabilitation has been described in 11 studies, whereby eight studies (nine comparisons) could be pooled in a meta-analysis (Ashe 1993; Beckie 2010; Farias-Godoy 2013; Focht 2004; Grace 2016; Hwang 2017; Kraal 2014; Lynggaard 2017). In the studies that were not pooled, Pack showed no difference in the continuation of cardiac rehabilitation when started at an early stage compared to the usual start of rehabilitation (Pack 2013). Bertelsen (2017) also showed no improvement in the continuation with a primary-care-setting model versus regular cardiac rehabilitation in a hospital. Lastly, McGrady (2014) showed that additional motivational interviewing and stress management/ relaxation resulted in a lower drop-out rate (average number of sessions attended (intervention 30.8 vs. control 28.1; p < 0.001) compared to regular cardiac rehabilitation.

Continuation of cardiac rehabilitation

In eight studies (9 comparisons), the efficacy of cardiac rehabilitation interventions compared to the efficacy of regular cardiac rehabilitation was measured in terms of compliance with (continuation of) cardiac rehabilitation (Ashe 1993; Beckie 2010; Farias–Godoy 2013; Focht 2004; Grace 2016; Hwang 2017; Kraal 2014; Lynggaard 2017). С

These studies describe a variety of interventions to increase compliance or completion, such as a preventative intervention focusing on a relapse in motivation, cardiac rehabilitation among people of the same gender, motivational interviewing, the implementation of treatment in a primary care setting, shortened cardiac programmes, cognitive exercise behaviour programmes, home-based rehabilitation, telerehabilitation, explanatory interviews and coping interventions, relaxation techniques and making an early appointment to start cardiac rehabilitation (< 10 days). The studies compare these interventions to giving basic information on exercise and regular cardiac rehabilitation.

The standardised average difference in the continuation of cardiac rehabilitation between the intervention and regular cardiac rehabilitation is (SMD) 0.38 points (95%–BI 0.20 to 0.55; n = 1654) to the advantage of interventions in a cardiac rehabilitation programme. See Appendix C.2–4 for the forest plots. The guideline panel considers this effect to be clinically non–relevant (Sawilowsky 2009). The evidentiary value was lowered by one level (GRADE) given the heterogeneous nature of the pooled interventions and is therefore reasonable.

Our GRADE assessment deviates from the one in the systematic literature review of Santiago de Araújo Pio (2019). The latter downgraded on indirectness, arguing that the population in the study consisted of white males. For the KNGF guideline, this was translated to the Dutch context, where cardiac rehabilitation is also predominantly given to white males, due to an under-representation of women or people whose skin colour is not white. It was therefore decided not to downgrade because of indirect evidence in the GRADE assessment.

Subgroup analyses for the continuation of cardiac rehabilitation

In this systematic literature review, previously established subgroup analyses were also performed on the outcome measures (the person performing the intervention, the format of the intervention, the cardiac rehabilitation setting, the risk of bias, a theory-based intervention, a multi-centre study, a cardiac indication and the region).

In the subgroup analyses a difference was found between the subgroups; however, these findings should not be overestimated considering the small number of studies included.

In the subgroup analysis of setting (5 studies), attention was given to supervised (under the watchful eye of a therapist) versus unsupervised settings and compliance with (continuation of) cardiac rehabilitation. Unsupervised refers to scaling down in contact moments with the therapist or training from a distance. The standardised mean difference (SMD) between the groups was 0.56 points (95%–BI 0.37 tot 0.76; n = 451) in favour of interventions that were partially unsupervised.

Efficacy and evidentiary value of cardiac rehabilitation interventions to facilitate the completion of cardiac rehabilitation

The effect of completing cardiac rehabilitation programmes compared to regular cardiac rehabilitation was described in seven studies (Ashe 1993; Focht 2004; Grace 2016; Lynggaard 2017; Oldridge 1983; Pack 2013; Varnfield 2014). See Appendix C.2–4 for the forest plots of the outcomes on completion of cardiac rehabilitation.

Completion of cardiac rehabilitation

In seven studies (8 comparisons), the efficacy of cardiac rehabilitation interventions compared to that of regular cardiac rehabilitation was measured in terms of completion of cardiac rehabilitation (Ashe 1993; Focht 2004; Grace 2016; Lynggaard 2017; Oldridge 1983; Pack 2013;
Varnfield 2014). The relative ratio (RR) between the groups was 1.13 points (95%–RI 1.02 to 1.25; n = 1565) in favour of cardiac rehabilitation interventions.

The studies describe a variety of interventions to increase compliance or completion, such as a preventative intervention focusing on a relapse in motivation, cardiac rehabilitation among people of the same gender, cognitive exercise behaviour programmes, home-based rehabilitation, telerehabilitation, explanatory interviews and coping interventions, relaxation techniques, self-management techniques, diaries and making an early appointment to start cardiac rehabilitation (< 10 days). In the meta analysis, these interventions are compared to giving basic information on exercise in the community, cardiac rehabilitation in the community or regular cardiac rehabilitation.

The guideline panel considers this effect to be clinically non-relevant.

The evidentiary value was lowered by one level given the heterogeneous nature of the pooled interventions and is therefore reasonable.

Our GRADE assessment deviates from the one in the systematic literature review of Santiago de Araújo Pio. The latter downgraded on indirectness, arguing that the population in the study consisted of white males. For the KNGF guideline, this was translated to the Dutch context, where cardiac rehabilitation is also predominantly given to white males, due to an under-representation of women or people whose skin colour is not white. It was therefore decided not to downgrade because of indirect evidence in the GRADE assessment.

Subgroup analyses for the completion of cardiac rehabilitation

In this systematic literature review, predetermined subgroup analyses were also performed on the outcome measures (the person performing the intervention, the format of the intervention, the cardiac rehabilitation setting, the risk of bias, a theory-based intervention, a multi-centre study, a cardiac indication and the region).

In two subgroup analyses (risk of bias and multi-centre/uni-centre) a difference was found between the subgroups; however, these findings should be interpreted with caution considering the small number of studies included.

In the subgroup analysis of multi-centre studies (7 studies), multi-centre versus uni-centrebased cardiac rehabilitation were assessed in terms of compliance with (continuation of) cardiac rehabilitation. The relative ration (RR) between the groups was 1.46 points (95%–RI 1.17 to 1.82; n = 388) in favour of interventions that were carried out in 1 location. This put into question the general nature of the multi-centre studies.

Undesirable effects

No undesirable effects were reported in the studies.

Remaining literature

In order to answer clinical question 2, the literature that was included based on the systematic search for inhibiting and facilitating factors was used in consultation with the guideline panel (see <u>B.2 'Inhibiting and facilitating factors'</u>) (Brouwers 2021a; Gaalema 2017; González-Salvado 2021; Nakayama 2020; Rao 2021; Sunamura 2017; Wittmer 2012). This literature was supplemented with information from evidence-based national and international guidelines for coronary artery disease or chronic heart failure (see further down). The results were analysed in a narrative manner and descriptively incorporated. Lastly, based on the response to clinical question 1, a translation was made to the response to clinical question 2.

Included studies on inhibiting and facilitating factors

In total, 23,596 patients (average age 57–71, 15–50% women) with a diagnosis of coronary artery disease or chronic heart failure were included in the seven studies. The population was to be divided according to the following sub-diagnoses: acute coronary syndrome (ACS), aortic disease, chronic heart failure, postoperative revascularisation (CABG) or percutaneous revascularisation (PCI), documented coronary artery disease without revascularisation, valve replacements or repair, and cardiovascular risk factors. All seven studies suggest both the orientation and form of cardiac rehabilitation to increase the number of patients who continue or complete phase II of cardiac rehabilitation. The characteristics of the included studies are provided in Appendix B.2–4 and B.2–5. Suggestions from the discussions in the studies are described below for each of the included studies.

Gaalema (2016)

This study explains that younger patients or patients with a low income might experience difficulties to attend cardiac rehabilitation several times per week or in the daytime. As a solution it is indicated that cardiac rehabilitation could be given outside regular working hours once a week. For patients who believe that they are not getting any benefit from attending cardiac rehabilitation, particularly patients who smoke or who have a low exertion tolerance, it is suggested to give more information.

González (2021)

González describes that older patients might also believe that they are achieving little by participating in cardiac rehabilitation. The recommend giving information at the right moment, which is also why it is not recommended to give information shortly after a cardiac incident. González also writes that giving home-based or telerehabilitation could contribute to the optimisation of cardiac rehabilitation (Anderson 2017; Kraal 2017; Pratesi 2019; Rawstorn 2016).

Nakayama (2020)

In this study it is indicated that alternative models such as home-based rehabilitation should be offered to patients who have difficulty travelling the distance to the cardiac rehabilitation centre. Nakayama also suggests that a recommendation to a local provider can facilitate the optimisation of cardiac rehabilitation.

Rao (2021)

In this study, it is described that for obese or depressed patients, it is better to stimulate an increase in physical activity and exercise than to promote maximum exercise capacity to optimise cardiac rehabilitation. Personal contact with the cardiac rehabilitation staff is also important for stimulating the motivation and behavioural changes.

Early integration of programmes aimed at risk factors, as well as reducing social isolation, can perhaps have a favourable impact on the optimisation of cardiac rehabilitation.

Rao describes the identification of everyday circumstances and in particular the personalised use of cardiac rehabilitation as a stimulus for the continuation and completion of cardiac rehabilitation. The study also refers to alternative models of cardiac rehabilitation, such as home-based and telerehabilitation or personalised, subsidised gym membership (Desveaux 2020; Maddison 2015; Santiago de Araújo Pio 2019; Xu 2019).

Improving the multidisciplinary cooperation will in particular contribute to the compliance of patients with psychosomatic complaints (Karmali 2014).

Sunamura (2017)

In this study, alternative cardiac rehabilitation programmes are suggested compared to regular cardiac rehabilitation as a suggestion for patients with logistic problems and with a low socioeconomic status (SES). Making contact with a patient at an early stage after hospitalisation (invitation interviews) followed by the use of self-management techniques could also facilitate participation (Beswick 2004; Karmali 2014; Pack 2013).

In addition, the use of supervised or unsupervised exercise therapy, in combination with selfmanagement techniques, are recommended to facilitate the completion of cardiac rehabilitation (Arrigo 2008; Moore 2006).

Besides the aforementioned interventions, this article makes mention of interventions that have an impact on family support, patient-friendly opening hours and personalised care (Clark 2013).

Wittmer (2021)

Wittmer supports the identification of factors that facilitate and inhibit cardiac rehabilitation according to which interventions can be personalised.

National and international guidelines

Below, the main national and international guideline(s) are shown that make a recommendation with regard to the way in which cardiac rehabilitation is organised for coronary artery disease or chronic heart failure and that can provide a response to the clinical question.

NICE Guideline Acute coronary syndromes (NG185) (Corbett 2021)

This guideline makes a number of recommendations to facilitate participation in cardiac rehabilitation:

- Provide cardiac rehabilitation in a non-judgemental, respectful and culturally sensitive way. Consider hiring bilingual peer educators or cardiac rehabilitation assistants who reflect the diversity of the local population.
- Determine people's health convictions and specific views on disease before giving lifestyle advice, and encourage participation in a cardiac rehabilitation programme.
- Offer cardiac rehabilitation programmes that are intended to motivate people to attend and complete the programme. Explain what the benefits of participation are.
- Discuss which factors might inhibit participation in a cardiac rehabilitation programme, such as transport problems.
- Offer cardiac rehabilitation programmes at various locations (including at the patient's home, but also at the hospital and in the neighbourhood) and at various times of the day, for example sessions outside of working hours. Explain the available options.
- Ensure that there is diversity in the exercises to accommodate the needs of all age groups or in the case of significant comorbidity. Do not exclude a patient from the entire programme if they choose not to attend certain parts of it.
- If there is sufficient demand, offer the cardiac rehabilitation programme for groups of the same gender.
- Enrol patients who have had a myocardial infarction with or without ST elevation (STEMI/ NSTEMI) in the current system of structured care, so that there are clear lines of responsibility for arranging the early start of cardiac rehabilitation.
- Invite the patient to a cardiac rehabilitation session as soon as possible after their discharge from hospital. Cardiac rehabilitation should start within ten days after discharge from hospital.

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Make contact with people who do not start or do not continue with the cardiac rehabilitation programme as a reminder, for example:

- a motivating letter;
- a previously arranged visit from a member of the cardiac rehabilitation team;
- a telephone call;
- a combination of the above.

Ask users of cardiac rehabilitation programmes for feedback and try to use this feedback to increase the number of people who start with and attend the programme.

Be aware of the wider health and social care needs of a person who has had a myocardial infarction (MI). Offer information and resources on:

- financial problems;
- welfare rights;
- issues regarding housing and social support.

Make cardiac rehabilitation accessible and relevant for all people after a STEMI/NSTEMI, in particular people from groups who do not have access to this service as easily. This includes patients from black, Asian and ethnic minorities, older adults, people from lower socio-economic groups, women, people from rural communities, people with an intellectual disability and people with mental and physical health problems.

Encourage all staff, including senior medical staff, who are involved in care for people after a STEMI/NSTEMI actively to promote cardiac rehabilitation.

Criteria for formulating the recommendations

From evidence to recommendation

Internationally recognised criteria were used to assess the evidence on which the recommendations are based. These criteria, as well as the remaining considerations formulated by the guideline panel, determine the strength of the recommendation.

Desirable effects

The guideline panel came to the assessment that compared to regular care, there is a clinically non-relevant effect of interventions that focus on an increase in the continuation and completion of cardiac rehabilitation in terms of the outcome measures continuing and completing cardiac rehabilitation.

Outcome measure	Effect (95% RI)	Magnitude of the effect	Evidentiary value
continuation of cardiac rehabilitation	SMD 0.38 SD higher (0.2;0.55)	clinically non-relevant	reasonable
completion of cardiac rehabilitation	84 more per 1,000 (from 13 more to 162 more)	clinically non-relevant	reasonable

Undesirable effects

The guideline panel came to the assessment that the undesirable effects of interventions aimed at increasing the continuation and completion of cardiac rehabilitation compared to regular care are unknown.

Quality of evidence

The guideline panel came to the assessment that the evidentiary value of the desirable effects is reasonable.

Patient values and preferences

The guideline panel came to the assessment that the patients attach great value to the intervention and that there is little variation among patients. This is supported by the Cardiac Rehabilitation record, a study that was carried out by Harteraad (the heart council) and through the barrier that was added by Harteraad (2020).

Balance between desirable and undesirable effects

The guideline panel is of the opinion that the desirable effects (positive effects on the continuation and completion of the exercise programme in phase II of cardiac rehabilitation) outweigh the undesirable effects (the prevention of 'major adverse cardiovascular effects').

Socio-economic considerations and cost-effectiveness

The guideline panel came to the assessment that the resources needed for the intervention are difficult to estimate. The suggested interventions are varying in nature, whereby such interventions have a varying impact on costs.

The intervention is, however, cost-effective. In the systematic literature review of Santiago de Araújo Pio (2019) two studies are cited that compared the cost-effectiveness of the interventions with that of regular care, where these were equal or to the advantage of the interventions.

Health equality

The guideline panel expects that the intervention will lead to an increase in health equality.

Acceptability

The guideline panel expects that the intervention will be accepted by all key stakeholders.

Feasibility

The implementation of a large part of the suggested interventions was seen as realistic by the guideline panel. However, implementing an individual personalised programme is an organisational challenge for cardiac rehabilitation centres, where it has to be kept in mind that there might be limitations.

Other considerations

The guideline panel is of the opinion that the following considerations are also important when building an exercise programme in phase II of cardiac rehabilitation based on the inhibiting and facilitating factors.

Offering the exercise programme in phase II of cardiac rehabilitation at home without accompaniment/supervision (home-based cardiac rehabilitation) may contribute in terms of several factors to optimising the continuation and completion of cardiac rehabilitation. This is confirmed by the retrieved literature in this module, in which home-based interventions were also investigated, and by other literature that was added (Anderson 2017; Ramachandran 2022; Terbraak 2022). Offering an exercise programme in phase II of cardiac rehabilitation with the physical or exercise therapist in a primary care setting may contribute in terms of several factors to optimising the continuation and completion of cardiac rehabilitation. See also C.4 'The exercise programme in a primary care setting'.

- Offering telerehabilitation may contribute in terms of several factors to optimising the continuation and completion of cardiac rehabilitation. This is confirmed by the retrieved literature in this module, in which telerehabilitation as an intervention was also investigated, and by other literature that was added (Brouwers 2020; Cavalheiro 2021; Jin Choo 2022; Veen 2017). See also C.6 'Telerehabilitation'.
- Offering cardiac rehabilitation in various locations (at a cardiac rehabilitation centre and at home) and at various moments may contribute in terms of various factors to optimising the continuation and completion of cardiac rehabilitation.
- Getting in touch with patient at an early stage (after release from hospital or when registering) to make an inventory of individual patients' needs and expectations may contribute to optimising the continuation and completion of cardiac rehabilitation.
- It is important here that the healthcare provider carefully aligns the cardiac rehabilitation with the patient's preferences and values, but also checks whether the patient is ready for a consultation. Possibilities include giving guidance, support for exercising or removing movement anxiety and giving information on cardiac rehabilitation. This applies in particular to patients who believe that they will not get any benefit from doing cardiac rehabilitation. Offering cardiac rehabilitation in various exercises and different types of exercise contributes to optimising the continuation and completion of cardiac rehabilitation. The exercises and types of exercise must be aligned with the patient's preferences and daily activities. It would for instance be better not to ask a patient who never cycles to exercise on a stationary bicycle, but rather to offer a more suitable form of training (e.g. a treadmill).
- Discussing and identifying inhibiting and facilitating factors in a timely manner contributes to optimising the continuation and completion of cardiac rehabilitation. Identifying anxiety and symptoms of depression or signalling cognitive problems at the start of cardiac rehabilitation can, for instance, contribute to better compliance with cardiac rehabilitation and the signalling of patients who are in need of a psychologist (Rao 2020; Sumner 2018). Also see <u>B.2 'Inhibiting</u> and facilitating factors'.
- It is important to align with the extent to which the patient prefers exercising alone or in a group. Research by Mulderij (2022) shows that group therapy can contribute to motivation, support and knowledge sharing.
- Additional motivational interviewing and stress management/relaxation can contribute to the completion of cardiac rehabilitation based on the retrieved literature (McGrady 2014). Psychosocial factors should therefore be identified at an early stage. See <u>B.2 'Inhibiting and facilitating factors'</u> Interventions can be adapted to this, but these interventions are not part of the exercise programme (see <u>C.1 'Introduction to cardiac rehabilitation programme'</u>), which is why no recommendation was drawn up for this. These interventions do, however, form part of the treatment goals of cardiac rehabilitation.
- The continuation and completion of cardiac rehabilitation as an outcome measure is important, but reaching individual rehabilitation goals is more relevant.
- In the Dutch context too, several studies have been conducted on various interventions that are aimed at facilitating the continuation and completion of cardiac rehabilitation or that evaluate a form of personalised care (Brouwers 2022, 2021b, 2021c; Jepma 2021; Keessen 2022; Kraal 2014,

2017; Snoek 2021; Terbraak 2022). These studies show that such interventions are applicable and generally comparable to cardiac rehabilitation that is done in a heart centre in a Dutch context. It is important that the essential components described in **B.1** 'Personalised care' should be taken into account when implementing interventions. It is important here to think carefully about the form of therapy (group/individual). For a number of patient categories, it seems preferable (e.g. patients with psychosocial complaints) to train in a group set–up.

Focus areas for implementation

See feasibility.

Knowledge gaps

The quality of evidence is mainly assessed as reasonable, due to the highly heterogeneous nature of the interventions. In order to make a targeted assessment about the efficacy, several studies will therefore have to be performed on the specifically effective aspects of tailored cardiac rehabilitation.

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C.3 Behavioural change in people with low SES/limited health literacy

Recommendations

Consider implementing the following behavioural change interventions in the exercise programme during phase II of cardiac rehabilitation to facilitate behavioural changes in all patients with coronary artery disease or chronic heart failure:

- cognitive behavioural therapy according to the 5G diagram;
- integrated-change model (I-Change);
- motivational interviewing;
- acceptance and commitment therapy (ACT);
- relaxation therapy.

Only do behavioural change interventions for which you are competent and qualified.

When giving behavioural change interventions for patients suffering from coronary artery disease or chronic heart failure with a low socio-economic status (SES) and/or limited health literacy, keep account of aspects such as those mentioned in B.3 'Low SES/limited health literacy'.

SUBSTANTIATION

Reason

One in three Dutch people has limited health literacy. This means that they find it difficult to get hold of, understand, assess and make use of health information. A part of this group has low literacy (Landelijk expertisecentrum Pharos).

In the Netherlands, people with a low SES and/or limited health literacy have an average life expectancy that is four years shorter, and as much as 15 years with lower perceived health, than people with higher vocational training HBO or a university education (Landelijk expertisecentrum Pharos). Cardiovascular diseases occur significantly more frequently among people with limited health literacy. Culture or ethnicity can play a role here. Hindi people from Suriname, for instance, have three times more cardiovascular diseases than the Dutch (Landelijk expertisecentrum Pharos). Cardiac rehabilitation focuses on preventing cardiovascular diseases by changing lifestyle and reducing risk factors. This behavioural change is effective for reducing cardiovascular risk factors (O'Connor 2020). It appears that patients with a low SES are less likely to adopt such behavioural changes, due to unknown underlying causes (Gaalema 2017). In practice too, experience shows that this sub-population is less able to adopt behavioural changes.

To bring about behavioural changes in patients with coronary artery disease or chronic heart failure who have a low SES and/or limited health literacy, it is important to adjust the treatment to the factors that inhibit behavioural change and to the needs of this sub-population.

Clinical question

How do you bring about behavioural change with the aim to facilitate continuation and completion of the exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure who have a low SES and/or limited health literacy?

Conclusions based on the literature

No literature was found that provided an answer to the clinical question.

Rationale of the recommendation

No literature was found on the effect of behavioural interventions to facilitate continuation and completion of the exercise programme in phase II of cardiac rehabilitation for patients with a low SES and/or limited health literacy. However, literature pertaining to behavioural interventions that applies to the population as a whole was selected. This literature was worked out narratively.

The guideline panel considers that the possible desirable effects of behavioural interventions outweigh the adverse effects. The economic considerations, health equity, cost effectiveness and patient values and preferences appear to be in favour of the proposed interventions. The remaining criteria used to evaluate the literature in the evidence-to-recommendation process (acceptability, feasibility and implementation) are found to be non-grievous for the interventions, which is why a conditional recommendation was formulated for the interventions.

The conclusion is that the evidence is very uncertain regarding the effect of behavioural interventions to facilitate the continuation and completion of the exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure and that the interventions must be done under specific conditions.

JUSTIFICATION

Literature

In order to answer the clinical question, a systematic literature review was carried out for the following research question (PICO):

Which behavioural change interventions (given by a physical or exercise therapist) are effective for facilitating the continuation and completion of the exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure who have a low SES and/or limited health literacy?

Relevant outcome measures

The guideline panel considers the continuation and completion of phase II of cardiac rehabilitation to be a crucial outcome measure for decision-making. The guideline panel considers physical functioning and undesirable effects linked to the intervention to be significant outcome measures for decision-making.

Per outcome measure:

Continuation of phase II of cardiac rehabilitation: The guideline panel defines compliance (continuation) as: following \ge 75% of the exercise programme of phase II of cardiac rehabilitation.

Continuation and completion of phase II of cardiac rehabilitation: The guideline panel defines an increase of 10 people out of a 100 as a significant effect (clinically relevant difference) for compliance (continuation) and completion of cardiac rehabilitation.

\checkmark

Undesirable effects: The guideline panel considers all major cardiac incidents that may be linked to the intervention as an undesirable effect (Bosco 2021). The guideline panel furthermore considers that if there is a significant difference, it is also a clinically relevant difference (an increase of, for example, 1 death is already relevant).

Search and selected literature

On 21 and 25 August 2022, an information specialist, Ms H.W.J. Deurenberg, conducted a systematic search in MEDLINE and Embase (see Appendix C.3–1 for the search justification). The systematic search produced 193 unique hits. After the title and abstract were screened (by DC and RA) based on the inclusion criteria, 192 articles were excluded.

Inclusion criteria		
Type of studies	Randomised or quasi-randomised controlled trials (RCTs) at an individual level, cluster level or in a parallel group or cross-over design	
Type of patients	Patients with coronary artery disease or chronic heart failure who have a low SES/ limited health literacy	
Type of intervention	Behavioural change interventions (given by the physical or exercise therapist)	
Type of comparison	Exercise programme in phase II of cardiac rehabilitation	
Type of outcome	 Crucial: compliance with phase II of cardiac rehabilitation (continuation); completion of phase II of cardiac rehabilitation. Important: physical functioning (peak V0₂, 6MWT). any major cardiac incidents that might be linked to the intervention. 	
Type of timeline	During cardiac rehabilitation	

The complete article was screened for one article; eventually the search yielded no usable studies. See Appendix C.3–2 for the flowchart of the exclusion process. Information on the article that was excluded based on the full text and the reason for the exclusion are listed in appendix C.3–3 (Nielsen 2013).

From evidence to recommendation

No literature was found in the systematic literature review that provided a direct answer to the clinical question. In order to give a direct answer to the clinical question, the most frequently used effective behavioural change techniques were looked for that facilitate physical functioning in all patients with coronary artery disease and chronic heart failure. The guideline panel translated this to patients with a low SES/limited health literacy using the recommendations from <u>B.3 'Low SES/</u> limited health literacy'.

For this purpose, on 27 October 2022, an orienting literature review was carried out of systematic literature reviews in the field of cardiac rehabilitation and behavioural change techniques in PubMed and literature was added by the guideline panel. The search terms were 'cardiac rehabilitation' and 'behavioural change techniques'. See Appendix C.3–4 for the search justification of this orienting literature review.

In this search, the same inclusion criteria were applied as for the answering of the clinical question in this module (B.3), except for the type of patient (now: patients with coronary artery disease or chronic heart failure) and the type of study (how: systematic literature review).

The orienting search produced 11 unique hits (Aggarwal 2021; Beckie 2019; Chong 2021; Cupples 2016; Duff 2017; Heron 2016; Hotz 1995; Lara–Breitinger 2021; McAuliffe 2021; Nichols 2021; Williams 2017). After screening of the title and the abstract, three (systematic) reviews were included that can give an indirect answer to the clinical question (Duff 2017; Heron 2016; McAuliffe 2021). The remaining articles were excluded since they did not meet the inclusion criteria.

Duff et al.

The purpose of the systematic literature review was to identify the main behavioural change techniques for facilitating the increase of physical activity in e-health for patients with cardiovascular diseases.

14 of the 23 studies that were included contained either an internet or web-based programme or a mobile intervention. Three studies pertained to telephone interventions and the remaining studies were based on telemonitoring, video calls and virtual reality. In the vast majority of the studies, a comparison was made with regular cardiac rehabilitation.

15 interventions had physical functioning as an outcome measure, and eight of these found a statistically significant difference in favour of the intervention group. In the five remaining interventions, no significant differences were reported and no difference was found between the intervention and the control group (Duff 2017).

No effect measures were described in the systematic literature review.

The presence of behavioural change techniques was scored based on the taxonomy (v1) of Michie (Michie 2013). The average number of behavioural interventions per study was 7.2 (range 1–14). The most frequently used behavioural change techniques in the eight seemingly effective interventions in 18/23 studies contained information on health impacts (behavioural change label 5.1), in 17/23 studies the setting of goals (behavioural change label 1.1) and in 11/23 studies a joint third place for self-monitoring of behaviour (behavioural change label 2.3) and social support (practical behavioural change label 3.2).

Heron et al.

The purpose of this systematic literature review was to identify the main behavioural interventions to improve impressionable cardiovascular risk factors during a home-based intervention for patients with cardiovascular diseases.

Of the 11 studies included, four contained the 'Heart Manual' intervention, three pertained to technological interventions (mobile, internet and telemonitoring) and the remaining four studies used interventions that were performed at home under the supervision of a physical therapist or nurse. The presence of behavioural change techniques was scored based on the taxonomy (v1) of Michie (2013). All the studies (11/11) contained social support (generic behavioural change label 3.1), 10/11 studies the setting of goals (behavioural change label 1.1), 7/11 studies the management of emotions (reducing negative emotions – behavioural change label 11.2) and 7/11 studies contained instructions on how the behaviour should be executed (behavioural change label 4.1). In his meta-analysis, Heron (2016) found no significant difference in peak V0₂ (1.19 ml/kg/min.; 95% RI 0.78 to 3.16; p = 0.24) and the distance waked in the Six Minute Walking Test (6MWT) (8.47 m; 95%-RI 10.98 to 27.92; p = 0.39). No forest plots of this meta-analysis were, however, published, which is

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why there is no description of the included studies and why no assessment of the meta-analysis can be done (Heron 2016).

The guideline panel in addition provided the following systematic literature review:

Goodwin et al.

The purpose of this systematic literature review was to identify the main behavioural interventions that are used for patients with coronary artery disease. Of the 22 studies included, the presence of behavioural change techniques was scored according to the 'Coventry Aberdeen and London-Refine' (CALO-RE) taxonomy (Michie 2011). An average of 8.3 (SD 3.1; range 4–16) behavioural change techniques were included in the interventions. The three most frequently used behavioural change techniques that were scored were providing information on the health impacts (generic and individual), giving instructions on how the behaviour should be done and setting goals (outcomes and behaviour).

In 20 studies the effect of the interventions was studied for the results in terms of physical functioning. However, the measurements differed to such an extent that the data could not be combined statistically. 12 of the 20 studies reported that the intervention had a positive effect on physical functioning (Goodwin 2016).

Integration of findings

In the literature, the following behavioural change techniques (according to the taxonomy of Michie; 2013) were found for patients with coronary artery disease or chronic heart failure:

- Setting goals (behavioural change label 1.1);
- Providing information on the health impacts (behavioural change label 5.1);
- Instructions on how to conduct the behaviour (behavioural change label 4.1).

The frequency at which these behavioural change techniques were applied is described in Appendix C.3–5.

The identified systematic literature reviews mostly first looked at which interventions were used most frequently that were effective for physical functioning, then examined which behavioural change techniques these were made up of and then described these techniques. Due to this, there is a lot of uncertainty about the effect of the most frequently used behavioural change techniques.

Criteria for formulating the recommendations

From evidence to recommendation

Internationally recognised criteria were used to assess the evidence on which the recommendations are based. These criteria, as well as the remaining considerations formulated by the guideline panel, determine the strength of the recommendation.

Desirable effects

No literature was found that directly defines the evidentiary value or effects to answer the clinical question. Because of this, the guideline panel did not formulate any desirable effects.

Undesirable effects

No literature was found that directly defines the evidentiary value or effects to answer the clinical question. Because of this, the guideline panel did not formulate any undesirable effects.

Quality of evidence

No literature was found that directly defines the evidentiary value or effects to answer the clinical question. Because of this, the guideline panel did not formulate any evidentiary value.

Patient values and preferences

The guideline panel considers that the patients attach great value to the use of behavioural interventions, aimed specifically at patients with a low SES and/or limited health literacy, and that there is little variation among patients.

This is supported by the report 'Quality criteria for cardiac rehabilitation. Formulated from the patient perspective', which was drawn up by De Hart&Vaatgroep in the scope of the programme 'Kwaliteit in Zicht' (Quality in Sight) (Harteraad 2012). The report explains that patient-centred care, aligned with the preferences, capabilities and needs of the individual patient, is an important quality criterion (formulated from the patient's perspective) (Harteraad 2012).

Balance between desirable and undesirable effects

No literature was found that directly defines the evidentiary value or effects to answer the clinical question. Because of this, the guideline panel did not establish a balance between desirable and undesirable effects.

Socio-economic considerations and cost-effectiveness

The guideline panel considers that the resources needed for the intervention are negligible. Behavioural interventions are, after all, already applied frequently. Some training is, however, still needed when it comes to interventions.

The intervention is cost-effective. The study of Beard (2022) shows that the behavioural change labels of 'setting goals', 'planning' and 'comparison of behaviour' are the most cost-effective. In addition, the cost-effectiveness of cardiac rehabilitation has already been demonstrated (see <u>A.2</u> 'Background').

Health equality

The guideline panel expects that the intervention will lead to an increase in health equality.

Acceptability

The guideline panel expects that the intervention will be accepted by all key stakeholders.

Feasibility

The implementation of behavioural change techniques is considered realistic by the guideline panel.

Other considerations

The guideline panel considers that the following recommendations are also important to bring about behavioural change with the purpose of continuing and completing the exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure who have a low SES/limited health literacy. In the population of patients with coronary artery disease or chronic heart failure as a whole, the following effective behavioural change techniques have been identified:

- Setting goals (behavioural change label 1.1);
- Providing information on the health impacts (behavioural change label 5.1.);
- Instructions on how to conduct the behaviour (behavioural change label 4.1.).

The behavioural change techniques recur in various models that are used in cardiac rehabilitation. Often-used models are:

- Cognitive Behavioural Therapy (CBT) according to the 5G model (event > thoughts > feelings > behaviour > impact) (Beck 1976);
- 'Integrated-change model' (I-Change) (De Vries 2017);
- Motivational Interviewing (MI); see the 'KNGF guideline on Self-management' (2022);
- 'Acceptance and Commitment Therapy' (ACT); see the 'KNGF guideline on Self-management'
- (Koninklijk Nederlands Genootschap voor Fysiotherapie 2022);
- breathing and relaxation therapy (Van Dixhoorn 2005).

These are, however, only the most frequently used models. Moreover, techniques are emerging where nudging of other relaxation techniques are used.

The guideline panel has concluded the following:

- The aforementioned models can also be used for patients with a low SES and/or limited health literacy, provided that the recommendations formulated in <u>B.3 'Low SES/limited health literacy'</u> are kept in mind.
- Besides identifying SES and health literacy, it is also important to identify subjective social status (Ntoumanis 2021; Rahman 2015). Questions in this regard are asked during the medical history taking (also see **B.4** 'Medical history taking').
- If cognitive limitations are suspected, a (neuro)psychologist and/or social worker and/or occupational therapist can do a short and simple screening to explain in which area the patient is experiencing problems and, if there is an indication for it, start a more extensive neuropsychological examination. With this knowledge, the physical therapist can align more closely with the patient and, in the education process, keep the patient's cognitive functioning in account.
- Besides individual therapy, group therapy can also be given. Research by Mulderij (2022) shows that group therapy can contribute to motivation, support and knowledge sharing.
- The therapist has a signalling function with regard to identifying patients with a low SES and/ or limited health literacy. The therapist has the duty to discuss suspicions in this regard during the multidisciplinary consultation with the cardiac rehabilitation team so that an adjustment of the cardiac rehabilitation programme can be considered.
- Cooperation with a (neuro)psychologist and/or social worker and/or occupational therapist is especially important for patients with a low SES and/or limited health literacy. The therapist acts, as described in the current professional profiles, according to a biopsychosocial model, which also includes the use of the aforementioned behavioural change techniques to improve physical functioning (Koninklijk Nederlands Genootschap Fysiotherapie 2021; Vereniging

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van Oefentherapeuten Cesar en Mensendieck 2019). In clinical practice, the guideline panel generally has a positive experience of close collaboration with a (neuro)psychologist or social worker and/or occupational therapist at the heart centre, and it is therefore recommended for all patients.

Focus areas for implementation

No focus areas were formulated for implementation other than those in **B.3 'Low SES/limited health** literacy'.

Knowledge gaps

No direct answer to the clinical question was found in the literature, which is why the following knowledge gap was formulated:

Which behavioural change interventions are effective for facilitating compliance and reducing drop-out among patients with coronary artery disease or chronic heart failure and what role does a low SES and/or limited health literacy play in this regard?

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C.4 The exercise programme in a primary care setting

Recommendations

For patients with coronary artery disease or chronic heart failure, consider introducing an exercise programme in a primary care setting practice in phase II of the cardiac rehabilitation programme to facilitate continuation and completion of the cardiac rehabilitation programme, but:

- take the essential components mentioned in **B.1 'Personalised care'** into account in this regard; and
- consider this only if the conditions are met that were defined in terms of quality, safety and facilities as are formulated hereafter.

Ensure that:

- an AED is within reach at the place where the exercise programme is conducted;
- during the execution of the exercise programme at least two team members are present on site who are competent and qualified to provide 'basic life support' (BLS) and use an automatic external defibrillator (AED);
- at least one therapist is present during the execution of the exercise programme who is competent and qualified to signal signs of overexertion and/or (life-)threatening situations in the event of coronary artery disease or chronic heart failure;
- there is proper communication between the secondary/tertiary care setting and the primary care setting therapist (such as an opportunity for (structural) consultation between the primary care setting therapist and the referring cardiologist);
- there has been a proper multidisciplinary transfer of information from the cardiac rehabilitation in a secondary and tertiary care setting to the therapist in a primary care setting;
- after completion of the exercise programme in phase II of cardiac rehabilitation, an end report is made (for the general practitioner and the cardiologist) (see <u>C.7 'Evaluation, stop criteria and</u> closure of the treatment');
- the practice includes a disaster plan that is regularly updated and that is known to all the team members involved.

SUBSTANTIATION

Reason

The execution of the exercise programme, as part of phase II of cardiac rehabilitation, in the physical or exercise therapy practice in a primary care setting, is a form of personalised care within cardiac rehabilitation. Besides group interventions and individual support in a heart centre,

components of the cardiac rehabilitation programme, such as the exercise programme, can also be offered in practice in a primary care setting. This form of cardiac rehabilitation used to be provided for exceptional cases and is described in the NVVC practice guideline; however, in recent years it has been used more frequently and broadly (Nederlandse Vereniging voor Cardiologie 2011). There has been an upsurge in recent years of moving care from a secondary or tertiary care setting to a primary care setting in this way due to patients' need to receive care close to or at home (Ministerie van Volksgezondheid Welzijn en Sport 2022; Taskforce Zorg op de juiste plek 2018). Substitution also has benefits for the secondary or tertiary care setting, in that it removes some of the burden caused by the increase in the number of absolute and relative indications within cardiac rehabilitation.

In addition, transmural care in cardiac rehabilitation plays an increasingly important role, with treatment in a primary care setting being an essential link in the chain to increase participation in cardiac rehabilitation (Vromen 2021).

The exercise programme, as part of phase II of cardiac rehabilitation in a primary care setting, consists of accompanying the patient in the exercise programme under the supervision of a physical or exercise therapist who works in a primary care setting.

Clinical question

Due to a growing demand from the field to know which patients might be eligible for phase II of cardiac rehabilitation in a primary care setting and under what conditions, the following clinical question was formulated.

Clinical question 1

Which patients (with coronary artery disease or chronic heart failure) are eligible for an exercise programme in a primary care setting, as part of the multidisciplinary phase II of cardiac rehabilitation in a transmural setting?

Clinical question 2

What are the conditions for offering an exercise programme as part of a transmural multidisciplinary phase II of cardiac rehabilitation in a primary care setting for patients (with coronary artery disease or chronic heart failure)?

Conclusions based on the literature

The clinical questions were formulated specifically for the context, in other words aimed at a primary care setting in the Netherlands. The guideline panel indicates that there is no literature available on the impact of an exercise programme in a primary care setting. The clinical questions were therefore answered by means of literature collected in a non-systematic way and that pertains to another setting, namely home-based cardiac rehabilitation.

The assessment was based on the effect size and the evidentiary value, after which the results were formulated in a standardised manner (Langendam 2022). This was translated to a primary care setting in the evidence-to-recommendation process.

Coronary artery disease

No standardised formulation of the results was made, as the evidentiary value was not formulated in the selected study. However, home-based telerehabilitation shows a clinically non-relevant improvement in physical functioning (measured on the 6MWT and peak VO₂) and quality of life

(SF-36 mental and physical component) compared to regular care (without an exercise programme). As opposed to cardiac rehabilitation in a heart centre, home-based cardiac rehabilitation was found to have comparable, clinically non-relevant positive impacts on all outcomes.

Chronic heart failure

Crucial outcome measures:

Home-based cardiac rehabilitation probably increases physical functioning (measured on the Six Minute Walking Test (6MWT) and the peak volume of oxygen (peak VO₂)) compared to regular care without an exercise programme.

Explanation: A clinically non-relevant positive effect (36.77 m and 2.69 ml/kg/min.) was found on physical functioning (measured on the 6MWT and peak VO₂) compared to regular care without an exercise programme, where the evidentiary value of these results is reasonable, whereby we are fairly certain of the impact that is demonstrated in the literature. Home-based cardiac rehabilitation makes very little if any difference to quality of life

- (measured on the 36-Item Short Form Health Survey (SF-36), mental and physical component) compared to regular care without an exercise programme.
- *Explanation*: A clinically non-relevant positive effect (1.56 and 3.28 points) was found in the difference in quality of life (measured on the SF-36 mental and physical components) compared to regular care without an exercise programme, where the evidentiary value of these results is high, whereby we are certain of the impact that is demonstrated in the literature. Home-based cardiac rehabilitation probably does not reduce related hospitalisation and mortality compared to regular care without an exercise programme.
- *Explanation*: A clinically non-relevant positive effect (OR 0.34 and OR 0.48) was found in the difference in related hospitalisation and mortality compared to regular care without an exercise programme, where the evidentiary value of these results is reasonable, whereby we are fairly certain of the impact that is demonstrated in the literature.
- Compared to telerehabilitation, cardiac rehabilitation in a heart centre or a hybrid form, home-based cardiac rehabilitation probably does not have an impact on physical functioning (measured on the 6MWT and peak VO₂), quality of life (measured with the SF-36 mental and physical component), related hospitalisation and mortality in the network analysis. *Explanation*: For the remaining comparisons in the network analysis, in most cases a clinically non-relevant impact was found between the various forms of rehabilitation, whereby the evidentiary value was mostly reasonable to high. The effectiveness of home-based cardiac rehabilitation is therefore comparable to that of other forms of rehabilitation.

Undesirable effects

No standardised formulation of the results was made, as the evidentiary value was not formulated in the selected study. However, home-based cardiac rehabilitation is a safe alternative for cardiac rehabilitation and is comparable to the numbers and severity of incidents that occur during cardiac rehabilitation in a heart centre.

Rationale of the recommendation

The guideline panel decided to include a conditional recommendation for the exercise programme in a primary care setting in this guideline, in response to both clinical questions.

The results of the systematic literature review, based on a comparable setting (home-based cardiac rehabilitation), show that there is an improvement on physical functioning compared to no exercise programme. In addition, the effects are mostly comparable to those of cardiac rehabilitation in a heart centre.

The guideline panel is of the opinion that the desirable effects (positive effects on physical functioning and quality of life) appear to outweigh the undesirable effects (cardiac incidents). Economic considerations, health equality, acceptability, feasibility, implementation, cost-effectiveness and values and preferences of the patient do not appear to be objections to performing an exercise programme in a primary care setting. The guideline panel indicates that offering this personalised form of cardiac rehabilitation may increase participation in and completion of an exercise programme.

The conclusion is that the evidence for the impact of introducing an exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure is uncertain, as the evidence is based on a comparable setting. The guideline panel does, however, consider that the favourable effects outweigh the undesirable effects and on this basis formulated a conditional recommendation for the intervention, on condition that the intervention meets specific conditions (see B.1 'Personalised care').

JUSTIFICATION

Literature

The clinical questions are aimed at a specific setting, namely a primary care setting in the Netherlands. The guideline group is not aware of any literature that focuses on this setting. A systematic literature review was therefore not considered to be meaningful for answering these clinical questions. The clinical questions are substantiated from systematic literature reviews that were gathered based on an orienting search and that pertain to another type of setting, namely the execution of an exercise programme at home (home-based cardiac rehabilitation) and existing national and international guidelines of high methodological quality.

Home-based cardiac rehabilitation

Home-based cardiac rehabilitation is done in phase II of cardiac rehabilitation in a home setting, for instance with the use of e-health. This form of cardiac rehabilitation can consist of, for example, cycling on a stationary exercise bike or exercising with step counters. The cardiac rehabilitation programme (including the exercise programme) is coordinated and accompanied by a heart centre. The support can take place 'live' (synchronous) during execution, but also by means of periodic assessments (asynchronous) of the cardiac rehabilitation (including the exercise programme) afterwards. This support is provided remotely (from the heart centre) by a physical or exercise therapist in a secondary or tertiary care setting.

With cardiac rehabilitation in a primary care setting, the same interventions are mostly used as in home-based cardiac rehabilitation from a heart centre; these interventions are comparable in terms of efficacy and safety. However, in physical or exercise therapy practice, support in a primary care setting is sometimes done by a primary-care physical or exercise therapist. The physical or exercise therapist is always present 'live' (synchronous) for the patient.

Research question

To answer the clinical question, a systematic review was carried out on the following research question (PICO):

What is the effect of an exercise programme that is carried out at home during phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure in terms of physical functioning, quality of life and safety compared to executing the exercise programme in a heart centre or not following any exercise programme at all?

Relevant outcome measures

The guideline panel considers physical functioning, quality of life, mortality, hospitalisation and major cardiac incidents as crucial outcome measures for decision-making. Per outcome measure:

- Standardised Mean Difference (SMD): The guideline panel defines an effect > 0.5 as a significant effect (clinically relevant difference) (Sawilowsky 2009).
- Peak volume of oxygen (peak VO₂): The guideline panel defines 1 ml/kg/min. as a significant effect for patients (clinically relevant difference) (0–0.5 is trivially small; 0.5–0.999 is small; >1ml is reasonable; >2 is a large difference) (Tegegne 2022).
- Score on the 36-Item Short Form Health Survey (SF-36) for physical functioning: The guideline panel defines 15.00 points as a significant effect for patients with chronic heart failure and coronary artery disease (clinically relevant difference) (Wyrwich 2005).
- Score on SF-36 for mental functioning: The guideline panel defines 15.00 points as a significant effect for patients with chronic heart failure and coronary artery disease (clinically relevant difference) (Wyrwich 2005).
- *Six Minute Walk Test (6MWT)*: The guideline panel defines 30.10 metres as a significant effect for patients with chronic heart failure (clinically relevant difference) (Shoemaker 2013; Tegegne 2022).
- Undesirable effects: Any major cardiac incidents that might be linked to the intervention are considered to be undesirable. The guideline panel considers that any significant difference is also a clinically relevant difference (an increase of, for example, 1 death is already relevant).

Search and selected literature

In order to answer the clinical question, an orienting literature review was conducted in PubMed on home-based cardiac rehabilitation, with a preference for a recent (< 5 years old) systematic review with meta-analysis (see Appendix C.4-1). This orienting literature search, which was done on 14 February 2023, yielded 20 unique hits (Bakhshayesh 2020; Bullard 2019; Castellanos 2019; Figueiredo 2020; Imran 2019; Long 2019; Mamataz 2022; Mares 2018; Oldridge 2019; Ramachandran 2022; Resurrección 2019; Santiago de Araújo Pio 2019; Sotirakos 2022; Stefanakis 2022; Taylor 2019a,b; Tegegne 2022; Xia 2018; Xu 2019; Zhang 2020). After screening of the title and the abstract and reading of the full manuscript, three articles were selected to provide an answer to the research question (Ramachandran 2022; Stefanakis 2022; Tegegne 2022). To limit an overlap of results between the various systematic literature reviews, the most recent literature review was selected separately for each indication (coronary artery disease or chronic heart failure) and for safety as an outcome in consultation with the guideline panel, and an assessment was made of the study quality.

Characteristics and efficacy of the included studies on coronary artery disease

In the systematic review of Ramachandran (2022), a meta-analysis was carried out to compare the efficacy of home-based telerehabilitation and cardiac rehabilitation in a heart centre in terms of significant outcome measures (physical functioning, quality of life, hospitalisation and mortality) with that of regular care (without an exercise programme).

14 RCTs were included in this systematic review, in which 2,869 patients with coronary artery disease were included. The age of the patients in the pooled population was 45.8 to 73.6 years, with 21.8% women (Ramachandran 2022).

The comparisons, efficacy and quality of evidence of this systematic review can be found in Appendix C.4–2.

Home-based telerehabilitation shows a clinically non-relevant improvement in physical functioning (measured on the 6MWT and peak VO₂) and quality of life (SF-36 mental and physical component) compared to regular care (without an exercise programme). As opposed to a cardiac rehabilitation programme in a heart centre, home-based cardiac rehabilitation was found to have comparable, clinically non-relevant positive impacts on all outcomes (Ramachandran 2022).

No evidentiary value was formulated.

Characteristics and efficacy of the included studies on chronic heart failure

In the systematic review of Tegegne (2022), a network meta-analysis was performed to compare efficacy between the exercise programme that was executed in the heart centre, home-based, telerehabilitation, regular care (without an exercise programme) and a hybrid form of care with regard to significant outcome measures (physical functioning, quality of life, hospitalisation and mortality) for patients with chronic heart failure.

In this systematic review, 139 randomised controlled trials (RCTs) were included, with a total of 18,670 patients with heart failure and with reduced or preserved ejection fraction. The average age in the pooled population was 61.1 years (range 44–81), with 71.4% men. The median duration of the intervention was 12 weeks (IQR 12–24) and the study follow–up took 16 weeks (IQR 12–26) (Tegegne 2022).

The comparisons, efficacy and quality of evidence of this systematic review can be found in Appendix C.4–3.

Of the 139 RCTs, 12 articles reported undesirable events (regardless of the setting or format) (which occurred during or immediately after exercising, namely: deterioration of heart failure, hospitalisation due to a heart attack, acute coronary syndrome, musculoskeletal injury, dyspnoea, hyperglycaemia, palpitations, angina pectoris, arrhythmia, presyncope or syncope, occlusion of peripheral bypass, ectopic heart beats, low blood pressure and back pain). No lethal incidents due to exertion were reported. No additional analyses were performed on these outcomes (Tegegne 2022).

Home-based cardiac rehabilitation probably results in an increase (in efficacy) of physical functioning (measured on the 6MWT and peak VO₂) compared to regular care without an exercise programme, and the impacts on quality of life (measured on the SF-36 mental and physical component), related hospitalisation and mortality are comparable.

In addition, home-based cardiac rehabilitation in a network analysis shows no significant differences compared to telerehabilitation, cardiac rehabilitation in a heart centre or a hybrid form in terms of physical functioning (measured on the 6MWT and peak VO₂), quality of life (measured on the SF-36 mental and physical component), related hospitalisation and mortality, except for physical functioning (measured with the 6MWT), compared to the hybrid form. The effectiveness of home-based cardiac rehabilitation is therefore comparable to that of other forms of rehabilitation (Tegegne 2022).

Safety of home-based cardiac rehabilitation

The systematic review of Stefanakis (2022) was carried out to describe the incidence and severity of the undesirable effects (cardiac incidents) of home-based cardiac rehabilitation.

In this systematic review, five studies were included with a total of 808 patients who qualify for cardiac rehabilitation. More than half of the included patients belong to a high-risk group. Only one study reported severe side effects that were associated with home-based cardiac rehabilitation. The incidence of the number of severe side effects from the sample were estimated at 1 out of 23,823 patient hours. No deaths or hospitalisations were found that could be linked to home-based cardiac rehabilitation.

Home-based cardiac rehabilitation is a safe alternative for cardiac rehabilitation and is comparable to the numbers and severity of incidents that occur during cardiac rehabilitation in a heart centre (Stefanakis 2022).

No evidentiary value was formulated.

From evidence to recommendation

A summary is given below of literature that was collected non-systematically, where existing national and international guidelines of high methodological quality were selected.

Summary of literature

Dutch practice guideline of the Dutch Society for Cardiologists (Nederlandse Vereniging voor Cardiologie 2011)

The purpose of this practice guideline is to guarantee the quality and safety of phase II of cardiac rehabilitation for the benefit of professionals who work in cardiac rehabilitation in the Netherlands.

In this practice guideline, it was decided based on the complexity of various patient populations to divide these into several levels of cardiac rehabilitation. For each of these levels, separate practice requirements were drawn up, distinguishing in terms of patient selection, location, quality, safety and facilities (Nederlandse Vereniging voor Cardiologie 2011).

In this guideline, it is explained that for level 1 cardiac rehabilitation patients (non-complex patients, i.e. with a low risk) an exception rule applies if it is impossible for the patient to follow the exercise programme in a hospital or cardiac rehabilitation centre for logistic reasons, such as distance and/or transport issues. They can then follow the programme in a physiotherapy practice in a primary care setting. The relaxation and lifestyle programme can in this case be followed outside the referring centre, provided that it is accompanied by appropriately trained

professionals; the information programme must in any event always be followed in the referring centre. If such an approach is chosen, in as far as the exercise programme is concerned, specific criteria as described in the NVVC practice guideline must be met. For level II heart patients (complex patients) and level III (cardiac rehabilitation in a clinical setting), no exceptions are made in this practice guideline (Nederlandse Vereniging voor Cardiologie 2011). See also Appendix C. 4–4 for specific criteria that the practice should meet.

Multidisciplinary Guideline for Cardiac Rehabilitation (Revalidatiecommissie NVVC/NHS en projectgroep PAAHR)

This guideline describes multidisciplinary cooperation with regard to Cardiac Rehabilitation in the Netherlands.

In this guideline, the guideline panel selected absolute and relative indications and contraindications for cardiac rehabilitation as being relevant for our clinical question. The guideline may soon be revised due to new scientific insights.

The guideline pertains to secondary or tertiary care settings, but the results might be generalised to a primary care setting.

Guideline on Heart Failure (Nederlands Huisartsen Genootschap 2021)

This guideline for general practitioners pertains to patients with acute and chronic heart failure. The guideline panel selected the following recommendations as being relevant for our clinical question:

Check how many patients are getting exercise and what limitation there might be.
 Advise patients who are stable to do regular exercise insofar as their symptoms allow it; keep account of the patient's possibilities and wishes.

- Consider referring to:
- multidisciplinary cardiac rehabilitation;
- a specialised physical or exercise therapist for exercise recommendations and support.

Cardiac rehabilitation could possibly lead to a reduced risk of hospitalisation and an improvement of quality of life, but only limited research has been done on cardiac rehabilitation among older adults, women and patients with heart failure with preserved ejection fraction and on exercising at home, according to this guideline. From a focus group study it appears that it is important to find a form of exercise that suits the patient.

The guideline pertains to secondary or tertiary care settings, but the results might be generalised to a primary care setting.

2020 ESC Guidelines on sports cardiology and exercise in patients with cardiovascular disease (Pelliccia 2021)

This guideline gives tips on exercising for patients with chronic heart failure. The guideline panel selected the following recommendations as being relevant for our clinical question:

The training session must be personalised and individually designed for several weeks, keeping account of symptoms and objective findings during exercise tests, such as the maximum exercise capacity, heartbeat response or arrhythmia. With atrial fibrillation (AF), exertion can only be monitored through strength or the Borg Rating of Perceived Exertion Scale (BORG (RPE) scale).

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 - During treatment, high-risk patients must be consulted more frequently in the first phase. Ideally, exercise should take place under supervision in an exercise programme to which homebased cardiac rehabilitation can gradually be added.
 - If the relevant measures are taken, the overall risk of physical exercise will be low, even for exercises with a high intensity and for patients with severe chronic heart failure.
 - The intervals between exercise sessions must depend on the severity of the disease and comorbidity, the setting of the session (under supervision vs. at home), age and the patient's compliance.

This guideline pertains to secondary or tertiary care settings, but the results might be generalised to a primary care setting.

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure (McDonagh 2021)

This guideline pertains to the cardiac rehabilitation for patients with chronic heart failure. The guideline panel selected the following recommendations as being relevant for our clinical question:

- The components of cardiac rehabilitation programmes for patients with heart failure vary and can consist of hospital-based approaches, home-based programmes, case management and hybrid forms thereof.
- Components of cardiac rehabilitation programmes such as telemonitoring can be applied at a local, regional or national level.
- No single form of cardiac rehabilitation seems to be superior.
- The organisation of a cardiac rehabilitation programme must be adjusted to the healthcare system, the available resources (infrastructure, facilities, staff and finances) and administrative policy and must be in line with the patient's needs.

NICE guideline on chronic heart failure in adults (NG106) (Real 2018)

This guideline pertains to patients with heart failure and is based on the review of Real (2018), where the effectiveness of home-based cardiac rehabilitation can be compared to that of cardiac rehabilitation in a heart centre in terms of the outcome measures of mortality, quality of life, undesirable events, continuation of the intervention and physical functioning. In this review, eight studies were included and assessed according to Grading of Recommendations Assessment, Development and Evaluation (GRADE).

The guideline makes a number of recommendations:

- Offer a personal, exercise-based cardiac rehabilitation programme to people with heart failure, unless their condition is unstable. The programme:
- should be preceded by an assessment to make sure that it is suitable for the person;
- must be offered in a form and in an environment (at home, in the community or in hospital) that is easily accessible for the person;
- must included a psychological and an educative component;
- can be included in an existing cardiac rehabilitation programme;
- must be accompanied by information on the available support by professionals in healthcare if the person continues with the programme.

NICE Guideline on Acute coronary syndromes (NG185) (Corbett 2021)

This guideline gives tips on the cardiac rehabilitation programme for patients with coronary artery disease.

The guideline panel chose the following recommendations for facilitating participation in cardiac rehabilitation as being relevant for our clinical question:

- Offer cardiac rehabilitation programmes that are intended to motivate people to attend and complete the programme. Explain what the benefits of participation are.
- Discuss factors that might prevent the patient from taking part in a cardiac rehabilitation programme, such as transport problems.
- Offer cardiac rehabilitation programmes at various locations (including at the person's home, at the hospital and in the community) and at various times of the day, for example outside of working hours. Explain the available options.
- Make cardiac rehabilitation accessible and relevant for anyone who has had a myocardial infarction with or without ST elevation (STEMI/NSTEMI), in particular for patients who do not have access to this service as easily such as people from black, Asian or ethnic minorities, older adults, people from lower socio-economic groups, women, people from rural communities, people with an intellectual disability and people with mental and physical health problems. Encourage all staff, including senior medical staff, who are involved in care for people after a STEMI/NSTEMI actively to promote cardiac rehabilitation.

Criteria for formulating the recommendations

From evidence to recommendation

Internationally recognised criteria were used to assess the evidence on which the recommendations are based. These criteria, as well as the remaining considerations formulated by the guideline panel, determine the strength of the recommendation.

Desirable effects

No literature was selected that defines the evidentiary value or effects in the same setting (primary care setting) as the formulated clinical questions. The guideline panel considers, however, that the results of the systematic literature reviews that describe a comparable setting (home-based cardiac rehabilitation) can be generalised to an exercise programme that is performed in a primary care setting.

The following desirable effects are described in the systematic literature reviews:

- The efficacy of home-based cardiac rehabilitation is comparable to that of telerehabilitation, cardiac rehabilitation in a heart centre or a hybrid form in terms of physical functioning (measured on the 6MWT and peak VO₂), quality of life (measured on the SF-36 mental and physical component), related hospitalisation and mortality, with the exception of physical functioning (measured with the 6MWT compared to the hybrid form).
- In addition, home-based cardiac rehabilitation probably results in a clinically relevant improvement of physical functioning (measured with the 6MWT and peak VO₂) compared to regular care without an exercise programme, and the impacts on quality of life (measured on the SF-36 mental and physical component), related hospitalisation and mortality are comparable.

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- These desirable effects are supported by recommendations in national and international guidelines (McDonagh 2021; Real 2018).
- Home-based cardiac rehabilitation is a safe alternative for cardiac rehabilitation, and the number and severity of incidents are comparable to those of cardiac rehabilitation in a heart centre. The fact that the implementation of the exercise programme is considered safe is supported in several studies and guidelines, even when the intensity of exercises increases (Pelliccia 2021; Rognmo 2012; Stefanakis 2022).
- The implementation of the exercise programme in a primary care setting is a form of personalised cardiac rehabilitation. There has been an national and international upsurge in recent years in offering new models of personalised cardiac rehabilitation (home-based, telerehabilitation or care in a primary setting, or a hybrid form thereof), driven on the one hand by technological developments and an increase in patients' digital literacy and on the other hand by the COVID-19 pandemic and the displacement of care to the home environment (Beatty 2023; Heindl 2022; Taylor 2022; Vromen 2021).
- The guideline panel considers that it is important to adapt care to the person, as this increases participation in cardiac rehabilitation and is in line with the principle of the right care in the right place and suitable care as a component of the Integral Health Agreement (Integraal Zorgakkoord or IZA) (Ministerie van Volksgezondheid Welzijn en Sport 2022).
- Likewise, the following (inter)national guidelines describe that cardiac rehabilitation in particular should be offered in a personalised way and that various forms of cardiac rehabilitation can be introduced in this regard (Corbett 2021; McDonagh 2021; Nederlands Huisartsen Genootschap 2021; Pelliccia 2021; Real 2018).

The guideline panel came to the assessment that the desirable effects of an exercise programme in a primary care setting are significant compared to not doing an exercise programme. The guideline panel considers that the desirable effects of an exercise programme in a primary care setting are reasonable compared to an exercise programme in a heart centre.

Undesirable effects

No literature was selected that defines the evidentiary value or effects in the same setting (primary care setting) as the formulated clinical questions. However, the guideline panel came to the conclusion that the results of the systematic literature reviews that describe a comparable setting (home-based cardiac rehabilitation) can be generalised to an exercise programme in a primary care setting.

No undesirable effects were found in the literature. The number and severity of undesirable cardiac incidents during cardiac rehabilitation in a primary care setting are comparable to those in a heart centre and are considered acceptable by the guideline panel.

The guideline panel considers that the undesirable effects of an exercise programme in a primary care setting are reasonable compared to not doing an exercise programme or doing an exercise programme in a heart centre.

Quality of evidence

No literature was selected that defines the evidentiary value or effects in the same setting (primary care setting) as the formulated clinical questions. The guideline panel considers, however, that the results of the systematic literature reviews that describe a comparable setting (home-based cardiac rehabilitation) can be generalised to an exercise programme in a primary care setting.

The guideline panel came to the assessment that the evidentiary value of the desirable effects is reasonable and that the evidentiary value of the undesirable effects is reasonable.

Patient values and preferences

The guideline panel considers that patients attach great value to the intervention and that there is little variation among patients. This is supported by the call from the NVVC in collaboration with the Harteraad (heart council) and the Hartstichting (heart foundation) to implement cardiac rehabilitation from a distance and also by the Cardiac Rehabilitation dossier that was established by these parties (Harteraad 2020).

Balance between desirable and undesirable effects

The guideline panel came to the conclusion that offering personalised care in cardiac rehabilitation will facilitate continuation and completion thereof and that it will also facilitate the impacts in the shorter and longer term.

The guideline panel considers that the desirable effects definitely outweigh the undesirable effects.

Socio-economic considerations and cost-effectiveness

The guideline panel considers that the resources needed for the intervention are negligible. The guideline panel expects that the procurement of the necessary resources will not entail any exorbitant costs.

The intervention is probably cost-effective. This assumption is based on the literature that is described in this module (in a different setting) and in the Equalis report (Van Drunen 2021).

Health equality

The guideline panel expects that the intervention will lead to an increase in health equality, since the introduction of an exercise programme in a primary care setting will increase the accessibility of cardiac rehabilitation.

Acceptability

The guideline panel expects that the intervention will probably be accepted by the majority of key stakeholders, since this barrier was given top priority in the preliminary phase. There are furthermore various examples of initiatives that are already offering this care successfully or that are making attempts to do so. It is expected that doctors, physical and exercise therapists as well as patients will accept this intervention. Since the reimbursement structure has not yet been set up, other stakeholders might object, for instance insurance companies (see also the 'Feasibility' item).

Feasibility

The implementation of the exercise programme in a physical or exercise therapy practice is considered by the guideline panel to be realistic but also challenging. The conditions for setting up the practice are feasible.

The coordination of a proper network where multidisciplinary consultation takes place is, however, not yet well implemented everywhere in the Dutch healthcare system. There is also a lack of opportunities for electronic data sharing by means of electronic patient records.

The financial reimbursement of care in a primary setting from a secondary or tertiary care setting (substitution) and the multidisciplinary consultation that goes with it is also not yet reimbursed in the Dutch healthcare system. At present, only phase II of cardiac rehabilitation that is performed in a secondary or tertiary care setting is reimbursed when the diagnosis treatment code for

medical specialist care is opened by the cardiologist. The cardiac rehabilitation journey, including the exercise programme, is reimbursed from these funds. Phase II of cardiac rehabilitation in a primary care setting is currently not reimbursed. For transmural collaborations that were set up during the drafting of the guideline, agreements were made at a local level and in consultation with insurance companies.

The implementation of this transmural care path is inhibited by the lack of funding. Such limitations are not new in the implementation of new care paths in the Netherlands (Rakers 2023). In recent years, there have been many efforts at policy level to speed up the implementation of new care paths (including substitution to a primary care setting) (Ministerie van Volksgezondheid Welzijn en Sport 2022, 2019; Taskforce Zorg op de juiste plek 2018; Zorginstituut Nederland 2023).

Other considerations

The guideline panel is of the opinion that the following considerations are also important for providing an answer to both clinical questions.

- It is important that the essential components described in **B.1 'Personalised care'** should be taken into account when implementing interventions.
- In addition to the key components, the physical and exercise therapist will, depending on local forms of collaboration, draw up an additional treatment plan that is based on the context of a primary care setting.
- It is important to verify in a procedural way: 1) whether the patient has an indication for an exercise programme; 2) what the patient's exercise goals are; 3) which form of therapy and setting would be suitable for this.

The guideline panel is of the opinion that in addition to the considerations, the following are also important for providing an answer to clinical question 1.

- It is important to align with current national and international guidelines. Unfortunately, the quality standards that were available at the time of writing this guideline are no longer in line with current practice and scientific findings. The guideline panel is focusing on the NVVC practice guideline and the 'Multidisciplinary Guideline for Cardiac Rehabilitation' (Nederlandse Vereniging voor Cardiologie 2011; Revalidatiecommissie NVVC/NHS en projectgroep PAAHR 2011). It is impossible to draw up a list of patients who are eligible for an exercise programme in a primary care setting, due to the fact that so many inhibiting factors come into play when establishing an indication for an exercise programme.
- When executing an exercise programme in a primary care setting, the therapist must keep account of the conditions defined in clinical question 2.

The guideline panel is of the opinion that in addition to the other considerations, the following are important for providing an answer to clinical question 2.

It is important to align with current national and international guidelines. Unfortunately, the quality standards that were available at the time of writing this guideline are no longer in line with current practice and scientific findings. The guideline panel is focusing on the NVVC practice guideline and the 'Multidisciplinary Guideline for Cardiac Rehabilitation' (Nederlandse Vereniging voor Cardiologie 2011; Revalidatiecommissie NVVC/NHS en projectgroep PAAHR 2011).

In this guideline, practice requirements were established for each level (in terms of patient complexity), distinguishing with regard to patient selection, location, quality and safety, and facilities. The guideline panel considers that it is good to align with this classification. To do so, the guideline panel has chosen criteria that are relevant for a primary care setting (Appendix C.4-4). The execution of an exercise programme by patients with coronary artery disease or chronic heart failure can lead to overexertion of the heart, which can even take on life-threatening proportions. The guideline panel therefore considers that during the execution of the exercise programme:

 at least one physical or exercise therapist must be present who is competent and qualified in signalling signs of overexertion and/or life-threatening situations in cases of coronary artery disease or chronic heart failure.

at least two members of the cardiac rehabilitation team must be present who are competent and qualified in *Basic Life Support* and the use of an automatic external defibrillator (AED).
 The competencies and skills of a general physical therapist and a cardiovascular and respiratory physiotherapist are described in the 'Professional Profile of the physical therapist' and the 'Professional Profile of the cardiovascular and respiratory physiotherapist' (Koninklijk Nederlands Genootschap Fysiotherapie 2021). The guideline panel considers that the physical or exercise therapist who treats patients with coronary artery disease and chronic heart failure in a primary care setting by means of an exercise programme in phase II of cardiac rehabilitation should have the same competencies and skills as a physical and exercise therapist in a secondary or tertiary care setting.

Structural agreements should be made regarding multidisciplinary collaboration and communication between the primary and the secondary or tertiary care setting. The shape that this collaboration and communication will take depends on local agreements. Structural agreements will pertain to:

- a proper multidisciplinary transfer from the secondary/tertiary care setting to the physical or exercise therapist in the primary care setting, stating in which programmes, besides the exercise programme, the patient is participating;
- structural opportunities for consultation across the lines of healthcare;
- an end report from the physical or exercise therapist in the primary care setting to the cardiologist and the general practitioner, stating whether the individual targets have been met and describing which complications, if any, have occurred.

It is desirable to be able to do interim assessments of the patient in a multidisciplinary dialogue (MDO). To this end, before starting with the treatment, structural multidisciplinary arrangements must be made. The end assessment must also take place in an MDO.

It is important that the practice has an AED at the place where the exercise programme is executed.

The practice must have an updated disaster plan that is available at the place where the exercise programme is executed and that all the team members involved are familiar with. It is important in an emergency to know which measures must be taken and how everyone can be brought to safety. If the practice is located in a facility-sharing building, it is also possible that an overarching plan has been set up for the entire building.

The disaster must include at least the following:

- names and telephone numbers of company aid providers (BHV) (if applicable);
- all emergency numbers;
- where fire extinguishers and first-aid equipment can be found;

- how staff/other team members are briefed in their jobs;
- who has to report the emergency to the aid agencies;
- what the escape route is.

The practice must comply with KNGF equipment and service requirements (Koninklijk Nederlands Genootschap Fysiotherapie 2022). This document also states that the practice must have adequate equipment to support investigation and treatment. The guideline panel wants to emphasise here that apparatuses for measuring blood pressure, saturation or heartbeat in this patient group is of specific importance.

Focus areas for implementation

For the implementation of phase II of cardiac rehabilitation in a primary care setting, feasibility plays an important role. In this regard, see the aforementioned considerations. Other basic conditions for the implementation of the recommendations are:

- investments that the practitioner must make in terms of practice facilities;
- reinforcement of regional collaborations;
- organising funding of care in a primary setting and collaboration with the secondary or tertiary care setting.

Knowledge gaps

No knowledge is currently available of the efficacy of conducting an exercise programme as part of phase II of cardiac rehabilitation in a primary care setting.

The efficacy of conducting the exercise programme has been studied extensively in a secondary and tertiary care setting. To determine whether the setting has an impact on the efficacy of cardiac rehabilitation in a primary care setting, a methodologically sound scientific study must be made. The following research question has been formulated for this:

'How (cost) effective is the implementation of an exercise programme as part of phase II of cardiac rehabilitation in a physical or exercise therapy practice in a primary care setting in the Netherlands for patients with coronary artery disease or chronic heart failure?

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C.5 FITT factors with chronic heart failure

Recommendations

Adjust the frequency, intensity, type and time (FITT factors) of training for a patient with chronic heart failure (with either reduced ejection fraction (HFrEF) or preserved ejection fraction (HFpEF)) aimed at optimising exercise capacity to each individual.

In doing so, take the essential components into account (see B.1 'Personalised care').

Consider in this regard:

- introducing aerobic training in particular (continuous training and interval training) to optimise exercise capacity;
- introducing 'high-intensity interval training' (HIIT) instead of continuous training;
- increasing the total energy expenditure of the aerobic training (a product of session frequency, session time, training intensity and duration of the programme) to optimise exercise capacity, keeping in mind that all training variables are inextricably linked to each other;
- combining aerobic training with other forms of exercise, such as:
 - strength training for patients who due to limited muscle strength cannot keep up aerobic training;
 - 'inspiratory muscle training' (IMT) for patients with reduced inspiratory breathing muscle strength (Pi-max ≤ 70% of what is predicted) or a ventilatory limitation in addition to aerobic training;
- applying FITT factors to patients with HFrEF or HFpEF in line with the target values in the following table.

Training modality	Scope and frequency	Intensity and duration		
aerobic training (CT, HIIT or LIT)	0–12 weeks: CT, HIIT or LIT: 3–5x/week	CT: 50-80% peak VO ₂ /HRR, 20-60 min. HIIT: 80-90% peak VO ₂ /HRR, active recuperatio 40-60% of peak VO ₂ /HRR, interval 4x4 min., active recuperation 3x3 min. LIT: 50% wattage, 10-12 interval 30 sec, recuperation 60 sec		
strength training (ST)	0–12 weeks: KT: 2–3x/week	KT: 30-80% 1RM, 8-10 exercises of large muscle groups, 2-3 sets of 10-15 repetitions, 1-2 min. rest (starting after 6-8* weeks)		
ʻinspiratory muscle training' (IMT)	0–12 weeks: IMT: 3–4x/week	IMT: 20-40% of Pi-max, 2x15 min./day		

FITT factors for optimising exercise capacity in patients with chronic heart failure and with HFrEF or HFpEF

CT = continuous training; HIIT = high-intensity interval training; LIT = low-intensity (interval) training; HRR = heart rate reserve; min. = minute; PI-max; MIP = $\underline{\text{maximum inspiratory mouth pressure}}$; RM = repetitions maximum; peak VO₂ = peak oxygen intake

* in consultation with the cardiologist, training can also start earlier (Ennis 2022)

SUBSTANTIATION

Reason

An important individual rehabilitation goal that therapists often strive for is to optimise exercise capacity (maximum oxygen consumption per minute (max. VO_2) of the peak volume of oxygen (peak VO_2)) of a patient with chronic heart failure. Higher exercise capacity leads to better experienced quality of life for patients with chronic heart failure (McDonagh 2021; Real 2018). To improve exercise capacity (peak VO_2), the FITT factors (frequency, intensity, type and time) must be applied

in a patient-specific way. Research shows that there is considerable variance in practice in the execution of an exercise programme in phase II of cardiac rehabilitation and that on average, there is often an 'underload' in training (Vromen 2013). For patients with chronic heart failure and reduced ejection fraction (HFrEF) or preserved ejection fraction (HFpEF), there is insufficient knowledge regarding the recommended way in which FITT factors should be applied in an exercise programme in phase II of cardiac rehabilitation to improve exercise capacity (peak V0,/max. V0,).

Clinical question

Which FITT factors are recommended for which patients with chronic heart failure (either HFrEF or HFpEF) in the exercise programme in phase II of cardiac rehabilitation to optimise exercise capacity (max. VO_/peak VO_)?

To answer the clinical question, three sub-questions were formulated.

Sub-question 1

What is the contribution of FITT factors for patients with chronic heart failure in terms of optimising exercise capacity (peak V0,/max. V0,)?

Sub-question 2

What type of training contributes the most to optimising exercise capacity (peak VO_2/max . VO_2) for patients with HFpEF?

Sub-question 3

What is the impact of the various training variables for aerobic continuous training in terms of optimising exercise capacity (peak VO,/max. VO,) in patients with HFrEF?

Conclusions based on the literature

In order to answer the clinical question, the guideline panel took results from the selected literature. The assessment was based on the effect size and the direction of the evidentiary value, and the results were then formulated in a standardised manner. These standardised formulations are accepted worldwide and make a statement about the certainty of the evidence found in a specific study (Langendam 2022).

Conclusions based on the literature sub-question 1

No systematic literature review was selected to answer sub-question 1. The clinical question was answered on the basis of existing guidelines and clinical expertise.

Conclusions based on the literature sub-question 2

Sub-question 2 was answered based on existing systematic meta-analyses.

Aerobic training versus regular care

Conclusion: Aerobic training probably results in an increase in peak VO₂ compared to regular care. *Explanation*: A clinically relevant positive effect was found in aerobic training regarding exercise capacity (peak VO₂) (WMD 2.14 ml/kg/min.) compared to regular care. The evidentiary value of these results is reasonable, which is why the guideline panel is reasonably sure of the impact that is demonstrated in the literature.

IMT versus regular care

Conclusion: IMT appears to result in an increase in peak VO₂ compared to regular care. *Explanation*: Respiratory muscle training was found to have a clinically relevant positive effect (WMD 2.46 ml/kg/min.) on exercise capacity (peak VO₂) compared to regular care. However, the evidentiary value of these results is low, which is why the guideline panel is uncertain of the effect that is demonstrated in the literature.

Strength training plus aerobic training versus regular care

Conclusion: The evidence is very uncertain regarding the effect of a combination of strength training on peak VO, compared to regular care.

Explanation: The combination of strength training and aerobic training was found to have a clinically relevant positive effect (WMD 2.27 ml/kg/min.) on exercise capacity (peak VO₂) compared to regular care. However, the evidentiary value of these results is very low, which is why the guideline panel is highly uncertain of the effect that is demonstrated in the literature.

Strength training versus aerobic training

Conclusion: The evidence is very uncertain regarding the effect of strength training on peak VO₂ compared to aerobic training.

Explanation: In only one study, the comparison between strength training and aerobic training was studied at peak VO_2 , where a small (non-significant) difference was demonstrated between the groups (WMD 0.40 ml/kg/min.). The difference is clinically non-relevant and the evidentiary value is very low, which is why the guideline panel is highly uncertain of the effect that is demonstrated in the literature.

High-intensity interval training (HIIT) versus aerobic continuous training

Conclusion: High-intensity interval training (HIIT) appears to result in an increase of peak VO₂ compared to aerobic continuous training.

Explanation: A clinically relevant positive effect of HIIT on exercise capacity (peak VO₂) was found compared to moderate aerobic continuous training (WMD 1.62 ml/kg/min.). The evidentiary value is considered low, which is why the guideline panel is uncertain of the effect that is demonstrated in the literature.

Conclusions based on the literature sub-question 3

Sub-question 3 was answered based on an existing systematic meta-analysis.

Optimisation of peak VO,/max. VO,

Conclusion: An increase in total energy use probably results in an increase in peak VO₂ compared to regular care.

Explanation: Energy use was found to have a clinically relevant effect (2.10 ml.min.⁻¹.kg⁻¹) on exercise capacity (peak VO_2). Only total energy use was significantly linked to an improvement in peak VO_2 , where peak VO_2 improved from 0.29 ml.min.⁻¹.kg⁻¹ for each 100 J.kg⁻¹ increase in energy use. The evidentiary value of these results is reasonable, which is why the guideline panel is reasonably sure of this impact that is demonstrated in the literature. After correction of total energy use, this also applied to session frequency, session time and session intensity; ordering the characteristics showed that total energy use had the biggest impact, followed by frequency and session time and lastly intensity and length of the programme.

Rationale of the recommendation

The guideline panel decided for an exercise programme in phase II of cardiac rehabilitation to include a conditional recommendation with regard to physical training that is aimed at optimising exercise capacity in patients with HFrEF or HFpEF.

The results of the literature review show that HIIT seems to contribute more to the improvement of exercise capacity (max. VO₂/peak VO₂) than aerobic continuous training. FITT factors for the optimisation of exercise capacity are based on current national and international cardiac rehabilitation guidelines and position statements, which are not systematically substantiated by scientific evidence but which are based on the vision of experts.

Total energy use probably contributes the most to an increase in exercise capacity (max. VO_2 /peak VO_2), but for such an increase, it is also necessary to have a sufficiently high training intensity.

The evidentiary value is low for adding IMT and/or strength training to aerobic training for patients with HFpEF with the aim to improve exercise capacity (max. VO_2 /peak VO_2). The guideline panel considers, however, that under certain conditions, adding strength training and IMT does merit thorough consideration. IMT can be used for patients with reduced inspiratory breathing muscle strength (Pi-max \leq 70 of predicted), a ventilatory limitation and/or dyspnoea symptoms in addition to aerobic training to optimise exercise capacity (max. VO_2 /peak VO_2). Strength training in particular for patients who due to limited muscle strength cannot keep up aerobic training seems to increase exercise capacity.

The guideline panel is of the opinion that the desirable effects (positive impact on exercise capacity (max. V0₂/peak V0₂)) outweigh the undesirable effects. The economic considerations, health equity, cost effectiveness and patient values and preferences also appear to be in favour of offering an exercise programme in phase II of cardiac rehabilitation compared to regular care. The remaining criteria that are used during the evidence-to-recommendation process (acceptability, feasibility and implementation) are not considered grievous by the guideline panel or are seen to be to the advantage of offering an exercise programme in phase II of cardiac rehabilitation. The guideline panel indicates that there are specific conditions under which the programme can be executed (see B.1 'Personalised care').

JUSTIFICATION

Literature

In this justification, the findings from the literature are discussed per sub-question based on the relevant outcome measures. The evidence-to-recommendation process was followed based on a combination of these sub-questions.

Relevant outcome measures

The guideline panel considers the maximum oxygen consumption per minute (max. VO_2) or the peak volume of oxygen (peak VO_2) to be crucial outcome measures for decision-making. The guideline panel considers undesirable effects linked to the intervention to be important outcome measures.

Per outcome measure:

- Standardised Mean Difference (SMD): The guideline panel defines an effect > 0.5 as a significant effect (clinically relevant difference) (Sawilowsky 2009).
- *Peak VO*₂ or max. *VO*₂: The guideline panel defines 1 ml/kg/min. as a significant effect for patients with chronic heart failure (clinically relevant difference) (0–0.5 is trivially small; 0.5–0.999 is small; >1 ml is reasonable; >2 is a large) (Tegegne 2022).
- Undesirable effects: Any major cardiac incidents that might be linked to the intervention are considered by the guideline panel to be undesirable (Bosco 2021). The guideline panel considers that any significant difference is also a clinically relevant difference (an increase of, for example, 1 death is already relevant).

Go to the discussion of sub-question 1, the discussion of sub-question 2, the discussion of sub-question 3 Go to the criteria for formulating the recommendations of sub-questions 1, 2 and 3

Discussion of sub-question 1

Search and selected literature for sub-question 1

The guideline panel decided not to conduct a systematic literature review to answer sub-question 1, but to answer this question with the use of existing guidelines and the clinical expertise of the guideline panel.

To do so, the following current (international) guidelines were examined:

- the 'Multidisciplinary Guideline for Cardiac Rehabilitation' of 2011 (Revalidatiecommissie NVVC/ NHS en projectgroep PAAHR)
- the 'European Society of Cardiology (ESC) Guidelines for the diagnosis and treatment of acute and chronic heart failure 2021' (McDonagh 2021);
- the 'Aerobic exercise intensity assessment and prescription in cardiac rehabilitation: a joint position statement of the EACPR, the American Association of Cardiovascular and Pulmonary Rehabilitation (AACPR) and the Canadian Association of Cardiac Rehabilitation (CACR)' (Mezzani 2013b);
- the 'Exercise intensity assessment and prescription in cardiovascular rehabilitation and beyond: why and how: a position statement from the Secondary Prevention and Rehabilitation Section of the European Association of Preventive Cardiology' (Hansen 2022);
- 'Exercise training in heart failure: from theory to practice. A consensus document of the Heart Failure Association (HFA) and the European Association for Cardiovascular Prevention and Rehabilitation (EACPR)' (Piepoli 2011);
- the 'NHG standard for Heart Failure' (M51) (Nederlands Huisartsen Genootschap 2021);
- the 'NICE Guideline Chronic heart failure in adults: diagnosis and management' (Real 2018);
- the 'American College of Sports Medicine Guidelines (ACSM) for exercise training' (Liguori 2021).

The following types of training were searched for:

aerobic training (continuous endurance training and low and high-intensity interval training); strength training of peripheral muscles and of inspiratory breathing muscles; a combination of these.

Summary of the literature for sub-question 1

The guideline panel has summarised the guideline that provide an answer to this sub-question as follows.

Multidisciplinary Guideline for Cardiac Rehabilitation (Revalidatiecommissie NVVC/NHS en projectgroep PAAHR)

This guideline gives a strong recommendation for cardiac rehabilitation for patients with chronic heart failure class (NYHA II–III), which are optimally set up with medication. It is not clear from the guideline on which literature this recommendation is based.

The physical goals can be reached best by a combination of strength and endurance training. The focus here is on training of the peripheral skeletal muscles (functional), (extensive) interval training and training of breathing muscles.

It is recommended to start the training session with a low physical load and then to extend the duration and frequency of the sessions. Duration and frequency can be adapted to the individual, functional and clinical status of the patient. Patients with a maximum exercise capacity of less than 3 METs (25 to 50 W) seem to benefit the most from very short but frequent training sessions. If the patient has reached an exercise tolerance of 3 to 5 MET (40 to 80 W), the frequency of training sessions can be reduced to 1 to 2 per day for 15 minutes at a time. Patients with a maximum exercise capacity of 5 MET (75 to 125 W) can settle for 3 to 5 training sessions per week for 20 to 30 minutes at a time. The training can include using an exercise bike, walking, circuit training and functional exercises. The advantage of using an exercise bike is that training can be done at a low intensity, that the intensity can be dosed meticulously, that the physical load on support and exercise equipment is lower than with walking or running and that larger muscle groups can be trained. With this training, there is the possibility to monitor the patient's heart rate and blood pressure. Walking is one of the most natural forms of training for patients with heart failure. This type of training can be done in a gym, on a (specially developed) circuit or on a treadmill. Compared to an exercise bike, walking is more specifically appropriate for functioning at ADL level in patients with heart failure (walking is primary, biking is secondary). Circuit training is specifically aimed at ADL activities and for training specific muscle groups. This type of training plays an important role in the overall programme for patients with heart failure.

It is recommended to train the breathing muscles three times a month for 15 to 20 minutes at a time, with an intensity of 25 to 35% of Pi-max. (Pi-max is the maximum forced breathing). With strength training of the peripheral muscles, it is recommended to start with a low resistance and somewhat repetitive frequency (10 to 12 repetitions). The physical load be at most 60 to 80% of the repetition maximum (1RM), divided into 1 minute of working out and 2 minutes of rest. Patients with chronic heart failure reached their maximum level of exercise capacity and physical fitness after a training period of 8 to 26 weeks.

European Society of Cardiology (ESC) Guidelines for the diagnosis and treatment of acute and chronic heart failure (McDonagh 2021)

This guideline indicates that high-intensity interval training (HIIT) for patients with heart failure (who are open to it and capable of doing it) leads to a higher peak VO₂. This recommendation is not based on a systematic literature review.

Aerobic exercise intensity assessment and prescription in cardiac rehabilitation: a joint position statement of the EACPR, the American Association of Cardiovascular and Pulmonary Rehabilitation (AACPR) and the Canadian Association of Cardiac Rehabilitation (CACR)' (Mezzani 2013b)

In this position statement, the various training modalities are critically substantiated with literature. In the choice of FITT factors, the following are central: 1) clinical and pathophysiological image of the patient; 2) specific physiological response and evidence-based benefits of the various training modalities and 3) the individual goals of the cardiac rehabilitation programme. In this position statement, training intensity is described for each exercise classification. The position statement was updated in 2022 (Hansen 2022) and is discussed below.

Light to moderate aerobic continuous training (CT) is recommended for low-resistance sedentary patients who beforehand had a higher risk of deterioration of heart failure (Oberman 1995). An improvement of exercise capacity was already observed with CT of low intensity (\geq 40% of peak VO₂). This training seems to be indicated mostly for patients who recently suffered haemodynamic decompensation, patients with a high risk of overexertion or patients with rehabilitation goals that require low-intensity training (for example impacting of cardiovascular risk factors). There is strong evidence that moderate to high-intensity training is safe both for HFpEF and for HFrEF patients. This training can be offered as CT with a duration of 15 to 30 minutes at a time. High-intensity to extreme training, such as HIT, was found to be effective. The most frequently used training consists of a 10-minute warm-up, followed by 4x4 minutes of interval training at 85 to 95% of the peak heart rate (peak HR), interspersed with 3-minute active-recovery bouts at 70% of peak HR.

The following table shows the physiological limits for each exertion level as described in the position statement.

light to moderate	Physiological	upper limit	Upper limit pe	erformance	Perceived exertion	ACSM classi- fication	
	VO ₂ , VO ₂ R at 1 st VT	60% HRR, 50% peak HR	WR at 1 st VT	50% peak WR	12-13 RPE BORG	very light to moderately intense	
moderate to high	NA	NA	СР	70% peak WR	50% peak WR	moderate to high intensity	
high to heavy	peak VO ₂	NA	WR at 2 nd VT highest WR to peak VO ₂ is maintained	≥100% peak WR	18-19 RPE BORG	high-intensity to maximum	
heavy to extreme	NA	NA	>> 100 peak WR	>> 100% peak WR	19-20 RPE BORG	not applicable	

Upper limit exercise intensity in different areas for aerobic continuous training

ACSM classification = 'American College of Sports Medicine exercise intensity classification'; NA = not applicable; V0₂R = reserve V0₂; 1stVT = 'first ventilatory threshold'; WR: 'work rate'; HR = 'heart rate'; HRR = 'heart rate reserve'; RPE = 'rating of perceived exertion'; CP = 'critical power'; 2ndVT = 'second ventilatory threshold'; >> much higher than.

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Exercise intensity assessment and prescription in cardiovascular rehabilitation and beyond: why and how: a position statement from the Secondary Prevention and Rehabilitation Section of the European Association of Preventive Cardiology (Hansen 2022).

The reasoning is based on English articles, position statements and guidelines, where the following electronic databases were consulted: MEDLINE, EMBASE and CINAHL. In this position statement, the conclusions of these original articles and documents were taken over. Professionals in cardiac rehabilitation were involved in the development of the statement; the 'Appraisal of Guidelines for Research and Evaluation tool' (Brouwers 2010) was also used, and data were taken from systematic reviews on cardiac rehabilitation, where the quality and scope of the data were assessed (Mehra 2020).

Information on the views and preferences of the target group were isolated from the literature (Boyde 2018). Based on the collected literature, opinions were formulated, limits in the studies were discussed and recommendations were then drawn up for physical training (Hansen 2022). Finally, the position statement was carefully aligned with other position statements in force (Ambrosetti 2020; Pelliccia 2021). A reflection is given hereafter of the effects of HIT, CT and strength training that were included in the position statement (Hansen 2022). This reflection is limited in particular to the outcome measure of exercise capacity.

There is considerable variation between randomised studies that focus on improving exercise capacity for patients with heart failure in phase II of cardiac rehabilitation (Uddin 2016). This variation can be explained by the differences between the various patients with heart failure, but also by the choice of training modalities. In a meta-analysis that studied both continuous training and HIT for heart failure, a higher training intensity was independently linked to a larger exercise capacity after completion of phase II of cardiac rehabilitation (Uddin 2016). For every 10% increase in the applied training intensity (% peak VO₂ or % peak heart rate (peak HR)), a higher average increase in peak VO₂ with 1.0 ml/kg/min. was found (p = 0.04) (Mitchell 2019; Swank 2012).

In the position statement (Hansen 2022), the various effects of HIT and CT were also discussed. Various reviews were published in which for patients with HFrEF or HFpEF, the effect of HIT was compared to that of CT (Araujo 2019; Gomes Neto 2018; Pattyn 2018). The most recent and comprehensive meta-analysis evaluated 24 studies (n = 11 on coronary artery disease, n = 11 on HFrEF and n = 2 on HFpEF) with a total of 1,080 participants (Araujo 2019). A significantly bigger improvement in peak VO₂ was observed after HIT compared to moderate-intensity CT (with +1.40 ml/min./kg, in favour of HIT; 95%-RI = 0.69 to 2.11; p < 0.001). This bigger improvement in peak VO₂ remained significant in patients with coronary artery disease and HFrEF respectively. When the study of Wisloff (2007) was excluded from the analysis, the differences were no longer significant. The effects that were found for HIT also seemed bigger in smaller studies (n < 20) than in large studies (n > 50). Based on this, it was concluded that there is a need for large-scale RCTs (Araujo 2019).

So far, one large multi-centre trial has been conducted (SMARTEX-HF study) in which NYHA category II (~70% of the total group) and III (~30% of the total group) heart failure patients were included who were stable for at least six weeks. The control group received the advice to train regularly without supervision (Ellingsen 2017b). In this study, contrary to reviews mentioned earlier, HIIT was not found to have any effect superior to that of CT in terms of improved exercise

capacity (max. VO_2). It seems as though HIT might be a more time-effective way to improve peak VO_2 , since the total time of training was significantly shorter than for CT. In two reviews it was concluded that the total training volume is the most relevant for the optimisation of exercise capacity (Ismail 2014; Vromen 2016). The number of patients that react well to HIT is comparable to the number of patients that react well to CT. However, optimal reaction to training will depend on the total training volume (Gevaert 2020). A larger training volume also seems to contribute the most to a reduced cardiovascular risk profile (Hansen 2018). Training programmes with a low training volume are therefore contraindicated both for optimising exercise capacity and for influencing the cardiovascular risk profile (Nichols 2020).

Overall, strength training with an intensity of 30 to 70% of 1RM is advised for the upper extremities and 40 to 80% of 1RM for the lower extremities, with 12 to 15 repetitions and two to three sets (Ambrosetti 2020). Large muscle groups and muscle groups that are relevant for daily activities in particular should be addressed in this regard. These recommendations are based in particular on research on healthy individuals and older adults, where dynamic strength training at higher resistance has a bigger effect on muscle strength than dynamic training with lower resistance (Borde 2015; Raymond 2013; Schoenfeld 2017). The optimal strength training therefore remains part of the debate (Hansen 2019).

Exercise training in heart failure: from theory to practice. A consensus document of the Heart Failure Association (HFA) and the European Association for Cardiovascular Prevention and Rehabilitation (EACPR) (Piepoli 2011)

No systematic literature review was conducted in this guideline to establish any recommendations. CT and HIT are recommended to improve aerobic exercise capacity. For patients with stable heart failure, CT is mostly recommended with a moderate to high intensity. For patients with greater deconditioning, it is recommended to start small (i.e. twice a week for 5 to 10 minutes at low intensity). If the patient can endure this sufficiently, the training time per session can first of all be increased and then the number of sessions per day, with the goal to train for 20 to 60 minutes at a time, three to five times per week, with moderate to high intensity. In the starting phase, it is recommended to build up the intensity gradually (50 to 80% of peak VO₂) followed by a build-up in time of 15 or 20 to 30 minutes. After three to six months, the maintenance phase will start.

Aerobic interval (or intermittent) training seems to be more effective than CT for the improvement of exercise capacity. A protocol of short variations of 10 to 30 sec. of moderate to high intensity (50 to 100% of maximum exercise capacity) and a recuperation phase of 60 to 80 sec. with little or no external resistance for a total time of 15 to 30 minutes is recommended. HIT is also discussed with four blocks at 90 to 95% of max. VO₂ and with three blocks of active recovery at low intensity, where a warming up and cooling down of 5 to 10 minutes is advised (Rognmo 2004; Wisloff 2007). Low-intensity interval training with blocks of 30 and 60 seconds, at a resistance of 50% of the maximum wattage reached (Wmax) in the maximum or symptom-limited exertion test with breath gas analysis, alternated with relative rest, where a total length of 15 minutes is recommended for patients with low tolerance. If the patient finds it difficult to keep up the total time of 15 minutes, blocks of 20/70 seconds or even 10/80 seconds, could be indicated. Depending on the chosen intensity of low-interval training, 10 to 12 blocks can be done, where the total time of the training session can be increased from 15 to 30 minutes.

The recommendations for strength training are shown in the table below.

Training programme	Training goal	Form	Intensity	Repetitions	Volume	
Step 1. Pre-training	learning phase/ improving coordina- tion/control	dynamic	< 30% 1RM, RPE< 20	5-10	2–3 sessions/ pw, 1–3 circuits per session	
Step 2. Strength/strength and stamina training	improve inter-mus- cular coordina- tion and strength stamina	dynamic	30-40% 1RM, RPE 12-13	12-25	 2-3 sessions/ pw, 1 circuit per session 2-3 sessions/ pw, 1 circuit per session 	
Step 3. Strength training, building up muscle mass	Improve strength/ hypertrophy/in- tra-muscular coordi- nation	dynamic	40-60% of 1RM, RPE<15	8-15		

Minimum recommendation for strength training

Modified according to Bjarnason-Wehrens (Bjarnason-Wehrens 2004).

1RM = 'one repetition maximum'; RPE = 'rating of perceived exertion'.

Studies on inspiratory muscle training (IMT) show an improvement in exercise capacity and quality of life for patients with heart failure and inspiratory muscle weakness (IMW) (Ribeiro 2009). Routine screening on IMW in addition to aerobic CT is recommended. If indicated, training will start at 30% of Pi-max and build up to a maximum of 60% (resistance tested and adapted every 7 to 10 days) (Laoutaris 2004). A training time of 20 to 30 minutes per day, three to five times a week for at least eight weeks is recommended. It is stated that any other form of aerobic CT also contributes to the improvement of muscle stamina in the inspiratory breathing muscles, but that more intensive IMT might also be needed for heart failure without IMW. In this position statement, it was concluded that there were no large RCTs that studied the

effectiveness of physical training for HFpEF.

ACSM Guideline (Liguori 2021)

In this guideline, FITT factors are recommended that are described in the following table. These recommendations are not based on a systematic literature review.

FITT factors recommended by the ACSM							
Aerobic training	frequency	3-5 times/week					
	intensity	start at 40-50% and build up to 70-80% of reserve VO ₂ (or HRR). In the presence of atrial fibrillation, train only on Borg (11-14 RPE)					
	time	20-60 minutes					
	type	aerobic or intermittent exercises					

Strength training	frequency	1–2x/week (non-consecutive days)
Liaining	intensity	start at 40%1RM for upper extremities and 50%1RM for lower extremi- ties, then gradual build-up to 70%1RM in weeks to months
	time	minimum 1–2 sets, 10–15 repetitions of large muscle groups
	type	fitness equipment or free exercises

Integration of findings

The evidence appears certain regarding the effect that aerobic training has on the improvement of exercise capacity (max. VO_2 /peak VO_2) for patients with HFrEF. For patients with severe chronic heart failure, higher fragility or comorbidity, the evidence is uncertain. No data are available on HFmEF. It appears that strength training can be used as a supplement to optimise exercise capacity (max. VO_2 /peak VO_2) in patients who cannot maintain aerobic training due to limited peripheral muscle strength and IMT for patients with reduced inspiratory breathing muscle strength (Pi-max \leq 70 of estimation), a ventilatory limitation and/or dyspnoea symptoms.

Various studies were performed on the effectiveness of the different FITT factors of physical training in order to improve the exercise capacity of patients with chronic heart failure. This variation can be explained by differences in patients, but also by the training modalities that are chosen. The application of FITT factors is determined multifactorially. FITT factors are inextricably linked to each other and their application relies to a large extent on the clinical reasoning of the therapist. No differences in FITT factors are described between HFrEF and HFpEF patients. In the table below, FITT factors are summarised based on the aforementioned guidelines and position statements.

Training modality	Scope and frequency	Intensity and duration			
aerobic training (CT, HIIT or LIT)	0–12 weeks: CT, HIIT or LIT: 3–5x/week	CT: 50-80% peak VO ₂ /HRR, 20-60 min. HIIT: 80-90% peak VO ₂ /HRR, active recuperatio 40-60% of peak VO ₂ /HRR, interval 4x4 min., active recuperation 3x3 min. LIT: 50% wattage, 10-12 interval 30 sec, recuperation 60 sec			
strength training (ST)	0–12 weeks: KT: 2–3x/week	KT: 30-80% 1RM, 8-10 exercises of large muscle groups, 2-3 sets of 10-15 repetitions, 1-2 min. rest (starting after 6-8 weeks)			
'inspiratory muscle training' (IMT)	0-12 weeks: IMT: 3-4x/week	IMT: 20-40% of Pi-max, 2x15 min./day			

FITT factors for optimising exercise capacity in patients with chronic heart failure

CABG = coronary artery bypass grafting; CT = continuous training; HIIT = high-intensity interval training; LIT = lowintensity (interval) training; HRR = heart rate reserve; min. = minutes; Pi-max. = maximum inspiratory breathing muscle strength.

Discussion of sub-question 2

The guideline panel decided not to perform a systematic literature review to answer sub-question 2, but to do an orienting review of FITT factors in HFpEF, with a preference for a systematic review with meta-analysis (see Appendix C.5–1).

Search and selected literature for sub-question 2

This orienting search, carried out on 28 September 2022, delivered 261 unique hits. After screening of the title and the abstract based on the inclusion criteria, 237 articles were excluded. For 24 articles, the full manuscript was screened. In consultation with the guideline panel, a systematic literature review was chosen to provide an answer to the sub-question (Boulmpou 2022). This systematic literature review was analysed according to the GRADE-ADOLPMENT system (Schünemann 2017).

Characteristics of the included studies for sub-question 2

The characteristics of the included studies in the review of Boulmpou (Boulmpou 2022) are shown in Appendix C.5–2. 18 studies were eventually included. Three studies, however, focus on the same study population and for four, there was too much missing data, which eventually resulted in the inclusion of 11 studies. These 11 studies (Adamyan 2013; Angadi 2015; Aniello Ascione A 2013; Brubaker 2020; Donelli da Silveira 2020; Edelmann 2011; Kitzman 2013; Maldonado–Martín 2017; Palau 2019, 2014; Smart 2012) included a total of 515 patients with HFpEF (left ventricle function \ge 50%, classified under NYHA class II–IV). The average age of the patients varied between 60 and 76 years and the percentage of women was 11 to 85%. In this review, physical training was compared to regular care. Physical training consisted of different modalities: aerobic continuous training, high–intensity interval training (HIIT), strength training of peripheral muscles and IMT. These different modalities were also compared to each other.

In this systematic literature review, the following inclusion criteria were described that were relevant to answer sub-question 3.

Type of studies	Randomised controlled trials
Type of patients	HFpEF chronic heart failure (NYHA II-IV)
Type of intervention	Continuous training focuses on improving peak VO ₂
Type of comparison	Regular care (mostly without cardiac rehabilitation)
Type of outcome	Crucial: exercise capacity peak VO ₂
Type of timeline	Patient undergoing training: period of 4 weeks to 4 months, where training fo- cused on improving exercise capacity

Inclusion criteria

Individual study quality (RoB) of literature for sub-question 2

The risk of bias (RoB) of the included studies in the systematic literature review of Boulmpou was added to Appendix C.5-3 (table 1).

The RoB was scored by DC and RA using AMSTAR-2 (Shea 2017). The assessment of the various items was discussed by DC and RA, after which consensus was reached (Appendix C.5-3, table 2).

Efficacy and evidentiary value of literature for sub-question 2

The efficacy and evidentiary value per outcome measure are described below as a GRADE assessment of the outcome (peak VO_2). The max. VO_2 was not described in this article. Appendix C.5-4 Figure 1 shows the forest plot for the difference between physical training and regular care before and after the training intervention. Appendix C.5-4 Figure 2 shows the forest plot in which aerobic training and other types of training are compared before and after the training intervention.

GRADE assessment during physical training compared to regular care for outcome measure peak VO₂ in patients with HFpEF (Boulmpou 2022)

Assessment of evidentiary value							Number of patients		Effect		Eviden- tiary	Impor- tance
Number of studies	Study design	Risk of bias	Incon- sistency	Indirect evidence	Inaccu– racy	Other factors	Training	Regular health- care	Relative (95% RI)	Absolute (95% RI)	value	
Peak VO	(aerobic t	raining v	ersus regul	ar care)								
4	Ran- domised trials	Not severe	Not severe	Not severe	Severe⁵	Not found	107	118	-	MD 2.14 higher (1.58 higher to 2.71 higher)	●●●○ Reason- able	CRUCIAL
Peak VO	(IMT versu	us regulai	care)									
2	Ran- domised trials	Not severe	Not severe	Severe	Severe⁵	Not found	29	25	-	MD 2.46 higher (1.68 higher to 3.24 higher)	●●○○ Low	CRUCIAL

2	Ran-	Severeª	Not	Not	Very	Not	72	36	-	MD 2.27 higher	•000	CRUCIAL
	domised		severe	severe	severe ^{b,d}	found				(0.18 higher to	Very low	
	trials									4.36 higher)		

RI = reliability interval; MD = mean difference

Explanation:

a. An individual RoB assessment by Adamyan (2013) and Aniello Acione (2013) shows a high risk of bias of the results, which is why the quality of evidence is lowered by 1 level.

b. n < 400 (intervention or control group); quality of evidence is therefore lowered by 1 level.

c. The population is of the same study group, which seems to jeopardise the generalisability, and the quality of evidence is therefore lowered by 1 level.

d. Broad reliability interval; quality of evidence is therefore lowered by 1 level.

GRADE assessment during aerobic training compared to other physical training modalities for the outcome measure peak VO₂ in patients with HFpEF (Boulmpou 2022)

Assessment of evidentiary value						Number of patients		Effect		Eviden- tiary	Impor- tance	
Number of studies	Study design	Risk of bias	Incon– sistency	Indirect evi– dence	lnaccu- racy	Other factors	Strength training or HIIT	Aerobic (contin- uous) training	Relative (95% RI)	Absolute (95% RI)	value	
Peak VO ₂	(strength	training v	versus aero	bic trainin	g)							
2	Ran- domised trials	Severeª	Not severe	Not severe	Severe ^{b,c}	Not found	47	47	-	MD o.4 higher (6.19 lower to 6.99 higher)	●○○○ Very low	CRUCIAL
Peak VO ₂	(HIIT versi	us aerobic	continuou	s training)						1		
2	Ran- domised trials	Not severe	Not severe	Not severe	Very severe⁵	Not found	19	15	-	SMD 1.62 SD higher (0.96 higher to 2.29 higher)	●●○○ Low	CRUCIAL

RI = reliability interval; MD = mean difference; SMD = standardised mean difference Explanation:

a. An individual RoB assessment by Adamyan (2013) and Aniello Acione (2013) shows a high risk of bias of the results, which is why the quality of evidence is lowered by 1 level.

b. n < 400 (intervention or control group) and are very small; the quality of evidence is therefore lowered by 2 levels.

c. Broad reliability interval; quality of evidence is therefore lowered by 1 level.

Efficacy and evidentiary value of aerobic training versus regular care (peak VO₂)

In four studies (n = 225 patients), aerobic exercise was linked to a larger increase in peak VO₂ (WMD 2.14 ml/kg/min., 95%–Rl 1.58 to 2.71, l² 0%; p = 0.88) compared to regular care (Brubaker 2020; Kitzman 2013; Maldonado–Martín 2017; Smart 2012).

The guideline panel considers this effect to be clinically relevant (Sawilowsky 2009). The evidentiary value was lowered by one level to reasonable, due to the observed inaccuracy.

Efficacy and evidentiary value IMT versus regular care (peak VO₂)

In two studies (n = 54 patients), breathing muscle training was linked to a larger increase in peak V0₂ compared to regular care (WMD 2.46 ml/kg/min., 95%-Rl 1.68 to 3.24, l²-0%; p = 0.36) (Palau 2019; Palau 2014).

The guideline panel considers this effect to be clinically relevant (Sawilowsky 2009). The evidentiary value was lowered by two levels to low due to the indirect evidence and the

observed inaccuracy.

Efficacy and evidentiary value of strength training and aerobic training versus regular care (peak V0,)

In two studies (n = 108 patients) in which a combination of aerobic training and strength training was compared to regular care, a higher peak VO₂ was observed in the training group (WMD 2.27 ml/ kg/min., 95%-RI 0.18 to 4.36, l² 0%; p = 0.68) (Ascione 2013; Edelmann 2011).

The guideline panel considers this to be a largely clinically relevant effect (Sawilowsky 2009). The evidentiary value was lowered by three levels to very low based on the risk of bias and inaccuracy. Efficacy and evidentiary value of strength training versus aerobic training (peak VO₂) In one study (n = 47 patients), the effect of strength training versus aerobic training was observed on peak VO₂ with no significant differences between the groups (WMD 0.40 ml/kg/min., 95%-RI 6.19 to 6.99) (Adamyan 2013).

The guideline panel considers this effect to be clinically non-relevant (Sawilowsky 2009). The evidentiary value was lowered by three levels to very low based on the observed risk of bias and the observed inaccuracy.

Efficacy and evidentiary value of high-intensity interval training (HIIT) versus aerobic continuous training (peak VO₂)

In two studies (34 patients), HIIT was linked to a significantly bigger improvement of peak VO_2 compared to moderate aerobic continuous training (WMD 1.62 ml/kg/min., 95%-Rl 0.96 to 2.29, $I^2 = 0\%$; p = 0.82) (Angadi 2015; Donelli da Silveira 2020).

The guideline panel considers this effect to be clinically relevant (Sawilowsky 2009). The evidentiary value was lowered by two levels to low due to the observed inaccuracy.

Discussion of sub-question 3

In order to answer the clinical question, the guideline panel contributed a systematic review with meta-analysis (Vromen 2016). This systematic literature review was analysed according to the GRADE-ADOLPMENT systematics (Schünemann 2017).

Search and selected literature for sub-question 3

What is the impact of the various training variables for aerobic continuous training in terms of optimising exercise capacity (peak V0,/max. V0,) in patients with HFrEF?

Characteristics of the included studies for sub-question 3

The characteristics of the included studies in the review of Vromen (Vromen 2016) are shown in Appendix C.5–2, tables 2 and 3. 17 studies were included (Antunes–Correa 2014; Beer 2008; Brubaker 2009; Eleuteri 2013; Erbs 2010; Kulcu 2007; Maiorana 2011; Malfatto 2009; Mandic 2013; Mezzani 2013a; Myers 2007; O'Connor 2009; Passino 2008; Patwala 2009; Sandri 2012; Terziyski 2009; Vasiliauskas 2007). In 16 studies, the inclusion range lay between 21 and 154 patients and in one study, 2,183 heart failure patients were included (O'Connor 2009). In total, 1,147 patients were assigned to the aerobic training group, with a median age of 62 and of which 17% were women. In 11 studies, the NYHA class was reported (the observed % of NYHA I/II/III/IV was 0.5/62.6/36.1/0.7). In this systematic literature review, the following training characteristics of aerobic continuous training for patients with heart failure were evaluated: session time, session frequency, training intensity, length of the programme in weeks and the product of all these factors or total energy expenditure. In this systematic literature review, the following inclusion criteria were described that are relevant for answering sub–question 3.

Inclusion criteria						
Type of studies	Randomised controlled trials; studies that describe an aerobic training protocol: session, duration, frequency, length, intensity of VO ₂ in terms of session time, session frequency, length of programme and training intensity (% of peak comparison with heart rate, heart rate reserve, peak VO ₂ and maximum wattage)					

Type of patients	Adults (\ge 18 years) with chronic heart failure who are eligible for cardiac rehabil- itation
Type of intervention	Continuous training focuses on improving peak VO ₂
Type of comparison	Regular care (mostly without cardiac rehabilitation)
Type of outcome	Crucial: exercise capacity/peak VO ₂
Type of timeline	Time after cardiac rehabilitation at which the patient underwent a peak VO_{2} assessment

Individual study quality (RoB) of sub-question 3

The risk of bias (RoB) of the included studies in the systematic literature review of Vromen (Vromen 2016) was added in Appendix C.5–3, table 3.

The risk of bias of the systematic literature review of Vromen was scored by DC and RA according to AMSTAR-2 (Shea 2017). The assessment of the various items was discussed by DC and RA, after which consensus was reached. An overview of the study quality assessment is provided in Appendix C.5-3, table 4.

Efficacy and evidentiary value of sub-question 3

The efficacy and evidentiary value of the outcome measure peak VO₂ are described below. For patients with heart failure, it appeared that the total energy expenditure was the only characteristic that was significantly associated with an improvement in peak VO₂. After correction for total energy expenditure, this also applied for session frequency, session time and training intensity. In other words, a ranking of the characteristics showed that energy expenditure had the biggest impact, followed by frequency and session time and finally intensity and length of the programme. The GRADE assessment is shown in the following table.

Assessment of evidentiary value						Number of patients		Effect		Eviden- tiary	Impor- tance	
Number of studies	Study design	Risk of bias	Incon– sistency	Indirect evi– dence	lnaccu- racy	Other factors	Con- tinuous training	Regular cardiac rehabil- itation	Relative (95% Rl)	Absolute (95% RI)	value	
peak VO ₂		•	-	•				1		1		
18	Ran- domised trials	Not severe	Severeª	Not severe	Not severe	Not found	1,488	1,447	-	MD 2.10 higher (1.34 higher to 2.86 higher)	●●●○ Reason- able	CRUCIAL

GRADE assessment of continuous training compared to regular care in the case of HFrEF heart failure for the outcome measure of peak VO, (Vromen 2016)

RI = reliability interval; MD = mean difference

Explanation:

a. The heterogeneous nature suggests a proof of inconsistency (l² > 60%); the quality of evidence is therefore lowered by 1 level. This lowering is explained by the HF action study.

Efficacy and evidentiary value of aerobic training versus regular care (peak V0₂) For 18 studies (Appendix C.5-4 Figure 3), the efficacy of aerobic training (n = 1,488) was pooled and compared to regular care (n = 1,447). The average difference in peak V0₂ between the intervention group and the control group was 2.10 ml.min.⁻¹.kg⁻¹ (95%–Rl 1.34 to 2.86; p < 0.001). Only total energy expenditure was significantly associated with the improvement of peak V0₂, which led to an improvement thereof of 0.29 ml.min.⁻¹.kg⁻¹ with each increase in energy expenditure of 100 J.kg⁻¹ (95%–Rl 0.22 to 0.36; p < 0.001) (Antunes–Correa 2014; Beer 2008; Brubaker 2009; Eleuteri 2013; Erbs 2010; Kulcu 2007; Maiorana 2011; Malfatto 2009; Mandic 2013; Mezzani 2013a; Myers 2007; O'Connor 2009; Passino 2008; Patwala 2009; Sandri 2012; Terziyski 2009; Vasiliauskas 2007). See the overview in the following table.

Training characteristics	effect scale	Effect size (ml.min. . kg ⁻¹)	95%-RI (ml.min.⁻¹. kg⁻¹)	P value	 ²	AIC
session frequency	1 session/week	0.12	-0.01-0.25	0.065	0.00	58.86
session time	10 minutes	0.16	-0.00-0.33	0.051	10.83	61.10
length of pro- gramme	2 weeks	0.08	-0.01-0.17	0.100	11.81	61.91
training intensity	10% of peak VO ₂	0.08	-0.01-0.16	0.073	11.96	62.10
total EE	100 joule,kg⁻¹	0.29	0.22-0.36	< 0.001*	8.34	63.79

Ranking of training characteristics based on effect size in model, corrected for energy expenditure

The effect size is given as a change in peak VO₂.

I² = residue heterogeneousness; AIC = Akaike's information coefficient (model fit); EE = energy expenditure.

* significant at *p* < 0.01.

After correction for total energy expenditure, session frequency, session time and training intensity were, however, also linked to an improvement in peak VO₂. The guideline panel considers this effect to be clinically relevant (Sawilowsky 2009).

The evidentiary value was lowered by one level to reasonable due to inconsistency.

Criteria for formulating recommendations for sub-questions 1, 2 and 3

From evidence to recommendation

Internationally recognised criteria were used to assess the evidence on which the recommendations are based. This led to nine considerations. These considerations, as well as the remaining considerations formulated by the guideline panel, determine the strength of the recommendation.

The desirable and undesirable effects and the balance between the two, as well as the quality of evidence, are described for each sub-question. For the other criteria, the sub-questions are taken together.

Desirable effects

Sub-question 1. No literature was selected that directly defines the evidentiary value or effects to answer the clinical question. Because of this, the guideline panel did not formulate any desirable effects.

Sub-question 2. The guideline panel considers the desirable effects of physical training aimed at improving exercise capacity (max. VO_2) compared to regular care to be clinically relevant for the outcome measure of peak VO_2 , with the exception of strength training versus aerobic training. The comparisons are shown in the table below.

Comparisons	Outcome measure	Effect (95% RI)	Effect	Evidentiary value
aerobic training versus regular care	peak VO ₂	MD 2.14 higher (1.58 higher to 2.71 higher)	clinically relevant	reasonable
inspiratory breathing training versus regular care	peak VO ₂	MD 2.46 higher (1.68 higher to 3.24 higher)	clinically relevant	low
combination of strength and aerobic training versus regular care	peak VO ₂	MD 2.27 higher (0.18 higher to 4.36 higher)	clinically relevant	very low
aerobic training versus strength training	peak VO ₂	MD 0.4 higher (6.19 lower to 6.99 higher)	clinically non- relevant	very low
high-intensity interval training versus aerobic continuous training	peak VO ₂	SMD 1.62 SD higher (0.96 higher to 2.29 higher)	clinically relevant	low

Evidentiary quality assessment for sub-question 2

Sub-question 3. The guideline panel is of the opinion that an increase in total energy expenditure is probably the most important FITT factor for a small improvement in peak VO_2 in patients with HFrEF. The comparison is shown in the following table.

Evidentiary quality assessment for sub-question 3

Comparisons	Outcome measure	Effect (95% RI)	Effect	Evidentiary value
energy expenditure vs. other FITT factors	peak VO ₂	MD 2.10 higher (1.34 higher to 2.86 higher)	clinically relevant	reasonable

To achieve the desirable effects, the guideline panel notes the following:

- These desirable effects are confirmed in current guidelines and position statements, which includes almost exclusively studies with HFrEF patients.
- Patients with a high degree of frailty obtain a larger benefit in exercise capacity with physical training (aerobic and strength training) compared to patients who are less frail (Pandey 2023). Strength training appears in particular to contribute to aerobic exercise capacity (max. $VO_2/$ peak VO_2) in patients with HFrEF or HFpEF who cannot keep up aerobic training due to limited peripheral muscle strength/muscle stamina (Ambrosetti 2020).
- For cachexic patients or patients with severe limitations in peripheral blood circulation and/ or severely reduced peripheral muscle stamina, it is still uncertain what he effect of combined training (strength training and aerobic (interval) training) is.
- IMT for patients with reduced inspiratory breathing strength (Pi-max. \leq 70 of predicted), a ventilatory limitation and/or dyspnoea symptoms also appear to contribute to exercise capacity (Palau 2019; Palau 2014).
- IMT also appears meaningful in the presence of a dysfunctional breathing pattern.
- A shorter or less intensive physical load during interval training can be advantageous for patient comfort and for the continuation of exercise in the longer term (Guiraud 2012). It is therefore important to adjust this properly to the individual patient.
- For HIIT, an active recovery interval of 40 to 60% of peak VO_2 seems to have a more favourable effect on the improvement of exercise capacity than a recovery interval of 40 tot 50% of peak VO_2 (Ballesta Garcia 2018).
- Besides the total training volume, a higher training intensity (both continuous training and HIT) appears to be an important FITT factor for increasing exercise capacity (max. VO_2 /peak VO_2) (Uddin 2016).

Undesirable effects

Sub-question 1. No literature was found that directly defines the evidentiary value or effects to answer the clinical question. Because of this, the guideline panel did not formulate any undesirable effects.

Sub-question 2. The guideline panel formulated the following undesirable effects:

- HIIT may possibly lead to reduced compliance (Ellingsen 2017).
- Scientific research on the effects of HIIT was performed particularly on male patients with chronic heart failure who have a good load resilience (Franklin 2022).
- The efficacy of HIIT for patients with an Implantable Cardioverter-Defibrillator (ICD) was not demonstrated and the safety of this training form is uncertain.
- Scientific research on the effects of strength training as a supplement to aerobic training was conducted on healthy individuals and older adults, where dynamic strength training at higher resistance had more impact on muscle strength than dynamic strength training at lower resistance (Borde 2015; Raymond 2013; Schoenfeld 2017).
- The risks of cardiac complications appear to be higher with HITT than with moderate-intensity continuous training, but both forms of training are considered safe (Ellingsen 2017a; Rognmo 2012).

Sub-question 3. No undesirable effects were formulated with respect to sob-question 3.

Quality of evidence

The guideline panel assesses the evidentiary value of the desirable effects as described above under desirable effects.

Sub-question 1. No literature was found that directly defined the evidentiary value or effects to answer the clinical question. Because of this the guideline panel did not formulate any evidentiary value.

Sub-question 2. The guideline panel rates the evidentiary value of the effects of exercise therapy on peak VO₂ compared to regular care as low.

It follows from this that the evidentiary value of:

- aerobic training compared to regular care is rated as reasonable;
- inspiratory breathing muscle training versus regular care is rated as low;
- combined training (strength training and aerobic training) versus regular care is rated as very low.

The guideline panel rates the evidentiary value of the effects of the various forms of training on peak VO, as low, where the evidentiary value of:

- aerobic training versus strength training is rated as very low;
- high-intensity interval training versus aerobic continuous training is rated as low.

Sub-question 3. The guideline panel rates the evidentiary value of the desirable effects of increasing the training volume/exercise expenditure on peak VO, as reasonable.

Patient values and preferences

The guideline panel is of the opinion that patients attach reasonable value to the use of physical training and that there is little variation between the various patients. it is important in particular to align with the patient's goals, values, preferences and expectations. This finding is supported by the Cardiac Rehabilitation dossier carried out by these stakeholders, as well as the barrier raised by the Dutch Cardiac Council (Harteraad).

Balance between desirable and undesirable effects

The guideline panel is of the opinion that the desirable effects probably outweigh the undesirable effects of physical training for patients with HFrEF or HFpEF. The motivation for this is that the effects of physical training lead to an improvement in exercise capacity.

Socio-economic considerations and cost-effectiveness

The guideline panel came to the assessment that the amount of equipment needed for the intervention is negligible to moderate. The guideline panel indicates that the therapist does not need to acquire any additional equipment to introduce such an intervention.

The guideline panel indicates that by adapting the FITT factors, the exercise programme can be made more personalised and might possibly lead to cost–savings, even if the specific contribution of a FITT factor to cost–effectiveness is unknown.

Health equality

The guideline panel expects that the intervention will lead to an increase in health equality. Offering physical training that is tailored to the individual might bring more equality to the possible positive effects of cardiac rehabilitation.

Acceptability

The guideline panel expects the intervention to be accepted by all key stakeholders. Physical training is currently already offered in cardiac rehabilitation.

Feasibility

The implementation of the exercise programme in phase II of cardiac rehabilitation is considered realistic by the guideline panel. Physical training is currently already offered in cardiac rehabilitation.

Other considerations

- Underload' training seems to occur frequently in clinical practice. It is important to be able to offer personalised care and to adapt the training intensity based on a maximum or symptom-limited exertion test with gas analysis. See B.6 'Measurement instruments'.
- The choice of FITT factors is affected by the capabilities, preferences and goals of the patient, while keeping account of comorbidity, severity of the disease, risk factors, kinesiophobia, limiting factors, medication, signs of cardiac overload/AP, ICD settings, etc.
- The clinical question only applies to the improvement of exercise capacity; however, this treatment goal is not seen as feasible for all patients due to the difference in trainability. Other goals are also aimed for in phase II cardiac rehabilitation, such as improving strength endurance in patients with strength-related limitations in general aspects of daily living. The guideline panel refers to the FITT factors in the article of Achttien (2015).
- In this model, there was no downgrading in GRADE for indirectness. The guideline panel considers that the outcome measure that was selected is directly linked to physical functioning as a component of the clinical question. Should a patient-related outcome measure be selected (e.g. quality of life), this would not give an answer to the clinical question. Based on the literature it is, however, known that an increase in peak VO₂ is linked to a lower risk of cardiovascular mortality or hospitalisation (Swank 2012).
- Strength training that leads to exhaustion or where strength is used with the Vasalva method or > 80% of 1RM with chronic heart failure is unsuitable. The patient should recover within 2 to 3 hours after training.
- Shortly after the orienting search that was carried out in this guideline for sub-question 2, a review with a meta-analysis appeared (Edwards 2023) in which it was concluded that HIIT is more effective than moderate-intensity aerobic continuous training for the improvement of exercise capacity in patients with HFrEF or HFpEF.
- The guideline panel is of the opinion that symmetrical functional movements below the pain threshold (for suppleness with breath control) can be started within 6 weeks after surgery in consultation with the cardiologist (Ennis 2022).
- That the starting point should be training principles that are related to the most limiting pathology/disease (for patients with comorbidities). If there is any uncertainty, it is recommended to start from low to moderate to intense. Borg < 12–13

- That pre-training is advisable, for example starting with strength training with an estimated resistance of < 30% of 1RM, with 2–3 series of 10 repetitions, before determining the RM. For HITT, 2 weeks of pre-training is recommended, with the possibility to opt for lower intensity with shorter blocks (2–3 min.), high intensity and/or longer blocks (\geq 4 min.) with low-moderate intensity.
- The essential components mentioned in <u>B.1 'Personalised care'</u> must be taken into consideration when implementing the intervention.
- Before offering the exercise programme, it must be verified whether this form of cardiac rehabilitation is in line with achieving the chosen rehabilitation goals (see <u>B.4 'Medical history</u> taking' and <u>B.5 'Physical examination and treatment plan'</u>).
- Before offering the exercise programme, it should be verified whether cardiac rehabilitation is in line with the patient's healthcare needs, individual characteristics, capabilities, wishes, needs, learning strategy and context (see B.1 'Personalised care').
- Before offering the exercise programme, it must be verified whether cardiac rehabilitation can be done, considering the (relative) contraindications and comorbidities (see <u>B.7 'Indication'</u>) and the complexity of the disease profile.
- The cardiologist is ultimately responsible for the cardiac rehabilitation and referral. The cardiologist can, however, choose to delegate certain tasks (such as coordination) to the cardiac rehabilitation coordinator or nurse specialist.
- Throughout the cardiac rehabilitation programme, it is decided together with the patient whether the chosen exercise programme is still sufficiently suited to the patient or whether it should be readjusted. If necessary, consultation should take place with the multidisciplinary cardiac rehabilitation team, so that an adjustment of the cardiac rehabilitation programme can be considered. In this regard also see C.7 'Evaluation, stop criteria and closure of the treatment'.

Focus areas for implementation

No focus areas were formulated.

Knowledge gaps

The quality of evidence for physical training for patients with HFpEF heart failure on the outcome measurement of peak VO₂ was mostly found to be low to reasonable due to the risk of bias and inaccuracy. In order to make a targeted assessment about the efficacy, more studies will therefore have to be performed on the specific FITT factors and a sufficiently large cohort will have to be included.

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C.6 Telerehabilitation

Recommendations

Consider introducing telerehabilitation (as a replacement for or supplement to regular cardiac rehabilitation) in the exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure to improve physical functioning and quality of life. In doing so, take the essential components into account (see B.1 'Personalised care').

SUBSTANTIATION

Reason

Telerehabilitation is a form of personalised care within cardiac rehabilitation. Along with group interventions and individual guidance performed in a heart centre, parts of the cardiac rehabilitation programme can also be offered remotely (telerehabilitation), where health data are monitored remotely to support coaching and feedback from the healthcare provider and tailored learning (Frederix 2015d; Nederlandse Vereniging voor Cardiologie 2018).

The effectiveness of telerehabilitation for heart patients has often been studied in the past, compared both to no rehabilitation and to regular cardiac rehabilitation performed in a heart centre (Anderson 2017; Frederix 2015d; Neubeck 2009; Rawstorn 2016). This systematic literature review reported that telerehabilitation appears to be at least as effective as cardiac rehabilitation that is performed in a heart centre in terms of improving functional capacity and impacting cardiovascular risk factors (Frederix 2015d; Neubeck 2009; Rawstorn 2016). In 2018, an Addendum on Telerehabilitation was also developed and added to the NVVC's 'Multidisciplinary guideline on cardiac rehabilitation' with recommendations for telerehabilitation (Nederlandse Vereniging voor Cardiologie 2018). Telerehabilitation has seen an upsurge in recent years, on the one hand due to technological developments and the increase in patients' digital literacy and on the other hand due to COVID-19 and the shift of care to the home environment.

Telerehabilitation consists of:

Telemonitoring: monitoring a patient from a distance. Monitoring takes place by collecting and interpreting clinical data that the patient sends from home to the healthcare provider. Tele-guidance: guiding a patient from a distance, where two-way interaction/communication can take place at various times during the treatment journey by means of physical or e-consultations (by telephone, in writing or in a screen-to-screen consultation) (Nederlandse Vereniging voor Cardiologie 2018).

This form of telerehabilitation can be done during the entire or part of the cardiac rehabilitation programme (in the latter case it is called hybrid).

In order to give an update on the current status with regard to the efficacy of telerehabilitation in an exercise programme in phase II of cardiac rehabilitation compared to regular cardiac rehabilitation and care for patients with coronary artery disease or chronic heart failure, the following clinical question was formulated:

Clinical question

What is the effect of telerehabilitation with the aim to improve physical functioning in an exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure compared to regular cardiac rehabilitation and care?

Conclusions based on the literature

In order to answer the clinical question, the guideline panel took results from the selected literature. The assessment was based on the effect size and the evidentiary value, and the results were then formulated in a standardised manner. These standardised formulations have been

accepted worldwide and make a statement about the certainty of the evidence found in a specific study (Langendam 2022).

Coronary artery disease

Crucial outcome measure:

The evidence is very uncertain regarding the effect of telerehabilitation on physical functioning (measured as the peak volume of oxygen (peak VO_2)) in patients with coronary artery disease in the exercise programme in phase II of cardiac rehabilitation compared to cardiac rehabilitation in the heart centre itself.

Explanation: The selected systematic literature review describes that telerehabilitation has an effect that is comparable to that of cardiac rehabilitation in the heart centre itself. Both have a positive impact on physical functioning. A clinically non-relevant positive effect (SMD 0.29 higher) on physical functioning was found (measured as peak VO₂) in favour of telerehabilitation compared to cardiac rehabilitation in the heart centre for patients with coronary artery disease in the exercise programme in phase II of cardiac rehabilitation. However, the evidentiary value of these results is very low, which is why the guideline panel is highly uncertain of the effect that is demonstrated in the literature.

Important outcome measures:

The evidence is very uncertain regarding the effect of telerehabilitation on quality of life (measured with the 36-Item Short Form Health Survey (SF-36) for physical functioning and EuroQol 5D (EQ-5D)) for patients with coronary artery disease in the exercise programme in phase II of cardiac rehabilitation compared to cardiac rehabilitation in the heart centre itself. *Explanation*: The selected systematic literature review describes that telerehabilitation has an effect that is comparable to that of cardiac rehabilitation in the heart centre itself. Both were found to have positive effects on quality of life. A clinically non-relevant positive effect (SMD 0.21) (measured with the SF-36 physical functioning) and a clinically non-relevant positive effect (SMD 0.49) (measured with the EQ-5D) were found in quality of life in favour of telerehabilitation compared to regular cardiac rehabilitation for patients with coronary artery disease in the exercise programme in phase II of cardiac rehabilitation. However, the evidentiary value of these results is very low, which is why the guideline panel is highly uncertain of the effect that is demonstrated in the literature.

Cardiac rehabilitation that is performed in a heart centre for patients with coronary artery disease in the exercise programme in phase II of cardiac rehabilitation probably results in an increase in quality of life (measured with SF-36 for mental functioning) compared to telerehabilitation. *Explanation*: The selected systematic literature review describes that telerehabilitation has an effect that is comparable to that of cardiac rehabilitation that is done in the heart centre itself. Both were found to have positive effects on quality of life. A clinically non-relevant positive effect (SMD 0.27 lower) on physical functioning was found (measured with the SF-36 for mental functioning) in favour of cardiac rehabilitation that is done in a heart centre compared to telerehabilitation for patients with coronary artery disease in the exercise programme in phase II of cardiac rehabilitation. The evidentiary value of these results is reasonable, which is why the guideline panel is reasonably sure of the impact that is demonstrated in the literature.

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 No studies were found that described the results of telerehabilitation for other important outcome measures: compliance with or completion of the exercise programme in phase II of cardiac rehabilitation, patient satisfaction and major cardiac incidents that might be linked to the intervention.

Chronic heart failure

Crucial outcome measures:

The evidence is very uncertain regarding the effect of telerehabilitation on physical functioning (measured as peak VO₂) in patients with chronic heart failure in the exercise programme in phase II of cardiac rehabilitation compared to cardiac rehabilitation and care in a heart centre. *Explanation*: The selected systematic literature review describes that telerehabilitation has an effect that is comparable to that of cardiac rehabilitation in the heart centre itself. Both were found to have positive effects on physical functioning. A clinically relevant positive effect (SMD 1.85 higher) was found on physical functioning (measured as peak VO₂) in favour of telerehabilitation compared to cardiac rehabilitation in the heart centre itself for patients with chronic heart failure in the exercise programme in phase II of cardiac rehabilitation. The evidentiary value of these results is, however, very low, which is why the guideline panel is highly uncertain of the effect that is demonstrated in the literature.

Telerehabilitation for patients with chronic heart failure in the exercise programme in phase II of cardiac rehabilitation appears to result in hardly if any difference in physical functioning (measured with the Six-Minute Walking Test (6MWT)) compared to regular cardiac rehabilitation and care.

Explanation: The selected systematic literature review describes that telerehabilitation has an effect that is comparable to that of regular cardiac rehabilitation. Both telerehabilitation and regular cardiac rehabilitation are found to have positive effects on physical functioning. A clinically non-relevant positive effect (MD 15.86 higher) was found on physical functioning (measured with the 6MWT) in favour of telerehabilitation compared to regular cardiac rehabilitation and care for patients with chronic heart failure in the exercise programme in phase II of cardiac rehabilitation; however, the evidentiary value of these results is low. We are therefore uncertain of the effect that is demonstrated in the literature.

Important outcome measures:

The evidence is highly uncertain regarding the effect of telerehabilitation on quality of life (measured with the SF-36 for physical and mental functioning) compared to cardiac rehabilitation in a heart centre or regular care.

Explanation: The selected systematic literature review describes that telerehabilitation has an effect that is comparable to that of regular cardiac rehabilitation. Both were found to have positive effects on quality of life. Clinically non-relevant positive effects (MD 0.24 and MD 0.38 higher) were found on quality of life (measured with the SF-36 for physical and mental functioning) in favour of telerehabilitation compared to regular cardiac rehabilitation and care for patients with chronic heart failure in the exercise programme in phase II of cardiac rehabilitation. The evidentiary value of these results is very low, which is why the guideline panel is highly uncertain of the effect that is demonstrated in the literature.

- The included studies did not find any major cardiac incidents.
- No studies were found that described the results for other important outcome measures: compliance with or completion of the exercise programme in phase II of cardiac rehabilitation or patient satisfaction.

Rationale of the recommendation

The guideline panel decided to include a conditional recommendation for telerehabilitation in this guideline.

The results of the systematic literature review show that telerehabilitation has equivalent effects on physical functioning and quality of life in the short term (< 1 year) to regular cardiac rehabilitation or care in the exercise programme in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure. The guideline panel concludes from this that telerehabilitation is not inferior to regular cardiac rehabilitation and that it can be a good alternative within cardiac rehabilitation. However, given the mostly low evidentiary value, this is still surrounded by some uncertainty.

The guideline panel is of the opinion that the desirable effects (positive effects on physical functioning and quality of life) appear to outweigh the undesirable effects. The economic considerations, health equality, cost-effectiveness and patient values and preferences appear to be equal to those of regular cardiac rehabilitation or care. The remaining criteria used to evaluate the literature in the evidence-to-recommendation process (acceptability, feasibility and implementation) were found to be non-grievous or in favour of telerehabilitation, with the exception of additional considerations.

To conclude, the guideline panel states that based on the literature, it is uncertain whether the use of telerehabilitation in phase II of cardiac rehabilitation for patients with coronary artery disease or chronic heart failure leads to a larger effect on the selected outcome measures than cardiac rehabilitation in the cardiac centre itself. The guideline panel does, however, consider that the favourable effects of telerehabilitation prevail and therefore has formulated a conditional recommendation for the intervention. The guideline panel does indicate that telerehabilitation must be performed under specific conditions (see B.1 'Personalised care').

JUSTIFICATION

Literature

To answer the clinical question, a systematic literature review was carried out for the following research question:

What is the effect of telerehabilitation in the exercise programme in phase II of cardiac rehabilitation on physical functioning for patients with coronary artery disease or chronic heart failure compared to regular cardiac rehabilitation in a heart centre?

Relevant outcome measures

The guideline panel came to the assessment that physical functioning was a crucial outcome measure for decision-making and that quality of life, compliance, completion of cardiac rehabilitation, patient satisfaction and undesirable effects linked to the intervention are important outcome measures.

Per outcome measure:

- Standardised mean difference (SMD): the guideline panel defines an effect > 0.5 as a significant effect (clinically relevant difference) (Sawilowsky 2009).
- Peak volume of oxygen (peak VO.): The guideline panel defines 1 ml/kg/min. as a significant effect for patients (clinically relevant difference) (0-0.5 is trivially small; 0.5-0.999 is small; >1 is reasonable; >2 is large) (Tegegne 2022).
- 36-Item Short Form Health Survey (SF-36) physical functioning: The guideline panel defines 15.00 points as a significant effect for patients with chronic heart failure and coronary artery disease (clinically relevant difference) (Wyrwich 2005).
- SF-36 mental functioning: The guideline panel defines 15.00 points as a significant effect for patients with chronic heart failure and coronary artery disease (clinically relevant difference) (Wyrwich 2005).
- Score on the Six-Minute Walking Test (6MWT): The guideline panel defines 30.10 metres as a significant effect for patients with chronic heart failure (clinically relevant difference) (Shoemaker 2013; Tegegne 2022).
- Undesirable effects: Any major cardiac incidents that might be linked to the intervention are considered to be undesirable (Bosco 2021). The guideline panel furthermore considers that if there is a significant difference, it is also a clinically relevant difference (an increase of, for example, 1 death is already relevant).

Search in the literature

On 09 September 2022 an information specialist, H.W.J. Deurenberg, conducted a systematic search in MEDLINE and Embase (see Appendix C.6-1). The systematic search produced 151 unique hits. After screening of the title and the abstract based on the inclusion criteria, 137 articles were excluded.

Inclusion criteria	
Type of studies	Systematic literature review
Type of patients	Patients with coronary artery disease or chronic heart failure
Type of intervention	Telerehabilitation (as a replacement for or a supplement to the treatment)
Type of comparison	Regular exercise programme in phase II of cardiac rehabilitation or care without telerehabilitation
Type of outcome	Crucial: • physical functioning (peak VO₂, 6MWT).

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Type of outcome continue	Important: – quality of life (EQ5D and SF-36) – compliance with the exercise programme in phase II of cardiac rehabilitation – completion of the exercise programme in phase II of cardiac rehabilitation – patient satisfaction – any major cardiac incidents that might be linked to the intervention
Type of timeline	During cardiac rehabilitation, 8 weeks to 6 months

For 14 articles, the full article was screened. Eventually the search yielded five studies (Cavalheiro 2021; Huang 2015; Jin Choo 2022; Rawstorn 2016; Tegegne 2022). See appendix C.6-2 for the flowchart of the inclusion process. The articles that were excluded based on the complete text and the reasons for the exclusion are listed in Appendix C.6-3 (Anderson 2014; Antoniou 2022; Blasco-Peris 2022; Cordeiro 2022; Harwood 2021; Kebapci 2020; Oldridge 2019; Wongvibulsin 2021; Xia 2018). In order to limit an overlap of results between various systematic literature reviews, the results of the most recent literature reviews with the highest methodological quality according to the AMSTAR-2 score (scored by DC and RA) were selected for each indication (coronary artery disease or chronic heart failure) in consultation with the guideline panel (Shea 2017).

Supplementary search

In order to include the most recent randomised controlled trials (RCTs), this search was supplemented with RCTs that were identified in the '<u>KNGF guideline on Remote care</u>'. Of 16 articles the full article was screened; eventually the search yielded two studies (Batalik 2020; Nagatomi 2022). For the search and inclusion and selection procedure of studies that are relevant for this guideline, see Appendix C.6–4.

Characteristics of the included studies

The characteristics of the included systematic literature reviews are provided in Appendix C.6-5.

Individual study quality (RoB)

The risk of bias (RoB) of the systematic literature reviews was scored by DC and RA using AMSTAR-2 (Shea 2017). Inconsistency in the assessment of the various items was discussed with DC and RA, after which consensus was reached. An overview of the study quality assessment (RoB) of the systematic literature reviews is provided in Appendix C.6–6.

The RoB of the studies (on coronary artery disease) that Jin Choo included can be found in Appendix C.6–7. The RoB of the studies (on chronic heart failure) that Cavalheiro included can be found in Appendix C.6–8.

Characteristics of studies on coronary artery disease

Studies in systematic literature review

The systematic literature review of Jin Choo contains eight studies with a total of 750 patients with coronary artery disease (Arthur 2002; Avila 2020; Batalik 2021; Frederix 2015c; Gordon 2002; Kraal 2014; Maddison 2019; Varnfield 2014). The search included studies up until 3 June 2020. The average age of the patients varied between 54.9 and 64.2 years. The studies were conducted in Canada, Belgium, Czech Republic, the USA, New Zealand and Australia. These pertain to a variety of tele-

interventions, including both telemonitoring and tele-guidance (see Appendix C.6-5), which are compared to the exercise programme in phase II of cardiac rehabilitation in a heart centre. The GRADE evidentiary value of the studies was once again assessed for the purposes of this guideline (see Appendix C.6-9 for the forest plots of the outcomes on peak VO₂, SF-36 and EQ-5D).

GRADE assessment of the studies on patients with coronary artery disease

Assessment of evidentiary value					Number of patients		Effect		Eviden- tiary	Impor- tance		
Num– ber of studies	Study design	Risk of bias	Incon- sistency	Indirect evi– dence	Inaccu– racy	Other factors	Telere- habili- tation	Cardiac rehabil- itation in a heart centre	Relative (95-% RI)	Absolute (95-% RI)	value	
Physical	functionin	ıg (peak V	0,)									
7	Ran– domised trials	Not severe	Very severe ^{a,b}	Not severe	Very severe ^{c,d}	Not found	339	335	-	SMD 0.29 higher (0.08 lower to 0.66 higher)	●○○○ Very low	CRUCIAL
Quality	of life (SF–3	6 physica	l functioni	ng)								
2	Ran- domised trials	Not severe	Not severe	Not severe	Very severe ^{c,d}	Not found	139	138	-	SMD 0.21 higher (0.02 lower to 0.45 higher)	●○○○ Very low	IMPOR- TANT
Quality	of life (SF–3	6 mental	functionin	g)			_					
2	Ran- domised trials	Not severe	Not severe	Not severe	Severe	Not found	139	138	-	SMD 0.27 Iower (0.51 lower to 0.04 lower)	●●●○ Reason- able	IMPOR- TANT
Quality	of life (EQ-	5D)			·	•					·	
2	Ran– domised trials	Not severe	Very severe ^{a,b}	Not severe	Very severe ^{c,d}	Not found	96	120	-	SMD 0.49 higher (1.27 lower to 2.26 higher)	●○○○ Very low	IMPOR- TANT

RI = reliability interval; SMD = standardised mean difference.

Explanation:

a. The heterogeneous nature suggests a proof of inconsistency (I² > 60%); the quality of evidence is therefore lowered by 1 level.

b. The heterogeneousness could be seen as a proof of inconsistency (RIs do not overlap); the quality of evidence is therefore lowered by 1 level. c. *n* < 400 (intervention or control group); quality of evidence is therefore lowered by 1 level.

d. The reliability interval includes a clinically non-relevant effect, with a possible negative effect compared to telerehabilitation; the quality of evidence is therefore lowered by 2 levels.

The efficacy and evidentiary value for each outcome measure are described hereafter.

Physical functioning (peak VO₂)

In seven studies, the efficacy of telerehabilitation was compared to that of cardiac rehabilitation that is performed in a heart centre, measured in terms of peak VO₂ (Arthur 2002; Avila 2020; Batalik 2021; Frederix 2015c; Gordon 2002; Kraal 2014; Maddison 2019). The standardised mean difference (SMD) between the groups (telerehabilitation n = 339; heart centre n = 335) was 0.29 points (95%-
RI -0.08 to 0.66) in favour of telerehabilitation. The guideline panel considers this effect to be clinically non-relevant (Sawilowsky 2009).

The evidentiary value was lowered by four levels to very low based on the observed heterogeneousness and inaccuracy.

Quality of life (SF-36 for physical functioning)

In two studies the efficacy of telerehabilitation was compared to that of cardiac rehabilitation in a heart centre, measured on SF-36 for physical functioning (Arthur 2002; Avila 2020). The standardised mean difference (SMD) between the groups (intervention group n = 139; control group n = 138) was 0.21 points (95%-RI -0.024 to 0.45) in favour of telerehabilitation. The guideline panel considers this effect to be clinically non-relevant (Sawilowsky 2009). The evidentiary value was lowered by three levels to very low based on the observed inaccuracy.

Quality of life (SF–36 for mental functioning)

In two studies, the efficacy of telerehabilitation was compared to that of cardiac rehabilitation in a heart centre, measured on SF-36 for mental functioning (Arthur 2002; Avila 2020). The standardised mean difference (SMD) between the groups (intervention group n = 139; control group n = 138) was 0.27 points (95%-RI -0.51 to -0.04) in favour of cardiac rehabilitation done in a heart centre.

The guideline panel considers this effect to be clinically non-relevant (Sawilowsky 2009). The evidentiary value was lowered by one level to reasonable, due to the observed inaccuracy.

Quality of life (EQ-5D)

In two studies, the efficacy of telerehabilitation was compared to that of cardiac rehabilitation in a heart centre, measured on EQ-5D (Maddison 2019; Varnfield 2014). The standardised mean difference (SMD) between the groups (intervention group n = 96; control group n = 120) was 0.49 points (95%-RI -1.27 to 2.26) in favour of telerehabilitation. The guideline panel considers this effect to be clinically non-relevant (Sawilowsky 2009).

The evidentiary value was lowered by five levels to very low based on the observed heterogeneousness and inaccuracy.

Other significant outcome measures

In none of the studies results were described for the other significant outcome measures: compliance with or completion of the exercise programme in phase II of cardiac rehabilitation, patient satisfaction and major cardiac incidents that might be linked to the intervention.

Undesirable effects

No undesirable effects were described that might be linked to the intervention.

Study in supplementary search

For the supplementary search, the RCT of Batalik (Czech Republic) were selected. This study included 56 patients that had had a percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG). The intervention group (n = 25, age 56, \pm 6.9 years, 80% male) trained at home with a bracelet that could monitor heart rate, time, training mode, duration and distance. The patients had weekly phone contact with a physical therapist for feedback. The control group (n = 26, age 57.7 \pm 7.6 years, 85% male) trained under the supervision of a physical therapist in a

heart centre with an activity bracelet that could monitor heart rate (which could only be read by a physical therapist). Both groups trained three times a week for 12 weeks (Batalik 2020). The effectiveness and evidentiary value of the outcome measure of this study are described below.

Physical functioning (peak VO,)

In both groups, a significant improvement was observed in peak VO₂ when training in a heart centre from 23.4 ± 3.3 to 25.9 ± 4.1ml/kg/min. (p < 0.001) and with telerehabilitation from 23.7 ± 4.1 to 26.5 ± 5.7ml/kg/min. (p < 0.01), without any significant difference between the two groups after 12 weeks. The compliance was equal in both groups.

Undesirable effects

Batalik (2020) found no major undesirable effects (Batalik 2020).

The findings of this RCT confirms the findings of the systematic literature review.

Characteristics of the included studies on chronic heart failure

Studies in systematic literature review

The systematic literature review of Cavalheiro 17 contains studies with a total of 2,206 patients with chronic heart failure. The included articles appeared between 1 January 1990 and 8 October 2021. The studies were conducted in India, Italy, Taiwan, Australia, Scotland, Brazil, Turkey, Canada, Poland, Belgium, China and the UK. These pertain to a variety of interventions (see Appendix C.6–5), which were compared to the exercise programme in phase II of cardiac rehabilitation in a heart centre or to regular care.

The effect of telerehabilitation on the crucial and significant outcome measures compared to that of cardiac rehabilitation done in a heart centre or regular care is described in twelve studies (Babu 2016; Bernocchi 2018; Chen 2018; Cowie 2014; Frederix 2015b; Hwang 2017; Karapolat 2009; Keast 2013; Piotrowicz 2010, 2020, 2015; Servantes 2012).

The GRADE evidentiary value was once again assessed for the purposes of this guideline (see Appendix C.6–10 for the forest plots of the outcomes on the 6MWT, peak VO_3 , SF–36 and EQ–5D).

Assessment of evidentiary value					Number of patients		Effect		Eviden-	Impor-		
Num– ber of studies	Study design	Risk of bias	Incon- sistency	Indirect evi– dence	Inaccu- racy	Other factors	Telere- habili- tation	Cardiac rehabilitation done in a heart centre/ regular care	Relative (95-% RI)	Absolute (95-% RI)	Eviden- tiary value	tance

GRADE assessment of the studies on patients with chronic heart failure

Physical functioning (peak VO₂)

to 3.53 higher)	8	Ran- domised trials	Not severe	Very severe ^{a,b}	Not severe	Severe	Not found	736	672	-	MD 1.85 higher (0.16 higher to 3.53 higher)	●○○○ Very low	CRUCIAL
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Physical functioning (6MWT)

10	Ran- domised trials	Not severe	Very severe ^{a,b}	Not severe	Not severe	Not found	722	787	-	MD 15.86 higher (7.23 higher to 24.49 higher)	●●○○ Low	CRUCIAL
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Quality of life (SF-36 physical functioning)

4	Ran- domised trials	Not severe	Very severe ^{a,b}	Not severe	Very severe ^{c,d}	Not found	136	120	-	MD 0.24 higher (5.79 lower to 6.26 higher)	●○○○ Very low	IMPOR- TANT
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Quality of life (SF-36 mental functioning)

4	Ran- domised trials	Not severe	Very severe ^{a,b}	Not severe	Very severe ^{c,d}	Not found	136	120	-	MD 0.38 higher (4.93 lower to 5.7 higher)	●○○○ Very low	IMPOR- TANT
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RI = reliability interval; SMD = standardised mean difference.

Explanation:

a. The heterogeneous nature suggests a proof of inconsistency (I² > 60%); the quality of evidence is therefore lowered by 1 level.

b. The heterogeneousness could be seen as a proof of inconsistency (RIs do not overlap); the quality of evidence is therefore lowered by 1 level. c. *n* < 400 (intervention or control group); quality of evidence is therefore lowered by 1 level.

d. The reliability interval includes a clinically non-relevant effect, with a possible negative effect compared to telerehabilitation; the quality of evidence is therefore lowered by 2 levels.

The efficacy and evidentiary value for each outcome measure are described hereafter.

Physical functioning (peak VO,)

In eight studies, the effectiveness of telerehabilitation was compared to that of cardiac rehabilitation done in a heart centre or of regular care, measured on peak VO_2 (Chen 2018; Frederix 2015b; Karapolat 2009; Keast 2013; Piotrowicz 2010; Piotrowicz 2020; Piotrowicz 2015; Servantes 2012). The mean difference (SMD) between the groups (intervention group n = 736; control group n = 672) was 1.85 points (95%–RI 0.16 to 3.53) in favour of telerehabilitation. This effect exceeds the previously defined threshold value for clinical relevance (MCID of 1 ml/kg/min.) and is described by the guideline panel as a clinically relevant effect.

The evidentiary value was lowered by three levels to very low based on the observed heterogeneousness and inaccuracy.

Physical functioning (6MWT)

In ten studies, the effectiveness of telerehabilitation was compared to that of cardiac rehabilitation in a heart centre or of regular care, measured with the 6MWT (Babu 2016; Bernocchi 2018; Chen 2018; Frederix 2015b; Hwang 2017; Karapolat 2009; Keast 2013; Piotrowicz 2010; Piotrowicz 2020; Piotrowicz 2015). The mean difference (SMD) between the groups (intervention group n = 725; control group n = 724) was 15.86 metres (95%–RI 7.23 to 24.49) in favour of

telerehabilitation. This effect does not exceed the previously defined threshold value for clinical relevance (MCID of 30.10 points) and is described by the guideline panel as a clinically non-relevant effect.

The evidentiary value was lowered by two levels to very low based on the observed heterogeneousness.

Quality of life (SF–36 for physical functioning)

In four studies the efficacy of telerehabilitation was compared to that of cardiac rehabilitation in a heart centre or of regular care, measured on SF-36 for physical functioning (Babu 2016; Cowie 2014; Karapolat 2009; Piotrowicz 2010). The mean difference (SMD) between the groups (intervention group n = 136; control group n = 120) was 0.24 points (95%–RI –5.79 to 6.26) in favour of telerehabilitation. This effect does not exceed the previously defined threshold value for clinical relevance (MCID of 15.00 points) and is described by the guideline panel as a clinically non-relevant effect.

The evidentiary value was lowered by four levels to very low based on the observed heterogeneousness and inaccuracy.

Quality of life (SF–36 for mental functioning)

In four studies the efficacy of telerehabilitation was compared to that of cardiac rehabilitation in a heart centre or of regular care, measured on SF-36 for mental functioning (Babu 2016; Cowie 2014; Karapolat 2009; Piotrowicz 2010). The mean difference (SMD) between the groups (intervention group n = 136; control group n = 120) was 0.38 points (95%-RI -4.93 to 5.70) in favour of telerehabilitation. This effect does not exceed the previously defined threshold value for clinical relevance (MCID of 15.00 points) and is described by the guideline panel as a clinically non-relevant effect.

The evidentiary value was lowered by four levels to very low based on the observed heterogeneousness and inaccuracy.

Quality of life (EQ-5D)

In two studies, the efficacy of telerehabilitation was compared to that of cardiac rehabilitation in a heart centre, measured on EQ5D. However, no differences were measured (Frederix 2015b; Hwang 2017).

Compliance with and completion of cardiac rehabilitation

In six studies, compliance is described as 'continuing with all sessions' (Babu 2016; Hwang 2017; Karapolat 2009; Piotrowicz 2015; Servantes 2012; Zielinska 2006). In these studies, the percentage of compliance varied in the intervention group from 70 to 100%; the control group was not described.

In four studies, compliance is defined as continuing with more than 80% of the sessions, where percentages of 71 to 95% are achieved in the intervention group; the control group was not described (Chen 2018; Cowie 2014; Lang 2018; Piotrowicz 2020).

Because of the different definitions reported in the studies, no meta-analysis was carried out.

Other outcome measures

No studies were found that described results for the outcome measure of patient satisfaction.

Undesirable effects

The included studies found no major cardiac incidents but did report small cardiac incidents or undesirable effects during exercise, such as: angina pectoris, palpitations, diaphoresis, an augmented heart failure, pain in the ankle, foot ulcers, skin reaction to the electrodes, in-stent restenosis, atypical thoracic pain, arrhythmias, pericarditis and peripheral artery disease.

Study in supplementary search

Nagatomi (Japan) (2022) describes 30 patients with chronic heart failure (New York Heart Association class II–III). The intervention group (n = 15, age 59.8, ± 10 years, 60% male) trained at home with an activity bracelet (Fitbit©). The patients were taught how to monitor blood pressure, weight and heart rate and received weekly feedback via the Fitbit© application or had phone contact with a physical therapist. The intervention group did 3 to 5 aerobic sessions and 2 to 3 resistance-training sessions. The control group (n = 15, age 67.6 \pm 8.9 years, 47% male) trained in a cardiac centre under the supervision of a physical therapist according to regular cardiac rehabilitation. Both groups did the programme for three months.

The effectiveness and evidentiary value of the outcome measure of this study are described below.

Physical functioning (6MWT)

Nagatomi found a significant improvement (p < 0.001) on the 6MWT in the intervention group (52.1 ± 43.9 m) compared to regular care (-4.3 ± 38.8 m).

Undesirable effects

No major undesirable effects were found in any of the two groups.

The findings of this RCT confirm the results of the systematic literature review.

Criteria for formulating the recommendations

From evidence to recommendation

Internationally recognised criteria were used to assess the evidence on which the recommendations are based. These criteria, as well as the remaining considerations formulated by the guideline panel, determine the strength of the recommendation.

Coronary artery disease

The following table contains an overview of the effects and evidentiary value of the studies on coronary artery disease for each outcome measure.

Efficacy and evidentiary value of studies on telerehabilitation for patients with coronary artery disease

Outcome measure	Effect (95% RI)	Effect size	Evidentiary value
physical functioning (peak VO ₂)	SMD 0.29 higher (0.08 lower to 0.66 higher)	clinically non-relevant	very low

 \checkmark

quality of life	SMD 0.21 higher	clinically	very low
(SF–36 physical functioning)	(0.02 lower to 0.45 higher)	non-relevant	
quality of life	SMD 0.27 lower	clinically	reasonable
(SF-36 mental functioning)	(0.51 lower to 0.04 lower)	non-relevant	
quality of life	SMD 0.49 higher	clinically	very low
(EQ-5D)	(1.27 lower to 2.26 higher)	non-relevant	

RI = reliability interval; EQ-5D = EuroQol 5D; SMD = standardised mean difference; SF-36 = 36-Item short Form Health Survey; VO_{3} = oxygen intake capacity

Desirable effects

The guideline panel considers the desirable effects on physical functioning and quality of life of telerehabilitation compared to regular cardiac rehabilitation carried out in a heart centre by patients with coronary artery disease in the exercise programme in phase II of cardiac rehabilitation to be clinically non-relevant.

Telerehabilitation here shows at least an equivalent, but often (except for SF-36 mental) also better clinical outcomes (on physical functioning and quality of life) than regular cardiac rehabilitation and care, although the differences are not clinically relevant.

Studies were also performed in the Dutch context regarding the effect of telerehabilitation for patients with coronary artery disease. Brouwers, for instance, demonstrates that both cardiac rehabilitation that is done in a heart centre and telerehabilitation bring a significant increase in the level of physician activity in the short term (< 1 year), but that in the longer term, these effects are not maintained for either of the interventions (Brouwers 2022, 2021). Den Uijl confirms this picture in a study where quality of life with regular cardiac rehabilitation in a heart centre is compared to that with telerehabilitation up to six months after the cardiac rehabilitation started. Both interventions appeared to lead to an increase in quality of life, with neither of the interventions being inferior to the other (den Uijl 2022). The study of Kraal shows a similar picture regarding peak V0, (Kraal 2014).

Snoek describes older patients (\ge 65 years) who initially refused to participate in cardiac rehabilitation but who could still be included in the telerehabilitation group, compared to no cardiac rehabilitation. This study, upon follow–up (1 year), shows that peak VO₂ in older adults who participate in telerehabilitation increases and differs significantly compared to no cardiac rehabilitation (Snoek 2021).

In the 'Addendum on telerehabilitation' of the 'Multidisciplinary guideline on cardiac rehabilitation', comparable conclusions were included for the entire cardiac rehabilitation programme (Nederlandse Vereniging voor Cardiologie 2018).

Undesirable effects

The guideline panel came to the assessment that the undesirable effects of telerehabilitation compared to regular cardiac rehabilitation or care for patients with coronary artery disease in an exercise programme in phase II of cardiac rehabilitation are small.

Although the selected literature in this guideline does not give any clarity in this regard, the

guideline panel is of the opinion that it is safe to do telerehabilitation for non-complex patients (level I NVVC practice guideline) (Nederlandse Vereniging voor Cardiologie 2011). This is confirmed by studies that were conducted in the Dutch context (Kraal 2014; Snoek 2021).

Quality of evidence

The guideline panel came to the conclusion that the evidentiary value of the desirable effects is very low for patients with coronary artery disease on the outcomes of physical factors and quality of life, with the exception of quality of life measured with SF-36 for mental functioning; this evidentiary value is considered to be reasonable.

It is important here to consider that this evidentiary value in particular was downgraded due to the observed heterogeneousness in the studies and the small study populations. This could be explained by the fact that telerehabilitation is still a fairly new field and that it is still difficult to compare interventions due to the diversity in telerehabilitation interventions.

Patient values and preferences

The guideline panel came to the assessment that patients attach great value to telerehabilitation and that there is little variation between patients.

This assessment is supported by the call from the NVVC in collaboration with the Harteraad (heart council) and the Hartstichting (heart foundation) to implement cardiac rehabilitation from a distance and also by the Cardiac Rehabilitation dossier that was established by these parties (Harteraad 2020).

Balance between desirable and undesirable effects

The desirable effects definitely outweigh the undesirable effects. This is based on the following:

- Telerehabilitation is a suitable alternative to regular cardiac rehabilitation or a replacement for regular cardiac rehabilitation with comparable desirable effects without any relevant undesirable effects.
- There are no indications that telerehabilitation is less safe than regular cardiac rehabilitation or care for non-complex patients with coronary artery disease.
- These findings concur with the recommendations in the Addendum on Telerehabilitation of the 'Multidisciplinary guideline on cardiac rehabilitation' (Nederlandse Vereniging voor Cardiologie 2018).

Socio-economic considerations and cost-effectiveness

The literature was not assessed on this criterion.

Health equality

The guideline panel expects that the intervention will lead to an increase in health equality.

Acceptability

The guideline panel expects that telerehabilitation will be accepted by all key stakeholders.

Feasibility

The guideline panel came to the assessment that the implementation of telerehabilitation is realistic.

Other considerations

The guideline panel is of the opinion that the following considerations are also important when setting up telerehabilitation as part of phase II of cardiac rehabilitation.

- The essential components mentioned in **B.1 'Personalised care'** must be taken into consideration when implementing the intervention.
- Telerehabilitation (as a supplement to or replacement for regular cardiac rehabilitation or care) can be offered in several ways: under the guidance of a physical or exercise therapist in a primary care setting, or home-based and coordinated by the physical or exercise therapist in a secondary care setting from the heart centre. For training in a primary care setting, see C.4 'The exercise programme in a primary care setting'.
- It is important to assess the patient's digital literacy, for example by means of a Quickscan (Pharos. Landelijk expertisecentrum sociaal-economische en etnische gezondheidsverschillen). The selected literature does not appear to give any direction for the specific indications of telerehabilitation. The guideline panel considers that it is very important to let the complexity of the disease profile of patients with coronary artery disease or chronic heart failure or contra-indications weigh in the balance when offering telerehabilitation.
- Due to the large degree of heterogeneousness in the literature found in terms of frequency, intensity, type and time of the studied interventions, no direction can be given on how to perform the intervention.
- A description of the content of the exercise programme of phase II of cardiac rehabilitation with remote sessions or the monitoring of the exercise programme of phase II of cardiac rehabilitation is shown in the 'Addendum on Telerehabilitation' to the '<u>Multidisciplinary</u> guideline on cardiac rehabilitation' (Nederlandse Vereniging voor Cardiologie 2018).
- It is wise, in addition to the recommendations described here, also to consider the general recommendations for remote digital Care from the generic guideline on 'Remote Care'.

Chronic heart failure

The following table contains an overview of the effects and evidentiary value of the studies on chronic heart failure for each outcome measure.

Outcome measure	Effect (95% RI)	Effect size	Evidentiary value
physical functioning	MD 15.86 higher (7.23	clinically	low
(6MWT)	higher to 24.49 higher)	non-relevant	
physical functioning (peak VO ₂)	MD 1.85 higher (0.16 higher to 3.53 higher)	clinically relevant	very low
quality of life	MD 0.24 higher	clinically	very low
(SF-36 physical functioning)	(5.79 lower to 6.26 higher)	non-relevant	
quality of life	MD 0.38 higher	clinically	very low
(SF-36 mental functioning)	(4.93 lower to 5.7 higher)	non-relevant	
compliance	no meta-analysis		

Effects and evidentiary value of studies on telerehabilitation for patients with chronic heart failure

RI = reliability interval; MD = mean difference; SF-36 = 36-Item short Form Health Survey; V0, = oxygen intake capacity; 6MWT = Six-Minute Walking Test

Desirable effects

The guideline panel is of the opinion that the desirable effects on physical functioning and quality of life of telerehabilitation compared to regular cardiac rehabilitation or care by patients with chronic heart failure in the exercise programme of phase II of cardiac rehabilitation are mostly clinically non-relevant, with the exception of physical functioning (measured as peak VO₂), where a clinically relevant effect was found.

Telerehabilitation here shows an at least comparable, but also better clinical outcome (on physical functioning and quality of life) than regular cardiac rehabilitation and care, although the differences are often not clinically relevant. Physical functioning (measured as peak VO₂) even shows a clinically relevant difference compared to regular cardiac rehabilitation and care.

These findings are not in line with the recommendations for telerehabilitation in the 'Addendum on Telerehabilitation' of the 'Multidisciplinary guideline on cardiac rehabilitation' for the entire cardiac rehabilitation programme. The NVVC describes that scientific evidence is still insufficiently available to reach a recommendation (Nederlandse Vereniging voor Cardiologie 2018). However, this KNGF guideline relies on updated scientific reasoning.

In addition, the guideline panel indicates that the use of telerehabilitation is also a sustainable form of care, since the patient does not need to be physically present at the cardiac rehabilitation centre. Since the patient is rehabilitating at home, it is no longer necessary for them to travel to the heart centre, which is a sustainable effect.

Undesirable effects

The guideline panel came to the assessment that the undesirable effects of telerehabilitation compared to regular cardiac rehabilitation or care for patients with chronic heart failure in an exercise programme in phase II of cardiac rehabilitation are small.

The included studies reported no major cardiac incidents (although there were some small undesirable effects). It must be taken into account that this was based on a small number of scientific articles (12 RCTs), which looked mainly at NYHA class \leq 3, and with only one study that described HFpEF. Recent studies show a similar picture, where no major cardiac incidents were reported (Batalik 2020).

Quality of evidence

The guideline panel came to the conclusion that the evidentiary value of the desirable effects for patients with chronic heart failure on the outcomes of physical functioning and quality of life, with the exception of physical functioning measured with the 6MWT, is very low; this evidentiary value receives a low score.

The guideline panel came to the assessment that the evidentiary value of the undesirable effects for patients with chronic heart failure is very low.

It is important here to consider that this evidentiary value in particular was downgraded due to the observed heterogeneousness in the studies and the small study populations. This could be explained by the fact that telerehabilitation is still a fairly new field and that it is still difficult to compare interventions due to the diversity in telerehabilitation interventions.

Patient values and preferences

The guideline panel assesses that the patients attach great value to telerehabilitation and that there is little variation among patients in this regard.

This assessment is supported by the call from the NVVC in collaboration with the Harteraad (heart council) and the Hartstichting (heart foundation) to implement cardiac rehabilitation from a distance and also by the Cardiac Rehabilitation dossier that was established by these parties (Harteraad 2020).

Balance between desirable and undesirable effects

The desirable effects definitely outweigh the undesirable effects. The motivation for this is:

- That telerehabilitation is a suitable alternative to regular cardiac rehabilitation or a replacement for regular cardiac rehabilitation with comparable desirable effects without any relevant undesirable effects.
- There are no indications that telerehabilitation is less safe than regular cardiac rehabilitation or care for non-complex patients with chronic heart failure.

Socio-economic considerations and cost-effectiveness

The guideline panel came to the assessment that the resources needed for the intervention could be seen as cost-saving.

The intervention is, however, cost-effective. Studies were conducted on the cost-effectiveness of telerehabilitation compared to regular cardiac rehabilitation for patients with coronary artery disease, which pointed in favour of telerehabilitation (Kraal 2017; Maddison 2019). Studies were also conducted on the cost-effectiveness of telerehabilitation compared to regular cardiac rehabilitation for patients with chronic heart failure. In these studies, a positive effect was found for telerehabilitation (Dalal 2019; Frederix 2015a; Hwang 2017). The systematic literature review of Shields (2018) supports these results.

Health equality

The guideline panel expects that the intervention will lead to an increase in health equality.

Acceptability

The guideline panel expects that telerehabilitation will be accepted by all key stakeholders.

Feasibility

The guideline panel considers the implementation of telerehabilitation to be realistic.

Other considerations

The guideline panel is of the opinion that the following considerations are also important when setting up telerehabilitation as part of phase II of cardiac rehabilitation.

The essential components mentioned in <u>B.1 'Personalised care'</u> must be taken into consideration when implementing the intervention. This module describes that the intervention should be tailored to the patient's healthcare needs, individual characteristics, capabilities, wishes, needs, learning strategy and context. The guideline panel is of the opinion that patients with reduced digital literacy should preferably not receive telerehabilitation. It is objectionable that the desirable effects of telerehabilitation for patients with chronic heart failure compared to regular cardiac rehabilitation or care are not in line with the recommendations of the Dutch cardiology association (Nederlandse Vereniging voor Cardiologie) in the addendum to the 'Multidisciplinary guideline on cardiac rehabilitation' (Nederlandse Vereniging voor Cardiologie 2018). The guideline panel is of the opinion that for low-complexity patients with chronic heart failure, telerehabilitation might be proposed in phase II of cardiac rehabilitation. It should, however, be kept in mind here that the referring cardiologist must comply with the following guidelines and may only deviate from this guideline if there is substantiation for it.

Telerehabilitation (as a supplement to or replacement for regular cardiac rehabilitation or care) can be offered in several ways: under the guidance of a physical or exercise therapist in a primary care setting, or home-based and coordinated by the physical or exercise therapist in a secondary care setting from the heart centre. For training in a primary care setting, see C.4 'The exercise programme in a primary care setting'.

It is important to assess the patient's digital literacy, for example by means of a Quickscan (Pharos. Landelijk expertisecentrum sociaaleconomische en etnische gezondheidsverschillen). The selected literature does not appear to give any direction for the specific indications of telerehabilitation. The guideline panel considers that it is very important to let the complexity of the disease profile of patients with coronary artery disease or chronic heart failure or contra-indications weigh in the balance when offering telerehabilitation.

Due to the large degree of heterogeneousness in the literature found in terms of frequency, intensity, type and time of the studied interventions, no direction can be given on how to perform the intervention.

A description of the content of the exercise programme of phase II of cardiac rehabilitation with remote sessions or the monitoring of the exercise programme of phase II of cardiac rehabilitation is shown in the 'Addendum on telerehabilitation' to the '<u>Multidisciplinary</u> guideline on cardiac rehabilitation' (Nederlandse Vereniging voor Cardiologie 2018).

Subsequent to the literature search, more recent literature was added by the guideline panel, such as the study of Isernia (2022) on telerehabilitation with chronic heart failure, which supports the findings from the literature search.

It is wise, in addition to the recommendations described here, also to consider the general recommendations for remote digital Care from the generic guideline on 'Remote Care'.

Focus areas for implementation

No focus areas for implementation were formulated.

Knowledge gaps

The quality of evidence is mainly assessed as very low, due to the highly heterogeneous nature of the interventions and the too small study populations. This can be explained by the diversity of the interventions, as well as the diversity of the included study populations. In order to make a targeted assessment regarding the efficacy, more studies will have to be conducted on telerehabilitation for patients with coronary artery disease or chronic heart failure who participate in the exercise programme in phase II of cardiac rehabilitation, with a specific focus on the evaluation of the FITT factors. There also continues to be a lack of scientific evidence to answer the question of whether it is safe and effective to offer telerehabilitation to complex patients with coronary artery disease or chronic heart failure.

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C.7 Evaluation, stop criteria and closure of the treatment

C.7.1 Evaluating the course of the exercise programme (monitoring)

Evaluate with the patient throughout the cardiac rehabilitation programme whether the chosen exercise programme is still sufficiently adapted to the patient or whether it should be adjusted, preferably with the use of measurement instruments such as described in <u>B.6 'Measurement</u> instruments'.

Consult (at least once or when necessary) in writing, orally or digitally with the cardiac rehabilitation team to decide whether it is necessary to stop the exercise programme or to adjust it, so that an adjustment of the entire cardiac rehabilitation programme (including the exercise programme) might be considered. And whether other healthcare providers should be involved to achieve the cardiac rehabilitation goals.

C.7.2 Stop criteria for training sessions

Stop the training session (temporarily) if there is any sign of (cardiac) overexertion:

- severe fatigue or dyspnoea (possibly in combination with reduced saturation) that is not related to the effort made;
- symptoms that go with cardiac problems that are not related to the effort made: ache or a feeling of tightness or stress in the chest, shooting pain towards the left shoulder or left arm or jaws, pain that also continues when resting for longer than 5 minutes, sweating, nausea, vomiting, dizziness, vertigo, feeling faint, feeling heavy, tendency to faint, looking pale or grey in the face. In women, these symptoms are manifested by an ache between the shoulder blades, in the neck or back, feeling uneasy or anxious, and extreme fatigue; signs of angina pectoris that are unfamiliar;
- increased breathing frequency that is not related to the effort made (> 40 breaths/minute);
 significant increase in heart rate that is not proportional to the effort made;
- significant decrease in pulse or blood pressure during exercise, in combination with or without symptoms; do an additional blood-pressure measurement and continue monitoring the blood pressure after the exercise has been stopped;

- increase in arrhythmia (alteration in known arrhythmia);
- if not taking any medication that affects training;
- an increase in peripheral/central oedema with heart failure (> 2 kg within 3 days);
- if with an implantable cardioverter-defibrillator the number of heartbeats increases to more than 20 heartbeats below the therapy zone.

C.7.3 Closure of the treatment (criteria to stop treatment)

After closure of the therapy, evaluate the goals, preferably using measurement instruments as described in B.6 'Measurement instruments'.

At closure, consider using the 'Samen Beslissen' (shared decision-making) and the '3 goede vragen' (3 good questions) models; see B.1 'Personalised care'.

Stop the therapy (prematurely) if:

- the patient's need for assistance has been fulfilled; and/or
- the therapeutic treatment goal(s) has/have been achieved; and/or
- the patient is sufficiently able to maintain or further improve their acquired skills; and/or
- the patient is not capable of taking own responsibility for the symptom, recovery, build-up and training (e.g. due to a lack of motivation); in this case, first discuss it with the patient before ending the treatment, and/or
- there is any contraindication; see B7 'Indication';
- the rehabilitation goals have not been achieved, but no further progress is expected;
- the patient indicates that they want to stop; in this case, first discuss it with the patient before ending the treatment.

C.7.4 Lifestyle advice

Encourage the patient during phase II of cardiac rehabilitation to develop/maintain/resume a healthy, active lifestyle.

Recommendations for an active lifestyle

- Give each patient exercise advice that is in line with the advise from the Dutch health council (Gezondheidsraad). Exercise is good; more exercise is better.
- Do at least 150 minutes per week of moderately intensive exercise, such as walking and cycling, spread out over several days. Integrate these activities in daily life. Longer, more frequent and/or more intensive exercise gives an additional health benefit. Or advise walking 8,800 steps per day.
- Advise avoiding excessive sitting (more than eight hours per day).

Advise the patient, if it seems that they are not active enough, to take up an exercise programme (again) with the physical or exercise therapist in a primary care setting, or to train in a gym that is registered with Harteraad (Dutch heart council) (phase III or post-rehabilitation phase).

C.7.5 Information exchange with the referrer and file keeping

Send a report to the general practitioner and referring cardiologist at the start and at the closure of the treatment.

Send an interim update:

- in response to a request for information from the physician;
- in response to a consultation request from the physician.

Consider sending an interim update:

if the patient remains under treatment for a long time or in the event of an abnormal course: report on the chosen course at fixed times.

Draft reports and final reports according to the current '<u>Guideline on Information Exchange</u> between General Practitioner and Paramedical Professional (HASP-paramedicus)', the '<u>KNGF</u> <u>Guideline on Physical Therapy File-keeping</u>' of the Koninklijk Nederlands Genootschap Fysiotherapie and the '<u>Guideline on Reporting</u>' of the Vereniging van Oefentherapeuten Cesar en Mensendieck.

SUBSTANTIATION

This module was not included in the guideline on the basis of a prioritised barrier. Every guideline of the Royal Dutch Society for Physical Therapy (Koninklijk Nederlands Genootschap voor Fysiotherapie – KNGF) includes a module on 'Evaluation, stop criteria and closure of the treatment'.

Reason

The period during which the therapy is offered depends on the start and stop criteria. The start criteria are described in <u>B.7 'Indication'</u>. This module describes when and how the treatment is evaluated (monitoring) and ended, and looks at information–exchange with the referrer. The following clinical questions were formulated to this end:

Clinical questions

- Which factors are important to keep monitoring during the execution of the exercise programme?
- 2. Which stop criteria are used for ending the exercise programme?
- 3. What lifestyle advice is applicable to patients with coronary artery disease or chronic heart failure?
- 4. What information exchange is taking place with the cardiologist and the general practitioner?

Rationale of the recommendation

In coordination with the guideline panel it was decided not to carry out any systematic search action for this clinical question, but to work out the clinical question narratively using the knowledge and clinical expertise of the guideline panel.

C.7.1 Evaluating the course of the exercise programme (monitoring)

Monitoring means that the therapist keeps an eye on the right intensity of the exercise programme in combination with the healthcare needs, focusing on the patient's individual response to the treatment and the extent to which the patient is tolerating the training effort, the patient's clinical stability and the individual characteristics, capabilities, wishes, needs, learning strategy and context of the patient.

During the exercise programme, it is important to continue assessing whether the chosen exercise programme is still suited to the patient or whether it should be adjusted to facilitate participation in the exercise programme (see <u>C.2 'Continuation and completion of cardiac rehabilitation'</u>). This assessment of the effect of the cardiac rehabilitation programme is done at interim stages (at minimum once, or more often if necessary) by having the rehabilitation team establish information on the risk profile and the subjective and objective physical, social and mental functioning. At the start of the exercise programme, each patient's blood pressure and heart rate (and cardiac rhythm) is measured structurally before, during and after training, in order to establish the right training intensity and avoid overexertion. This period of supervision can be extended if arrhythmia, ischaemia, signs of angina pectoris or blood–pressure anomalies occur during training. During the exercise programme, the patient learns how to estimate the exercise intensity according to the Borg RPE scale (see <u>B.6 'Measurement instruments'</u>). Being able to self-assess exertion during activities of daily living facilitates self-management.

Consult with the cardiac rehabilitation team when necessary to decide whether to (temporarily) stop the exercise programme or to adjust it, so that an adjustment of the entire cardiac rehabilitation programme (including the exercise programme) might be considered.

C.7.2 Stop criteria for training sessions

During cardiac rehabilitation, the therapist will be attentive to phenomena that occur during or immediately after the training session.

C.7.3 C losure of the treatment (criteria to stop treatment)

The final evaluation will determine to what extent the goals formulated in the indication have been reached. This final evaluation is done by the multidisciplinary treatment team. The final evaluation of the outpatient cardiac rehabilitation can lead to the formulation of goals for the post-rehabilitation phase (phase III) or a continuation of phase II. In the final evaluation, in as far as possible, the same measurement instruments and values should be used as during the examination (see <u>B.5 'Physical examination and treatment plan'</u> and <u>B.6 'Measurement</u> instruments').

The stop criteria that have been formulated in the 'Professional Profile of the Physical Therapist' serve as guideline (Koninklijk Nederlands Genootschap Fysiotherapie 2021). The stop criteria as formulated in the Practice Guideline are commensurate with the patient's context and are aligned with the patient's context. The guideline panel adds the following criteria to this:

The healthcare needs, individual characteristics, capabilities, wishes, needs, learning strategy and context of the patient may change during therapy.

The patient themselves may indicate that they want to stop, for example for personal reasons, reasons stemming from the patient's social context or for financial reasons.

C.7.4 Lifestyle advice

During phase II of cardiac rehabilitation, the therapist will encourage patients with coronary artery disease or chronic heart failure to develop and continue or to resume an active lifestyle. Continuing with physical activities further reduces the chances of mortality and re-hospitalisation (Knuuti 2020; McDonagh 2021; Pelliccia 2021; Federatie Medisch Specialisten 2019). A recent study in the Netherlands looked at the number of steps of over 11,130 people (Stens 2023). The conclusion was that health benefits could be measured starting from about 2,500 steps. Every 500 steps more will reduce the chances of premature death or cardiovascular disease by 8%. The chance of cardiovascular disease is already reduced to the maximum at 7,126 steps and of mortality at 8,763 steps. To prevent the likelihood with other disease profiles (such as preventing inflammation), it is necessary to walk more than 7,126 steps. 8,800 steps are therefore recommended. It is furthermore recommended to build up gradually with 1,000 steps at a time (Stens 2023).

The guideline panel indicates that it is important to let patients choose activities that appeal to them and in which they can participate for a longer period.

Post-rehabilitation phase (phase III)

By means of an evaluative medical history-taking dialogue (using 'motivational interviewing' techniques), the therapist will establish whether the patient is motivated to continue with an active lifestyle after their cardiac rehabilitation.

For patients with coronary artery disease or chronic heart failure who cannot yet maintain a fully active lifestyle or who have not reached all the therapeutic goals during the outpatient phase, even though this is considered possible, the guideline panel advises following or continuing with a phase III of cardiac rehabilitation in a primary care setting.

However, basic health insurance at present does not allow for any structural reimbursement for physical or exercise therapy care in the post-rehabilitation phase (phase III). Some patients fall under the conditions for reimbursement of combined lifestyle interventions (patients with a higher body mass index (BMI) and/or a higher risk of one or more diseases that are linked to overweight, such as cardiovascular diseases or type 2 diabetes). Doing sport under professional supervision (exercise coaches) in the patient's neighbourhood also gives the patient the opportunity continue with an active lifestyle. Exercise clubs like these, with specific knowledge of cardiovascular disease, can be found through <u>Harteraad</u>. The decision to refer a patient to physical or exercise therapy in a primary care setting or to an association or institute that is registered with the exercise clubs of Harteraad can be made by the treating physical or exercise therapist and the multidisciplinary cardiac rehabilitation team in consultation with the patient.

C.7.5 Information exchange with the referrer and file keeping

During the cardiac rehabilitation journey, there are various times when the therapist will take a moment to exchange information with the referring cardiologist. In phase II of cardiac rehabilitation, this alignment takes place regularly through multidisciplinary dialogue (see A.3 'Organisation of healthcare').

The Guideline on Information Exchange between General Practitioner and Paramedical Professional (HASP-paramedicus) contains recommendations for this information exchange based on consensus by the guideline panel. The recommendations for information-sharing from the paramedical professional to the doctor, mostly the referring cardiologist, have been incorporated into this guideline (Buiting-van der Zon 2020).

For information on file keeping, see the prevailing 'KNGF guideline on Physical Therapy File Keeping 2019' of KNGF (Driehuis 2019), the 'Guideline on Reporting' of VvOCM (Kooiman 2020) and the 'Guideline on Information–Sharing between the general practitioner and the paramedical professional (HASP–paramedicus)' (Buiting–van der Zon 2020).

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Colophon

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