

Rééducation cardiaque: efficacité clinique et utilisation en Belgique

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KCE reports 140B

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Titre:	Rééducation cardiaque: efficacité clinique et utilisation en Belgique
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PRÉFACE

Les pathologies cardiovasculaires constituent la première cause de décès en Belgique, et elles entraînent plus de 200.000 admissions hospitalières par an. Il est donc légitime de s'interroger au sujet du rôle de la rééducation cardiaque, par exemple après une intervention coronaire. Est-ce que ce type de rééducation a une influence positive sur la mortalité, le taux de réhospitalisation, la qualité de vie ? Si oui, est-elle utilisée à bon escient et atteint-elle les patients qui devraient en bénéficier ?

En 2007, un groupe de travail ministériel s'est penché sur la question. Ce groupe suggérait que seule une fraction de la population de patients potentiellement bénéficiaires de cette rééducation la suivaient effectivement. Ce manque de compliance est similaire à la situation observée dans les autres pays européens. Les auteurs avançaient plusieurs hypothèses pour l'expliquer: répartition géographique des centres, attitude du patient, suivi médical inadéquat, conditions de remboursement trop strictes. L'INAMI a sollicité l'expertise du KCE afin d'étayer ces hypothèses par des données objectives.

Déjà dans son rapport n°87, publié en 2008, le KCE s'était penché sur le monde de la rééducation et son mode de financement un peu particulier en Belgique. Dans le présent rapport, nous avons triangulé les enseignements de la littérature scientifique, la pratique telle qu'observée dans notre pays au travers des bases de données administratives, et le point de vue des patients, afin de pouvoir nous prononcer sur les questions qui nous étaient posées. Pour ce faire, nous avons bénéficié d'une collaboration scientifique de qualité avec les équipes de chercheurs de Deloitte et Abacus International. Nous tenons également à remercier les cardiologues et patients qui se sont investis dans l'enquête relative aux motivations des patients.

Jean Pierre CLOSON
Directeur général adjoint

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Résumé

CADRE DE L'ÉTUDE

La rééducation cardiaque est, selon l'OMS, l'ensemble des interventions médicales, psychologiques et sociales qui permettent au patient cardiaque de se rétablir aussi rapidement que possible et grâce à des efforts personnels de réintégrer une place aussi normale que possible dans la société.

FORMES DE RÉÉDUCATION CARDIAQUE

Bien que l'OMS définisse la rééducation cardiaque comme étant de nature multidisciplinaire, les études de la littérature internationale regroupent sous ce terme trois types de rééducation:

- rééducation monodisciplinaire sous forme de programmes d'exercices;
- rééducation multidisciplinaire comprenant notamment des exercices ;
- rééducation multidisciplinaire sans exercices mais avec d'autres interventions (e.a. style de vie, diététique).

QUESTIONS DE RECHERCHE

En 2007, un groupe de travail ministériel^a suggérait que seuls 15 à 30% des patients qui pourraient tirer bénéfice d'une rééducation cardiaque suivaient effectivement ce programme. Ce rapport vise à fournir des éléments pour objectiver cette problématique, en essayant de répondre aux trois questions de recherche suivantes:

Question de recherche	Méthode
Chez les patients adultes avec pathologie cardiaque, la rééducation multidisciplinaire est-elle plus (coût)-efficace que d'autres options telles que des programmes d'exercices monodisciplinaires ou un traitement usuel ?	Revue systématique de littérature Medline, EMBASE, PEDro, Cochrane Library, CRD (Centre for Reviews and Dissemination) et consultation des sites des membres de l'INHATA
En Belgique, après une intervention cardiaque, quel est le recours à la rééducation multidisciplinaire et à la rééducation monodisciplinaire (supervisée par un spécialiste en médecine physique et réadaptation (MPR) ou par un kinésithérapeute) ? Quels en sont la répartition géographique et les coûts ?	Analyse de données administratives belges (Agence Intermutualiste-AIM) relatives à la rééducation après un événement cardiaque
Quelles conclusions peuvent être tirées au sujet de la compliance des patients pour la rééducation cardiaque proposée/prescrite et quelles sont les raisons de (non) participation des patients à ces programmes ?	Enquête auprès de patients cardiaques

a Sous-Groupe de Travail Ministériel: réadaptation cardiaque. Février 2007. Disponible (accès Octobre 2010): www.riziv.fgov.be/care/nl/revalidatie/general-information/studies/ministeria-working-group-readaptation/pdf/cardio.pdf

RÉÉDUCATION CARDIAQUE EN BELGIQUE

L'étude actuelle inclut uniquement la rééducation cardiaque (mono- ou pluridisciplinaire) incluant des exercices puisque les programmes belges en comprennent systématiquement.

En Belgique, la rééducation multidisciplinaire (« rééducation cardiaque » suivant les termes officiels) est réservée à un nombre limité de centres reconnus qui répondent à des conditions précises (personnel, équipement). Seuls les patients qui remplissent deux conditions ont droit à un remboursement (maximum 30 séances en hôpital, 45 séances en ambulatoire) :

- pathologie cardiaque^b spécifique ayant nécessité une hospitalisation;
- introduction d'une demande, basée sur une évaluation multidisciplinaire, réalisée dans les 15 premiers jours d'hospitalisation.

Les patients qui ne rentrent pas dans ces conditions et/ou n'ont pas la possibilité de se rendre dans un centre de rééducation cardiaque peuvent éventuellement suivre un programme d'exercices (monodisciplinaire) sous la supervision soit d'un médecin spécialiste en MPR soit d'un kinésithérapeute. Dans ces cas, on peut donc parler d'une rééducation monodisciplinaire sous forme de programmes d'exercices.

En 2010, les coûts par séance en ambulatoire sont de 32€ (10€ pour le patient) pour la rééducation multidisciplinaire, 22€ (8€ pour le patient) pour la MPR monodisciplinaire (18 premières séances) et 20€ (5€ pour le patient) pour la kinésithérapie.

REVUE SYSTÉMATIQUE DE LITTÉRATURE : EFFICACITÉ CLINIQUE DE LA RÉÉDUCATION CARDIAQUE MULTIDISCIPLINAIRE

Cette revue de littérature relative à la rééducation multidisciplinaire s'est limitée aux études primaires qui incluaient au moins deux professionnels de la santé et comportaient un volet d'exercices. La qualité de chaque étude (49 revues systématiques de littérature et 45 études randomisées contrôlées) a été analysée (cf. annexes).

Importance de l'exercice physique

Les **programmes d'exercices** (mono ou pluridisciplinaires) comprennent généralement des activités aérobies telles que marche, vélo. Ces exercices ont un impact positif sur la qualité de vie, le taux de réhospitalisation et la mortalité, et ce pour l'ensemble des pathologies cardiaques.

L'estimation de la **diminution du risque de mortalité** varie d'une revue systématique à l'autre. On retrouve des chiffres de l'ordre d'une réduction d'un cinquième (RR=0.80) dans une population hétérogène de patients cardiaques, voire d'un tiers chez des patients décompensés cardiaques qui suivent un programme d'exercices monodisciplinaire par rapport à des patients sous traitement usuel (c-à-d un suivi médical sans programme de rééducation). Les programmes multidisciplinaires incluant des exercices ont un effet positif du même ordre de grandeur (RR:0.8-0.9).

Cependant les données actuellement disponibles ne montrent **pas de supériorité d'un traitement multidisciplinaire** avec exercices par rapport aux programmes d'exercice monodisciplinaires pour des populations hétérogènes de patients cardiaques (e.a. après infarctus du myocarde, après intervention chirurgicale). Ces comparaisons ne sont pas disponibles de manière spécifique pour les patients décompensés cardiaques. De manière générale, il manque des essais de bonne qualité qui comparent de manière directe un programme multidisciplinaire avec exercices à un programme d'exercices monodisciplinaire.

b Arrêté Royal du 10 janvier 1991 établissant la nomenclature des prestations de revalidation visée à l'article 23, §2, ALINEA 2, de la loi relative à l'assurance obligatoire

Quant au **risque d'incident cardiovasculaire ou autre induit par l'exercice** même, la littérature sélectionnée ne donne aucune raison de croire que le programme d'exercices lui-même présente des risques qui justifient une supervision médicalisée. Une revue Cochrane récente renforce cette conclusion pour une population de patients décompensés cardiaques. Il faut cependant noter que la majorité des études incluent des populations de patients à risque faible ou modéré d'événement cardiaque ultérieur.

Une autre revue Cochrane récente a analysé **le lieu d'intervention** de manière spécifique. Elle conclut que la rééducation dans un centre ou à la maison produit des résultats comparables chez les patients avec angor, décompensation cardiaque, après infarctus aigu du myocarde, après intervention coronarienne. Les interventions analysées dans cette revue sont hétérogènes et la majorité des études portent sur des patients avec un faible risque d'événement indésirable.

Limitations

Les études analysées présentent des restrictions qui limitent les conclusions de cette revue systématique de littérature. Premièrement, les populations incluses sont hétérogènes en termes d'affection cardiaque. Deuxièmement, les interventions (surtout multidisciplinaires) ne sont pas toujours bien décrites et varient de manière substantielle suivant les études (cf. appendices). Des études plus spécifiques sont requises pour identifier les facettes qui déterminent leur succès (composantes, fréquence, durée optimale) chez quels patients (suivant leur profil de risque).

En l'absence de données probantes relatives à la supériorité de programmes multidisciplinaires par rapport aux exercices, l'étude actuelle n'a pas approfondi les aspects coûts-efficacité.

RECOURS A LA RÉÉDUCATION APRES EVENEMENT CARDIAQUE

L'étude des données de l'AIM a sélectionné **29021 patients** qui en 2007 avaient subi une intervention percutanée coronaire ou une intervention chirurgicale (pontage coronarien, chirurgie valvulaire). L'analyse des données a détaillé la consommation de soins durant l'année suivant l'intervention initiale: rééducation multidisciplinaire, rééducation monodisciplinaire (MPR ou kinésithérapie), consultations et tests diagnostiques en rapport avec une affection cardiaque.

Ces données administratives présentaient deux types de **limitations** : d'une part, elles ne permettaient pas d'identifier les patients avec décompensation cardiaque. D'autre part le lien entre l'affection cardiaque et la rééducation monodisciplinaire ne pouvait être certifié, même si des conditions de continuité de traitement ont été définies lors de l'analyse des données.

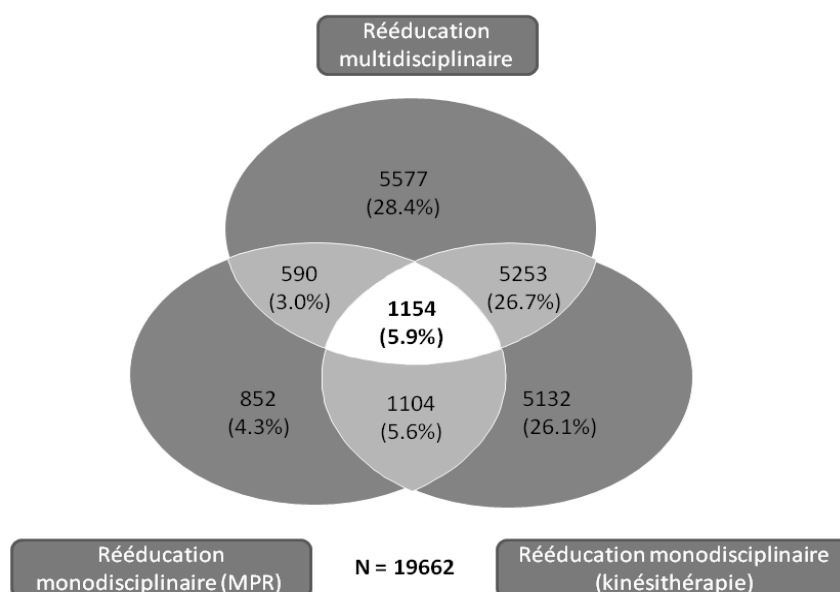
Résultats descriptifs

Un tiers des patients (32%) n'a suivi aucune rééducation (ni pendant l'hospitalisation, ni après le retour à domicile). Moins de la moitié des patients (44%) ont eu au moins une séance multidisciplinaire mais 10% de ces patients se sont limités à une seule séance de ce type.

Après la sortie de l'hôpital, plus de la moitié des patients (55%) n'ont suivi aucun traitement de rééducation.

Complexité des trajets de rééducation

Pour les patients qui ont reçu au moins une séance de rééducation, la figure ci-dessous illustre la complexité des trajets suivis.



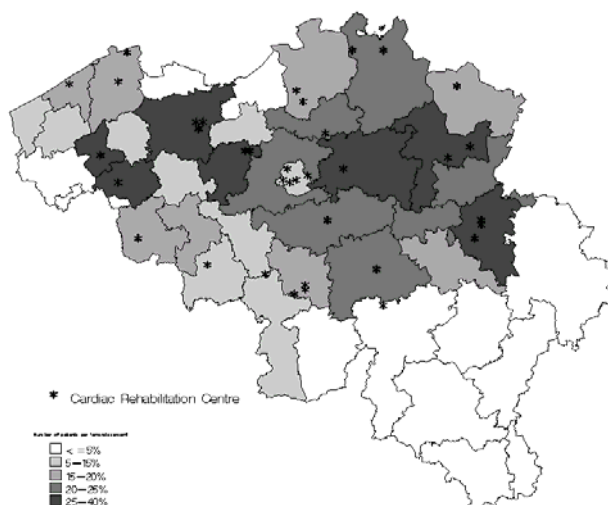
Le profil de rééducation diffère suivant l'intervention initiale. Après une intervention chirurgicale, quatre patients sur cinq reçoivent au moins une séance de rééducation multidisciplinaire à l'hôpital. Un patient opéré sur cinq (19%) continue cette rééducation multidisciplinaire après l'hospitalisation. La durée totale médiane de rééducation après chirurgie (tous types de rééducation confondus) est de 48 jours. Après une intervention de type percutané, un quart des patients reçoivent au moins une séance multidisciplinaire. Après cette intervention et retour à domicile, 14% de ces patients poursuivent une rééducation multidisciplinaire. Leur durée médiane de rééducation est de 14 jours.

Variations en fonction du lieu de résidence du patient

La carte ci-dessous montre pour les patients opérés le pourcentage de rééducation après hospitalisation et ce en fonction de leur lieu de résidence. Dans les régions où n'existe aucun centre de rééducation cardiaque, seul un très faible pourcentage de patients (parfois < 5%) suit une rééducation multidisciplinaire. La seule exception est Bruxelles, où se trouvent quatre centres : le très faible pourcentage de rééducation multidisciplinaire est sans doute lié à d'autres facteurs socio-démographiques.

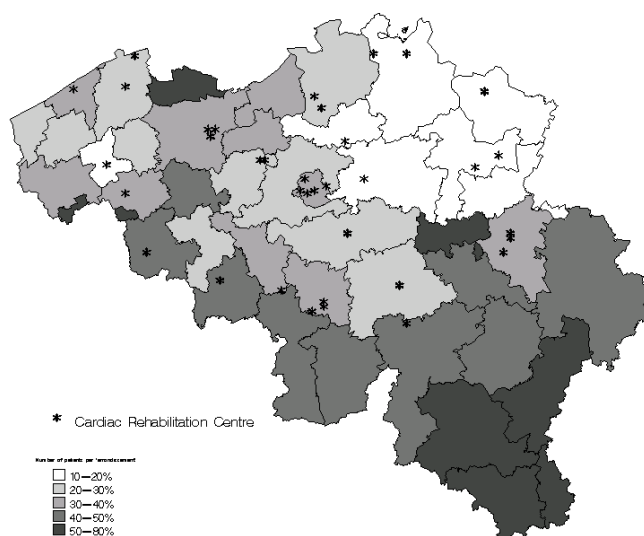
Dans le rapport, une carte similaire illustre ces pourcentages pour les interventions percutanées : les régions avec centres reconnus sont également celles où un plus grand pourcentage de patients suivent une rééducation multidisciplinaire, même si ces pourcentages sont systématiquement plus faibles que pour la chirurgie cardiaque.

Pourcentage des patients qui après chirurgie reçoivent au moins une séance multidisciplinaire après sortie de l'hôpital



Par contre la carte ci-dessous illustre en foncé les régions où un pourcentage élevé de patients ne reçoit aucune rééducation (ni multidisciplinaire, ni monodisciplinaire) à la maison après chirurgie cardiaque.

Pourcentage des patients qui après chirurgie ne reçoivent aucune séance de rééducation après sortie de l'hôpital



Coûts de la rééducation

Les coûts de la rééducation après l'hospitalisation sont plus élevés pour les patients qui suivent une rééducation multidisciplinaire que pour ceux qui suivent une rééducation monodisciplinaire: en moyenne €1116 après chirurgie et €756 après intervention percutanée. Ces coûts plus élevés sont en partie expliqués par le coût unitaire des sessions multidisciplinaires. Les montants correspondants pour l'intervention personnelle du patient sont €290 après chirurgie et €191 après intervention percutanée.

Analyse multivariée: facteurs qui influencent le recours à la rééducation multidisciplinaire après hospitalisation

La rééducation après le retour à domicile représente la majeure partie du traitement en terme de durée et de nombre de sessions mais cette rééducation est celle qui pose un problème d'accessibilité à de nombreux patients. Il apparaît que les personnes plus âgées et les femmes ont moins de chances de suivre cette rééducation multidisciplinaire. En outre, un niveau d'éducation supérieur, des revenus élevés, un statut salarié (versus retraité, indépendant ou invalide) de même que l'existence d'un centre de rééducation cardiaque dans l'arrondissement de résidence sont associés à une plus grande probabilité de rééducation multidisciplinaire. Ces données sont en concordance avec celles de la littérature internationale.

Par ailleurs, le sexe masculin, l'âge avancé et le statut d'indépendant sont associés à une plus grande probabilité de ne recevoir aucune rééducation après l'hospitalisation.

RAISONS DE (NON) PARTICIPATION AUX PROGRAMMES DE RÉÉDUCATION CARDIAQUE EN BELGIQUE

Une enquête a été effectuée dans 15 hôpitaux belges qui ont accepté de participer à cette étude (parmi les 126 établissements sollicités). L'objectif initial était de récolter les opinions de 400 patients cardiaques répartis de manière égale entre trois groupes : chirurgie, infarctus et intervention percutanée. L'analyse finale comprend 226 répondants, suite à des difficultés majeures de recrutement et des centres et des patients eux-mêmes.

La plupart des participants (86%, n=195) ont reçu une proposition de rééducation et la majorité d'entre eux ont accepté (81%, n=158/195). Les trois-quarts des patients qui avaient accepté (77%, n=121/158, soit la moitié seulement de l'échantillon initial) disent avoir terminé le traitement qui leur a été prescrit. Ces pourcentages relativement élevés (par rapport aux données de l'AIM) doivent tenir compte des biais de sélection: 10 des 15 centres sélectionnés étaient en effet reconnus pour la rééducation cardiaque, les cardiologues ont recruté eux-mêmes les patients et ils étaient intéressés par cette problématique.

Les quatre principales raisons invoquées par les patients pour refuser la rééducation étaient la distance jusqu'au centre, la confiance en soi pour guérir sans le programme, le manque de temps et le manque de moyens de transport.

La principale raison invoquée pour arrêter le traitement était l'existence d'autres problèmes physiques, suivie par la confiance en soi, le coût, la distance et les obligations professionnelles. Lorsque la distance était évoquée comme problème, elle variait de 6 à 50 kms (médiane = 15 kms), soit une distance légèrement supérieure à celle reportée par les patients qui avaient suivi le traitement (11.3 Kms).

Les principaux points positifs évoqués par les patients qui ont terminé le traitement étaient l'amélioration de la condition physique et psychique, la qualité du support et la motivation par le groupe.

CONCLUSION

La littérature confirme les bénéfices d'une rééducation cardiaque comprenant des exercices pour les patients avec un niveau de risque faible ou modéré. Il n'existe pas de données spécifiques pour les patients à risque élevé (arythmie, ischémie ou décompensation cardiaque sévère). Il existe également des données relatives à l'effet positif de la rééducation multidisciplinaire comprenant des exercices mais les données actuelles ne permettent pas de spécifier les autres composantes de l'intervention qui auraient un impact sur quelles populations de patients.

L'analyse des données montre le pourcentage limité de patients qui poursuivent une rééducation (surtout multidisciplinaire) après leur hospitalisation, de même que les facteurs socio-démographiques qui ont un impact sur le suivi de ce traitement.

Les raisons pour refuser ou arrêter le traitement sont d'ordre personnel (temps, obligations, confiance en soi pour guérir sans le programme, autres problèmes physiques) et logistique (distance, moyens de transport, coût).

RECOMMANDATIONS^c

En matière de bonnes pratiques médicales

- **Après une intervention coronaire ou une hospitalisation pour un accident coronaire ou une décompensation cardiaque, tout patient doit bénéficier**
 - d'une mise au point médicale relative à son profil de risque cardiovasculaire ;
 - d'un programme d'exercices répondant à ses besoins spécifiques (valable pour les patients avec risque d'événement cardiaque ultérieur faible ou modéré) ;
 - ce programme devrait être élaboré de préférence suivant l'avis d'un médecin spécialiste agréé comme spécialiste en rééducation cardiologique;
 - d'un nombre limité de séances d'accompagnement complémentaires dont l'objectif est l'amélioration de son profil de risque cardiovasculaire (alimentation, arrêt du tabac, gestion du stress). Pour des questions d'accessibilité géographique, ces séances d'accompagnement devraient pouvoir être dispensées aussi bien par plusieurs intervenants en pratique ambulatoire que par l'équipe multidisciplinaire d'un service de rééducation cardiaque reconnu;
- Les séances d'exercices et autres séances relatives aux facteurs de risque identifiés devraient être étalées sur plusieurs mois afin d'assurer l'ancrage et le maintien des modifications des habitudes de vie ;
- La sensibilisation et la formation des médecins généralistes sont essentielles pour qu'ils soient conscients de l'importance de l'exercice, adapté de manière individualisée à chaque patient cardiaque ;
- Les médecins généralistes et cardiologues devraient sensibiliser les patients à l'importance de ces exercices. En cas de refus ou de non compliance au programme proposé, ils devraient systématiquement en investiguer les raisons afin de convaincre le patient de suivre le programme ou de trouver des solutions alternatives pour surmonter les obstacles identifiés.
- Un suivi à vie par le médecin traitant est nécessaire afin de maintenir ces bonnes « habitudes de vie » ;

En matière de gestion de l'assurance-maladie :

- La nomenclature des séances de rééducation cardiaque devrait distinguer :
 - l'évaluation pluri disciplinaire proprement dite effectuée par le médecin spécialiste agréé comme spécialiste en rééducation cardiologique, en collaboration avec d'autres professionnels de la santé (cf. recommandations similaires pour la rééducation, rapport KCE 87) ;
 - les séances de rééducation conduites par un kinésithérapeute et bénéficiant d'une nomenclature de kinésithérapie spécifique pour la rééducation cardiaque, inscrite dans la liste F ;
 - des séances données par d'autres professionnels de la santé à prévoir dans la nomenclature de chacune des professions concernées grâce à un code spécifique de la rééducation cardiaque.

Agenda de recherche

- Il conviendrait d'évaluer l'apport spécifique des professionnels de santé qui agissent sur d'autres facteurs de risque cardiovasculaire que le manque d'exercice (diététicien, tabacologue, psychologue).

^c Le KCE reste seul responsable des recommandations faites aux autorités publiques

Scientific summary

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GLOSSARY

ADL	Activities of daily living
CABG	Coronary artery bypass graft
CAD	Coronary artery disease
CHD	Coronary heart disease
CI	Confidence interval
CR	Cardiac Rehabilitation
EQ-5D	EuroQol-5D
GP	General/primary care practitioner
ESRD	End stage renal disease
HF	Heart failure
HRQoL	Health related quality of life
HTA	Health technology assessment
ICSI	Institute for Clinical Systems Improvement
IMA/AMI	Database from the Common Sickness Funds Agency
INAHTA	International Network of Agencies for Health Technology Assessment
INAMI-RIZIV	National Institute for Health and Disability Insurance
ISCED	International Standard Classification of Education
MDCR	Multidisciplinary cardiac rehabilitation
MESH	Medical index subject headings
MI	Myocardial Infarction
MLHFQ	Minnesota living with heart failure questionnaire
MMSE	Mini mental state examination
MKG/RCM	Minimale Klinische Gegevens/Résumé Clinique Minimum
MEG	Mutually exclusive group
Nomenclature codes	The codes used by Belgian health authority to identify the medical services provided by the medical professionals for the purpose of reimbursement and finance
PCI	Percutaneous coronary intervention
NYHA	New York heart association
NICE	National Institute for Clinical Excellence
NIHDI	National Institute for Health and Disability Insurance
OR	Odds ratio
PCI	Percutaneous Coronary Intervention
PRM	Physical and Rehabilitation Medicine
PRO	Patient reported outcome
QoL	Quality of life
RCT	Randomised controlled trial
RR	Relative risk
SD	Standard deviation
SF-36	Short form 36 health survey
SIGN	Scottish Intercollegiate Guideline Network
SS	Statistical sector
WMD	Weighted mean difference

I BACKGROUND AND RESEARCH QUESTIONS

I.1 BACKGROUND

I.1.1 Cardiac rehabilitation

‘Heart disease’ encompasses a number of acute and chronic conditions with differing symptoms, treatment needs and goals. While pharmacological and surgical interventions provide first-line, often life-saving treatment, they are insufficient for rehabilitating the patient and facilitating a return to a normal active life, and also in preventing secondary cardiac events. Cardiac rehabilitation (CR) aims to reverse the adverse pathophysiological and psychological consequences of cardiac events and prevent the occurrence of further events. The World Health Organisation defines CR as ‘the sum of activity and interventions required to ensure the best physical, mental, and social conditions so that patients with chronic or post-acute cardiovascular disease may, by their own efforts, preserve or resume their proper place in society and lead an active life’¹. CR therefore needs to be multi-faceted and comprehensive.

CR programmes usually include exercise training, as well as psychological and educational components²⁻⁴, designed to reduce anxiety and depression⁵⁻⁷ and encourage behavioural change in order to eliminate risk factors principally related to diet, smoking and exercise¹⁻³.

I.1.2 Different approaches to cardiac rehabilitation

CR can broadly be divided into multidisciplinary programmes that include exercise training (called “pluridisciplinary CR programmes” in Belgium), multidisciplinary programmes without exercise, and exercise only programmes (as the monodisciplinary physical therapy (PRM) and physiotherapy sessions in Belgium). While generally multidisciplinary programmes with an exercise component are recommended¹⁻³, many clinical trials have focussed on other aspects of CR (e.g. psychoeducational interventions or telemonitoring).

I.1.3 Heart disease and treatment goals

The roots of CR lie in the 1950s, when short daily walks were recommended for recovering cardiac patients⁸. Initially CR focussed on ischaemic patients⁹, but it was soon recognised that it could be of benefit to other cardiac patients, including patients suffering from heart failure or myocardial infarction or after cardiac surgery (e.g. CABG). The treatment goals of CR can be summarised as follows⁸:

- To reduce the physiological, psychological and social effects of heart disease;
- To reduce the risk of a secondary event;
- To relieve cardiac symptoms;
- To slow or improve atherosclerosis through exercise, education, counselling, and modification of risk factors^a;
- To allow patients a return to a functional status in their families and in society.

CR programmes may affect patients differently according to the type of heart disease they suffer from. To date however, no specific programmes for different disease states have been developed.

^a Primary prevention encompasses almost the same interventions (such as healthy diet, exercise etc); however, the scope of this report is secondary prevention

1.1.4 Organisation of multidisciplinary cardiac rehabilitation in Belgium

1.1.4.1 Eligibility criteria

Patients are eligible for pluridisciplinary CR if they have been hospitalised for one of the following conditions¹⁰:

- Acute myocardial infarction;
- Coronary surgery;
- Percutaneous intervention;
- Surgery for heart abnormality;
- Heart (lung) transplant;
- Cardiomyopathy with left ventricular dysfunction.

An additional eligibility criterion is a multidisciplinary rehabilitation evaluation within the 15 first days of the hospitalisation, under the supervision of a specialist physician specialized in CR.

Pluridisciplinary CR sessions in hospital are provided individually to the patients (with a reimbursement up to 30 sessions). Multidisciplinary outpatient sessions have a minimal duration of 60 minutes and are group sessions (with a reimbursement up to 45 sessions).

1.1.4.2 Criteria for official cardiac rehabilitation centres

Thirty-six CR centres are officially authorized in Belgium^b for the provision of pluridisciplinary CR. These centres have to fulfil specific conditions defined by the legislation¹⁰:

- Minimal human resources: specialist physician specialized in CR, physiotherapist, psychologist, social worker;
- Possibility to appoint a dietician, an occupational therapist;
- Adapted premises for training and for conversation.

These official CR centres have an unequal spread throughout the country (see maps in 3.2.5.3).

1.1.5 Treatment access

A report of a working group on CR stated in 2007 that a part of the population who might benefit from multidisciplinary CR (MDCR) may not have access to it: only 15 to 30% of patients for whom CR may be beneficial, would have access to this service¹¹. This expert group suggested different hypotheses:

- Inadequate geographical spread;
- Patient's refusal;
- Insufficient medical follow-up;
- Current accessibility criteria, e.g. patients initially treated in a hospital without authorized CR centre are not entitled to an outpatient reimbursement for MDCR sessions.

Patients who do not fulfil the conditions or do not have the possibility to go to a centre can follow a monodisciplinary rehabilitation pathway, either under the supervision of a PRM specialist or under the supervision of a physiotherapist ("kinésithérapeute/kinesitherapeut").

This research has been set up to determine the clinical and economic effectiveness of different CR programmes. The utilisation, geographical spread and the costs of MDCR, of monodisciplinary PRM and of physiotherapy in Belgium are analysed and discussed in relation to the latest available evidence. Finally, causes of non compliance and possible solutions to facilitate the compliance with CR programmes, when indicated, are identified

1.2 RESEARCH QUESTIONS

The following research questions are investigated in this report:

1. In adult patients with cardiovascular disease, is multidisciplinary cardiac rehabilitation (MDCR) more effective, safer (and more cost-effective) than other options i.e. exercise therapy, usual care, or no treatment?
2. What is the utilisation, geographical spread and the cost of MDCR, of monodisciplinary rehabilitation supervised by a PRM specialist and of physiotherapy after defined cardiac procedures, throughout Belgium?
3. What can be concluded regarding compliance with proposed/prescribed CR programmes and the reasons for the (non) participation of patients in a CR?
4. What can be concluded regarding CR utilisation, organization and the reasons for possible inequalities in accessibility? What can be proposed to the Belgian health policy makers to improve the current situation?

1.3 PARTS OF THE STUDY

First a systematic review of the effectiveness of different pathways of CR has been performed following the KCE process on GCP¹².

Secondly, an analysis of the data provided by the Common Sickness Funds Agency (IMA/AMI)¹³ evaluated the utilisation and costs of multidisciplinary CR, of monodisciplinary PRM and of physiotherapy in patients who underwent cardiac surgery or percutaneous coronary intervention (PCI).

Finally, a survey among patients analysed their reasons for (non)-participation in a CR programme in Belgium. A questionnaire was given to patients who had specific cardiac events and were eligible for this rehabilitation programme

For the two last parts of the study approval has been obtained from the “Comité Sectoriel Santé – Sectoriaal Comité Gezondheid” of the Belgian privacy commission (<http://www.privacybelgium.be/>).

2 SYSTEMATIC LITERATURE REVIEW

2.1 RESEARCH QUESTION

This systematic review addresses the question whether, in adult patients with cardiovascular disease, multidisciplinary cardiac rehabilitation (MDCR) is more effective and safer than other options i.e. exercise therapy, usual care, or no treatment.

2.2 METHODS

2.2.1 Selection of studies

2.2.1.1 *Patient population*

Publications had to include patients eligible for CR, who underwent heart surgery, coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI), or suffered myocardial infarction (MI), heart failure (HF), angina or coronary artery disease (CAD). Patients who had undergone a heart transplant or suffered from congenital diseases were specifically excluded.

2.2.1.2 *Intervention*

For the purposes of the project, MDCR had to include exercise and was defined as “A multidisciplinary team intervenes in a coordinated interdisciplinary way in the presence of goals which require rehabilitation activities belonging to the unique domain of several disciplines.”¹⁴

Exercise therapy was defined as a regimen or plan of physical activities designed and prescribed for specific therapeutic goals where the purpose is to restore normal musculoskeletal function or to reduce pain caused by injuries or diseases (cf. MESH thesaurus).

It should be noted that nomenclature may differ between trials (e.g. the definition of “home-based” is not necessarily consistent and often further information is not reported). Since precise definitions of terms are rarely available in publications of clinical trials, those terms have been quoted as they were used in the original referenced publication.

2.2.1.3 *Comparators*

Included studies had to compare MDCR programmes (which included exercise as a programme component) with exercise therapy, usual care, or no treatment. Comparisons between exercise therapy and usual care or no care were also considered.

2.2.1.4 *Outcomes*

Outcomes of interest included, but were not restricted to:

Clinical outcomes

- Safety issues (physician supervision, intensive care needs)
- Mortality
- Morbidity
- Adherence
- Health-related quality of life/patient reported outcomes (PROs) measured using disease-specific or generic instruments:
 - Overall health status (e.g. EQ-5D scale)
 - Parent or patient global assessment of overall wellbeing
 - Functional measures of activities of daily living (ADLs)

Health service use related outcomes

- Re-admission
- Health service utilisation (e.g. participation by the patient)

Only hard outcome measures were considered relevant to the review (as defined above). Other outcomes such as physiological changes that are often reported in the CR setting (such as exercise tolerance or $\dot{V}O_2$ max) were not considered.

The analysis of the efficiency of CR programme (through full economic evaluations of CR programmes) was scheduled in the protocol of this systematic review. However, as stated further, the available literature did not show firm evidence of an additional clinical value of multidisciplinary CR including exercise in comparison with exercise only. Moreover, the analysis of IMA-AIM data has shown that patients who received outpatient multidisciplinary rehabilitation sessions had higher overall rehabilitation costs (including all types of sessions, inpatient and outpatient) than other patients. Investigating the incremental cost-effectiveness ratio of multidisciplinary CR was therefore not necessary after these conclusions.

2.2.1.5 Language

Databases were searched for publications in English, French, Dutch or German.

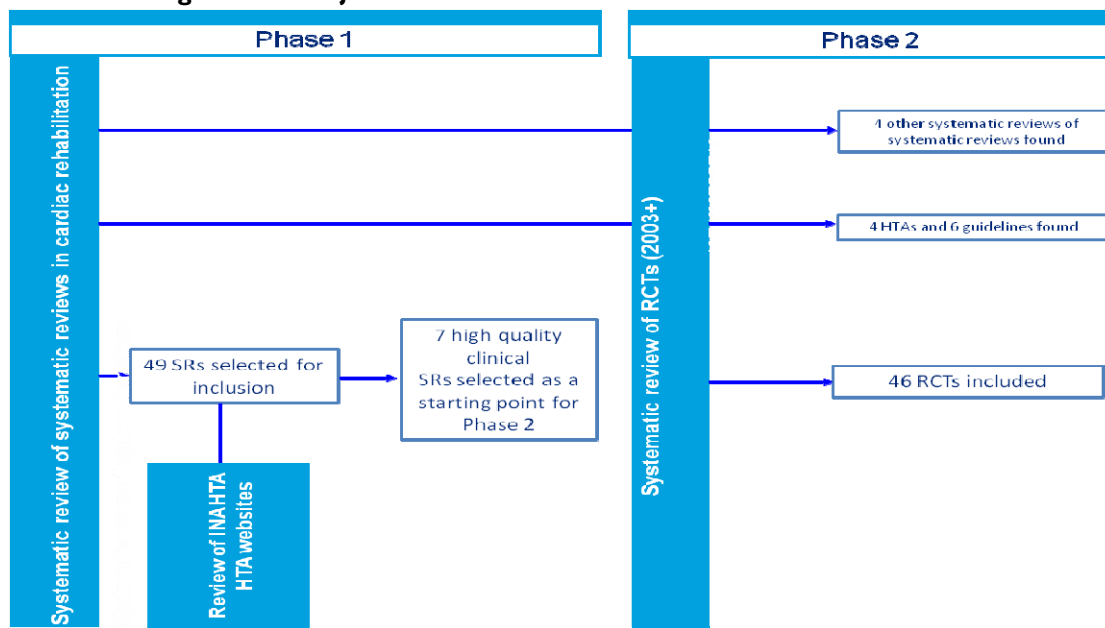
2.2.1.6 Design

For phase I, only systematic reviews were eligible as evidenced by the description of a systematic search of one or more electronic databases. For phase II only RCTs were eligible. All studies were required to include a reference to randomisation and a control/comparator treatment.

2.2.2 Project Outline

The wealth of research literature in this particular therapeutic area made a de novo systematic review for the effectiveness of MDCR impractical. In order to manage the volume of literature anticipated, the project was segmented into two phases. Phase I was a systematic review of existing systematic reviews; searches were conducted across a series of databases and supplemented by searches of INAHTA member websites. The most recent high quality systematic review was used as a starting point for a de novo systematic review of original RCTs (Phase II).

Figure 2-1: Project outline



2.2.3 Literature search strategy

2.2.3.1 *Phase I – identifying systematic reviews and meta-analyses*

Using the search terms detailed in appendix the following databases were systematically searched from 1999 onwards in August 2009 for systematic reviews of studies in MDCR:

- Cochrane Library,
- The Centre for reviews and Dissemination database (CRD database) including NHS Economic Evaluation Database (EED), DARE, and HTA database,
- OVID Medline,
- OVID EMBASE,
- PEDro.

Additional handsearches were undertaken using the bibliographies of retrieved studies and INAHTA member websites to ensure that all relevant information was captured (see appendix 3 of the literature review for details of member websites searched). The results of these searches were reviewed for relevant systematic reviews not already identified by the database searches undertaken. Four potentially relevant studies were identified through handsearching of bibliographies. No additional systematic reviews were identified via the INAHTA websites.

2.2.3.2 *Phase II – identifying original RCTs*

As well as the criteria specified above, the following conditions were applied to the selection of randomised controlled trials (RCTs) published since the last high quality systematic review. These criteria were designed to identify predominantly larger studies with a focus on exercise and outcomes relevant to the research question.

- Exercise had to be part of the intervention;
- Studies had to include at least 30 participants;
- Outcomes were restricted to hard outcomes (other outcomes such as physiological changes that are often reported in the CR setting were not considered):
 - Cardiac events
 - Readmissions
 - Mortality/survival
 - Symptoms
 - QOL outcomes
 - Safety outcomes

In order to ensure a sufficient overlap between the systematic reviews and the RCTs, searches were conducted from the year before the searches in the selected systematic review. Search terms are described in the appendix I of the literature review. Searches were otherwise performed as described in section 2.2.3.1.

2.2.4 Assessing methodological quality and risk of bias

2.2.4.1 *Phase I*

The methodological quality of systematic reviews and associated risk of bias was rated using a modified version of the SIGN tool¹⁵. In order for publications to be included, three of the four following criteria had to be rated as “well covered” or “adequately addressed”:

- Appropriate and clearly focussed study question
- Description of methodology
- Sufficiently rigorous literature searches
- Quality of identified data assessed and taken into account

2.2.4.2 Phase II

RCT quality and risk of bias was rated using a modified version of the SIGN tool¹⁶. In order for publications to be included, three of the following criteria had to be rated as “well covered” or “adequately addressed”:

- Randomisation
- Blinding: given the nature of the intervention it was not possible to blind the patients and medical staff involved. In this instance blinding refers specifically to blinding of the outcome assessor
- Allocation concealment
- Treatment groups comparable at baseline
- Description of dropouts and withdrawals

2.2.5 Data extraction

Data were extracted from eligible publications by a reviewer into a pre-prepared Excel[®] spreadsheet. A second reviewer reviewed the publication in full in order to check the extracted information and to check for any available information that had not been extracted by the first reviewer. Methodological assessment was undertaken in the same manner. Any discrepancies were resolved through discussion with an independent third party.

The conclusions of this systematic review were thereafter compared to those of the few guidelines published on the topic.

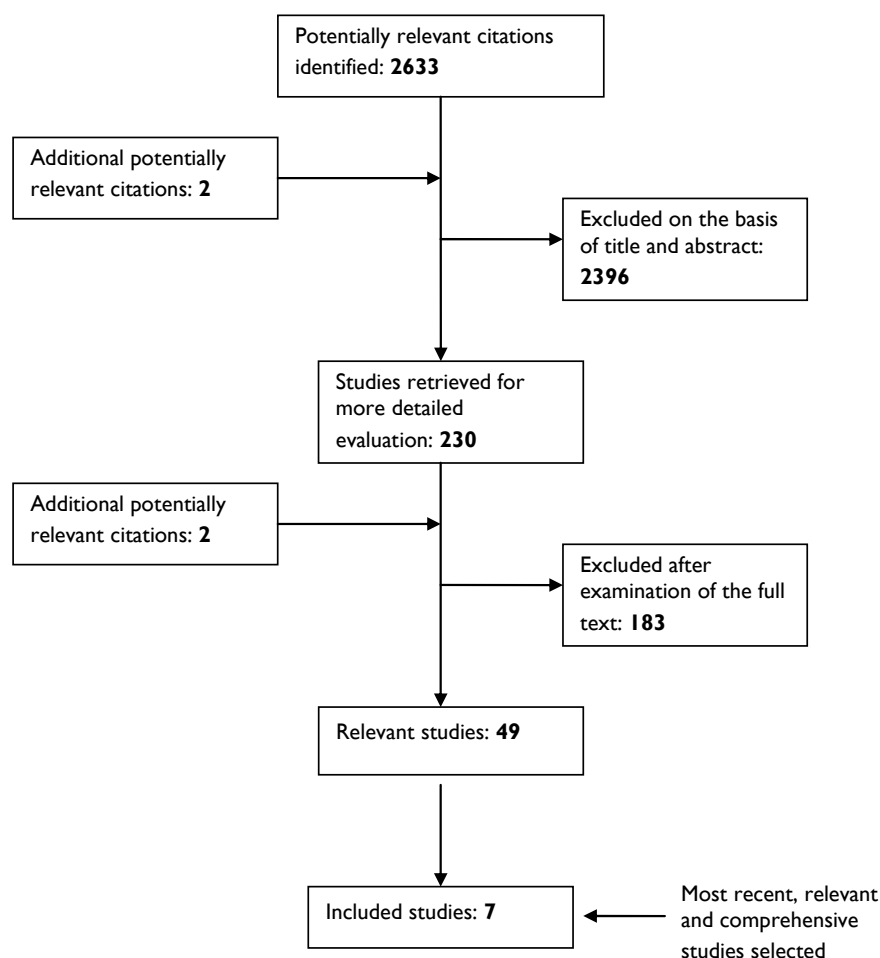
2.3 RESULTS

2.3.1 Phase I: systematic reviews and meta-analyses

In the systematic literature search performed in 2009 August, 2633 citations on the topic of CR were identified (figure 2-2). The supplementary searches of INAHTA member websites yielded no additional references. The majority of citations were excluded on the basis of title and abstract; 230 citations were retrieved and reviewed in full.

All evidence tables and the results of the methodological quality appraisal are in appendix 4 of the literature review.

On the basis of the full text, 49 reviews were included. They are summarised from table 1 to table 6 in this appendix. The results of their critical appraisal are listed in table 7.

Figure 2-2: Systematic review of systematic reviews, trial flow

Forty-six clinical systematic reviews were identified, and three systematic reviews addressing clinical as well as economic aspects. Most of the included studies performed well against quality appraisal indicators. Studies that were rated as poor and presenting results potentially associated with a greater risk of bias typically lacked explicit selection criteria, failed to undertake any methodological quality appraisal of studies selected for inclusion or presented only a limited number of studies (despite describing systematic search methods). The systematic reviews were split by intervention:

- MDCR versus usual care; exercise versus usual care;
- MDCR or exercise versus usual care;
- MDCR versus exercise.

They were then further grouped according to the population selected in the review. The nature of the populations included in the systematic reviews only permitted two categories, heart failure and 'mixed'. The intended split of the patient population (heart surgery, MI, HF and CAD) could therefore not be reproduced in the results of the review. The majority of studies included a mixed population, typically reflecting a mixture of surgical (e.g CABG), MI, and CAD patients. The systematic reviews for each group were then compared with regards to the date of the searches, relevance and comprehensiveness, and outcomes reported. Studies that did not report at least either mortality, QoL, resource use or another outcome listed in Section 2.2.4.2 were not eligible for selection. Where there was little difference between the reviews and the search dates were similar, both reviews were accepted and presented. This process identified seven key clinical publications¹⁷⁻²⁴. Many reviews did not provide sufficient detail of the characteristics of the MDCR or exercise intervention reported by the included studies.

Even less information was typically available for the comparator included in the study, often 'usual care' was left undefined for example.

In the course of this search, four systematic reviews of systematic reviews were identified: they are described in the discussion.

2.3.1.1 Exercise only versus usual care

Heart failure patients

The first table in appendix 4 of the literature review summarises all 12 reviews on exercise therapy in heart failure patients. Several studies were discounted on the basis of an earlier publication date or high risk of bias²⁵⁻²⁸, other reviews were discounted for focussing on physiological parameters²⁹⁻³¹. Two reviews^{32, 33} were rejected on the grounds that, despite being published at least two years later, the information reported was subsumed by the information provided by the three studies published in 2004. Between them, these selected reviews^{23, 24, 34} report on the key outcomes of mortality, hospital admission, walking distance, and QoL. One review in particular represents a comprehensive review of the relevant literature and includes a large number of studies not included in other studies²³. Table 2-1 below presents their findings. Only one review comes to the conclusion that exercise has a significant benefit with regards to mortality²⁴. All three reviews include a study by Belardinelli et al.³⁵. This study of an extended exercise intervention (420 days) was undertaken with the supervision of a cardiologist, an unusual feature in the literature although similar to the Belgian situation. The results were significant and, given that fewer studies were included in the ExTraMATCH review, may have overly influenced the conclusions. Nevertheless, the reviews agree that exercise is safe and reduces adverse events and rehospitalisations, while also increasing QoL in heart failure patients.

Table 2-1: Selected systematic reviews evaluating exercise therapy in heart failure patients

Study	Comparator(s)	Supplementary information	Results	Summary
ExTraMATCH 2004 ²⁴	Usual care	Patients with HF and left ventricular systolic dysfunction with stable disease (ejection fraction <50% , stable for at least 3 months) 9 studies included	Lower mortality with exercise (RR 0.65, 95% CI 0.46-0.92) RR for death or admission to hospital 0.72 (95% CI 0.56-0.93)	Exercise significantly reduced deaths and hospital re-admission among patients with stable HF
Rees 2004 ³⁴	Usual care	Patients with NYHA functional status class II or III heart failure (ejection fraction <40%) 29 studies included	OR for all-cause mortality is 1.12 (95% CI 0.58-2.15), peak O2 consumption +2.16 ml/kg/min (95% CI 2.82-1.49), exercise duration +2.38 min (95% CI 2.85-1.92), max work capacity +15.1 (95% CI 64.7-17.1), 6 min walk +40.9m (95% CI 64.7-17.1) 7/9 studies found improvement of HRQoL in intervention group compared with control.	Exercise training improves exercise capacity and HRQoL in patients with NYHA functional status class II or III heart failure.
Smart 2004 ²³	Various/none (studies were included irrespective of comparator or trial design)	Baseline ejection fraction <40%, concurrent drug therapy allowed. 81 studies included (30 RCTs)	OR for adverse events 0.83 (95% CI 0.50-1.39). OR for adverse events and death 0.98 (95% CI 0.61-1.32). OR for death 0.71 (95% CI 0.37-1.02)	Exercise training is safe and effective in patients with heart failure. The risk of adverse events may be reduced, but further studies are required to determine whether there is any mortality benefit.

Mixed patient population

The results of the seven included reviews on exercise-only CR in mixed patient populations are summarised in the second table of appendix 4. Two reviews were excluded on the basis of an early publication date ^{36, 37}, two further reviews focused narrowly on the QoL outcomes of operationalization of self-efficacy ³⁸, or energy and fatigue ³⁹. Another review⁴⁰ included a limited number of studies due to using resistance exercise as an inclusion criterion. The most relevant and comprehensive review (that related to a previously published review in 2004) is presented in the table 2-2 below.

Taylor et al.¹⁸ found that, in a mixed patient population (predominantly MI, revascularisation and angina), exercise therapy led to a 28% relative risk reduction in mortality (80 deaths were observed with exercise compared with 110 observed with usual care), although they speculate that approximately half of this reduction might be due to smoking cessation or a reduction in other major risk factors. As these reviews are related (the later publication is a meta-analysis of suitable papers selected from the systematic review), both are presented.

Table 2-2: Selected systematic reviews evaluating exercise therapy in mixed patient groups

Study	Comparator(s)	Supplementary information	Results	Summary
Taylor 2006 ¹⁸ (related to Taylor 2004 ¹⁷)	Usual care	Subpopulation of RCTs from Taylor 2004 analysed using the IMPACT coronary heart disease model Myocardial infarction, revascularisation, angina 19 studies included	Exercise reduced cardiac mortality by 28% (95% CI 5-45%); 80 deaths were observed with exercise (30 less than with usual care 110). Greater risk factor decreases were seen with exercise training (18% decrease in smoking prevalence; pooled mean difference of 0.11 mmol/l for cholesterol, and 2.0 mmHg for systolic blood pressure. Smoking cessation accounted for 24% of mortality reduction, systolic blood pressure reduction for 15% and cholesterol for 19.7% and in total accounted for 57% of the reduction in total mortality.	Approximately half of the 28% relative reduction in cardiac mortality achieved with exercise-based CR may be attributed to reductions in major risk factors, particularly smoking.

2.3.1.2 Multidisciplinary cardiac rehabilitation versus usual care

Heart failure patients

Of 19 included systematic reviews (summarised in table 3 in appendix) considering the effect of MDCR in heart failure patients, several studies were not considered further due to presenting a greater risk of bias ⁴¹⁻⁴⁶. Of the remaining reviews, one review was clearly much older ⁴⁷. Of the several reviews published between 2004 and 2005, using similar criteria and methods, Taylor et al., 2005 ¹⁹ was the most comprehensive in terms of inclusion criteria and relevant outcomes reported and a high quality review (published as a Cochrane review, table 2-3). MDCR was defined as enhanced or novel service provision for patients with heart failure (in-patient, out-patient or community based interventions) and their carers or relatives. RCTs on drug treatment or education alone were excluded.

Specialist nurses were common to all studies and the other health professionals involved varied according to the interventions. Most of them described an educational component. Other components were frequently described e.g. self management, weight monitoring. It is important to note that only six out of the 16 included RCTs specified exercise as an intervention although that was an inclusion criteria in the search for RCTs in the present systematic review. They found no significant benefits, but reported that MDCR may increase overall survival, improve QoL, and possibly reduce rehospitalisations.

Table 2-3: Selected systematic review evaluating multidisciplinary cardiac rehabilitation in heart failure patients

Study	Comparator(s)	Supplementary information	Results	Summary
Taylor 2005 ¹⁹	Usual care	<p>All studies identified patients during an index hospital admission for CHF</p> <p>Patients diagnosed with NYHA II, III, and IV all represented across the included studies</p> <p>16 studies included</p>	OR for mortality: 0.86 95% CI 0.67-1.10, p=0.23, but interventions differed in content, duration and follow-up (only 6/16 included RCTs reported exercise)	<p>There is some evidence that case management interventions (with specialist nurse) may confer benefit in terms of overall survival and a tentative suggestion that they might be associated with a reduction in hospital readmissions for HF. It should be noted that this SR on MDCR for HF patients includes a large proportion of trials that do not report exercise in the intervention.</p> <p>There is also evidence that some case management interventions may be associated with improvements in health related quality of life.</p> <p>A single RCT of a multidisciplinary intervention showed evidence of benefits in terms of reduced heart-failure related re-admissions in the short term.</p>

Mixed patient population

Table 4 in appendix lists details of the nine included review publications on MDCR in mixed patient populations. One review was much older than the other eligible studies and was not considered further⁴⁸. Two reviews focused on angina-specific symptom measures and QoL but did not report other outcomes of interest^{49, 50}. Several reviews were published between 2004 and 2008 and used similar criteria and methods^{22, 51-53} however, Clark et al.²¹ was the broadest and included the greatest number of relevant studies. A second related publication provided additional results from the same review. Therefore we considered Clark et al., 2005²¹ as well as Clark et al., 2007²⁰ to be most comprehensive and selected these reviews for use (Table 2-4). In 2005, Clark et al. report that a wide variety of secondary prevention programmes improve health outcomes in patients with coronary heart disease. Following on from these results, the additional analyses of Clark et al. from 2007 finds that shorter programmes, provided by GPs, are sufficient to confer benefits to most patients. The authors still note that due to inclusion criteria the population of the studies is usually with stable disease, younger and with fewer co-morbidities than the patients usually seen in practice.

Table 2-4: Selected systematic reviews evaluating multidisciplinary cardiac rehabilitation in mixed patient populations

Study	Comparator	Condition	Supplementary information	Results	Summary
Clark, 2005 ²¹	Usual Care	Majority: acute MI, surgical procedure, CAD	MI, CABG, PCI, surgery or angina 63 studies included	The summary risk ratio for all 40 trials reporting all-cause mortality (16 142 patients) was 0.85 (95% CI, 0.77 to 0.94; P for heterogeneity = 0.96; I ² 0%). The treatment effects did not statistically significantly differ among the 3 types of secondary prevention programmes, even if all exercise-based programmes were combined (27 trials, 6940 patients) (summary risk ratio, 0.83 [CI, 0.72 to 0.96]) and compared with non-exercise-based programmes (14 trials, 9202 patients) (summary risk ratio, 0.87 [CI, 0.76 to 0.99]; P 0.64). Recurrent MI rate: The summary risk ratio for reinfarction for all 11 723 patients over a median follow-up of 12 months was 0.83 (CI, 0.74 to 0.94; P for heterogeneity = 0.55; I ² = 0%).	Secondary prevention programmes positively affect processes of care (risk factor profiles and use of proven efficacious therapies) and functional status or quality of life for participants and reduce MIs by 17% over a median follow-up of 12 months. The mortality benefit derived from participation in secondary prevention programmes (15% overall and 47% at 2 years) became apparent with longer follow-up and was of similar magnitude in recently published trials and in trials published more than 2 decades ago (before the widespread use of contemporary medical therapies). Benefits did not differ among the 3 types of programmes
Clark 2007 ²⁰	Usual care	Coronary artery disease	46 studies included	RR for all-cause mortality 0.87 (95% CI 0.79-0.97) RR stratified by duration: <10 hrs. RR 0.80(95%CI 0.68 to 0.95), 10-25 hrs. 1.03 (95% CI 0.83 to 1.27), 25-50 hrs. 0.99 (95% CI 0.40 to 2.47), >50 hrs. 0.79 (95% CI 0.48 to 1.29) RR stratified by location hospital 0.90 (95% CI 0.79 to 1.03), general practice 0.76 (95% CI 0.63 to 0.92), other 1.15 (0.78 to 1.69) Results of meta-regression (p-values): length of programme 0.49, general practice versus hospital setting (excluding in-patient treatment) 0.14, specialist versus non-specialists 0.29	The all-cause mortality benefit was similar across programmes. Shorter programmes, programmes based in GP practice settings, and programmes delivered by non-specialists were just as effective as longer programmes, programmes delivered in hospital-settings and programmes staffed by specialists.

2.3.1.3 Multidisciplinary cardiac rehabilitation and exercise versus usual care

Only in two publications, both for a mixed population, were both exercise and exercise as part of MDCR both reviewed (Table 2-5).

Taylor et al., 2004¹⁷ report that, in a subgroup analysis, indirect comparison suggests there was no significant difference in mortality risk between the exercise only (versus usual care) and MDCR (versus usual care) interventions.

Jolliffe et al., 2001⁵⁴ also compare exercise only versus usual care and MDCR versus usual care. All cause mortality was only significantly reduced by exercise (compared with usual care). Both exercise-only and MDCR significantly reduced total cardiac mortality (versus usual care). Results for CABG and PCI were few and heterogeneous.

Table 2-5: Systematic reviews evaluating exercise therapy and multidisciplinary cardiac rehabilitation

Study	Condition	Supplementary information	Results	Summary
Subgroup analysis in Taylor 2004 ¹⁷	Mixed	<p>Patients with coronary heart disease who had a myocardial infarction, coronary artery bypass graft, percutaneous coronary intervention or angina pectoris or coronary heart disease defined by angiography.</p> <p>48 studies included</p>	<p>Total mortality: exercise only: 12 trials versus usual care, OR=0.67; 95% CI 0.59 to 0.98; comprehensive CR: 20 trials versus usual care; OR=0.84; 95% CI: 0.72 to 0.99</p> <p>Other subgroup analyses demonstrated no significant differences between exercise only versus usual care and MDCR versus usual care in 'dose' of intervention, duration of follow-up, Jadad quality score, and year of publication</p>	No significant difference in mortality risk between exercise only versus usual care and comprehensive CR versus usual care.
Jolliffe 2001 ⁵⁴	Mixed	<p>Patients of all ages in both hospital-based and community-based settings with myocardial infarction, coronary artery bypass graft or percutaneous coronary intervention or who have angina pectoris or coronary artery disease.</p> <p>32 studies included</p>	<p>Exercise only: 27% reduction in all cause mortality (13% for MDCR). Total cardiac mortality reduced by 31% and 26% respectively. Pooled adverse clinical outcomes: pooled effect estimate 0.81 (0.65, 1.01) for exercise only and 0.81 (0.69, 0.96) for MDCR.</p>	Total mortality reduced for exercise only vs. usual care (also, but less so for comprehensive cardiac rehabilitation). Cardiac mortality reduced. CR reduces pooled adverse clinical outcomes. Changes in HRQoL were small.

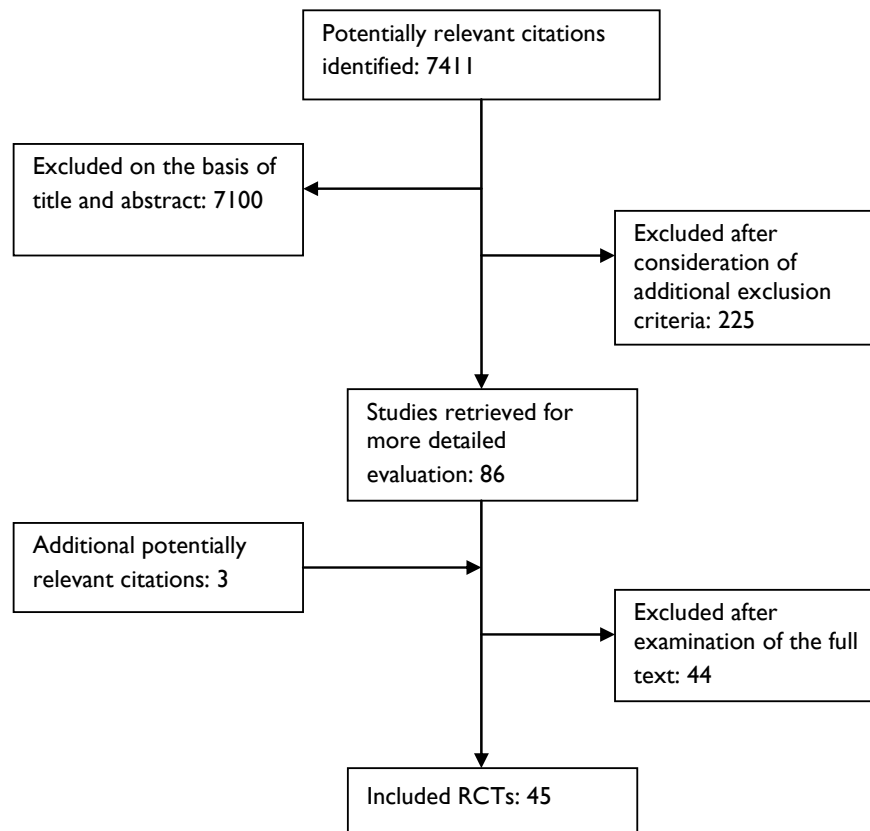
Key points – systematic reviews

- Many studies included in the SR did not provide sufficient detail of the characteristics of the MDCR or exercise intervention. Moreover the comparator 'usual care' was often left undefined.
- Given these facts, the overall quality of evidence of these SR can be considered to be at best of moderate level.
- The available data suggest that exercise is the key element of successful CR:
- -exercise appears to reduce adverse events and rehospitalisation rates, while increasing QoL in heart failure patients;
- -a reduction in mortality was observed in mixed patient populations following an exercise CR regimen.
- MDCR may increase overall survival, improve QoL, and reduce rehospitalisations in heart failure patients.
- There is some evidence which is inconclusive that for CAD patients shorter MDCR programmes, programmes based in GP practice settings, and programmes delivered by non-specialists are just as effective as longer programmes, programmes delivered in hospital-settings and programmes staffed by specialists.
- Based on indirect comparisons, MDCR (with an exercise component) in a mixed cardiac population (without HF patients) does not appear to be more beneficial than exercise only CR.

2.3.2 Phase II: original RCTs

Given the publication date of the relevant systematic reviews, the search on original studies started from 2003 onwards. In the systematic literature search 45 RCTs on cardiac rehabilitation were identified and divided in three groups: those investigating MDCR only, those examining exercise-only CR regimens and those comparing MDCR with exercise-based CR.

Figure 2-3: Systematic review of RCTs published since last high quality systematic review



2.3.2.1 Characteristics of included studies

Searches identified over 7000 citations for review; 7100 citations were excluded on the basis of title and abstract and an additional 225 were excluded after imposing additional inclusion criteria relating to a minimum number of patients (at least 30) and outcomes restricted to cardiac events, readmissions, mortality/survival, symptoms, QoL outcomes, and safety outcomes. Eighty six papers were retrieved in full along with three RCTs retrieved through hand searching. Overall, 45 RCTs were included. Allowance has to be made for the fact that intervention-related terms (e.g. "in-patient" or "home-based") may not refer to the same treatment parameter in all trials (e.g. "home-based" may refer to an activity performed at home, but it may also refer to an activity performed at a centre or clinic, by a patient not staying in hospital). Since definitions are not always provided, those terms have been used as in the original publication.

The details on all RCTs are provided from table 8 to table 25 in the appendix 4 of the literature review. In tables 9, 11, 13, 15, 17, 19, 21, 23 and 25, it is indicated for each RCT the components that were offered in each trial i.e. dietary or medical advice, advice on smoking cessation, psychological advice, general life habits advice or other intervention as for example music therapy, relaxation.

The results of the methodological quality appraisal of all RCTs are displayed in table 26.

2.3.2.2 *Multidisciplinary cardiac rehabilitation*

Twenty-five of the included publications evaluated MDCR, compared with either usual care or a different MDCR/CR (table 8 to 15 in appendix 4 of the literature review). Of these publications, three (based on two trials, and including an update publication) considered only heart failure patients, three surgical patients, five considered only MI patients and the patient population of the remaining 14 studies was mixed.

Tables 9, 11, 13 and 15 indicate for each RCT whether the components mentioned above were provided or not: dietary or medical advice (offered in 16/25 trials, respectively), advice on smoking cessation and psychological advice (each offered in ten trials), general life habits advice or counselling (provided in 19/25 trials) or any other type of psychological support (available in five trials).

As to the components of MDCR, only MDCR including exercise therapy was accepted in the review, as mentioned earlier. The tables in appendix mention if exercise therapy was undertaken with supervision and if specific performance goals were stipulated. It was also noted whether there was a coordinator for the MDCR team, and whether there were pre-specified rehabilitation goals (not shown in appendix 4, available from the authors on request). MDCR coordinators are mentioned in fewer than 50% of publications (10/25). However, it should be noted that the level of reported detail with regards to organisation of CR was low and the real percentage of coordinator-involvement may have been higher. Rehabilitation goals were specified in 12 of 25 trials.

Heart failure patients

Tables 8 and 9 in appendix 4 of the literature review provide details of the two included trials (both associated with a low risk of bias) on MDCR versus clinical follow-up in heart failure patients. Both studies included medical advice, exercise, dietary advice and counselling, one study used a similar care package without exercise as the comparator, the other study failed to define 'usual care'. Neither trial reported any difference in mortality between treatment arms. Azad et al.⁵⁵ do not find any significant differences (compared with usual care and with regards to Mini Mental State Examination [MMSE], Minnesota Living with Heart Failure Questionnaire [MLHFQ], SF-36, hospitalisations, GP visits, etc.), except for cardiologist visits, which were higher in the MDCR group. Although the MDCR programmes were similar in the trials Austin et al.⁵⁶ found that sustained MDCR (compared with usual care) resulted in improved walking distance, NYHA class and QoL, while also reducing hospital readmissions and days in hospital. After five years QoL-related advantages are mostly retained in the MDCR group. At five years there was no difference in resource use between the treatment arms.

Surgical patients

The two included RCTs, both of weak quality associated with a high risk of bias, assessed a mixed population composed of patients post heart surgery, PTCA and CABG^{57, 58}. Both studies reported pre-specified goals for exercise intensity, all studies incorporated dietary advice, and two also reported counselling and/or another form of psychological intervention.

TIMING OF MDCR

Of the two included RCTs that evaluated MDCR in surgical patients (tables 10 and 11 in appendix), one compared early with traditional timing of CR⁵⁸. Any initially significant differences were found not to persist at one year.

HOME-BASED VERSUS INPATIENT MDCR

The other trial found that the results for home-based CR (for intervention details, see table 11) were similar to those for in-patient CR⁵⁷.

MI patients

Table 12 in appendix summarises the five included trials on MDCR (for intervention details, see table 13) in MI patients. Only one study pre-specified exercise targets, two studies included counselling whilst three studies included an additional form of psychological support. All studies included 'usual care' as a comparator. Of the five included trials, two presented a low risk of bias.

Two trials, comparing home-based with hospital-based MDCR^{59, 60} found little or no difference between them. One of these trials presented a low risk of bias, the other a high risk of bias. In the latter paper, reported positive effects are more prolonged for the home-based CR group⁶⁰. The authors speculate that this may be connected to the advanced age of the patients involved, making interventions less efficacious. It was shown in one trial that early rehabilitation may be beneficial (compared with traditional timing) with regards to self-care ability and mental status⁶¹.

Results from another trial (low risk of bias) indicate that, after 6 months, early return to normal activities without any formal CR may be just as effective as five weeks of MDCR before a delayed return to normal activities (in low-risk patients)⁶². Finally, a trial (high risk of bias) investigating long-term reinforced MDCR⁶³ found that, while the combined endpoint (improvement in mortality and various heart conditions) was not reached, extended MDCR improved risk factors, lifestyle and medication adherence as compared with usual care.

Mixed patient population

An overview of the fourteen included trials is provided in table 14 in appendix 4 of the literature review. Five trials presented a high risk of bias. MDCR was compared with standard care in six of the trials⁶⁴⁻⁶⁹. The details of the components of MDCR are described in table 15 in appendix. Patients were typically drawn from mixed cardiac populations including heart surgery (acute recovery and secondary prevention), myocardial infarction, and heart failure. QoL measures were the most frequently used outcomes. Exercise capacity and global risk (assessed using the FRA risk score⁷⁰) were also used as primary outcomes. With the exception of one trial, where only the SF-36 component of "physical function" was found to be increased with MDCR⁶⁸, QoL measures generally favour MDCR compared with standard care. Global risk was found to be reduced⁶⁹ and exercise capacity increased⁶⁵ with MDCR versus usual care in one trial, respectively.

Two trials investigated the effect of MDCR duration, comparing four with ten weeks of MDCR⁷¹, as well as a specified number of MDCR sessions spread over either three or 12 months⁷². The first study presented a greater risk of bias, but no significant differences were identified in either case.

Two trials with a low risk of bias investigated the addition of either telephone counselling⁷³ or self-monitored exercise with the help of a pedometer⁷⁴ to standard care (which consisted of information leaflets, also covering exercise). In both cases the intervention was considered to be successful, improving QoL and increasing physical activity.

Comparing home-based with centre-based MDCR, Jolly et al., 2009⁷⁵ found no significant differences in the main outcomes (study associated with a low risk of bias). Neither did a comparison of MDCR with exercise only (greater risk of bias show any significant differences⁷⁶).

Focht et al., 2004⁷⁷ set out to compare a group-mediated cognitive behavioural physical activity intervention programme with traditional CR. Their findings indicate that HRQoL differs as a function of treatment, gender and initial mental health status.

Compared with standard care, provision of patients with detailed planning strategies and diaries did result in enhanced physical activity and fewer depressive symptoms, but findings from this study were associated with a high risk of bias⁷⁸.

2.3.2.3 Exercise

Twenty-one publications evaluating exercise-based CR were included, describing 19 clinical trials (two publications reported trial result updates). An overview is provided from table 16 to table 23 in appendix 4.

Heart failure patients

Exercise was compared with usual care in seven publications (see table 16 in appendix)⁷⁹⁻⁸⁵, representing six trials (and one update presentation⁸¹). All but one presented a low risk of bias. Exercise (for details of intervention, see table 17 in appendix) led to benefits in all trials, including the reduction of hospitalisations and improvements in QoL and/or functional capacity.

Two trials included the use of a pedometer in the usual care arm as well as in the exercise arm^{82, 83}. Corvera-Tindel et al.⁸³ report improved walking distance as well as global symptom rating with exercise versus usual care, in spite of increasingly poor compliance over the course of the 5-week programme. On the other hand, Evangelista et al.⁸² found reductions in weight and hospital readmissions, without any additional functional or psychological benefits (for exercise versus usual care).

Educational measures were the comparator in the four remaining trials^{75, 86-89}, but only one of these was of low risk of bias. With the exception of Gary et al.⁸⁶, who report improved adherence, walking distance and QoL with exercise over education, few significant improvements with exercise were found (increased exercise tolerance, improved QoL, reduced depression).

Surgical patients

In the three trials considering the effect of exercise in surgical patients (see tables 18 and 19 in appendix), the comparators were standard care⁹⁰ (low risk of bias), hospital-based versus home-based exercise⁹¹ (high risk of bias) and high-frequency versus low-frequency exercise⁹² (low risk of bias). Exercise was found to confer a transient increase in walking distance, but no other benefits, when compared to usual care. Hospital-versus home-based exercise did not show any significant between-group differences (with the exception of VO2 max). Compared to low-frequency exercise, high-frequency exercise did lead to the earlier achievement of functional milestones and higher patient satisfaction.

MI patients

Myocardial infarction patients were either treated with exercise, PCI^{93, 94} or routine drug treatment with absolute bedrest⁹⁵ (tables 20 and 21 in appendix). The two first studies presented a low risk of bias^{93, 94} whilst the third one had a high risk of bias and tested bedrest, an intervention that is not anymore used in European countries. Exercise was superior to PCI, leading to increased event-free survival. Early mobilisation led to a significant reduction in length of hospital stay and recurrence of MI, as well as increased Barthel index and self-care ability.

Mixed patient population

A mixed patient population was included in three trials (tables 22 and 23 in appendix). Compared with standard care both exercise and stress management improved outcomes⁹⁶. However, the trial was not powered to detect clinically significant differences. Hage et al., 2003, a high risk of bias trial⁹⁷, found that exercise increased levels of physical activity when compared to usual care, but no between-group differences in QoL were detected. Aerobic exercise was compared with aerobic exercise in combination with strength training by Arthur et al., 2007⁹⁸ (low risk of bias trial). They found no significant between-group differences.

2.3.3 Multidisciplinary cardiac rehabilitation versus exercise

Both trials that compared MDCR with exercise studied a mixed patient population. They were associated with a high risk of bias (see tables 24 and 25 in appendix) and did not find any significant differences in outcomes between the two intervention groups^{76,77}. Focht et al., 2004⁷⁷ in particular find that improvements are equally dependent on treatment, gender, and initial mental health status.

Key points – RCTs

- **Both MDCR (including exercise) and exercise appear to reduce rehospitalisation rates and improve QoL (versus usual care). Walking distance is generally improved with exercise versus usual care (Moderate level of evidence);**
- **When MDCR was directly compared to exercise (in only two trials), no significant differences emerged. The validity of this comparison is uncertain given the high risk of bias associated with the results of these trials.**
- **Limited evidence suggests that home-based CR is not worse than centre-based CR for low to moderate risk patients;**
- **Substantial heterogeneity exists in many aspects of the included trials such as the research question, the patient population, the details of the experimental as well as the control intervention and the outcomes measured;**
- **The evidence from the RCTs is at best of moderate level as half of the RCTs had a high risk of bias.**

2.4 HTA DOCUMENTS

The systematic literature search identified three Health Technology Assessment (HTA) reports.

Table 2-6 : HTA and guideline documents

Author/year	Title	Country	Document type
ICSI ¹ , 2002 ⁹⁹	Technology Assessment Update CR	USA	HTA
Brown, 2003 ³⁷	Exercise-Based CR Programmes for Coronary Artery Disease: A Systematic Clinical and Economic Review	Canada	HTA
Beswick, 2004 ¹⁰⁰	Provision, uptake and cost of CR programmes: improving services to under-represented groups	UK	HTA
Sharpe, 2002 ¹⁰¹	CR	New Zealand	Practice Guideline
Liu, 2003 ¹⁰² (updated by Arnold, 2006 ¹⁰³)	The 2002/3 Canadian Cardiovascular Society Consensus Guideline Update for the Diagnosis and Management of Heart Failure	Canada	Guideline
Isles, 2003 ¹⁰⁴	The SIGN guideline on CR	UK	Guideline
NICE ² , 2003 ¹⁰⁵	Chronic heart failure Management of chronic heart failure in adults in primary and secondary care	UK	Guideline
Arnold, 2006 ¹⁰³	Canadian Cardiovascular Society consensus conference recommendations on heart failure 2006: Diagnosis and Management	Canada	Recommendation
Bundesärztekammer, 2008 ¹⁰⁶	Chronische KHK 2008	Germany	Guideline
Joanna Briggs Institute, 2006 ¹⁰⁷	Nurse-led cardiac clinics for adults with coronary heart disease	Australia	Information on best practice
NICE, 2007 ²	MI: secondary prevention	UK	Guideline

¹ ICSI Institute for Clinical Systems Improvement; ² NICE National Institute for Health and Clinical Excellence

Three HTA documents were identified, published by US, Canadian and UK bodies, respectively.

A US document ⁹⁹, published by the Institute for Clinical Systems Improvement, is a general report, focussing neither on a specific patient group, nor on a specific rehabilitation regimen. It is an update of a report dating from 1994. The report does not include the method used to identify relevant publications. The update in 2002 includes explicitly patients with atherosclerosis or PCI although other cardiac patients in general are not mentioned anymore in comparison with the publication from 1994. Rehabilitation programmes with an aerobic and/or strength training component are specifically noted to be safe. The document states that no gold standard programme for CR has been established and it is unclear whether exercise only or more comprehensive programmes are more beneficial. It is also noted that no advantage of supervised versus unsupervised exercise has been demonstrated.

The Canadian Agency for Drugs and Technologies in Health has published a systematic review on exercise-based CR for CAD ³⁷. This is based on a previous Cochrane systematic review ⁵⁴, updated through a comprehensive literature search. The data was meta-analysed where appropriate. The results confirm that exercise reduces mortality in CAD patients. In addition, an increasing body of evidence suggests that other cardiac patient groups, notably CABG, angioplasty or angina pectoris patients, would also benefit from CR. No evidence for an improvement in health-related quality of life (HRQoL) was found. A comparison between exercise only and comprehensive programmes (including exercise) showed paradoxical differences. While exercise only programmes reduced mortality, comprehensive programmes reduced risk factor levels (which should translate into lower mortality), indicating either an element of chance or insufficient power of the analysis.

The third HTA document ¹⁰⁰ investigates the provision, uptake and cost of CR programmes. Relevant data was directly collected from hospital discharge statistics and surveys of CR programmes. In England, Wales and Northern Ireland, only 45-67% of eligible patients (acute MI, unstable angina or having undergone revascularisation) were referred, and only 27-41% attended outpatient CR. When ischaemic heart disease patients were included in this group, the referral and attendance rates sink to 22-33% and 13-20% respectively. Older people and women were less likely to be referred and attend. Ethnic minorities and patients with angina or heart failure may equally be underrepresented. A systematic review of interventions designed to improve patient uptake, adherence and professional compliance was undertaken but the quality of the studies did not allow definite conclusions.

Keypoints - Health Technology Assessment reports

- **The results of two HTAs confirm that exercise is beneficial in CAD patients and in other cardiac patient groups;**
- **It is unclear whether exercise only or more comprehensive programmes are more beneficial;**
- **In a HTA from the UK only 45-67% of eligible patients were referred and only 27-41% attended outpatient cardiac rehabilitation: older people, women, ethnic minorities and patients with angina or heart failure were underrepresented**

2.5 SUMMARY OF RESULTS AND DISCUSSION

2.5.1 Summary of results

The following statements can be made after the analysis of the systematic reviews:

- In heart failure patients: exercise compared to usual care appears to reduce adverse events and rehospitalisation rates, while increasing QoL. MDCR compared to usual care may increase overall survival, improve QoL, and reduce rehospitalisations;
- In mixed patient populations a reduction of mortality was observed following an exercise CR regimen.
- Short MDCR programmes, programmes in a GP setting and supervision by non-specialists appears as effective as longer programmes, hospital-based MDCR programmes and programmes with the supervision of a specialist.
- MDCR (with an exercise component) does not appear to be more beneficial than exercise-only CR (indirect comparison);
- Few studies provided details on the health professional who supervised the sessions. Physicians had a coordinating role of MDCR in a minority of the programmes²⁰ and specialist nurses were common to all studies with heart failure patients¹⁹.

Only two trials (with high risk of bias) compared MDCR to exercise but no significant differences emerged. All other RCTs compared either MDCR or exercise only to usual care.

More than half of the identified RCTs compared MDCR (including exercise) to usual care. The results of the trials with low risk of bias can be summarised as follows:

- In heart failure patients, sustained MDCR (but not standard MDRC) appeared to confer significant benefits (improved walking distance and QoL, reduced hospital admissions) (one trial).
- For MI patients, differences between home-based and outpatient CR were found to be small (one trial);
- In mixed patient populations:
 - Several trials show that MDCR appears to improve QoL;
 - The duration (one trial) or location (one trial with home-based versus centre-based) of MDCR was not observed to have a significant effect;
 - Inclusion of telephone counselling, detailed planning strategies/diaries or pedometer use appears to be beneficial (e.g. improved QoL, physical activity)(2 trials).

Exercise only trials with low risk of bias came to the following conclusions:

- Exercise proved beneficial (versus usual care) in heart failure patients, improving QoL and reducing hospitalisation rates (several trials);
- High-frequency exercise confers some benefits in surgical patients (compared with usual care or low-frequency exercise) (one trial).
- For MI patients, exercise leads to better outcomes than usual care: two trials conclude that exercise also leads to better outcomes than surgical interventions.
- In mixed patient populations, strength training did not add benefits to those achieved with aerobic training (one trial).

2.5.2 Additional Cochrane reviews published in 2010

In 2010, after completion of the systematic review presented here, two Cochrane reviews on CR were published: the first one on home-based versus centre-based CR¹⁰⁸ and the second one on exercise based CR in heart failure patients¹⁰⁹.

2.5.2.1 *Home-based versus centre-based cardiac rehabilitation*

Dalal et al.¹⁰⁸ focus on a comparison between home-based and centre-based CR programmes with supervision by health professionals. RCTs that compared home-based programmes with centre-based CR (e.g. hospital, gymnasium, sports centre) in a mixed population (myocardial infarction, angina, heart failure or who had undergone revascularisation) were sought. Twelve RCTs satisfied the eligibility criteria and were included.

The results for 'hard' outcomes that are of relevance for this review are summarised below:

- Cardiac events - No significant difference was found in cardiac events between home-based and centre-based settings in either of the two studies reporting this outcomes;
- Survival - Pooled analysis of the four studies reporting all-cause mortality at 3-12 months (a fifth study reported no events in either group) revealed no significant difference in mortality between home and centre (fixed effect RR = 1.31, 95% CI 0.65 to 2.66, P = 0.8);
- Quality of life - There was no evidence of a statistically significant difference in overall QoL or domain score between home and centre-based groups, consistent improvements QoL at follow up in both treatment groups (heterogeneity prevented a pooled analysis);
- Healthcare costs - Three studies reported healthcare costs associated with home-based CR as lower than centre-based but only in one study was this difference statistically significant. One other study found the costs of home CR to be more expensive. Six studies reported different aspects of healthcare resource consumption that included rehospitalisations, primary care consultations and use of secondary care medication; no significant differences were reported.

2.5.2.2 *Exercise based CR for heart failure patients*

Data on the effect of CR on HRQoL, mortality and hospital admissions in patients with heart failure is synthesised by Davies et al.¹⁰⁹. RCTs evaluating exercise therapy (alone or as part of a MDCR programme) in patients diagnosed with heart failure and with at least 6 months duration of follow-up were sought. Nineteen RCTs satisfied the eligibility criteria and were included.

The results for 'hard' outcomes that are of relevance for this review are summarised below;

- Hospital readmission - Whilst there was a trend towards a reduction in the number of patients experiencing hospital admissions with exercise, none of these reductions were statistically significant at or beyond 12 months follow-up.
- Survival - Thirteen studies reported all-cause mortality at up to 12-months follow up, pooled analysis revealed no significant differences (fixed effect RR 1.02, 95% CI 0.70 to 1.51, P = 0.90) (two studies reported no events). There was evidence of a non-significant trend towards a reduction in mortality with longer (up to 30 months) follow-up.
- Quality of life - At follow up studies reporting quality of life described consistently higher QoL in exercisers versus standard care controls.
- Healthcare cost – One clinical study only was accompanied by a cost-effectiveness analysis with results extrapolated to 15.5 years (costs from 1999). This clinical study was unusual in using a sustained intervention with supervision from a cardiologist.

Keypoints – 2 recent Cochrane reviews (2010)

- In concordance with the present review, the first review does not find a significant difference between the home based and centre based CR (clinical outcomes, health-related QoL outcomes, adherence, healthcare costs). The included studies include a mixed cardiac population with exclusion of high risk patients.
- Exercise does not increase all-cause mortality in heart failure patients, while it appears to reduce hospital admissions and improve HRQoL.

2.5.3 Discussion of results

These data suggest that exercise is the key element of successful CR. However these conclusions are limited by the heterogeneity of the populations and interventions (duration, components).

2.5.3.1 Populations of the interventions

There is little data on which patient groups will benefit most from the interventions and which are most at risk from complications. This issue has been addressed in a clinical trial reported by Vanhees et al., 2004¹¹⁰. They investigated the effect of CR in eight patient groups, defined by pathology (e.g. CABG, angina or AMI patients) and also looked at the incidence of serious complications (requiring resuscitation) in relation to CR location and patient characteristics. The study found that absolute changes in peak VO_2 were related to age and training characteristics, while baseline exercise performance (followed by training characteristics) was a predictor for relative changes in peak VO_2 . Serious complications (requiring resuscitation) appeared to be connected with the use of anti-arrhythmic agents as well as ST-segment depression at baseline.

Other authors speculate that not every patient group benefits equally from CR^{77 60 62} but for the majority of patients, a short CR programme, should be sufficient to confer significant benefits. Another author identifies some patient groups who might benefit from longer care⁵⁶.

2.5.3.2 Components of the intervention

Exercise sessions

The results of this review confirm the role of exercise either alone or within a multidisciplinary CR programme. A large majority of programmes include or focus exclusively on aerobic exercise. In the course of systematic literature searches, four systematic reviews of systematic reviews were identified¹¹¹⁻¹¹⁴. Two reviews focussed on MDCR^{111 112} and the other ones focussed on exercise only^{113, 114}. Their results also emphasise the importance of aerobic exercise for the rehabilitation of cardiac patients. Results throughout are positive, independent of the type of cardiac event the patients suffered from.

The duration and number of sessions greatly vary between the studies as underlined in the recent Cochrane review of Dalal et al.¹⁰⁸ A Belgian RCT in CAD patients¹¹⁵ indicated that brief exercise sessions (40 min/session) can be as effective as slightly longer exercise sessions (60 min/session) with regards to body anthropometrics, blood plasma lipid profile and exercise capacity. Conversely, the number of CR sessions may be important: a direct correlation between the number of sessions attended and long-term outcomes (risk of death or MI) was seen in Medicare patients eligible for CR¹¹⁶. However this study was observational and the data has to be interpreted with caution^{116, 117}.

In spite of evidence that is already available, the use of standardised rehabilitation regimens and outcomes in future trials would allow more reliable conclusions, and facilitate comparisons meta-analysis.

Multidisciplinary sessions

A study on MDCR versus usual care for patients after PCI confirms the positive role of MDCR (with exercise) in the Belgian health care setting¹¹⁸.

One systematic review of systematic reviews¹¹² concluded that for most lifestyle or dietary changes the evidence of an effect on all-cause mortality in CAD patients was limited whilst smoking cessation, increased physical activity and moderate alcohol consumption were exceptions. Another systematic review¹¹¹ in a low risk population concluded that psychosocial interventions might improve quality of life and blood pressure. After the completion of this review, a study on the influence of adherence to behavioural recommendations after acute coronary syndrome was published¹¹⁹. Chow et al. came to the conclusion that (in the short term) the cardiovascular risk of these patients can be substantially lowered by behavioural modifications, like diet, exercise, and smoking cessation.

However this review identified serious limitations that prevent from concluding that MDCR confers greater benefits than exercise only in terms of mortality, QOL or readmissions. The systematic reviews relied on indirect comparisons and they also included MDCR studies without exercise component. There is currently a lack of evidence for a direct comparison between MDCR and exercise only. It is reasonable to assume that some components of MDCR may benefit some patients more than others whereas exercise confers benefits for all; the impact of different components warrants assessment in future research

2.5.3.3 Safety

One outcome of interest was the safety of CR programmes. Overall though, the search did not identify studies that focussed on this outcome. In the results, no significant clinical disadvantage of CR was identified in any of the trials reviewed in the discussed publications.

One Cochrane review¹⁰⁸ described above focussed on a comparison between home-based and supervised centre-based CR programmes. The authors found only two trials that described cardiac events during the exercise programme: no significant difference has been found between both regimens. However, it should be noted that most studies included patients with low risk of subsequent event. Patients with severe arrhythmias, MI or HF were excluded.

2.5.4 Systematic review of the economic literature

The systematic review of the clinical effectiveness of CR clearly concludes to the benefits of exercise interventions for CR. There is also a body of evidence for the effectiveness of multidisciplinary CR. However, there is a lack of clinical evidence to show an added value of multidisciplinary CR in comparison with exercise only. One hypothesis might be that multidisciplinary CR has an added value for specific groups of patients according to their specific risk profile. However, the heterogeneity of populations and multidisciplinary interventions does not allow drawing conclusions on those groups of patients who would benefit from specific interventions.

The lack of evidence on the effectiveness of multidisciplinary CR in comparison with exercise triggered the research team's decision to limit the systematic literature review to its clinical effectiveness part only. The search for full economic evaluations on the possible cost-effectiveness of multidisciplinary CR (including exercise) would have been meaningful if this intervention has been proven to be superior to exercise only. In the absence of this evidence and by knowing that multidisciplinary CR is expected to be more costly than exercise only (according to IMA-AIM data), it is currently not necessary to investigate further the cost-effectiveness of multidisciplinary CR (including exercise) in comparison with exercise only. In the same way, the comparison of multidisciplinary CR with usual care is of little interest: the first option to consider is the cost-effectiveness of exercise before examining the cost-effectiveness of a more complex (and as effective) intervention.

2.5.5 Comparison of the current results with guidance documents

2.5.5.1 *Guidance documents: what do other countries do?*

This section presents 8 country-specific guidance documents in relation to CR in order to put the above results into perspective. One ¹⁰² is not discussed here, having been superseded by a later, updated version ¹⁰³. Their main conclusions are summarised below (Table 2-7). Only interventions that refer to CR are listed.

Table 2-7: Guideline documents

Author/year	Patient group(s)	Recommended intervention
UK		
Isles, 2003 ¹⁰⁴	Coronary heart disease	CR should include both psychological and educational interventions (using the “Heart Manual”). Exercise training should form a core element of CR, at least twice weekly for at least eight weeks.
NICE, 2003 ¹⁰⁵	Chronic heart failure	Heart failure care should be delivered by a multidisciplinary team with an integrated approach across the healthcare community.
NICE, 2007 ²	Post myocardial infarction	All patients (regardless of their age) should be given advice about and offered a CR programme with an exercise component. Reminders should be used to improve uptake of CR. Comprehensive CR programmes (which may be home based) should include health education and stress management components. Stress management should be offered in the context of comprehensive CR. Anxiety or depression should be treated.
Australia		
Joanna Briggs Institute, 2006 ¹⁰⁷	Coronary heart disease (especially atherosclerosis)	Nurse-led clinics may increase attendance and follow-up rates and should be used for the implementation of lifestyle changes to decrease the risk of adverse outcomes.
Canada		
Arnold, 2006 ¹⁰³	Heart failure	Regular physical activity recommended for all patients with stable HF and impaired LV systolic function. Three to five exercise sessions should be considered for stable NYHA class II to III HF patients with LVEF less than 40%. Optimal target heart rate should be determined individually. Exercise training should be of moderate intensity. Exercise training may initially be performed in a supervised setting.
Germany		
Bundesärztekammer, 2008 ¹⁰⁶	Coronary heart disease	CR can be inpatient or outpatient, according to available service provision and the patient’s wishes. CR should be recommended after STEMI and NSTEMI, after CABG (with or without valve surgery), and in some cases after elective PCI. CR should encompass somatic care (optimal medication, risk stratification, exercise), education, psychological and social support.

New Zealand		
Sharpe, 2002 ¹⁰¹	Coronary heart disease	<p>Moderate exercise on most days is recommended, increasing gradually over time.</p> <p>Exercise advice should be individualised. Referral to a comprehensive CR programme is recommended.</p> <p>A cardioprotective diet is recommended, supported by intensive dietary advice.</p> <p>Overweight patients should reduce their weight initially by 10%, preferably through reduction of fat intake.</p> <p>Smoking cessation is recommended, support should be provided.</p> <p>Comprehensive CR should include psychosocial interventions. Anxiety or depression should be treated by a trained practitioner.</p> <p>Comprehensive CR should embrace a case management approach.</p> <p>CR should be considered for all patients after MI, CABG and angioplasty.</p> <p>CR programmes (including education) should be individualised.</p> <p>CR can be home or hospital based, according to the patient's need.</p> <p>Referral to a CR programme should be irrespective of gender, age, or ethnicity.</p> <p>The needs of women, Maori and Pacific peoples need to be considered.</p> <p>There should be audits every six months.</p>

2.5.5.2 *Concordance of the current results with guidance documents*

The majority national guidance documents focus on exercise, which is well supported by the available literature and in agreement with the present systematic review and the other published reviews presented. Where this is mentioned, home-based CR is considered an alternative to in-patient CR, which is also in agreement with published literature. Further to those core measures, however, some guidelines also recommend psychological or educational programmes, for the effectiveness of which there is so far little evidence. Treatments for anxiety and depression, or lifestyle changes, which are recommended by some national bodies, have not yet been thoroughly investigated. Overall, there is no fundamental disagreement between national guidance and the published results of systematic reviews and clinical trials with regards to CR. However, while encompassing this clinical evidence, national bodies are likely to also rely on expert advice, drawing from personal experience with patients, in order to collate their advice.

Keypoints of the systematic literature review

What we know from this review:

- **Aerobic exercise programmes and MDCR programmes including these exercises are beneficial in heart failure patients (e.g. in terms of QOL, rehospitalisation rates);**
- **Aerobic exercise programmes and MDCR programmes including these exercises are also beneficial for MI patients and after cardiac surgery (e.g. in terms of QOL, mortality);**

Limited evidence:

- **The available data suggest that home-based versus centre-based CR programme are equally effective for patients with a low risk of further cardiac event;**
- **Current evidence, although only of moderate quality, suggests that MDCR is not more effective than exercise alone;**
- **For the majority of patients, a short CR programme would be as effective as a longer programme;**

Further research is needed:

- **To make direct comparisons between aerobic exercise regimens and MDCR programmes including an exercise component;**
- **To quantify the optimal duration and frequency of exercise sessions and the duration of CR programmes;**
- **To identify patient groups who will most benefit from MDCR interventions;**
- **To quantify the benefits associated with particular components of MDCR in homogeneous patient groups.**

3 REHABILITATION AFTER DEFINED CARDIAC PROCEDURES IN BELGIUM: DATA ANALYSIS

The second research question is: “What is the utilisation, geographical spread and costs of multidisciplinary CR, of monodisciplinary Physical Medicine and Rehabilitation (PRM) and of physiotherapy (without medical supervision) after defined cardiac procedures throughout Belgium?”

This analysis is **NOT** intended to establish a causal relationship between types of rehabilitation and outcome. This analysis only intends to report patterns in utilisation throughout Belgium.

3.1 METHODOLOGY

This section details the following key design elements for the analysis of the IMA Database:

- Data source
- Study period and observation period
- Target population and patient selection procedure
- Data collection
- Patient classification
- Data analysis

3.1.1 Data source

The data source for this analysis was the data provided by the Common Sickness Funds Agency (IMA/AMI)¹³, hereafter called the IMA Database. This database contains two main databases having data obtained from Belgian Sickness Funds^c:

- A population database including demographic data (e.g. date of birth, gender, community, decease date, data on the insurance status and data on professional status);
- A database including detailed information on medical costs. Information on reimbursements, co-payments and supplements of all reimbursed medical interventions (as specified in the nomenclature) and all reimbursed pharmaceutical products.

3.1.2 Study period and observation period

The study period covers the 2 most recent calendar years for which data were available (i.e. 2007 and 2008). During the first year (2007) of this 2 year study period, patients eligible for inclusion in the study were selected, based on the criteria described in section 0 below.

The observation period for every patient was one year, starting from the first cardiac procedure of that patient in 2007.

^c Van de Sande S, De Wachter D, Swartenbroeckx N, Peers J, Debruyne H, Moldenaers I, Lejeune B, Van Damme V, Ramaekers D, Leys M. Inventaris van databanken gezondheidszorg. KCE Reports vol. 30A Brussel : Federaal Kenniscentrum voor de gezondheidszorg (KCE) ; Mei 2006.. Ref. D/2006/10.273/14.

3.1.3 Target population and patient selection procedure

Initially (see chapter 1), three groups of adult patients were considered as target population:

1. Patients with myocardial ischemia (myocardial infarction, coronary disease, angina pectoris),
2. Patients who underwent cardiac surgery,
3. Heart failure patients.

The researchers decided to use only the IMA database without coupling it with data from hospitalisations (MKG/RCM^d database): such a coupling is indeed a source of considerable delay in data access. The disadvantage of the IMA database as the only data source is that the medical diagnosis (e.g. heart failure) is not recorded in this database but only interventions and medical acts reimbursed by the NIHDl. For this reason the definition of the target population is slightly different of the definition used in the systematic literature review:

4. Myocardial ischemia patients who had an invasive procedure (coronary artery bypass graft (CABG) and/or PCI. These patients were selected based on one of the procedure codes described in Table 3-1

Table 3-1: Nomenclature codes for selection of myocardial ischemia patients who underwent an invasive procedure

Patient group	Procedure	Nomenclature code ^e	
		outpatient	Inpatient
CABG	Surgical procedure	229574	229585
		229611	229622
		229633	229644
PCI	Percutaneous procedure	589013	589024

5. Patients who underwent cardiac surgery other than CABG. These patients were selected if one of the nomenclature codes in Table 3-2 were identified in the IMA database.

Table 3-2: Nomenclature codes for selection of surgery patients (other than CABG)

Patient group	Procedure	Nomenclature code	
		outpatient	inpatient
Heart transplant	Surgical procedure	318054	318065
Valve replacement		229596	229600
		229515	229526

It should be noted that the third target group (heart failure) included in the literature review was not included in this section of the study as it was not possible to identify those patients based on the data obtained from IMA.

The patient selection was based on the year 2007 as explained in section 3.1.2. The first procedure detected in the database with one of the above mentioned codes was the index procedure and this defined the group the individual patient was going to be included in (even if the patient underwent other procedures afterwards). The date of the procedure was considered as the starting date of the observation period and data for each selected patient was collected for a total observation period of 1 year.

^d MKG/RCM: Minimale Klinische Gegevens/Résumé Clinique Minimum

^e Details enclosed in Appendix

3.1.4 Data collection

In addition to the data components explained above the following were obtained from the IMA database:

- Patient socio-demographic data
- Cardiac centre related data
- Rehabilitation related data
- Cardiac disease related medical care consumption (outpatient visits and diagnostic tests)

3.1.4.1 *Patient socio-demographic data*

- Age
- Gender
- “Arrondissement” of main residence
- Statistische sector/secteur statistique (See 3.1.4.5)
- Employment status (worker, self-employed, unemployed, pensioner or pre-retired, invalid or handicapped)
- Entitlement to increased reimbursement (BIM or OMNIO) (yes/no)

3.1.4.2 *Cardiac centre related data (i.e. hospital where the index procedure was performed)*

- Geographical data: “Arrondissement”
- Type of cardiac care programme (A, B1, B2-B3)
- Type of rehabilitation offered (hospital with or without officially authorized centre for CR).

3.1.4.3 *Rehabilitation related data (i.e. all kind of rehabilitation during the observation period)*

- Type(s) of rehabilitation offered (multidisciplinary, monodisciplinary, physiotherapy)
- Duration and number of sessions, per type
- Geographical data to identify where the rehabilitation is offered
- Costs related to rehabilitation

3.1.4.4 *Cardiac disease related medical care consumption (outpatient visits and diagnostic tests)*

Cardiac disease related resource use was collected for the one year observation period (all codes presented in appendix):

- Outpatient cardiologist visits: number of visits
- Diagnostic tests e.g. ECG, lung function tests, echocardiography

3.1.4.5 *Statistical Sector (SS): Small area information variables*

Because there was no information available on education level and income level for each individual patient in the IMA records, statistische sector/secteur statistique data of the patients' main residence was used as proxy to identify the income level and the education level of the patients. The information on the SS of the patient was matched to the National Socio-Economic Survey data from 2001 for education and the national fiscal data for the level of income (2005)

- The median taxable income of the SS of the patient (five groups) Table 3-3)

- The education level of the SS of the patient was aggregated using the International Standard Classification of Education (ISCED)^f. We used the share of individuals having attained post-secondary education (ISCED 4 and 5) over the total population aged 18 years or more.

Table 3-3: Lower and upper limits in €'s to define income quintiles (based on SS median income^g)

Quintile	Lower limit (€)	Upper limit (€)
1	682	16 450
2	16 451	18 611
3	18 612	20 310
4	20 312	22 305
5	22 306	57 195

Table 3-4: Lower and upper limits to define education quintiles using International Standard Classification of Education (ISCED)^f: Percent of the adult population having attained a post secondary degree

Quintile	Lower (%)	Upper (%)
1	0	13.78
2	13.79	18.80
3	18.81	23.57
4	23.58	30.10
5	30.11	100

3.1.5 Patient classification

One objective of this part was to determine whether differences in utilisation, geographical spread and costs related to different types of rehabilitation exist in Belgium. The different aspects of the research question are:

- What is the pattern of utilisation of different types of rehabilitation, such as number of rehabilitation sessions and duration of the sessions?
- Which patients had a prescription of multidisciplinary rehabilitation?
- What is the geographical spread of the utilisation of the different types of rehabilitation?
- What is the consumption of medical care other than rehabilitation (i.e. diagnostic tests, outpatient visits) related to the different types of rehabilitation?
- What are the costs of the different types of rehabilitation?

3.1.5.1 Summary table

The cardiac patients selected from the IMA Database were classified into “rehabilitation groups” according to the type of rehabilitation they received. Table 3-5 gives an overview of the patient classification methods for the different data analysis purposes. More details are given in the section below.

^f Unesco. International Standard Classification of Education (ISCED): 1997 Unesco; 2006.UNESCO Institute for Statistics (3.14): The international Standard Classification of Education was designed by UNESCO in early 1970's to serve “as instrument suitable for assembling, compiling and presenting statistics of education both within individual countries and internationally.”

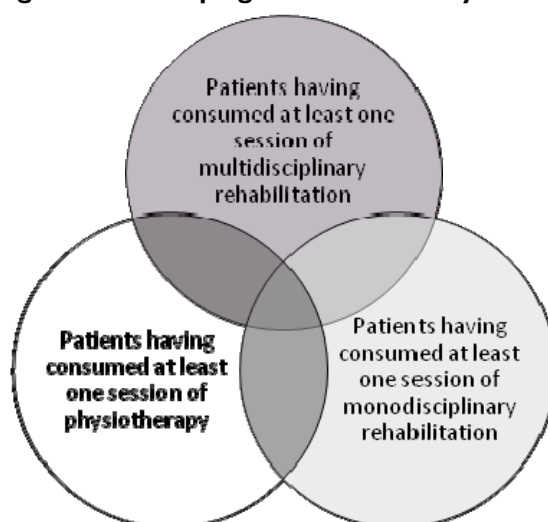
^g The SS median income represents the median income per statistical sector (SS). For example, in the 5th quintile, the median income of people residing in this SS ranges between €22,306 and €57,195.

Table 3-5: Patient classification for the different data analysis purposes

Data analysis purpose	Patient grouping/classification method
Utilisation of different types of rehabilitation	Grouping into not mutually exclusive groups
Which patients are prescribed multidisciplinary rehabilitation?	Overall patient classification; not taken into consideration the patient setting (inpatient or outpatient)
What is the geographical spread of the different types of rehabilitation?	Based on outpatient rehabilitation profile
What is the medical resource consumption other than rehabilitation (visits and tests) related to the different types of rehabilitation?	Based on outpatient rehabilitation profile
What are the costs of the different types of rehabilitation?	Based on outpatient rehabilitation profile

Because a patient may have received different types of rehabilitations during the observation period, different methods for grouping or classification were used:

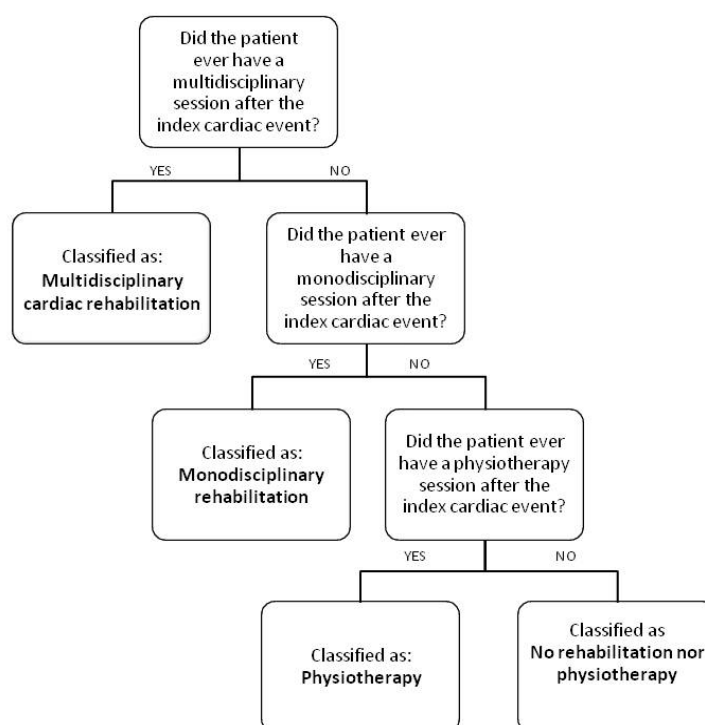
- I. Three different but not mutually exclusive groups (NMEG) were defined:
 - A group of multidisciplinary CR: patients having consumed at least one session of multidisciplinary rehabilitation;
 - A group of monodisciplinary PRM: patients having consumed at least one session of monodisciplinary PRM;
 - A group of physiotherapy: patients having consumed at least one session of physiotherapy.

Figure 3-1: Grouping into not mutually exclusive groups

It should be noted that, based on nomenclature codes, we were not able to identify whether “exercise” therapy is part of the “physiotherapy” or not. Moreover, “physiotherapy” can be related to whatever pathology occurring in parallel with the cardiac event.

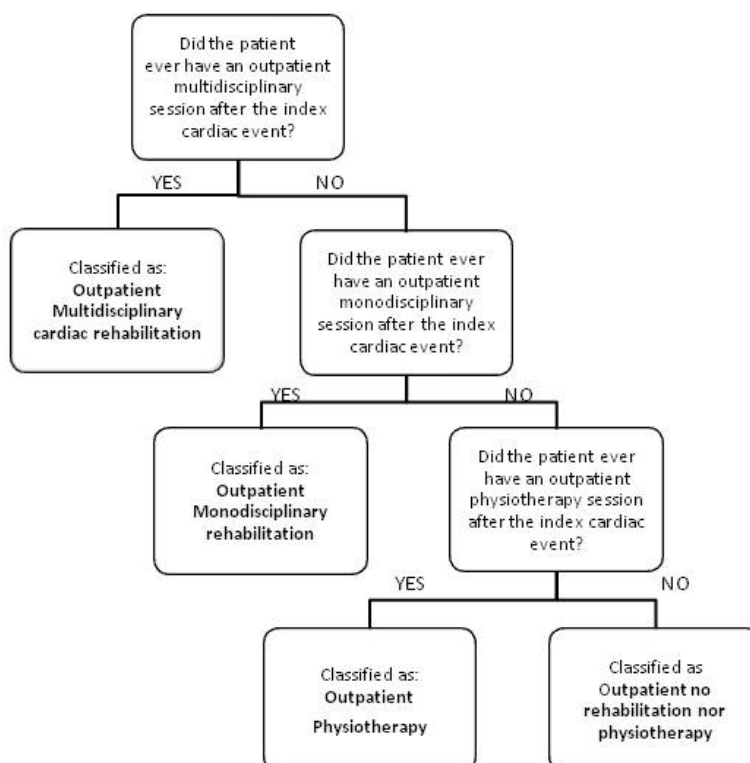
2. Overall Patient Classification: Patients were also grouped into mutually exclusive groups not taking into consideration the patient treatment setting (inpatient or outpatient).

Figure 3-2: Overall patient classification: not taking into consideration the patient setting (inpatient or outpatient)



3. Outpatient patient classification: Patients were classified in mutually exclusive groups according to the outpatient rehabilitation profile (Figure 3-3)

Figure 3-3: Outpatient patient classification (based on outpatient rehabilitation profile)



The reasons why a specific type of grouping or classification is used is explained in the section below.

3.1.5.2 *Utilisation of different types of rehabilitation*

Patients who had at least 1 session of any type of rehabilitation were included in the analysis of the number of rehabilitation sessions and the duration of the rehabilitation episode. The patients were grouped according to the first type of grouping (not mutually exclusive groups).

3.1.5.3 *Which patients are prescribed multidisciplinary rehabilitation?*

The rules and regulations on the reimbursement of rehabilitation services play a role in CR utilisation. The chapter 1.1.4 detailed the conditions for the reimbursement of a multidisciplinary treatment. In particular, the first session should have been prescribed during the hospital stay for the initial cardiac event and the number of sessions is limited (45 outpatient sessions).

Therefore some patients receive one multidisciplinary session during the hospital to be allowed to a later reimbursement even though they stop their therapy afterwards or sign up to another type of rehabilitation after discharge. On the other hand some patients who stay in a hospital without official CR centre do not qualify for reimbursement of multidisciplinary treatment even if this is clinically justified.

The overall patient classification as described in Figure 3-2 was used to show the patients who were prescribed multidisciplinary CR.

3.1.5.4 *What is the geographical spread of the different types of rehabilitation?*

As long as a patient is hospitalized, the geographical spread of the rehabilitation centres should not be an issue because transport to the rehabilitation centre is arranged for inpatients. However, as from the moment of discharge after the index event, the distance between the patient's residence and the health care centre providing the rehabilitation services might be an important factor influencing the decision to continue with the rehabilitation programme. The outpatient rehabilitation profile, as described in Figure 3-3, was considered in order to evaluate the effect of this on the utilisation of rehabilitation services.

3.1.5.5 *What is the consumption of medical care other than rehabilitation related to the different types of rehabilitation?*

Different types of rehabilitation might be associated with different patterns of consumption of medical care other than rehabilitation. To answer the question on indirect consumption again the outpatient patient classification was used as described in Figure 3-3.

3.1.5.6 *What are the costs of different types of rehabilitation?*

To answer this question the outpatient patient classification was used as described in Figure 3-3.

3.1.6 *Data analysis*

3.1.6.1 *Descriptive analysis*

For continuous data, mean, standard deviation (SD), median, minimum, maximum and percentiles (25% and 75%) are presented. For dichotomous data, percentages are presented.

3.1.6.2 Statistical analysis

We used logistic regression models to identify which factors are associated with the use of the multidisciplinary CR, and which factors are associated with the fact that patients did not receive any form of CR during the observation period.

Two outcomes are studied (receiving outpatient multidisciplinary rehabilitation and patients not receiving any form of outpatient rehabilitation nor physiotherapy) for two groups (PCI or surgery), leading to 4 logistic models:

- Model 1: Patients received outpatient multidisciplinary rehabilitation after PCI
- Model 2: Patients received outpatient multidisciplinary rehabilitation after surgery
- Model 3: Patients did not receive any form of outpatient rehabilitation nor physiotherapy after PCI
- Model 4: Patients did not receive any form of outpatient rehabilitation nor physiotherapy after surgery.

The independent variables included in the analysis are: work status, gender, age, presence of an officially authorized CR centre in the “arrondissement” of residence, co-payment, education quintile and income quintile.

Odds ratio, 95% CI and p-values are presented for each of the 4 models.

3.2 RESULTS

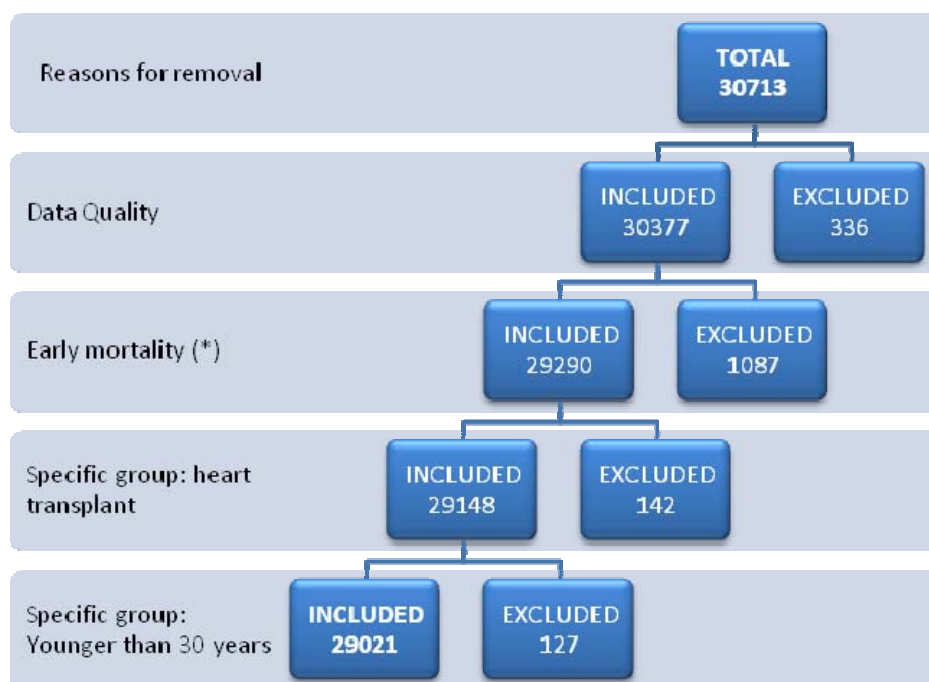
- **These analyses are NOT used for a comparison between different types of rehabilitation in terms of outcomes: the main purpose of the analyses is to report the differences in utilisation patterns and geographical spread.**

3.2.1 Patients selected for analysis

Initially, the sample selected from the IMA database included the data of 30713 patients. After cleaning the data and applying the exclusions criteria described below, a total of 29021 patients (=94.4%) were selected in the analyses.

3.2.1.1 Criteria for exclusion

An overview of the exclusion criteria and corresponding number of excluded patients is provided in Figure 3-4. A detailed description is in appendix 2.2.

Figure 3-4: Patient Selection Diagram (overall classification)

(*) Patients who died during the calendar month of the index event or during the consecutive month were excluded from the analysis

The classification of the 29021 patients is described in Table 3-6.

Table 3-6: Final patient classification into procedure groups: Frequency Table

Patient Group	Frequency	Percent
Valve Replacement	1749	6.03%
Combined interventions (CABG + heart valve, or 2 valves)	2069	7.13%
CABG	5474	18.86%
PCI	19110	65.85%
Surgery Post PCI	619	2.13%
Total	29021	100%

PCI and surgery post PCI were first considered as 2 separate groups, but preliminary analyses showed that patients with surgery after PCI had a similar rehabilitation profile than patients with surgery only. Therefore, patients who underwent surgery post PCI were classified into the surgery group as explained in the following sections.

3.2.2 Patient Geographical Spread

Geographical spread of the patients' main residence (N=29,021) was analyzed in order to depict which regions have the highest number of patients need. The highest concentration of patients are in the "arrondissement" of large cities as Brussels and Antwerp, that contain more than 2000 patients included in this study. Moreover, between 1500 and 2000 patients reside in the "arrondissements" of Liège, Halle-Vilvoorde and Ghent.

3.2.3 Type of Rehabilitation

Based on a selection of nomenclature codes (see Appendix 2.1), all the selected patients were divided into 4 rehabilitation groups: 'multidisciplinary rehabilitation', 'monodisciplinary PRM', 'physiotherapy' and 'no rehabilitation nor physiotherapy'. Two classification methods were applied for classifying patients in the 4 rehabilitation groups, as described in section 3.1.5: overall classification (irrespective whether inpatient or outpatient), and classification based on outpatient utilisation of the different types of rehabilitation.

Patients could also undergo many different rehabilitation paths (sequences of different types of rehabilitation). Further details of the most frequent rehabilitation sequences are provided in appendix 2.3.

Figure 3-5 and Figure 3-6: Patient flow between overall classification and outpatient classification

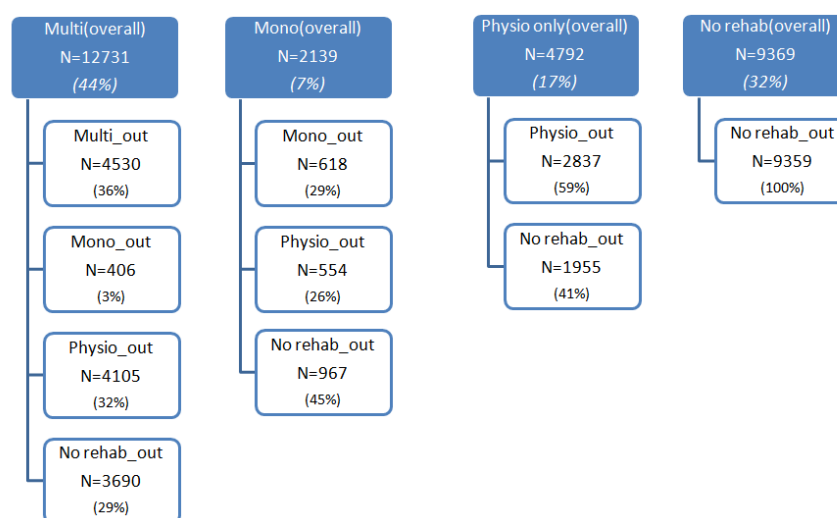


Figure 3-7 provides an overview of the proportion of patients in the four rehabilitation groups, according to the previously mentioned two classification methods. If the setting of the rehabilitation sessions (inpatient or outpatient) is not considered (i.e. overall classification, Figure 3-2), then 44% of the patients received at least one session of multidisciplinary rehabilitation while 32% of patients did not receive any type of rehabilitation during the entire observation period.

When only the outpatient setting is considered (i.e. outpatient classification: Figure 3-3), a larger percentage of the patients (55%) are classified into the group 'no rehabilitation at all' and the proportion of patients classified as multidisciplinary was reduced to one third compared to the overall classification.

Figure 3-5: Proportion of patients in the different rehabilitation types, according to overall classification (inpatient and outpatient)

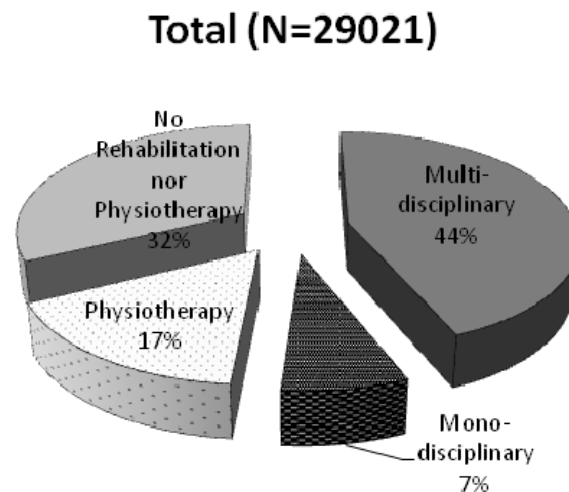


Figure 3-6: Patient flow between overall classification and outpatient classification

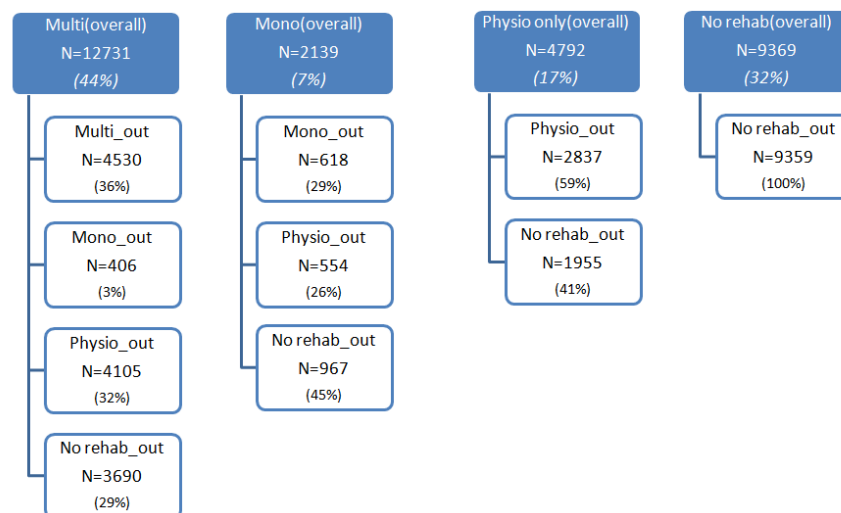
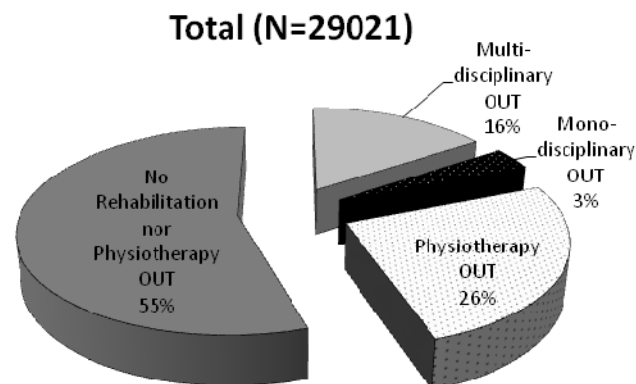


Figure 3-7: Proportion of patients in the different rehabilitation types, according to outpatient classification



The descriptive statistics of those four groups and the type of procedure they underwent are presented in Table 3-7 (overall classification) and Table 3-8 (outpatient classification).

Overall (Table 3-7), 80% of the patients who underwent surgery received at least one session of multidisciplinary rehabilitation whereas multidisciplinary rehabilitation is only observed in 25% of the PCI group. The difference is far less pronounced (19% versus 14%) when outpatient classification is used (Table 3-8).

In the overall classification, 48.5% of the patients did not get any type of rehabilitation or physiotherapy after PCI, compared to only 1% of the patients after surgery. This difference is also observed in the outpatient classification (68% versus 30%).

Table 3-7: Frequency Table for Type of Rehabilitation - overall classification

Group	Procedure Type	Rehabilitation Type				Total
		Multi-disciplinary	Mono-disciplinary	Physiotherapy only	No Rehabilitation nor Physiotherapy	
Surgery	Valve Replacement	1437 82.2%	118 6.7%	177 10.1%	17 1.0%	1749 100%
	Combined interventions (CABG + heart valves, or 2 valves)	1692 81.8%	149 7.2%	207 10.0%	21 1.0%	2069 100%
	CABG	4330 79.1%	459 8.4%	628 11.5%	57 1.0%	5474 100%
	Surgery Post PCI	489 79.0%	39 6.3%	86 13.9%	5 0.8%	619 100%
	Total Surgery	7948 80.2%	765 7.7%	1098 11.1%	100 1.0%	9911 100%
PCI		4783 25.0%	1374 7.2%	3694 19.3%	9259 48.5%	19110 100%
Total		12731 43.9%	2139 7.4%	4792 16.5%	9359 32.2%	29021 100%

Table 3-8: Frequency Table for Type of Rehabilitation - outpatient classification

Group	Procedure Type	Rehabilitation Type				Total
		Multi-disciplinary OUT	Mono-disciplinary OUT	Physiotherapy only OUT	No Rehabilitation nor Physiotherapy OUT	
Surgery	Valve Replacement	314 18.0%	55 3.1%	804 46.0%	576 32.9%	1749 100%
	Combined interventions (CABG + heart valves, or 2 valves)	331 16.0%	74 3.6%	1064 51.4%	600 29.0%	2069 100%
	CABG	1074 19.6%	249 4.6%	2512 45.9%	1639 29.9%	5474 100%
	Surgery Post PCI	153 24.7%	40 6.5%	276 44.6%	150 24.2%	619 100%
	Total Surgery	1872 18,9%	418 4,2%	4656 47,0%	2965 29,9%	9911 100%
PCI		2658 13.9%	606 3.2%	2840 14.9%	13006 68.0%	19110 100%
Total		4530 15,6%	1024 3,5%	7496 25,8%	15971 55,0%	29021 100%

Key points

- The probability of receiving neither rehabilitation nor physiotherapy in the outpatient setting is very different for patients after PCI (68% of PCI patients received neither outpatient rehabilitation nor physiotherapy) compared to patient after cardiac surgery (30% of surgery patients received no outpatient rehabilitation nor physiotherapy).
- A minority only of patients who began a multidisciplinary rehabilitation in the inpatient setting continue with this type of rehabilitation in the outpatient setting (i.e. 4530 out of 12731 inpatients with multidisciplinary rehabilitation).

Considering the significant difference observed in the utilisation of CR between the surgery and PCI group, two pooled groups were defined for analysis on resource use and costs on rehabilitation:

- Surgery group, comprising:
 - Valve Replacement
 - Combined interventions (CABG + heart valves, or 2 valves)
 - CABG
 - Surgery Post PCI
- Percutaneous group: PCI

3.2.4 Rehabilitation related data

The following sections describe the rehabilitation related data to answer the research question related to calculating the utilisation of CR in Belgium.

Duration of the first rehabilitation episode after the index cardiac event

The analysis of the duration of rehabilitation was performed irrespective of the type of rehabilitation. The total number of rehabilitation days was defined as the number of days between the first date of any rehabilitation and the last day of the first rehabilitation episode. The first rehabilitation episode after the index cardiac event was defined as a sequence of all types of rehabilitation sessions following the index event. If the time interval between two consecutive rehabilitation sessions exceeds 30 days, the first rehabilitation episode was considered as finalized at the date of the first session of this >30 days interval¹²⁰.

Only patients having at least one session of rehabilitation were considered for this analysis. 9359 patients were not included in the analysis as they did not get any type of rehabilitation, which means that 19662, out of the total 29021 were included. Due to our definition of the one year observation period, the duration of a rehabilitation programme can be a maximum of 366 days.

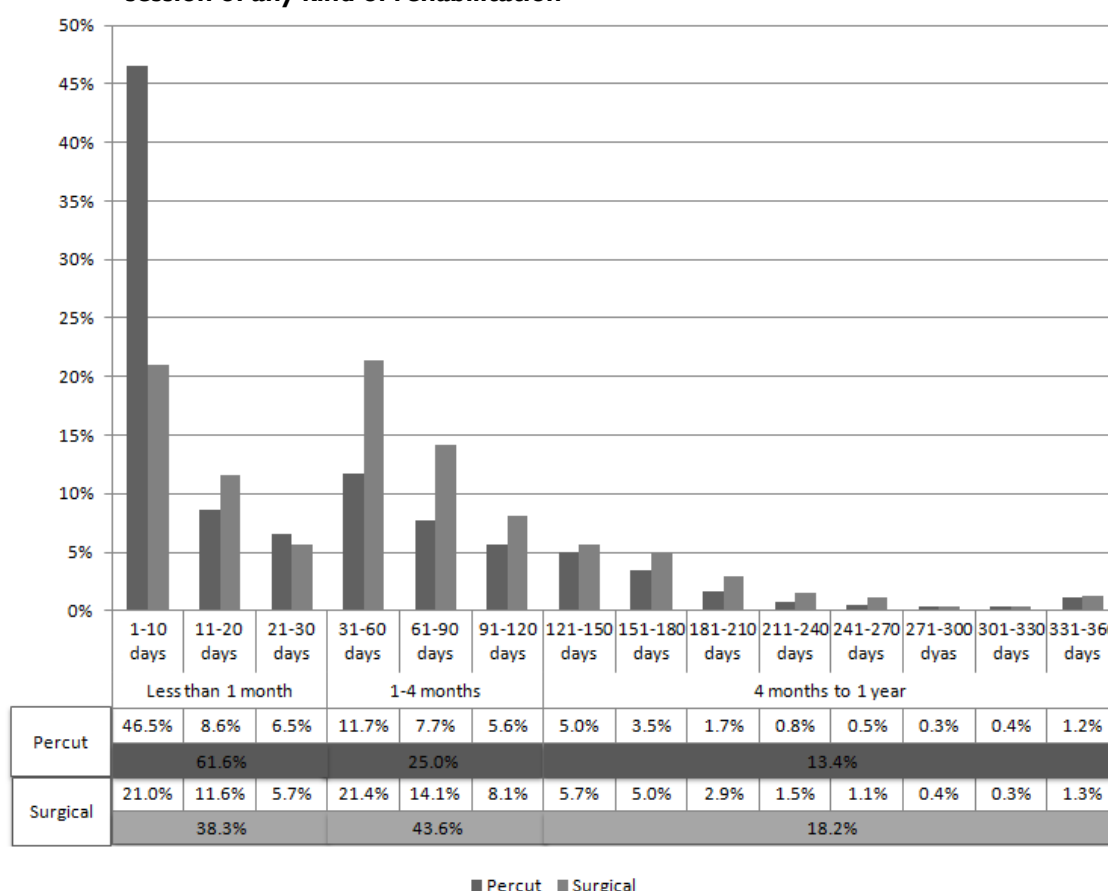
Table 3-9: Descriptive statistics of the duration of the first rehabilitation episode (in number of days)

	After PCI (days)	After surgery (days)	Total (days)
N of patients	9851	9811	19662
Average number of days	46.69	67.73	57.19
StdDev	68.02	69.74	69.68
Min- Max	1-366	1-366	1-366
Median	14	48	31
25% percentile	2	12	8
75% percentile	67	93	83

The average and median rehabilitation duration is much longer in the surgery group, compared to the PCI group. The first episode lasts more or less 2 months on average (graphically displayed in Figure 3-8). After PCI, the duration of rehabilitation was maximum ten days for 46.5% of the patients, compared to 21% of the patients who underwent surgery. 25% of the patients who received PCI had a rehabilitation of 1 to 4 months, compared to 43.6% of the patients after surgery.

Similar results are observed if the total observation period is taken into consideration instead of the first episode (see appendix 2.4). The differences between inpatient and outpatient rehabilitation will be explained later.

Figure 3-8: Distribution of the total duration of the first episode of rehabilitation (in days) per procedure type for patients having at least one session of any kind of rehabilitation



Key point

- The duration of the first rehabilitation episode (inpatient and outpatient) is on average 2 months.
- This duration is much shorter for patients who underwent a PCI (median 14 days) than for patients who underwent surgery (median 48 days).

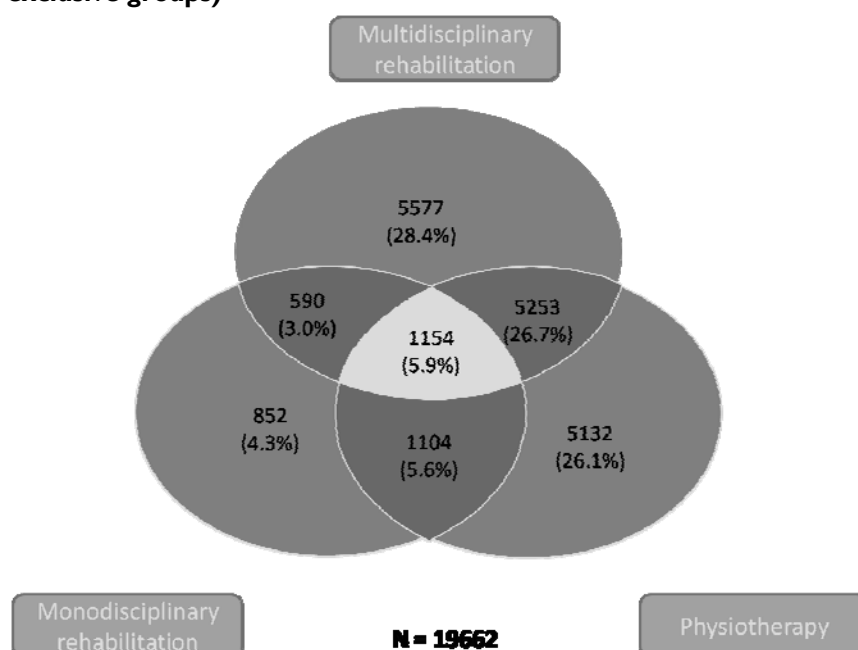
3.2.4.1 Number of rehabilitation sessions during the first rehabilitation episode

For this analysis, the “grouping into not mutually exclusive groups” classification type was used as explained in section 3.1.5.2. Only patients having at least one session of rehabilitation of any kind are included in the analysis. This corresponds to a total of 19662 patients. Each type of rehabilitation was considered separately, e.g. a patient was classified in a specific rehabilitation group as soon as he/she received at least one session of this type of rehabilitation. As such, a patient can be represented more than once in the different rehabilitation groups.

Number of rehabilitation sessions during the first rehabilitation episode – any cardiac procedure

Figure 3-9 shows the patient number overlap over the rehabilitation types received in the first episode. For example, 1154 patients received all three types of rehabilitation programmes during the first episode, whereas 5577 had only multidisciplinary sessions.

Figure 3-9: Diagram of patient number overlap over the different types of rehabilitation received in the 1st episode (grouping into not mutually exclusive groups)



In Table 3-10, the statistics of the number of rehabilitation sessions are displayed for the first rehabilitation episode as defined in section 3.2.4.1. Patients having multidisciplinary rehabilitation received on average 14.3 sessions of this type (and half of the patients received up to 8 sessions).

Table 3-10 Descriptive statistics of the Number of Rehabilitation Sessions (1st rehabilitation episode)

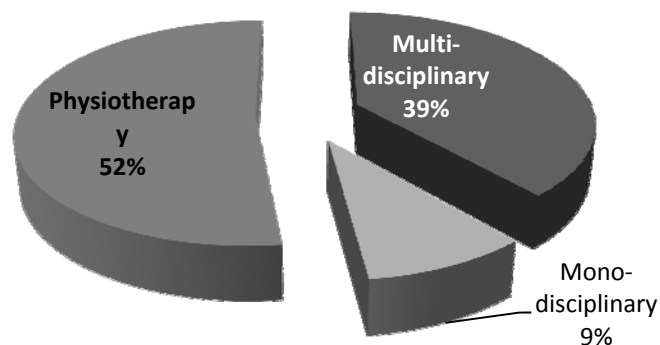
	Multi-disciplinary	Mono-disciplinary	Physiotherapy	Total number
N of patients	12574	3700	12643	19622 ^h
Mean N of sessions	14.33	11.90	19.21	23.75
StdDev	15.96	14.40	24.11	26.56
Min- Max	1-177	1-114	1-309	1-309
Median	8	6	11	15
25% percentile	4	3	4	5
75% percentile	18	15	23	34
Total N of sessions	180157	44036	242837	467030

Figure 3-10 describes the proportion of the total number of rehabilitation sessions in the first episode received by the entire patient group who received at least one session of any type of rehabilitation or physiotherapy (19,622 patients). The pie chart indicates that almost half of the patients have at least one session of either multidisciplinary or monodisciplinary PRM.

It should be noted that, based on nomenclature codes, it could not be determined whether “only exercise” therapy is a part of this “physiotherapy”. Moreover, “physiotherapy” could be related to whatever pathology occurring in parallel with the cardiac event. This is a limitation of this analysis

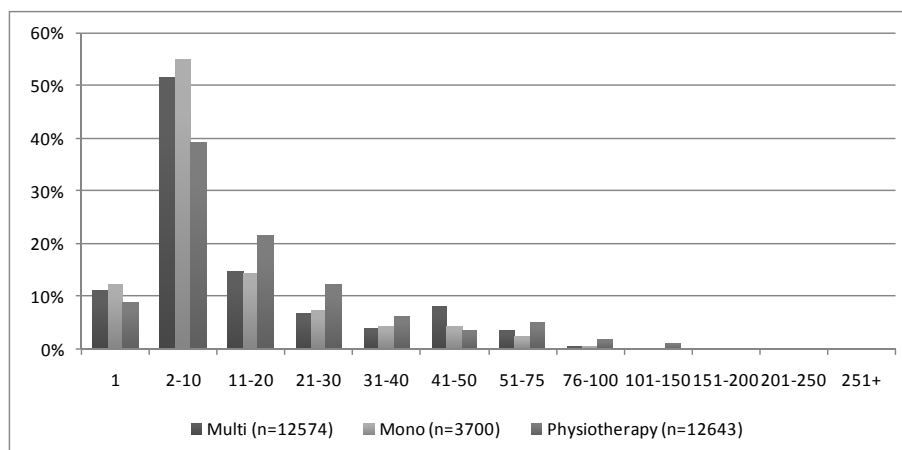
^h As explained earlier, a patient can be represented more than once in the 3 rehabilitation groups, and hence the total number of patients represented in the last column is not the sum of the first three columns; it represents the actual patient number included in this analysis, and hence this column reports the statistics of number of sessions for the total patient group (irrespective of the type of rehabilitation).

Figure 3-10 Total number of rehabilitation sessions in the entire patient group (19622 patients) (1st rehabilitation episode)



The distribution of the total number of sessions over the 3 types of rehabilitation (multidisciplinary rehabilitation, monodisciplinary PRM and physiotherapy – only first episode is considered) is graphically represented in Figure 3-11. In each rehabilitation group, all patients are considered having received at least one session of this type of rehabilitation.

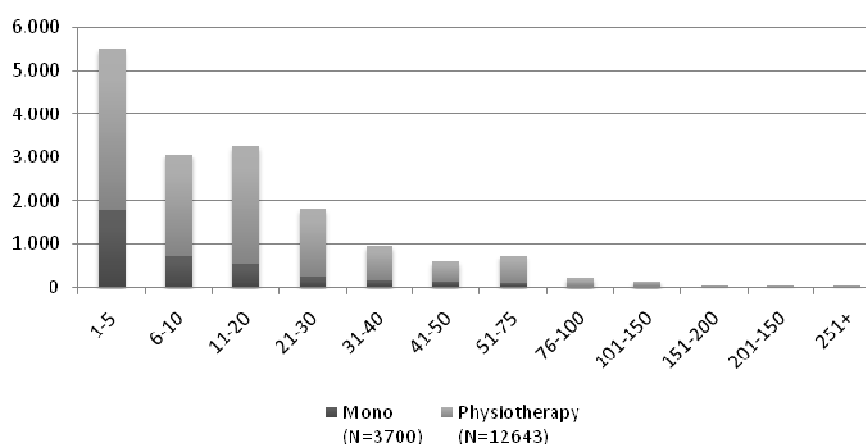
Figure 3-11: Distribution of the number of rehabilitation sessions after any cardiac procedure (Surgery and PCI)



Approximately 10% of the patients only received one session. More than half of the patients received 2-10 sessions, 15% of patients in this group received 11-20 sessions. Interestingly, a relatively high percentage of patients (8%) received 41-50 sessions which generates a minor peak in the curve.

The histogram (Figure 3-12) of the number of monodisciplinary PRM and physiotherapy sessions after any cardiac procedure (absolute values) shows that the number of patients who received monodisciplinary PRM is much smaller than the number of patients who received physiotherapy. Hence, the decision was made to pool both types of rehabilitation into one group, labelled 'physiotherapy with or without medical supervision'.

Figure 3-12: Histogram of the number of monodisciplinary PRM and physiotherapy sessions after any cardiac procedure (Surgery and PCI)



Key points

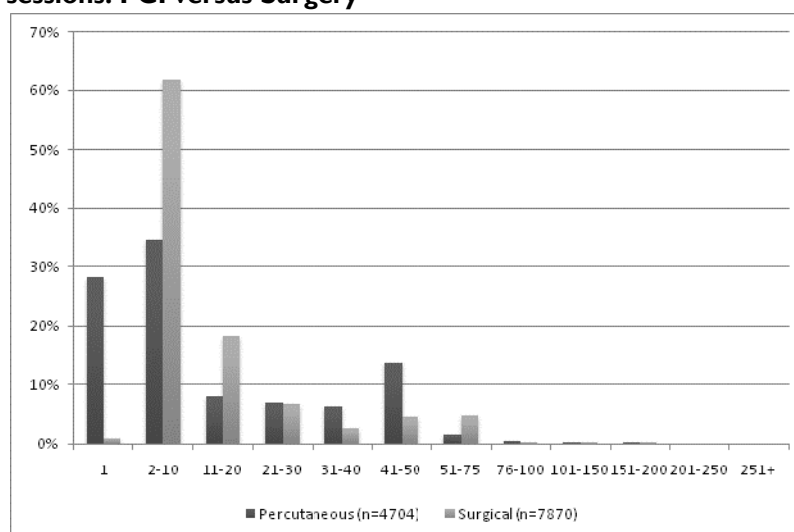
- **Multidisciplinary rehabilitation represents 39% of all sessions of cardiac rehabilitation, monodisciplinary PRM represents 9%.**
- **Patients having multidisciplinary rehabilitation receive on average 14.3 sessions of this type and half of them receive up to 8 sessions).**
- **Approximately 10% of patients receive one session only of any one of the rehabilitation types.**

For both multidisciplinary and 'physiotherapy with or without medical supervision' sessions, a split was made between PCI and surgery patients. Results are described in the following sections.

Multidisciplinary rehabilitation

The patterns in the number of sessions of multidisciplinary rehabilitation are very different after PCI than after surgery. The proportion receiving only 1 session is much higher after PCI than after surgery (28% vs 0%), and the surgery group has a much higher percentage of patients receiving 2-10 therapies (62% vs 35%). It is also observed that 14% of patients who underwent PCI received 41-45 sessions, while this is only the case in 4.6% of the patients after surgery.

Figure 3-13: Distribution of the number of Multidisciplinary Rehabilitation sessions: PCI versus Surgery



4.7% of the patients in the surgery group received 51-75 sessions, compared to only 1.6% in the PCI group. The latter differences might be explained by the fact that surgery patients remain longer in hospital, allowing them receiving more (reimbursed) inpatient sessions of multidisciplinary rehabilitation.ⁱ

The statistics in Table 3-11 show that the median number of multidisciplinary rehabilitation sessions is twice as high as after surgery, compared to PCI. However, the average number is similar.

Table 3-11: Descriptive statistics of the number of multidisciplinary rehabilitation sessions: PCI versus surgery

	PCI	Surgery	Total
N of patients	4704	7870	12574
Mean	14.68	14.12	14.33
StdDev	18.14	14.50	15.96
Median	4	8	8
25% percentile	1	6	4
75% percentile	26.50	15	18

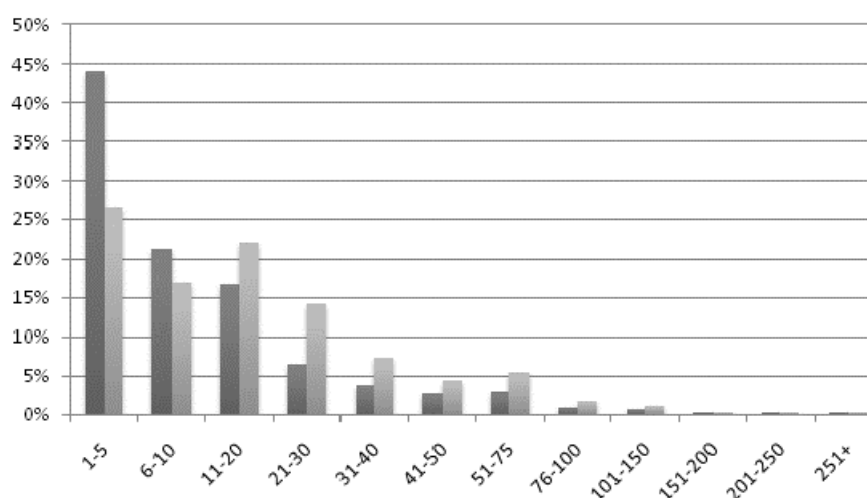
Key points

- **After PCI, 28% of the patients who received multidisciplinary rehabilitation had only one session.**
- **Patients in the surgery group receive more multidisciplinary rehabilitation sessions (median 8 sessions) than patients in the PCI group (median 4 sessions).**

Physiotherapy with or without medical supervision

The number of sessions of physiotherapy with or without medical supervision is different in the PCI group than in the surgery group. Almost 45% of the patients who received physiotherapy with or without medical supervision in the PCI group received maximum five sessions, while this is only 26% in the surgery group.

Figure 3-14: Distribution of the number of sessions of physiotherapy with or without medical supervision (monodisciplinary + physiotherapy): PCI versus Surgery



ⁱ The maximum number of reimbursed sessions of multidisciplinary rehabilitation is 30 inpatient sessions and 45 outpatient sessions.

It should be noted that, based on nomenclature codes, no distinction can be made whether “only exercise” therapy is part of this “physiotherapy”; moreover, “physiotherapy” can be related to whatever pathology occurring in parallel with the cardiac event; therefore, it is recognised as a limitation of this analysis.

The distribution of the number of sessions of physiotherapy with or without medical supervision is different in the PCI group than in the surgery group. Almost 45% of the patients who received physiotherapy with or without medical supervision in the PCI group received maximum five sessions, while this is only 26% in the surgery group.

Table 3-12 shows that after surgery, a patient has on average more physiotherapy sessions with or without medical supervision in the PCI group, even though this might not be of clinical relevance.

Table 3-12: Descriptive statistics of the number of sessions of physiotherapy with or without medical supervision: PCI versus Surgery

	PCI	Surgery	Total
N of patients	6740	9603	16343
Mean	13.55	20.36	17.55
StdDev	20.24	23.55	22.49
Median	7	14	10
25% percentile	3	5	4
75% percentile	17	26	21

Key points

- **After PCI, almost 45% of the patients who received physiotherapy therapy (with or without medical supervision) had only from 1 to 5 sessions.**
- **Patients in the surgery group have more physiotherapy sessions (with or without medical supervision)(median 14 sessions), than patients in the PCI group (median 7 sessions).**

3.2.4.2 *Costs related to rehabilitation according to payer's (public and patient) perspective*

This section compares the costs of rehabilitation or physiotherapy sessions for different rehabilitation subgroups. We used the outpatient classification and calculated the costs from a health care payer perspective, including only direct medical costs. Costs are split in publicly reimbursed costs (public health care payer RIZIV/INAMI) and patient copayments. Only the cost of the first rehabilitation episode is reported in the main content of this report. A similar analysis for cost over the entire year is included in appendix 2.5.2. Figure 3-15 and Figure 3-16 provide an overview of the average rehabilitation costs during the first episode for patients in the PCI and surgery groups.

Cost comparisons among the four rehabilitation groups, based on the outpatient classification, are graphically displayed in Figure 3-15 (PCI group) and in Figure 3-16 (surgery group). The costs for patients, who did not receive any rehabilitation or physiotherapy, are explained by the rehabilitation costs incurred during the initial hospital stay during which the index event was performed. Rehabilitation costs for patients in the outpatient multidisciplinary group are much higher than in the other three groups. Rehabilitation costs after surgery are higher compared to these costs after PCI. The average number of sessions after surgery is higher and they have more often multidisciplinary sessions whose unit cost is higher (see appendix 2.5.1).

Rehabilitation costs after surgery are higher compared to the costs after PCI. The average number of sessions after surgery is higher than after PCI resulting in higher costs.

The patient co-payment is as high as €191 and €291 over the first episode of multidisciplinary rehabilitation for the PCI and surgery groups respectively.

Figure 3-15: Average rehabilitation cost during the 1st episode of patients in the PCI group (outpatient classification)

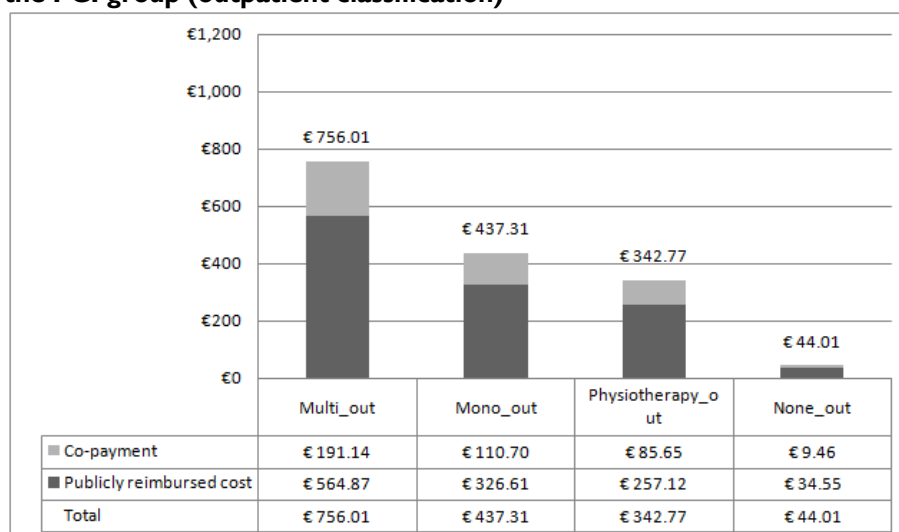
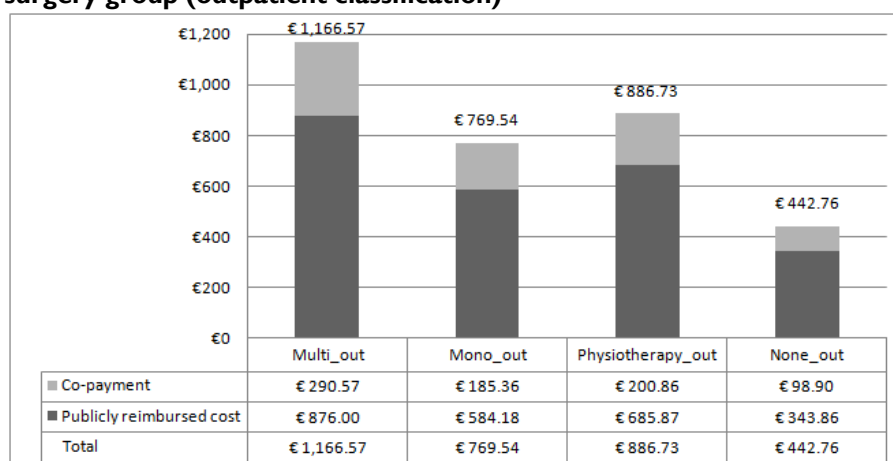


Figure 3-16: Average rehabilitation cost during 1st episode of patients in surgery group (outpatient classification)



Key points

- Patients who received outpatient multidisciplinary rehabilitation sessions had higher overall rehabilitation costs (including all types of sessions, inpatient and outpatient) than other patients. This was the case after surgery (average cost of rehabilitation € 1116) as well as after PCI (average cost of rehabilitation € 756). One explanation is certainly the higher unit cost of multidisciplinary sessions.
- Patient co-payment is high particularly in case of multidisciplinary rehabilitation. A patient pays on average €191 after PCI and € 290 after cardiac surgery.

3.2.5 Utilisation of rehabilitation types per socio-demographic patient characteristics

For the descriptive analysis in this section, patients were classified using the overall classification, irrespective of them being treated in an inpatient or an outpatient setting (Figure 3-2).

These sections are descriptive, and assess the influence of each characteristic independently of the other (univariate analyses). At the end of the section, a multivariate regression is performed, which assess the influence of all factors concomitantly.

3.2.5.1 Age

After PCI, the chance of receiving multidisciplinary rehabilitation decreases with increasing age. After surgery, age doesn't seem to be a factor that influences the rehabilitation type.

Figure 3-17: Distribution of patients per age category and per type of rehabilitation after PCI

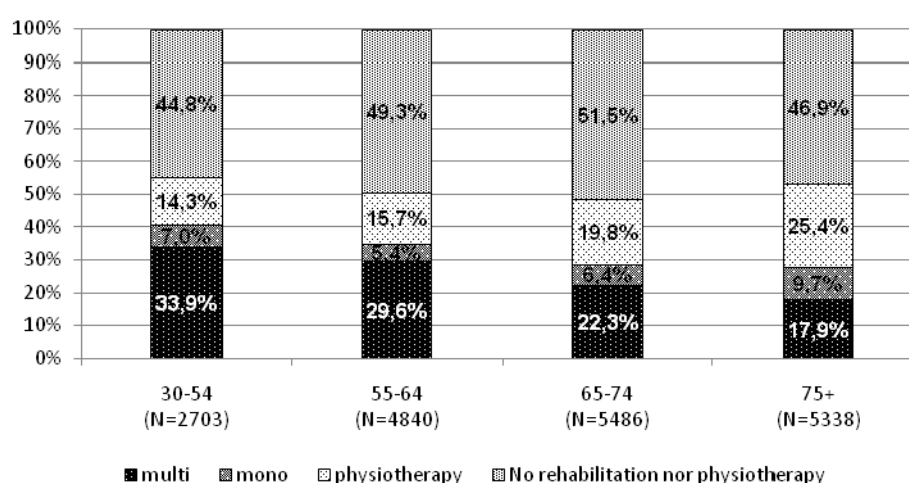
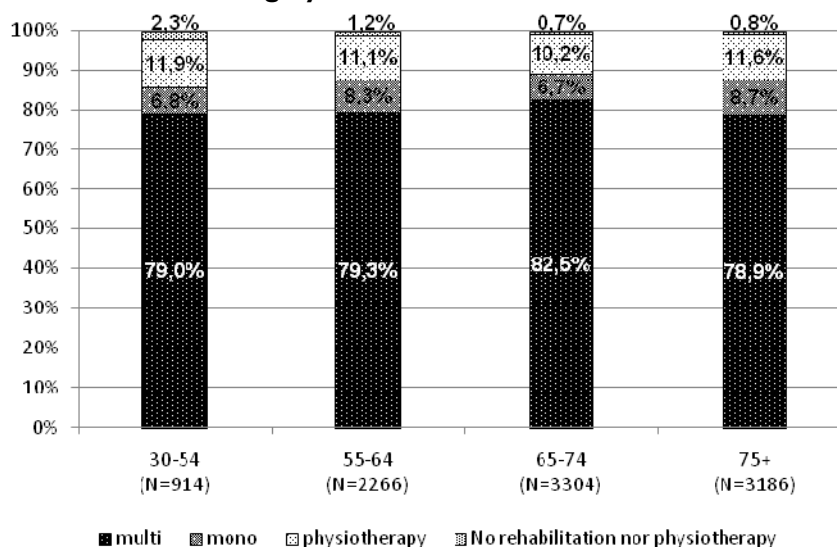


Figure 3-18: Distribution of patients per age category and per type of rehabilitation after surgery



3.2.5.2 Gender

Figure 3-19: Distribution of patients per gender and per type of rehabilitation after PCI

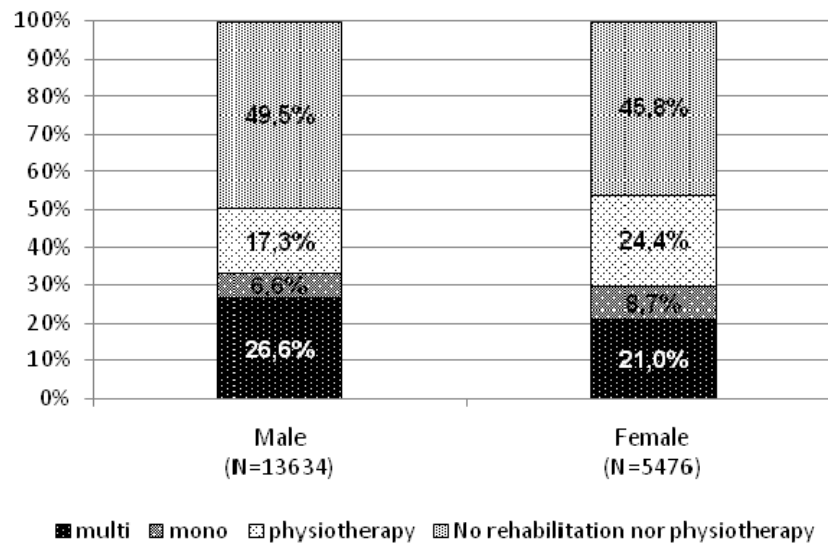


Figure 3-20: Distribution of patients per gender and per type of rehabilitation after surgery



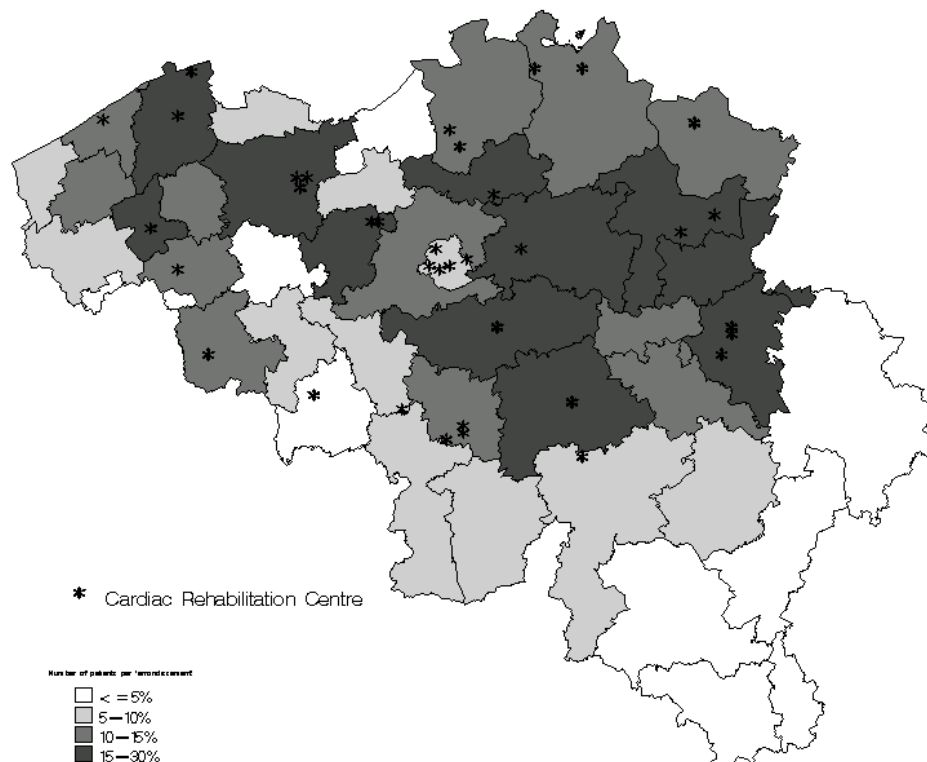
26.6% of male patients received multidisciplinary rehabilitation after PCI, compared to 21.0% of female patients.

After surgery, no clear differences are observed between male and female patients.

3.2.5.3 Geographical intensity of patients in outpatient multidisciplinary rehabilitation

Figure 3-21 and Figure 3-22ⁱ show the proportion of patients classified as outpatient multidisciplinary group out of the total number of patients living in that “arrondissement”, for PCI and surgery group respectively. The stars on the maps indicate the location of multidisciplinary centres. Similar maps for patients in monodisciplinary PRM, physiotherapy and no rehabilitation nor physiotherapy groups are included in appendix 7.

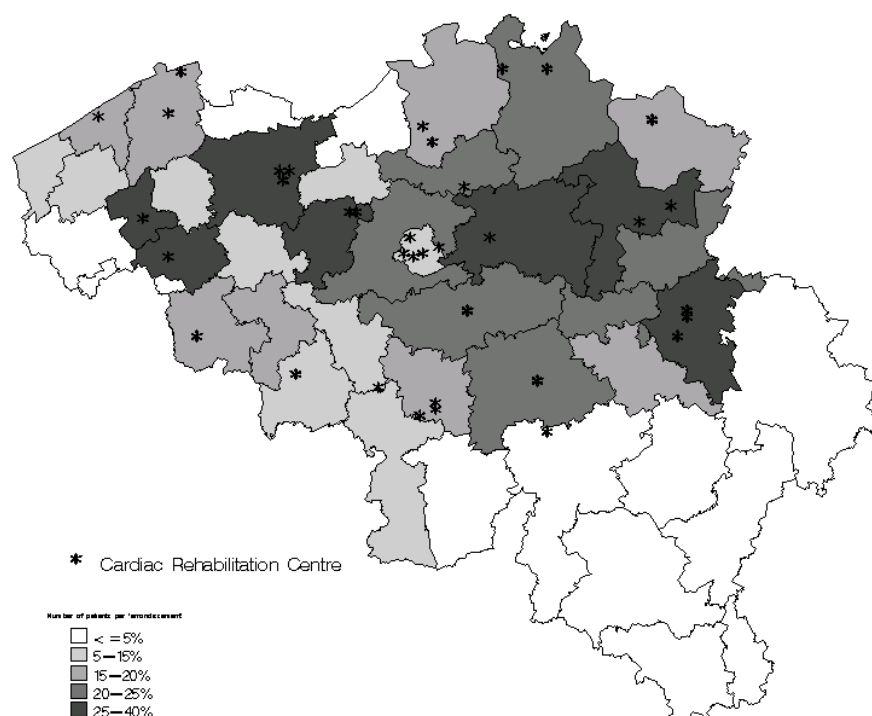
Figure 3-21: Geographical variability in the percentage of patients receiving outpatient multidisciplinary sessions after PCI



The highest proportions are mostly observed in the regions where a multidisciplinary rehabilitation centre is located, except for the Brussels region. There are four rehabilitation centres located in the Brussels region, but the proportion is only 5-10% or 5-15% for patients after PCI or surgery. In Walloon regions without rehabilitation centres, the proportion of patients with outpatient multidisciplinary rehabilitation is less than 5%.

ⁱ Readers should pay attention to the legend of these two maps as the colour representing patient intensity level is different.

Figure 3-22: Geographical variability in the percentage of patients receiving outpatient multidisciplinary sessions after surgery



(Please note the legends of the maps are different across in above two maps)

3.2.5.4 Statistical Sector

Municipalities (FR=Commune; NL=Gemeente) in Belgium, represent the smallest unit in the official classification of territorial units for statistics (NUTS)^k However, information on several socioeconomic variables is available at a smaller geographical unit, the statistical sector (SS). Statistical sectors divide municipalities into homogeneous entities according to 4 criteria; they reflect similar "neighbourhoods" in terms of socioeconomic, urban and morphological characteristics. Approximately 20 000 statistical sectors exist in Belgium. Many variables describing each statistical sector are available: yearly fiscal data (based on the tax income reported by inhabitants of each SS) and all data included in the last "Socio-Economic Survey" performed in 2001 (database owned by the Federal Public Service Economy).^l

In this report, information on the income and educational level of the SS's was used.

Income

Q1 to Q5 of the statistical income sector represent respectively the first to the 5th quintile in terms of income of the Belgian population.

^k Regulation (EC) 1059/2003 of 26 May 2003 on the establishment of a common classification of territorial units for statistics (NUTS). Official Journal of the European Communities 21/06/2003. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:154:0001:0041:EN:PDF>

^l SPF Economie/FOD Economie. Carrefour de l'Economie. In: SPF Economie, P.M.E., Classes moyennes & Energie; 2003. p. 20.

Figure 3-23^m: Distribution of patients per statistical income sector (quintile) and per type of rehabilitation after PCI

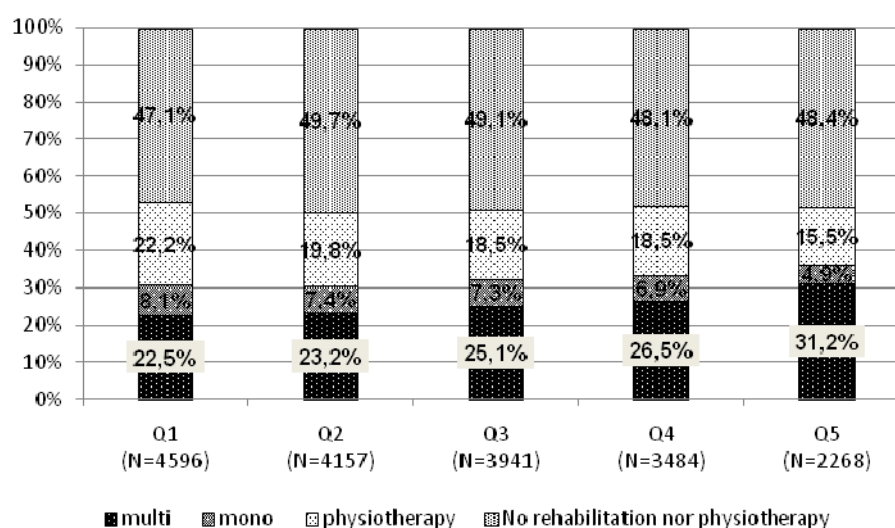
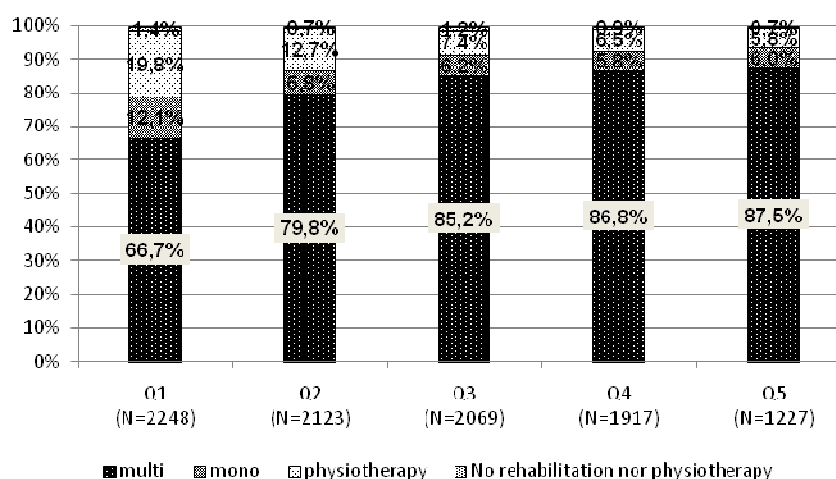


Figure 3-24ⁿ: Distribution of patients per statistical income sector (quintile) and per type of rehabilitation after surgery



After surgery, the difference between the first quintile and the other quintiles is prominent.

In the statistical sector with the highest average income, a clearly higher percentage of patients received multidisciplinary rehabilitation, both after PCI and surgery. In the sectors with on average a lower income, relatively more patients received monodisciplinary PRM. The percentage of 'No rehabilitation nor physiotherapy' patients remains mostly constant over the quintiles.

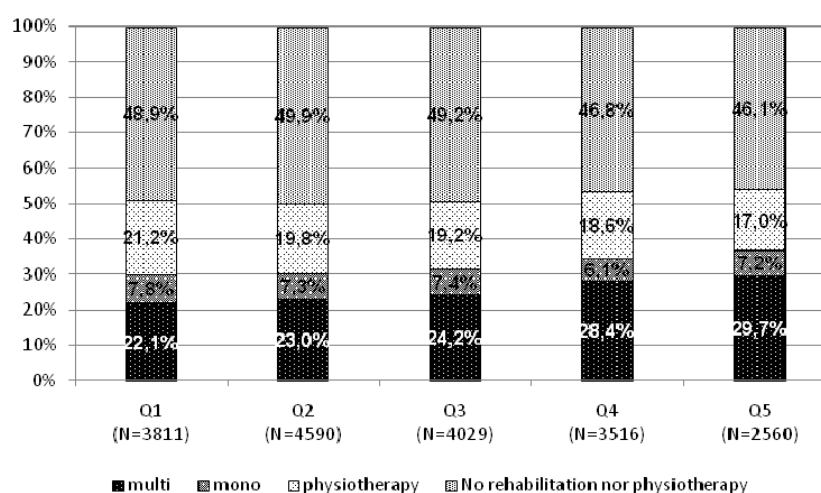
Education

The statistical education sector divides statistical sectors according to quintiles based on the % of the total population having attained post secondary education. Q1 to Q5 represent respectively the first to the 5th quintile.

^m Missing values: PCI group: N=664

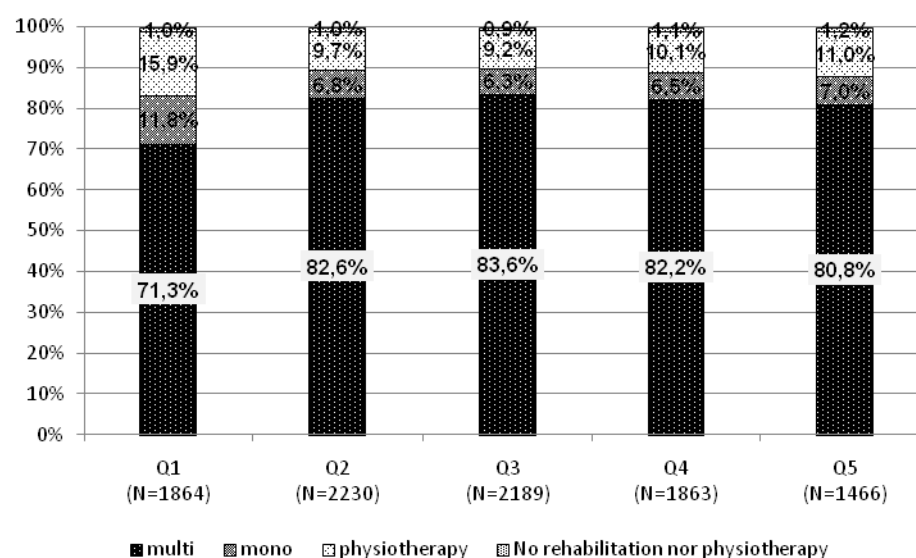
ⁿ Missing values: surgery group: N=327

Figure 3-25°: Distribution of patients per statistical education sector (quintile) and per type of rehabilitation after PCI



The percentage of patients that received monodisciplinary PRM after PCI appears to be constant across quintiles. An increasing percentage of multidisciplinary rehabilitation is observed in the higher quintiles

Figure 3-26°: Distribution of patients per statistical education sector (quintile) and per type of rehabilitation after surgery



After surgery, especially the difference between the first quintile and the others is prominent. In the statistical sector with the lowest percentage of inhabitants who received postsecondary education, the percentage of patients who received multidisciplinary rehabilitation is at least 10% lower than in the other quintiles. This is in favor of monodisciplinary PRM.

° Missing values: PCI group: N=604

P Missing values: surgery group: N=299

Employment Status

Differences in the proportion of patients classified in the rehabilitation groups are observed across employment statuses. It is noteworthy that 61% and 11% of patients in the self-employed group did not take any type of rehabilitation in the PCI and surgery group, respectively, making self-employed the professional occupation with the highest no-physiotherapy rate among the five employment states.

In patients who underwent PCI, the “pensioners or unemployed pre-retired” group had the lowest percentage of multidisciplinary rehabilitation patients, whereas patients in the “worker” group have the highest percentage.

In patients who underwent surgery, the “unemployed” group has the lowest percentage of multidisciplinary rehabilitation, whereas patients in the “self-employed” group have the highest percentage.

Figure 3-27^q: Distribution of patients per employment status and per type of rehabilitation after PCI

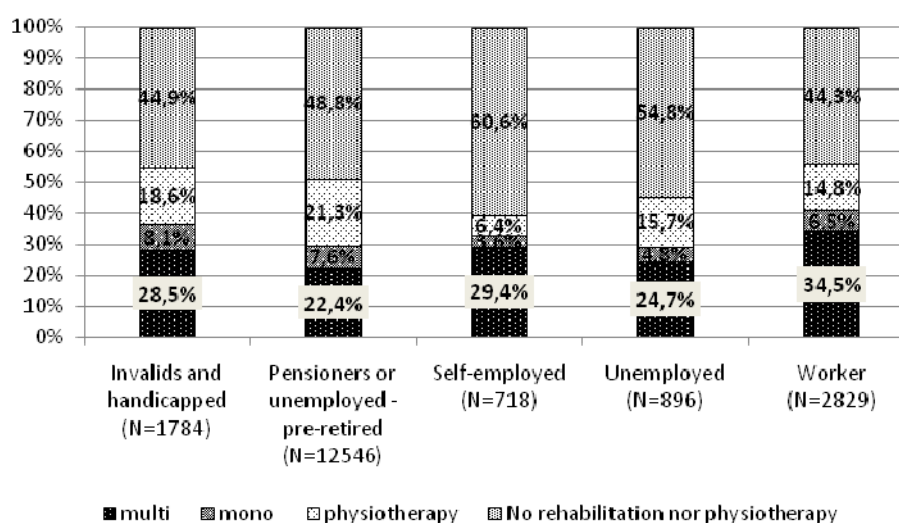
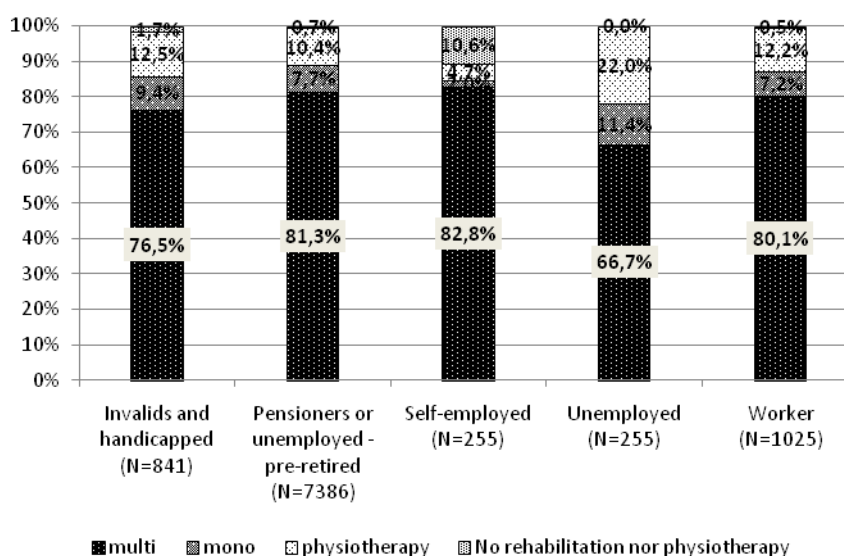


Figure 3-28^r: Distribution of patients per employment status and per type of rehabilitation after surgery



^q Missing value: PCI group: N=337

^r Missing value: surgery group: N=149

3.2.5.5 Co-payment category

Patients entitled to increase reimbursement (indicated as 'YES' in Figure 3-29 and Figure 3-30) received less multidisciplinary rehabilitation (especially after PCI: 27% vs 21%).

Figure 3-29: Distribution of patients per co-payment category and per type of rehabilitation after PCI (yes= entitled to increased reimbursement)

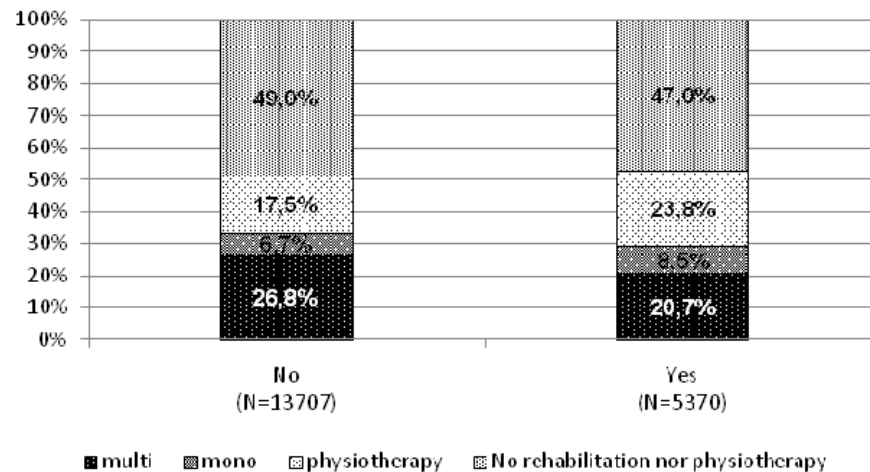
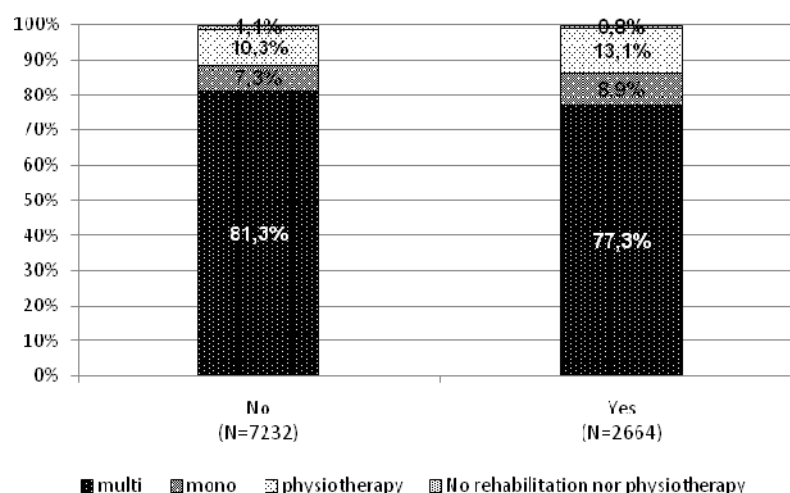


Figure 3-30: Distribution of patients per co-payment category and per type of rehabilitation after surgery (yes= entitled to increased reimbursement)



3.2.6 Cardiac centre related data

We planned to analyse whether the availability of a CR centre in the hospital where the patient was treated for his/her index event had an influence on the rehabilitation pattern. Due to the process of making the data anonymous it was not possible to retrieve which hospitals had an agreement with the authorities to prescribe CR. For this reason we were not able to perform this analysis.

3.2.7 Multivariate analysis

Multivariate analysis was only performed for the outpatients receiving CR. This decision answered to the focus of the data analysis i.e. 'to evaluate the accessibility of CR services'. The patients who receive CR in hospital have indeed a direct access to CR services when they stay in a hospital with a CR centre. The question is to identify factors that influence the utilisation when the patient goes back home. Moreover, when a patient completes a CR treatment, the outpatient rehabilitation represents the highest number of CR sessions, as the hospitalisation usually lasts less than 14 days for cardiac surgery and even less than 3 days for PCI ⁵.

The overview of the odds ratio's (by holding other variables constant) and their confidence intervals is enclosed in appendix 2.9. The paragraphs below present the components of this multivariate analysis in different chapters. Although they refer to explanatory variables of the same regression the odd ratios are presented separately in order to facilitate the understanding of their influence on the outcome.

The independent variables are: work status, gender, age, official CR centre in the "arrondissement" of residence, co-payment, education and income quintiles.

3.2.7.1 Age

We observe that as the patient's age increases, the probability of receiving multidisciplinary rehabilitation is decreasing. After PCI or surgery, patients aged over 75, had 82% to 83% lower chance of receiving multidisciplinary rehabilitation compared to patients aged between 35 and 54.

A similar trend was observed for patients who did not receive any type of rehabilitation. The older the patients are, the higher the chance that they will not receive any type of rehabilitation. Patients aged 75 or above, who underwent PCI, had a 119% higher chance of receiving no rehabilitation compared to the group of patients aged between 30 and 54 years. After surgery, patients aged 75 or above had a 65% higher chance of receiving no rehabilitation at all compared to the group of patients aged between 30 and 54 years.

Table 3-13: Multivariate logistic regression: effect of age (Odds Ratio and 95% CI)*

	Outcome: receiving at least one outpatient multidisciplinary session		Outcome: not receiving rehabilitation nor physiotherapy in outpatient setting	
	PCI	Surgery	PCI	Surgery
	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)
Age:55-64 (versus 30-54)	0.816 (0.720 - 0.926)	Not Significant	1.178 (1.061 - 1.308)	Not significant
Age:65-74 (versus 30-54)	0.425 (0.356 - 0.507)	0.505 (0.398 - 0.641)	1.668 (1.449 - 1.919)	1.400 (1.110 - 1.765)
Age:75 plus (versus 30-54)	0.171 (0.140 - 0.21)	0.183 (0.141 - 0.238)	2.190 (1.895 - 2.531)	1.647 (1.304 - 2.080)

(*) Reported odds ratio's are corrected for the other predictor variables retained the logistic regression model (reference category: age 30-54)

⁵ This is described in detail in section 3.1.5.3

Gender

Table 3-14 shows after PCI, female patients had 22% lower chance of receiving multidisciplinary rehabilitation than male patients; and had a 29% lower chance after surgery.

Female patients who underwent PCI had 10% lower chance of receiving no rehabilitation at all compared to male patients. There were no differences after surgery.

Table 3-14: Results from multivariate logistic regression: effect of gender (Odds Ratio and 95% CI) (*)

	Outcome: receiving at least one outpatient multidisciplinary session		Outcome: not receiving rehabilitation nor physiotherapy in outpatient setting	
	PCI	Surgery	PCI	Surgery
	Odds ratio (95% Confidence Limits)	Odds ratio (95% Confidence Limits)	Odds ratio (95% Confidence Limits)	Odds ratio (95% Confidence Limits)
Gender (Female versus male)	0.780 (0.698 - 0.871)	0.714 (0.626 - 0.814)	0.901 (0.838 - 0.969)	1.013 (0.916 - 1.120)

(*) Reported odds ratio's are corrected for the other predictor variables retained the logistic regression model

Employment status

Table 3-15 shows after PCI, "Invalids and handicapped" and "Unemployed" patients had a lower chance of receiving multidisciplinary rehabilitation compared to "Workers" (respectively a 27% and 46% lower chance). The effect of the employment status was stronger (respectively a 33% and 49% lower chance) for patients who underwent surgery. Self-employed patients who underwent PCI had a 33% lower chance of receiving multidisciplinary rehabilitation.

On the other hand, after PCI, "Invalids and handicapped", "Unemployed" patients had a higher chance of receiving no rehabilitation at all compared to "Workers" (respectively a 30%, 88% higher chance). After surgery, the percentages were respectively 53% and 70%. It is worth to notice that, after surgery, "self-employed" patients had a 296% higher chance of receiving no rehabilitation at all.

Table 3-15: Results from multivariate logistic regression: effect of employment status (Odds Ratio and 95% CI) (*)

	Outcome: receiving at least one outpatient multidisciplinary session		Outcome: not receiving rehabilitation nor physiotherapy in outpatient setting	
	PCI	Surgery	PCI	Surgery
	Odds ratio (95% Confidence Limits)	Odds ratio (95% Confidence Limits)	Odds ratio (95% Confidence Limits)	Odds ratio (95% Confidence Limits)
Invalids and handicapped (versus worker)	0.729 (0.618 - 0.861)	0.673 (0.535 - 0.847)	1.299 (1.138 - 1.482)	1.528 (1.224 - 1.908)
Unemployed (versus worker)	0.543 (0.436 - 0.676)	0.510 (0.356 - 0.729)	1.883 (1.585 - 2.236)	1.701 (1.243 - 2.328)
Self-employed (versus worker)	0.667 (0.540 - 0.825)	Not significant	1.982 (1.648 - 2.385)	3.964 (2.937 - 5.349)

(*) Reported odds ratio's are corrected for the other predictor variables retained the logistic regression model (reference category: workers)

Officially authorized CR centre in the “arrondissement” of residence

If the patient lives in an arrondissement with an officially authorized CR centre, the probability of receiving multidisciplinary rehabilitation after PCI was 110% higher, while after surgery, this was 108% higher compared to patients residing in “arrondissements” without any CR centre.

Table 3-16: Significant odds ratio's for official CR centre in the “arrondissement” of the patient in multivariate logistic regression (Odds Ratio and 95% CI) (*)

	Outcome: receiving at least one outpatient multidisciplinary session		Outcome: not receiving rehabilitation nor physiotherapy in outpatient setting	
	PCI	Surgery	PCI	Surgery
	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)
Centre in arrondissement (versus no centre in arrondissement)	2.100 (1.872 - 2.357)	2.078 (1.805 - 2.393)	0.775 (0.719 - 0.835)	0.638 (0.576 - 0.705)

(*) Reported odds ratio's are corrected for the other predictor variables retained the logistic regression model
(reference category: no centre in arrondissement)

Co-payment

Patients entitled to increased reimbursement (therefore from a lower socio-economic status) had a 34% lower chance of receiving multidisciplinary rehabilitation after PCI compared to patients not entitled to increased reimbursement. After surgery, this chance was 39% lower.

Similarly, patients entitled to increased reimbursement had a 14% higher chance of receiving no rehabilitation at all after PCI compared to patients not entitled to increased reimbursement. After surgery, the probability was 28% higher.

Table 3-17: Significant odds ratio's for co-payment of the patient in multivariate logistic regression (Odds Ratio and 95% CI) (*)

	Outcome: receiving at least one outpatient multidisciplinary session		Outcome: not receiving rehabilitation nor physiotherapy in outpatient setting	
	PCI	Surgery	PCI	Surgery
	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)
Patients with increased reimbursement (versus patients without)	0.659 (0.582 - 0.747)	0.606 (0.520 - 0.706)	1.142 (1.056 - 1.236)	1.282 (1.154 - 1.425)

(*) Reported odds ratios are corrected for the other predictor variables retained the logistic regression model
(reference category: patient without increased reimbursement)

Statistical sector : education

Patients living in the areas belonging to the highest education quintiles (residing in statistical sectors with more highly educated persons) had a higher chance of receiving outpatient multidisciplinary rehabilitation than patients residing in areas with fewer highly educated persons. This appears to be the case both for PCI group (30% increase in probability) and surgery group (68%).

Similarly, PCI patients living in areas with more highly educated persons had less chance of receiving no rehabilitation at all.

Table 3-18 Significant odds ratio's for education quintile of the patient in multivariate logistic regression (Odds Ratio and 95% CI) (*)

	Outcome: receiving at least one outpatient multidisciplinary session		Outcome: not receiving rehabilitation nor physiotherapy in outpatient setting	
	PCI	Surgery	PCI	Surgery
	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)
Education Q2 (versus Q1)	Not significant	Not significant	0.899 (0.813 - 0.995)	Not significant
Education Q3 (versus Q1)	Not significant	Not significant	0.893 (0.801 - 0.995)	Not significant
Education Q4 (versus Q1)	1.364 (1.163 - 1.6)	1.306 (1.066 - 1.6)	0.790 (0.704 - 0.885)	Not significant
Education Q5 (versus Q1)	1.300 (1.085 - 1.558)	1.677 (1.345 - 2.092)	0.761 (0.668 - 0.868)	Not significant

(*) Reported odds ratios are corrected for the other predictor variables retained the logistic regression model (reference category quintile one)

Statistical sector : income

Patients who underwent PCI and residing in a statistical sector with a high income (the fourth quintile), had a 28% higher chance of receiving multidisciplinary rehabilitation than patients in the first quintile. For patients belonging to the other quintile of statistic income sectors as the income quintile increased the chance of receiving multidisciplinary rehabilitation also increased in both patients who underwent PCI and surgery.

Table 3-19: Significant odds ratio's for different income quintile of the patient in multivariate logistic regression (Odds Ratio and 95% CI) (*)

	Multidisciplinary_out		No outpatient rehabilitation or physiotherapy	
	PCI	Surgery	PCI	Surgery
	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)	Odds ratio (95% Wald Confidence Limits)
Income Q2 (versus Q1)	1.219 (1.058 - 1.404)	Not significant	Not significant	0.718 (0.627 - 0.821)
Income Q3 (versus Q1)	1.308 (1.131 - 1.513)	1.378 (1.143 - 1.66)	0.876 (0.791 - 0.971)	0.544 (0.470 - 0.629)
Income Q4 (versus Q1)	1.279 (1.094 - 1.494)	1.455 (1.195 - 1.770)	0.893 (0.799 - 0.997)	0.545 (0.466 - 0.637)
Income Q5 (versus Q1)	1.616 (1.356 - 1.927)	1.464 (1.171 - 1.829)	0.874 (0.767 - 0.997)	0.498 (0.412 - 0.603)

(*) Reported odds ratios are corrected for the other predictor variables retained the logistic regression model (reference category: quintile one)

Key points

- Female patients had less chance than males of receiving outpatient multidisciplinary rehabilitation after PCI or surgery. However, the women also had less chance of receiving no outpatient rehabilitation at all after PCI.
- With increasing age, the probability of receiving outpatient multidisciplinary rehabilitation decreased and the chance of receiving no rehabilitation at all increased.
- Employed patients had the highest chance of receiving outpatient multidisciplinary rehabilitation and the lowest chance of receiving no rehabilitation. Self-employed patients had the highest probability of receiving no outpatient rehabilitation at all.
- The higher the education and income level, the higher the probability of receiving outpatient multidisciplinary rehabilitation.
- The presence of a authorized centre in the same arrondissement as the patient's residence significantly increased the probability of receiving outpatient multidisciplinary rehabilitation and reduced the probability of receiving no rehabilitation at all.

3.2.8 Cardiac disease related resource use: outpatient visits and diagnostic tests

It is important to stress that the IMA database does not give any information on patients' co-morbidities, nor their actual diagnosis. Therefore it is impossible to evaluate for which reason patients visit their physician or why these tests were prescribed. Hence, drawing conclusions from comparisons between different types of rehabilitation are not appropriate given the limitations of the data.

For the following analyses, patients were classified following the outpatient classification as explained in section 3.1.5. Table 3-20 represents the total number of patients included in the resource use analyses per outpatient rehabilitation group. Patient numbers vary from those in the outpatient classification frequency table (Figure 3-3) as patients with incomplete and/or erroneous data were removed from the analyses (in total, 1515 patients have been removed from the resource use analysis: 710 for the PCI group and 805 for the surgery group).

Table 3-20: Total number of patients by rehabilitation type (outpatient classification)*

Patients Group	Multi_out	Mono_out	Physiothera py_out	None_out	Total
Procedure type	Number (% of total)	Number (% of total)	Number (% of total)	Number (% of total)	Number (% of total)
PCI	2585 (14.0%)	582 (3.2%)	2724 (14.8%)	12509 (68.0%)	18400 (66.9%)
Surgery	1781 (19.6%)	387 (4.2%)	4326 (47.5%)	2612 (28.7%)	9106 (33.1%)
Total	4366 (15.9%)	969 (3.5%)	7050 (25.6%)	15121 (55.0%)	27506 (100.0%)

* Resource use is collected since patient discharged from hospital after the index event, for up to one year afterwards

The resource use analysis is here also performed separately for surgery and PCI patients respectively. Resource use is collected since patient discharged from hospital after the index event, for up to one year afterwards. In other words, the initial stay during which the index event occurred is not included in this resource use analysis.

The resource used after the index event was categorized into two main categories:

- Outpatient visits (consultation/cardiologist visit and internist visit)
- Diagnostic tests (invasive tests and non-invasive tests)

3.2.8.1 Outpatient visits

Table 3-21 and Table 3-22 describe the number of patients who had an outpatient cardiologist or internist visit and the average number of visits in each outpatient rehabilitation group after PCI or surgery.

Both Table 3-21 and Table 3-22 show that cardiologist visits are the most popular outpatient visits for all four patient groups. Patients belonging to the outpatient multidisciplinary group had the highest proportion of patients with cardiologist visits as well as the highest average number of visits per patient.

Patients who underwent surgery had more or less the same rate of internal medicine visits across rehabilitation types. However in the PCI group, multidisciplinary rehabilitation patients had the lowest rate of internist visits with the highest average number of visits.

Table 3-21: Outpatient visit frequency of patients per rehabilitation type after PCI*

Resource type	Multi_out		Mono_out		Physiotherapy_out		None_out	
Patient number	2585		582		2724		12509	
Number of patient and mean visits	Number (% of total)	Mean visits (25- 75 percentile)	Number of patients (% of total)	Mean visits (25- 75 percentile)	Number of patients (% of total)	Mean visits (25- 75 percentile)	Number of patients (% of total)	Mean visits (25- 75 percentile)
Consultation/ Cardiologist visit	2393 (92.6%)	3.67 (2-4)	527 (90.5%)	3.56 (2-4)	2375 (87.2%)	2.77 (2-3)	10442 (83.5%)	2.62 (2-3)
Internist visit	448 (17.3%)	2.98 (1-4)	162 (27.8%)	2.71 (1-3)	646 (23.7%)	2.81 (1-3)	2495 (19.9%)	2.55 (1-3)

* Resource use is collected since patient discharged from hospital after the index event, for up to one year afterwards

Table 3-22: Outpatient visit frequency of patients per rehabilitation type after surgery*

	Multi_out		Mono_out		Physiotherapy_out		None_out	
Number of patients	1781		387		4326		2612	
Number of patients and mean visits	Number / (% of total)	Mean visits / (25- 75 percentile)	Number / (% of total)	Mean visits / (25- 75 percentile)	Number / (% of total)	Mean visits / (25- 75 percentile)	Number / (% of total)	Mean visits / (25- 75 percentile)
Consultation/ Cardiologist visit	1631 (91.6%)	3.62 (2-5)	356 (92.0%)	3.02 (2-4)	3809 (88.0%)	2.6 (2-3)	2060 (78.9%)	2.49 (1-3)
Internist visit	363 (20.4%)	3.08 (1-4)	78 (20.2%)	2.35 (1-3)	877 (20.3%)	2.54 (1-3)	498 (19.1%)	2.47 (1-3)

* Resource use is collected since patient discharged from hospital after the index event, for up to one year afterwards

3.2.8.2 Diagnostic tests

Diagnostic tests here are classified into invasive and non-invasive tests:

- Invasive test: diagnostic coronarography, invasive vascular imaging and invasive monitoring
- Non-invasive test: pulmonary function, nuclear test, X-ray, Holter, non-invasive monitoring, Doppler ultrasound, Electrophysiological examination (EFO), echocardiogram and exercise test

Only the top four most frequently used non-invasive diagnostic tests are reported here. The use of the other non-invasive diagnostic tests is reported in Appendix.

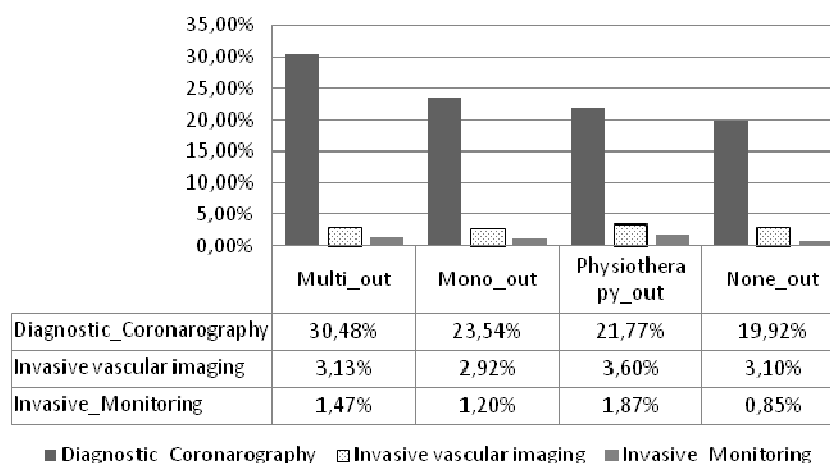
Figure 3-31 and Figure 3-32 present the use of invasive diagnostic tests, for the PCI and surgery groups respectively. Invasive tests are applied more frequently in the outpatient multidisciplinary rehabilitation group compared to the other groups. Diagnostic coronarography is used in 30% of patients in outpatient multidisciplinary group after PCI. Given this high percentage, the time span between hospital discharge after the index event and the first diagnostic coronarography has been checked (Table 3-23).

Table 3-23: Time span (in number of days) between hospital discharge after the index event and the first diagnostic coronarography

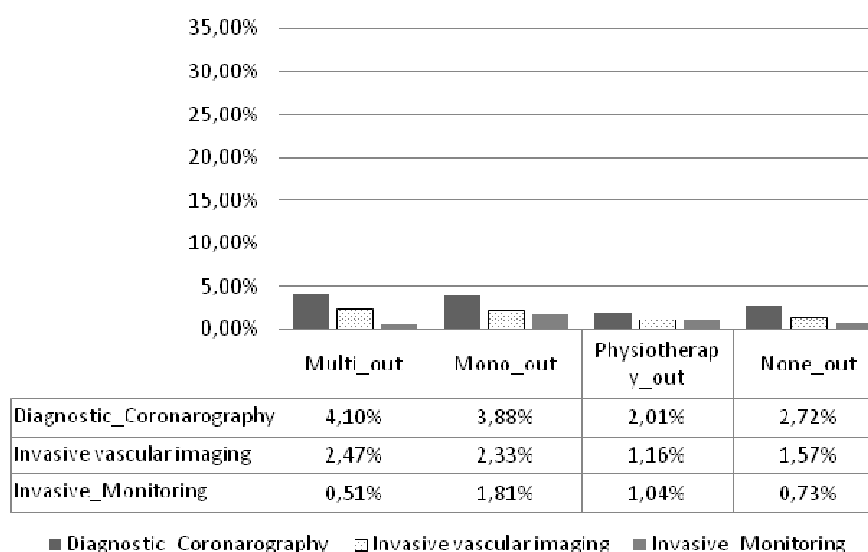
	Multi_out	Mono_out	Physiotherapy_out	None_out
Number of patients	2585	582	2724	12509
Number of days between discharge and first diagnostic coronarography				
Average	125	170	159	171

Diagnostic coronarography is performed in only 3% of patients in the outpatient multidisciplinary rehabilitation group after surgery. Invasive tests are rarely performed in patients who underwent surgery (Figure 3-32).

Figure 3-31: Invasive diagnostic tests per rehabilitation group after PCI*



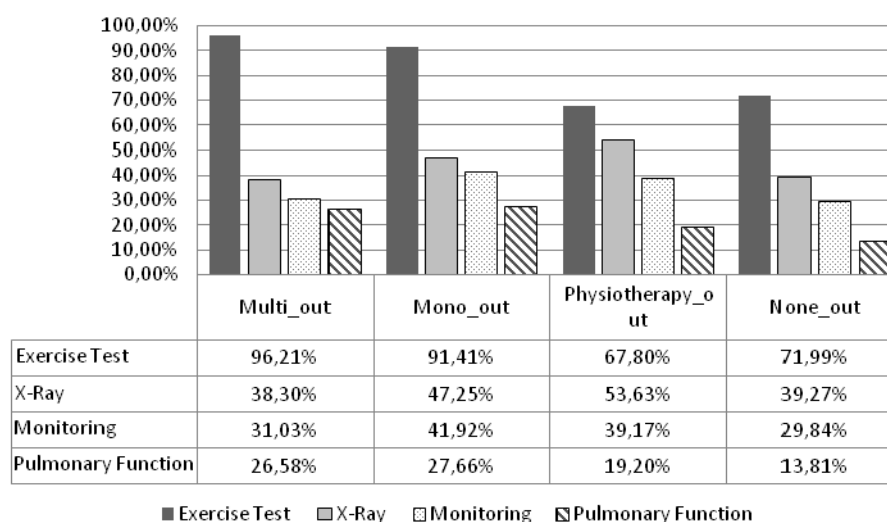
* Resource use is collected since patient discharged from hospital after the index event, for up to one year afterwards

Figure 3-32: Invasive diagnostic tests per rehabilitation group after surgery*

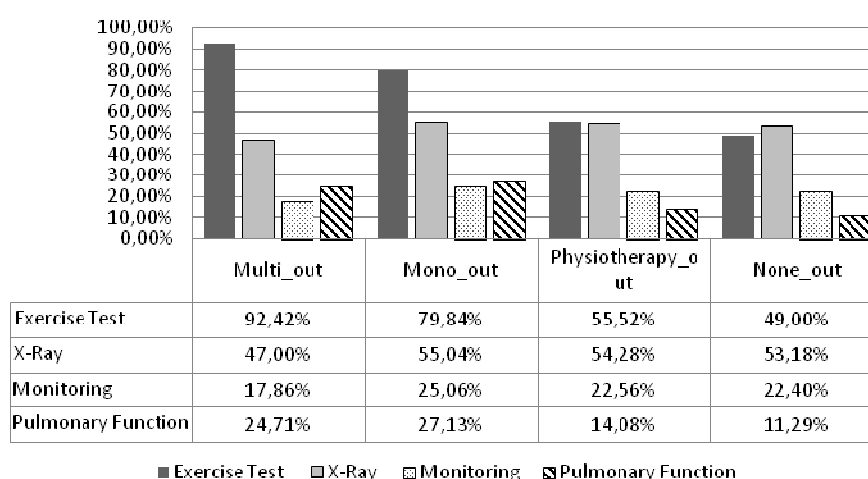
* Resource use is collected since patient discharged from hospital after the index event, for up to one year afterwards

Figure 3-33 and Figure 3-34 report the top four performed non-invasive diagnostic tests: exercise test, X-ray, monitoring test and pulmonary function test. Exercise tests are the most frequently used non-invasive test in all four rehabilitation groups which is particularly true in the multidisciplinary outpatient group. This can be explained by the fact that exercise tests are essential parameters to evaluate the rehabilitation and for that reason area part of the programme.

Patients who underwent PCI had more non-invasive diagnostic tests than patients who underwent surgery.

Figure 3-33: Non-invasive diagnostic tests per rehabilitation group after PCI*

* Resource use is collected since patient discharged from hospital after the index event, for up to one year afterwards

Figure 3-34: Non-invasive diagnostic tests per rehabilitation group after surgery*

* Resource use is collected since patient discharged from hospital after the index event, for up to one year afterwards

Key points[†]

- The majority of outpatient visits consisted of cardiologic consultations.
- Patients classified in the outpatient multidisciplinary rehabilitation group had the highest rate of cardiologist visits, probably explained by the fact visits are a part of the programme.
- The use of diagnostic tests was the highest in the outpatient multidisciplinary rehabilitation group.
- Surgery patients underwent fewer invasive diagnostic tests than patients with PCI.
- Exercise tests were the most frequently used tests among all rehabilitation groups. It should be noted that these tests are part of the multidisciplinary cardiac rehabilitation programme.
- The data did not allow linking the diagnosis with the utilisation of physiotherapy, outpatient visits and diagnostic tests.

3.3 SUMMARY AND LIMITATIONS

The purpose of this analysis was to answer the second research question: “What is the utilisation, geographical spread and costs of three types of CR after defined cardiac procedures throughout Belgium?”. Rehabilitation utilisation (type, number of sessions, duration) and associated costs were analysed during one year for a group of patients who underwent either cardiac surgery (CABG, valve replacement or the combination of both procedures) or PCI during in 2007.

3.3.1 Summary of the descriptive statistics

Multidisciplinary rehabilitation represented 39% of all sessions of rehabilitation. Those patients received on average 14.3 multidisciplinary sessions and half of them received up to 8 sessions. Approximately 10% of patients only received one session of rehabilitation.

The rehabilitation profile after cardiac surgery differs from the profile after PCI. After cardiac surgery, 80% of patients received multidisciplinary CR during their initial hospital stay. However after hospital discharge only 19% of the surgery patients continued this multidisciplinary rehabilitation. The duration of the first rehabilitation episode (including all types of rehabilitation and physiotherapy) is on average 2 months (median duration 48 days). The median number of multidisciplinary rehabilitation sessions is 8 sessions.

[†] Note: the initial hospital stay during which index event occurred is not included in this resource use analysis

After PCI only 25% of patients started multidisciplinary rehabilitation in the hospital and only 14% of them continued this type of rehabilitation after discharge. The probability of receiving neither rehabilitation nor physiotherapy in the outpatient setting is much higher for PCI patients than for cardiac surgery patients. The median duration of the first rehabilitation episode was 14 days. More than one out of four PCI patients who received multidisciplinary rehabilitation only had one session (28%) with a median number of multidisciplinary rehabilitation sessions being four.

Patients who received outpatient multidisciplinary rehabilitation sessions had higher overall rehabilitation costs (including all types of sessions, inpatient and outpatient) than other patients. After surgery the average cost of rehabilitation was € 1116 and after PCI this average cost was € 756. Patient co-payments appeared to be high particularly in the case of multidisciplinary rehabilitation. A patient pays on average € 191 after PCI and € 290 after cardiac surgery.

3.3.2 Summary of the multivariate analyses

The consumption of rehabilitation types per socio-demographic patient characteristics were analysed by means of multivariate statistical techniques.

Female patients had a lower chance of receiving outpatient multidisciplinary rehabilitation than males after PCI as well as after surgery. However, female patients had lower chance of receiving no rehabilitation at all after PCI.

With increasing age, the probability of receiving outpatient multidisciplinary rehabilitation decreased and the chance of receiving no rehabilitation at all increased.

Employed patients had the highest probability of receiving outpatient multidisciplinary rehabilitation and the lowest chance of receiving no rehabilitation. Self-employed patients had the highest probability of not receiving outpatient rehabilitation at all.

When the level of education or income is higher, the probability of receiving outpatient multidisciplinary rehabilitation also increases.

The presence of an official CR centre in the same arrondissement as the residence significantly increased the probability of outpatient multidisciplinary CR and reduced the probability of receiving no rehabilitation at all.

3.3.3 Strengths and limitations of the data analysis

This analysis provided an insight into the issue of utilisation and access to CR in Belgium. The analysis relied on the whole Belgian patient IMA database as explained above. This was crucial to capture the geographical spread of rehabilitation utilisation in the country. Furthermore the follow-up was over one year as rehabilitation periods might be quite long in Belgium. Finally the available data provided details on the sociodemographic factors that influence the utilisation pattern in Belgium.

A limitation is the use of the IMA database that does not provide information on the clinical diagnosis. The IMA database only provides codes linked to the medical consumption. For this reason the target population was restricted to patients who underwent a cardiac procedure (surgery or PCI). This is a subgroup of the patients allowed reimbursement for multidisciplinary CR.

Patients were classified into rehabilitation groups for the analysis. If a patient received multidisciplinary rehabilitation after the index event, that rehabilitation was linked to that event. For the other forms of rehabilitation (monodisciplinary PRM or physiotherapy) the reasons why these sessions were prescribed were unknown. They might be linked to the CR or to other diseases. In some circumstances the prescription of multidisciplinary CR is indeed hampered by specific reasons (as for example the beginning of rehabilitation after discharge and/or no authorized centre in the area). In those cases the physicians may prescribe monodisciplinary PRM or physiotherapy to diminish the patient's co payment. The exact nature of those rehabilitation treatments is unknown (exercise component, multidisciplinary intervention) : a link between intervention and outcome is therefore impossible.

4 PATIENT SURVEY

The objective of the patient survey is to draw conclusions with regard to the compliance of the patients with the proposed/prescribed rehabilitation programme and their reasons for (non) participation in this programme. A cross sectional survey among cardiac patients eligible for CR was performed in 19 Belgian hospitals.

4.1 METHODOLOGY

This section details the key design elements of this patient survey:

- Study design
- Study population
- Patient recruitment
- Time horizon
- Data management & privacy
- Data collection

4.1.1 Study design

All Belgian hospitals registered with the National Institute for Health and Disability Insurance (RIZIV/INAMI) as having a “cardiac pathology programme” (=“A, B1 & B2” hospitals) were sent an invitation for participation (n=126). Twenty hospitals agreed to participate. A reply form was sent to these hospitals to collect data from the participating cardiologists. All but one hospitals replied positively (n=19, list in appendix 3.2). Ethics committee approvals were obtained from eighteen ethics committees, as one cardiologist participated in the study on his private name instead of the hospital.

A concise patient questionnaire (in Dutch and French) was developed by the research team in order to capture the patient reported reasons for (non) participation. Patients were asked to fill in the questionnaire during an outpatient consultation and to return it to the investigator or study nurse after completion (Questionnaires in Appendix 3.1).

4.1.2 Study population

The following patient groups were included in the patient survey:

- PCI group: Patients who underwent PCI
- Surgery group: Patients who underwent a major cardiovascular surgery (heart transplantation, CABG, heart valve repair or replacement)
- AMI group: Patients who suffered from myocardial infarction (AMI) but did not receive PCI or surgery.

Only patients who provided a signed informed consent were included in the study. Each patient was asked to sign two copies of the informed consent form, one for the patient and one for the investigators.

4.1.3 Time horizon

Initially, it was planned that patients who had one of the 3 predefined cardiac events (defined in section 4.1.2) in the second half of 2008 were to be entitled to participate in this survey. However, due to difficulties in recruiting sufficient number of patients it was decided to prolong the time horizon to the first half of 2009. In other words, patients who experienced one of the cardiac events between June 30th 2008 and June 30th 2009 were eligible to participate in this study.

4.1.4 Patient recruitment

The investigators were asked to recruit 7 consecutive eligible patients from each of the three above mentioned patient groups (PCI, surgery and AMI) during an outpatient consultation i.e. 21 patients per hospital. If a patient was not willing to participate the following patient was asked, until each of the above mentioned patient groups were completed with 7 patients per participating centre. If a patient was not willing to participate, his/her refusal was recorded along with the reasons to refuse. The investigators or study nurses were contacted on a regular basis via email, post and phone regarding the recruitment status.

However, several centres reported difficulties in recruiting patients to the AMI group (without PCI). Several alternative solutions were proposed and evaluated (See section 4.3, Conclusion and limitations). It was finally decided that the centres with problems for recruiting AMI patients would recruit more patients from the other two groups. Due to this corrective action, fewer patients were included in the AMI group compared to the other two groups.

4.1.5 Data management & privacy

The investigator was responsible for handing over the questionnaire to the participating patient and for collecting the completed questionnaire with the patient's informed consent. In order to ensure anonymity, the questionnaire was handed out to the patient in an open envelope and, after completion of the questionnaire, was returned back to the investigator or study nurse, in a sealed envelope.

The questionnaire was identical for all 3 patient categories. Only the colour of the envelope differed between the 3 patient groups, in order to facilitate the investigator's distribution of the questionnaire. By processing in this way, the investigator was aware of the type of patients participating in the study, but was not able to see the answers patients provided. The data management team was, on the other hand, aware of the answers provided by patients but not of the patients' identities.

4.1.6 Data collection

4.1.6.1 *Centre/ hospital / cardiologist related data:*

In addition to the patient questionnaires, another form collected the following data:

1. Data on the participating centre:
 - Geographic localization,
 - Number of cardiac hospital beds within the hospital and for the hospital association,
 - Facilities for CR, invasive cardiology and cardiac surgery,
 - Having (or not) an official recognition as CR centre.
2. Data on participating cardiologists:
 - Clinical activity (e.g. CR, invasive cardiology, non-invasive cardiology),
 - Years of activity as a cardiologist,
 - General perception of rehabilitation programmes

4.1.6.2 *Patient related data (patient questionnaire):*

1. Socio-demographic data:
 - Age and gender
 - Nationality and origin
 - Marital status
 - Employment status
 - Level of education
2. Rehabilitation programme – prescription and compliance (Yes/No questions):

- Did the physician propose to the patient a CR programme? Was that accepted by the patient?
 - If the patient agreed to participate did she/he fully comply with the programme?
 - Type of the rehabilitation programme
 - Patient's satisfaction after the rehabilitation programme
3. Rehabilitation programme – reasons for (non) compliance and patient satisfaction:
- Reasons for not following the rehabilitation programme recommended by a cardiologist
 - Reasons for not completing the programme
 - Positive and negative aspects of the CR programme

4.1.7 Data analysis

Descriptive analyses are performed on:

4.1.7.1 *Participating centres and cardiologists:*

- Opinion on CR programmes
- Years of activity as cardiologist
- Clinical activity (CR, invasive cardiology, non invasive cardiology, other)
- Official recognition or CR facility
- Centres per region and per province

4.1.7.2 *Patients:*

1. General information: number of questionnaires per patient group
2. Demographic data:
 - Age and gender
 - Nationality and origin
 - Marital status
 - Employment
 - Education level
3. Cardiac rehabilitation programme per disease group:
 - Number of patients to whom CR was not proposed by the cardiologists
 - Number of patients refusing to participate in a CR programme proposed by the cardiologists and their (categorized) reasons for refusal
 - Number of patients not completing the entire programme as prescribed by the cardiologists and their (categorized) reasons for non completion
 - Number of patients attending the entire programme and overview (keywords table) of positive and negative aspects of the programme
 - Impact of demographics, having an official CR centre, patient population characteristics and the experience of cardiologists on:
 - physicians' decision to propose rehabilitation programme to the patient,
 - patients' decision to participate in the programme or not, and
 - patients' decision to complete the programme

Due to the small sample size of the survey and the descriptive nature of the analysis of the survey data we tried to identify and provide comparisons if the differences between groups were greater than 5% and if the sample size for the specific comparison was >30.

4.2 RESULTS

4.2.1 Cardiologists

All participating investigators (=cardiologists) were asked to complete a questionnaire in order to get their opinion on prescribing CR after one of the pre-defined events (surgery, AMI and PCI). Most (n=17) of the 19 participating cardiologists completed and returned this questionnaire. The details of their characteristics are in appendix 3.3.

Thirteen cardiologists (n=13) would always prescribe a CR programme to the surgery patients. Fifteen of them would always do this prescription for AMI patients. Only 7 cardiologists would always prescribe CR to PCI patients. None of the cardiologists claimed that CR should never be prescribed.

4.2.2 Characteristics of the patients

At the beginning 399 patients from the 19 centres were expected to take part in the survey (i.e. 21 patients * 19 centres). The researchers called the cardiologists from these 19 centres on average 5 to 6 times by phone throughout the recruitment period. Although the deadline was extended twice (April 30th 2010 and May 31st 2010), it was not possible to obtain the expected number of participants. At the final closure of the collection period, 226 questionnaires had been returned from 15 centres (57% of the total expected) and included in the analysis (see discussion in section 4.3).

Table 4-1: Number of questionnaires per patient group

Patient groups	Received number	% of total	Target number	% the target (received number/target number)
Surgery	83	36.7%	133	62.4%
AMI	44	19.5%	133	33.1%
PCI	99	43.8%	133	74.4%
Total	226	100.0%	399	56.6%

A summary of the patients' characteristics is presented in the following sections and in appendix

4.2.2.1 Age and Gender

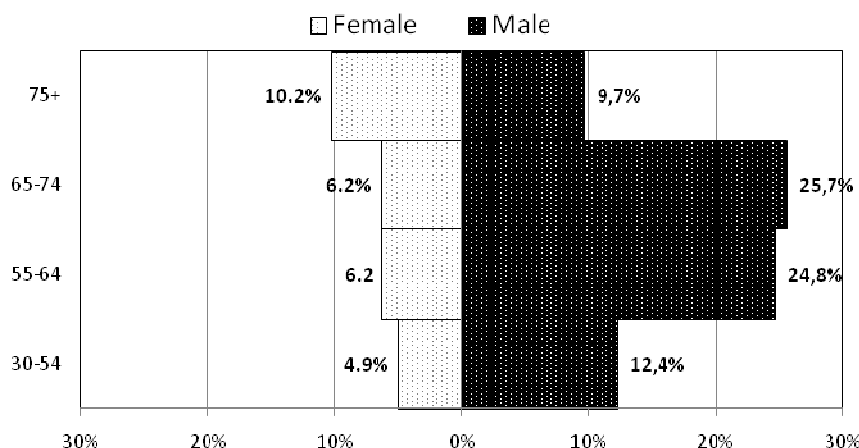
Table 4-2 shows an overview of the mean age per patient group. The mean age of all participating patients was 65 years. AMI patients were slightly younger (63 years).

Table 4-2: Patients' age^u

Patient group	Surgery	AMI	PCI	Total
N of patient	N=83	N=44	N=99	N=226
Mean Age	65.8	62.8	65.5	65.1
StdDev	9.90	11.36	10.16	10.33
Median	66	63	66	65
Min – Max	42 - 87	42 - 88	44 - 84	42 - 88

Figure 4-1 shows that 73% (n=165) of the recruited patients were men and 27% (n=61) were women. The majority of patients (63%, n=142) were aged between 55 and 74.

^u The same age categories are applied as in the analysis of the Belgian data (See chapter 3).

Figure 4-1: Distribution of patients' gender per age category

The appendix 3.4.1 shows the age and gender of patients per patient group. More than half of the patients in surgery and PCI group are above 55 years old, whereas the majority of the included AMI patients were younger than 64 years. In each group a higher proportion of male patients participated in the study than female patients.

4.2.2.2 *Origin and marital status*

The appendix 3.4.2 details the nationality and marital status of the participants.

- Non-Belgian nationals (10 out of 226) and the patients who defined themselves as not ethnically Belgian (17 out of 226) were a minority in the sample;
- Most participants (75%, n= 169) were married or had a partner.

4.2.2.3 *Education and employment status*

A quarter of the participants had no degree or finished primary school only (25%, n=56). About half of the participants had a secondary school degree (48%, n=109) and a quarter of the patients obtained a high school or university degree (27%, n=60).

More than half of the patients (56%, n=126) were retired (60% in the surgery group). The other patients had the following employment status: 23% employees (n=52), 5% self-employed (n=11), 8% with a disability status (n=18), 7% Housewife/man (n=16) and 1% unemployment (n=2).

The details by diagnostic group are in appendix 3.4.3.

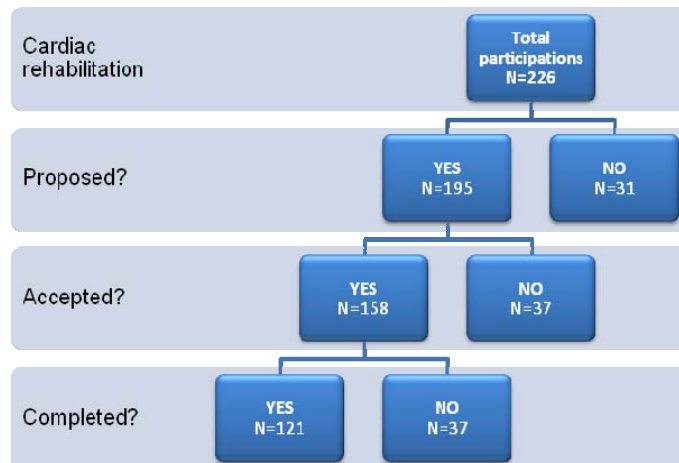
4.2.2.4 *Distance between home and rehabilitation centre*

The distance between home and rehabilitation centres was collected from patients who were asked to participate in a CR programme (N= 195). Fifteen of those patients did not report distance and five patients were excluded because they only had CR during their hospitalization.

The minimum reported distance was 1 km, the maximum 50 km. Three quarters of the patients (74%, n=130) live less than 20 kilometres away from the rehabilitation centre (details in appendix 3.4.4).

4.2.3 *Participation to the cardiac rehabilitation programme*

195 out of 226 patients were proposed a CR programme (multidisciplinary; monodisciplinary PRM; or physiotherapy). Out of these 195 patients, 158 patients accepted and 121 of them completed it. In other words, of all recruited patients, 86% was proposed a CR programme, of which 81% accepted it; and 77% of the patients that accepted also completed the programme. On the whole, of the 226 recruited patients, 121 (54%) fully completed a CR programme.

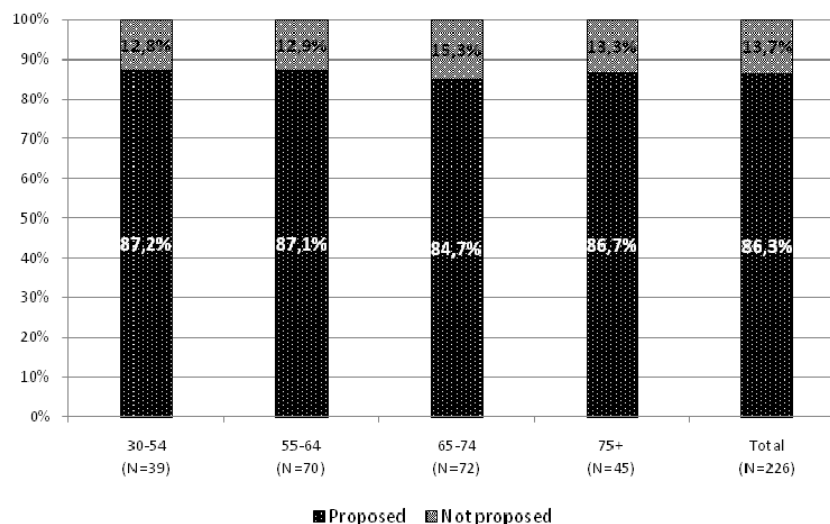
Figure 4-2: Cardiac rehabilitation status of the patients

4.2.3.1 *Impact of demographic data*

The following sections show the proposal of treatment according to the patient's characteristics. Within each section, the first graph shows the proportion of patients who were proposed some kind of CR (multidisciplinary; mono-disciplinary PRM; or physiotherapy). The graphs in appendix 3.5 show the percentage of patients accepting and completing the proposed CR programme as well as details by subgroups.

Age

Figure 4-3 shows the relationship between the age of the patient and the CR prescription. A total of 86% (n= 195) of the patients were proposed a CR programme.

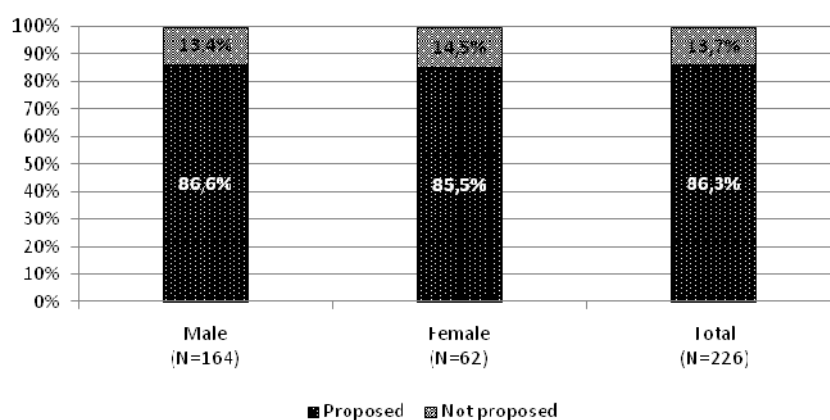
Figure 4-3: Percentage of patients who were proposed cardiac rehabilitation programme per age category

The appendix 3.5.1 gives details of the percentage of patients who accepted and who completed the entire programme per age category. In general the acceptance rate was high (more than 3 patients out of 4) except for multidisciplinary rehabilitation in the oldest age group (58%, n=26). After agreeing to participate in the rehabilitation programme more than three quarters of the patients (n=121) completed it.

Gender

Similar proportions of men and women were proposed CR (Figure 4-4).

Figure 4-4: Percentage of patients who were proposed cardiac rehabilitation programme by gender



The details in appendix 3.5.2 shows that 80 % of the men (n=99) and 72% of the women (n=39) accepted the proposed multidisciplinary rehabilitation programme. Globally the acceptance of multidisciplinary CR is low compared to the other types of rehabilitation. The completion of the multidisciplinary programme was above 70% in both genders.

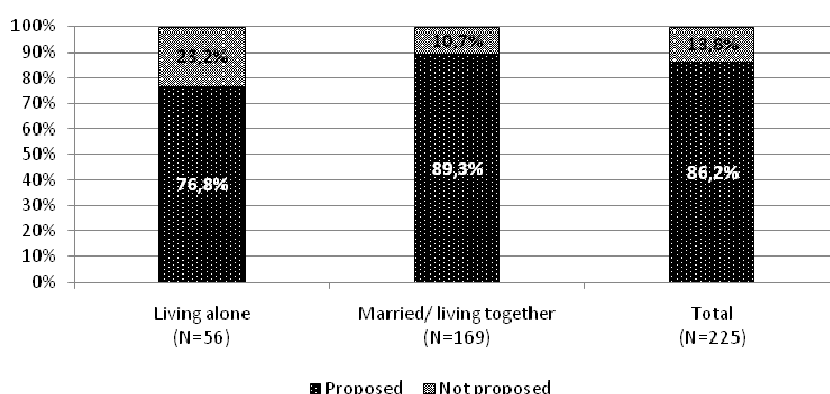
Origin

Eleven out of the 17 patients (65%) with a non-Belgian origin were proposed a rehabilitation programme. This proportion appears to be low in comparison to the rest of the patients (88%, n=183 out of 208 patients) but the small numbers do not allow any conclusion (see details in appendix 3.5.3).

Marital status

Patients who are married or live together with a partner had more often a proposal of CR (Figure 4-5) than patients who lived alone (widow or single). They seemed also more likely to accept and complete the programme but the small sizes of the groups do not allow any conclusion (see details in appendix 3.5.4).

Figure 4-5: Percentage of patients who were proposed cardiac rehabilitation by marital status^v



^v Missing value = 1

Education level

The figure below shows the proportion of patients who were proposed CR in each education group (Figure 4-6). The figures in appendix 3.5.5 show the proportion who accepted it and completed it and details by programme.

Figure 4-6: Percentage of patients who were proposed cardiac rehabilitation programme by education level^w

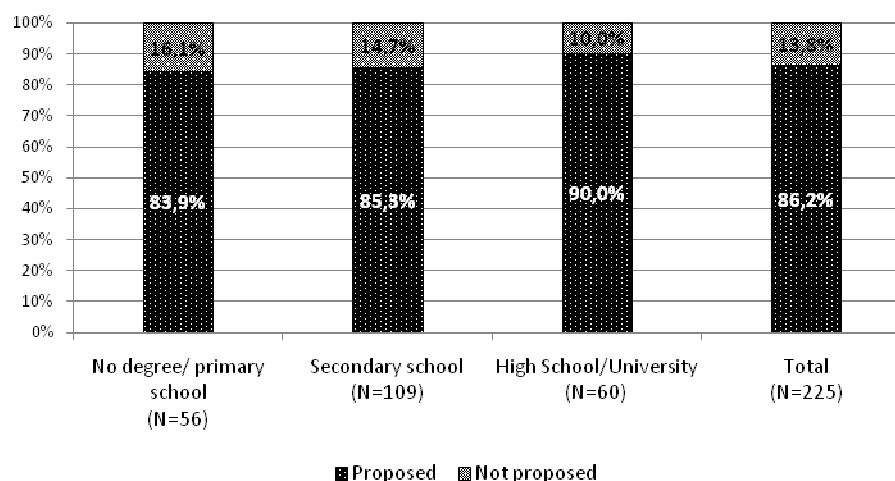
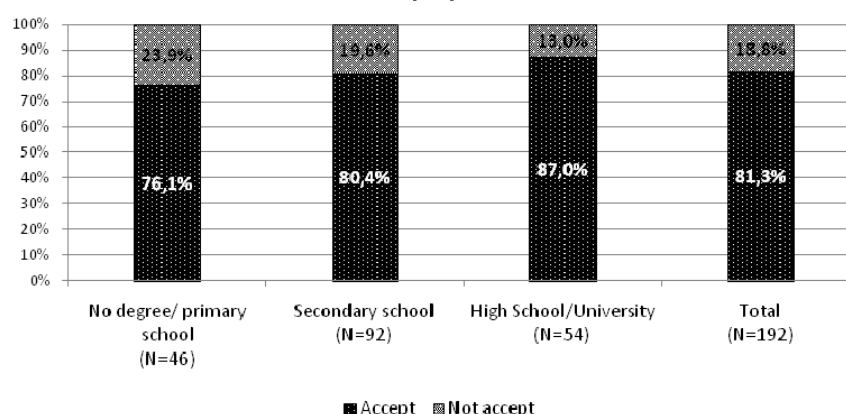


Figure 4-7: Percentage of patients who accepted and completed cardiac rehabilitation programme by education level (all types of rehabilitation)

% of patients accepting cardiac rehabilitation after having been proposed



Employment status

Similar analyses were performed as above and the details are displayed in appendix 3.5.6. For the proposed treatments there were few differences between groups according to employment status.

^w Missing value=1

4.2.3.2 Type of CR centre and proposed, accepted and completed rates of cardiac rehabilitation programmes

Initially, 19 centres agreed to participate to the study: only 15 centres returned the questionnaires (Table 4-3). Details on the centres are in appendix 3.5.7.

Table 4-3: Frequency table of centres per region

	N agreed to participate	% of Total	N actually returned questionnaires	% of Total
Centres in Flanders region	11	57.9%	9	60.0%
Centres in Wallonia region	7	36.8%	5	33.3%
Centre in Brussels	1	5.3%	1	6.7%
Total	19	100.0%	15	100.0%

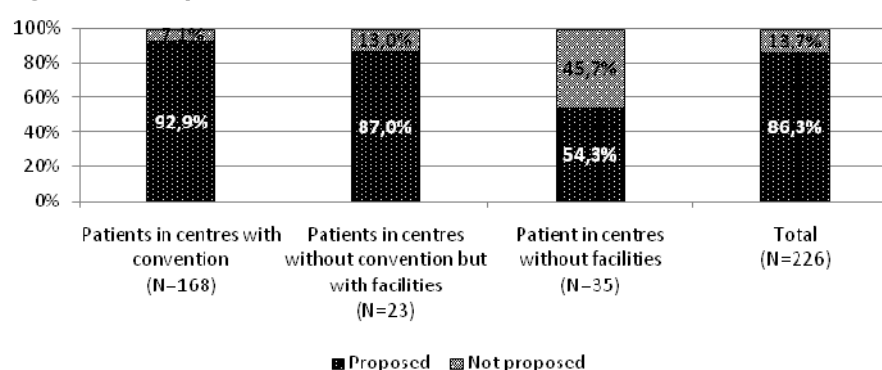
Half of the (10 out of the 19) participating centres were officially authorized CR centres. Two centres had their own facilities for CR without official recognition. Five centres had no CR facilities. Two centres that did not complete the questionnaire were assumed to have no facility.

Table 4-4: Characteristics of the participating centres

	N of centers agreed to participate	% of Total	N of centers actually returned questionnaires	% of Total	N patients from the centers	% of Total
Officially authorized CR Centres	10	52.6%	10	66.7%	168	74.3%
Centres without official recognition but with CR facilities	2	10.5%	1	6.7%	23	10.2%
Centres without facilities	7	36.8%	4	26.7%	35	15.5%
Total	19	100.0%	15	100.0%	226	100.0%

Figure 4-8 shows that most patients in officially authorized CR centres were proposed CR (93%, n=156). The centres without CR facilities proposed the rehabilitation to half of their patients.

Figure 4-8: Percentage of patients who were proposed cardiac rehabilitation programme for patients in different centres

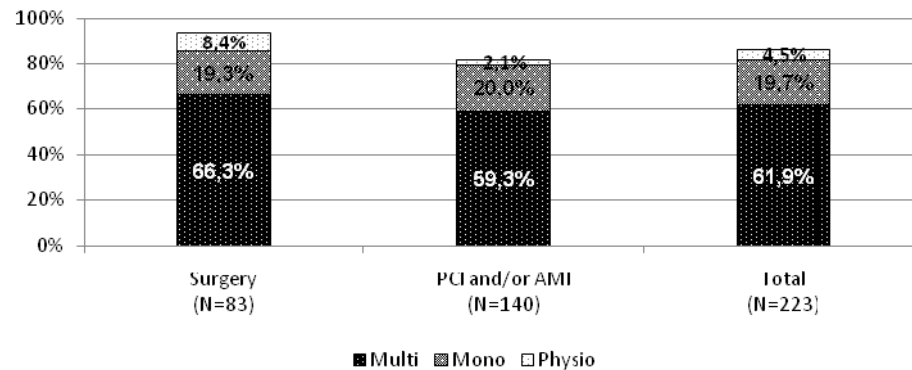


The figures in appendix 3.5.7 show that the acceptance of a multidisciplinary CR is high in the officially authorized CR centres.

4.2.3.3 Patient group and proposed, accepted and completed rates of cardiac rehabilitation programmes

Figure 4-9 shows that patients who underwent surgery had slightly more often a proposal to join a multidisciplinary rehabilitation programme than the other groups of patients.

Figure 4-9: Percentage of patients who were proposed cardiac rehabilitation programme per patient group



The figures in appendix 3.5.8 shows that the acceptance rate of multidisciplinary rehabilitation is similar in all groups.

4.2.3.4 Cardiologists' experience and proposed, accepted and completed rates of cardiac rehabilitation programmes

There is no difference between the patients of the more experienced (>15 years) and less experienced cardiologists in terms of proposal rates, acceptance and compliance. The corresponding figures in appendix 3.5.9. The cut-off of 15 years of experience was the average time the cardiologists participating in the study reported to be active clinicians

4.2.3.5 Reasons for not accepting to enrol in the proposed cardiac rehabilitation programme

Overall 37 patients refused to follow a CR programme, even though it was proposed by their cardiologists. Out of the 37 patients, 13 belonged to the surgery group, 6 to the AMI group and 18^x to the PCI group.

A list of reasons for not accepting the rehabilitation was given in the questionnaires and they were asked to state the importance of each reason by selecting one of the following answers: "Not a reason", "Not an important reason" or "An important reason". Patients were also given the option to write down their individual reasons beyond what the list included (Questionnaires in appendix 3.1).

The top four important reasons for patients' unwillingness to accept the rehabilitation were (Figure 4-10)

1. Cardiac centres too far from patient's residence (43%, n=16)
2. Patients believe they can handle their own problem (27%, n=10)
3. No time to go to the centre (24%, n=9)
4. Patients did not have transportation to go to the centre (24%, n=9)

^x One of the patients in PCI group did not clarify which type of rehabilitation he refused

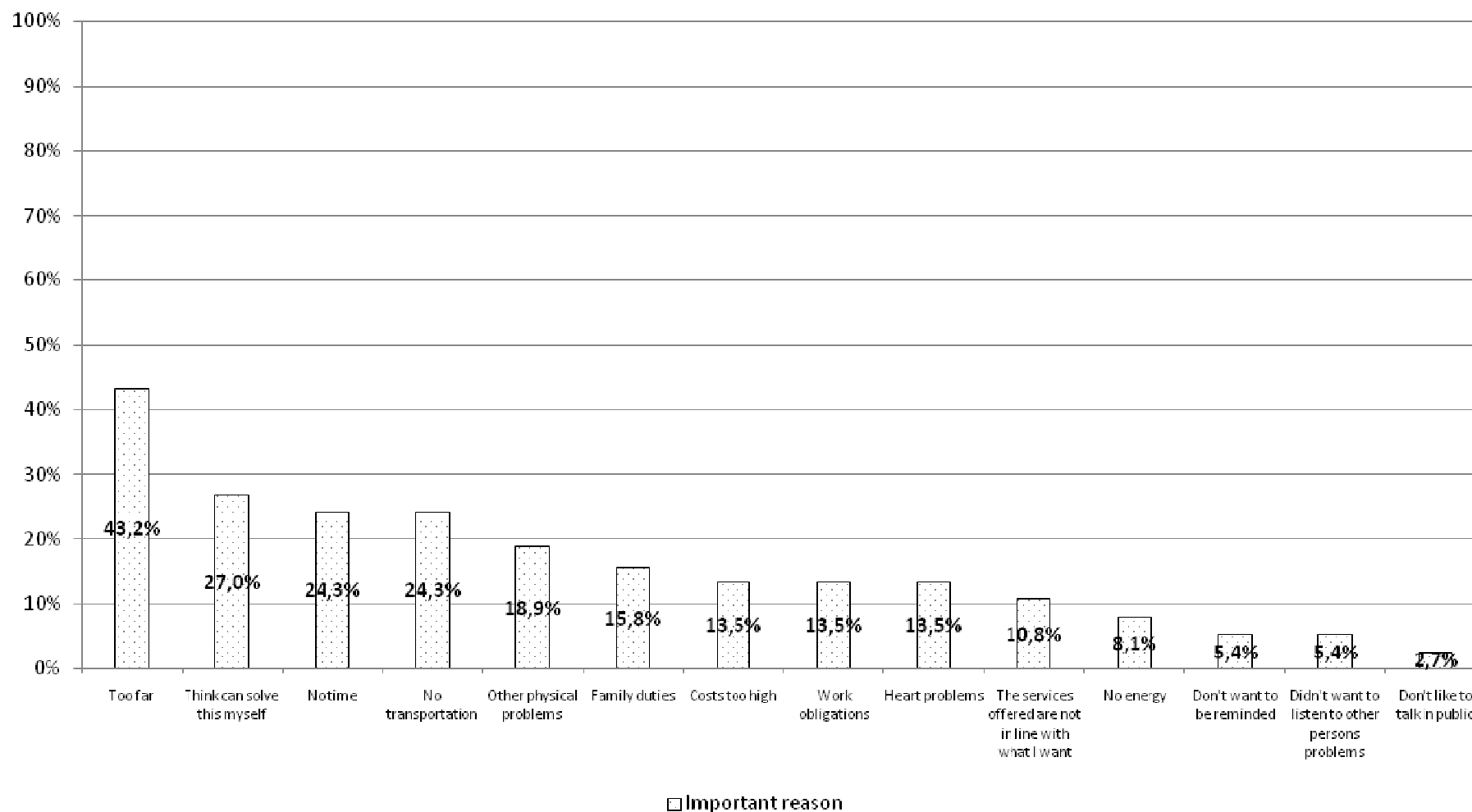
Figure 4-10: Overview of the important reasons for patients' refusal of receiving cardiac rehabilitation (N=37)

Table 4-5 shows the reported distance for patients who had the perception that the CR centre was too far (n=15). The distances reported by the patients who accepted the programme were slightly shorter than the ones who refused to join the programme.

Table 4-5: Descriptive statistic of patients who claimed 'Too far' is an important reason for refusal and their reported distance^y

	Patients who refused the CR and reported 'Too far' as an important reason	Patients who accepted the CR
N of patient	N=15	N=195
Average reported distance	19.4 Km	13.8 Km
StdDev	12.6	10.3
Median	15.0 Km	11.5 Km
Min – Max	7 – 50 Km	1 – 50Km

Reasons according to age, gender and employment status

Males (n= 24) and females (n=13) reported different reasons for not accepting the proposed rehabilitation. The most frequent reasons for male patients were consistent with the overall reasons listed above. For female patients 'No transportation' (7/13) and 'cardiac centre is too far' (5/13) were the most reported reasons. Four female patients reported 'heart problems' as an important reason to refuse the proposed CR.

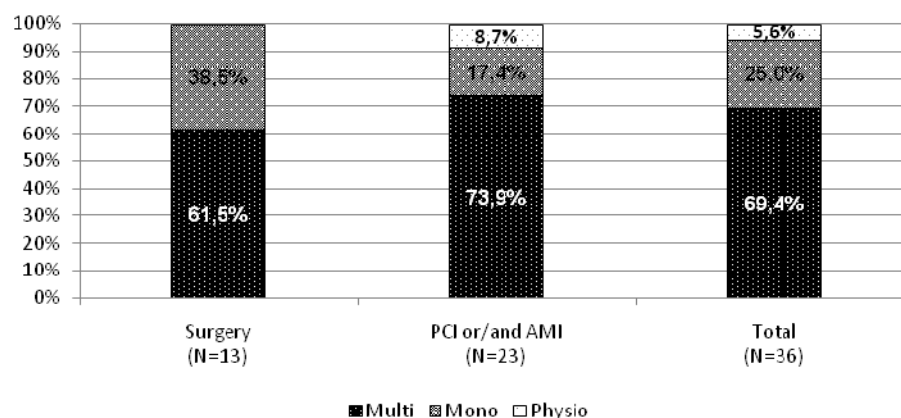
Patients younger than 75 years stated that 'too far' (10/23), 'they can handle their own problem' (9/23) and 'no time' (7/23) to be the important reasons to refuse rehabilitation. Patients aged over 75 stated that 'too far' (6/14), 'no transportation' (5/14) and 'other physical problems' (5/14) were important reasons to refuse rehabilitation.

For people currently in employment (8/37), 'not having the time' (5/8) and 'work obligations' (4/8) were the main reasons to refuse CR. A large proportion of retired patients stated that the distance to the cardiac centre was an important factor (11/19).

4.2.3.6 Reasons for not completing the entire cardiac rehabilitation programme

Overall another 37 patients began but did not complete their CR programme. The figure below shows that the patients in the AMI and/or PCI groups, compared to the surgery group, reported higher rates of not completing of multidisciplinary rehabilitation and physiotherapy.

Figure 4-11: Distribution of patients not completing a rehabilitation programme per patient group^z



^y Missing value=1

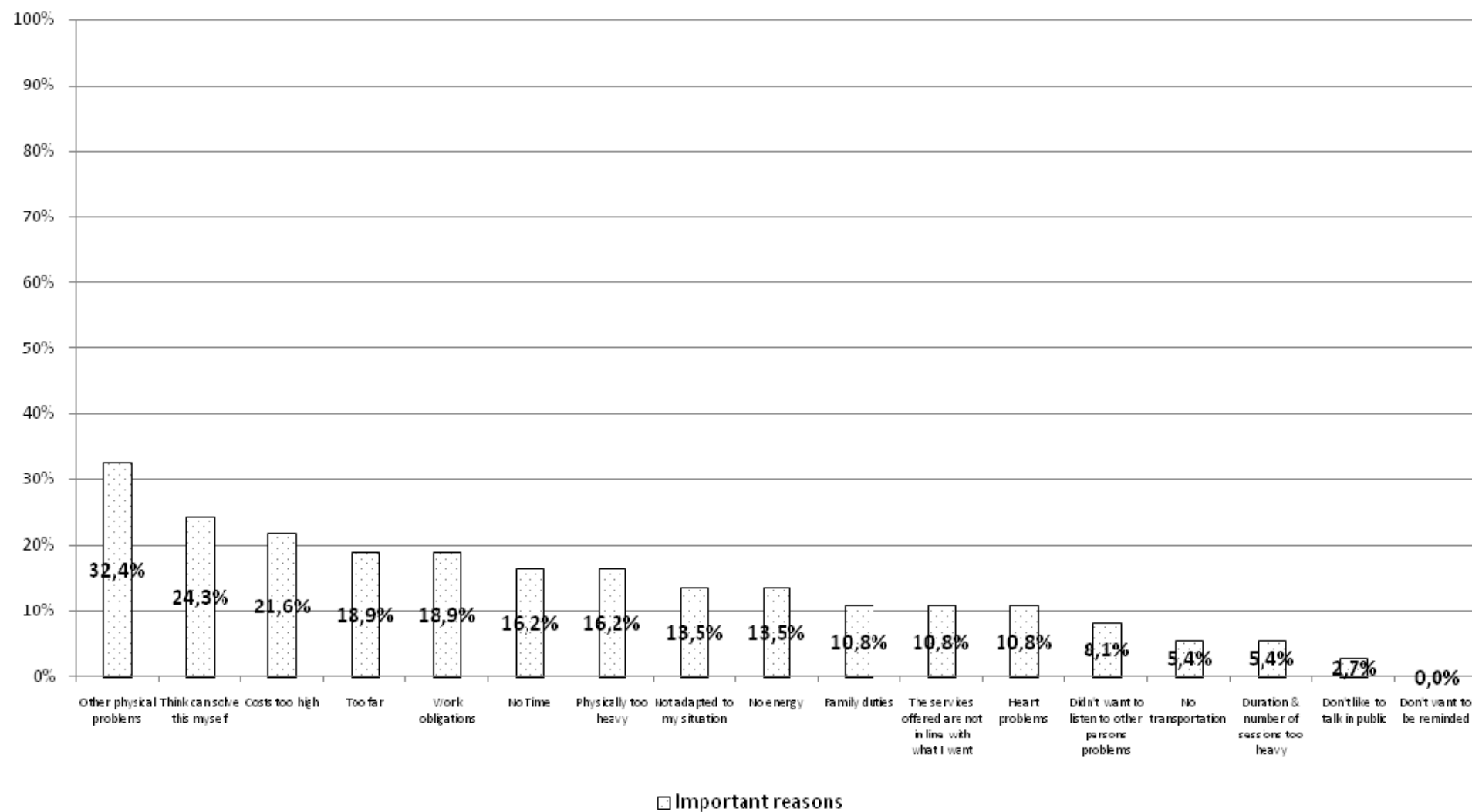
^z Missing value=1

Figure 4-12 provides an overview of the reasons for not completing the prescribed rehabilitation programme. The top five important reasons were:

1. Other physical problems (32%, n=12)
2. Patients believe they can handle their own problems (24%, n=9)
3. Cost of rehabilitation (22%, n=8)
4. Cardiac centres too far from patients' residence (19%, n=7)
5. Work obligations (19%, n=7)

The reasons for not completing the CR programme differ from the reasons for not accepting to enrol in the programme. The primary reason for not accepting to enrol in the proposed CR (i.e. the cardiac centres are too far from patients' residence), is the fifth reason for not completing the entire rehabilitation programme.

Figure 4-12: Overview of the reasons for patients' not completing the prescribed rehabilitation (N=37)



From the descriptive statistics in Table 4-6, it is observed that patients who stopped before the end of the rehabilitation programme on average followed 6.5 weeks of CR. In general, patients following multidisciplinary rehabilitation continued for longer than the patients who followed monodisciplinary PRM or physiotherapy.

Table 4-6: Descriptive statistics of number of weeks patients participated before stopping rehabilitation

	Multi	Mono	Physio	Overall
N of patients	23	9	2	34
Average weeks	7.3	5.4	2.5	6.5
Stdev	6.0	6.3	2.1	6.0
Median	6	2	2.5	4
CI-	4.9	1.3	-0.4	4.5
CI+	9.8	9.6	5.4	8.5
Min - Max	1 - 22	2 - 20	1 - 4	1 - 22

Six patients only stated that the CR centre was too far from their residence as an important reason to stop CR. The reported average distance was similar to the distance reported by the patients who refused the programme i.e. 15.4 kilometres with a range of 6 to 30 kilometres.

The reasons to stop attending the rehabilitation programme for male (N=24) and female (N=13) patients were different. 'Other physical problems' (8/24) and 'can handle the problem themselves' (7/24) were the most reported reason for male patients to stop the rehabilitation. Female patients reported 'had other physical problem' (4/13) and 'physically too heavy' (4/13) as important reasons.

The reasons also varied according to age. For the patients in the 30-54 age brackets, the most reported reasons to stop was the 'lack of time' (4/8) and 'other physical problem' (4/8). For patients in the age-category 55-64, the most reported reason was that they thought they would be able to handle their own problems (6/13). One of the least important reasons for this category was the costs (1/13). The most important reason for the patients aged 65-74, were 'other physical problems' (5/11), 'heart problems' (3/11), 'physically too heavy' (3/11) and 'cost too high' (3/11).

Participants who worked (Including salaried workers and self-employed) claimed that 'work obligations' (6/12) was the most important reason to stop CR. Retired patients stated 'other physical problem' (7/20), 'believe they can handle their own problems' (5/20), 'physically too heavy' (4/20) and 'not adapted to my situation' (4/20) as important reasons for giving up.

4.2.3.7 *Feedback of the patients in relation to the cardiac rehabilitation programme*

Patients who completed the programme: positive feedback

The 121 patients who attended the entire CR programme were invited to provide feedback, positive and negative, on the CR programme. Most of the patients (109) patients gave positive feedback and 39 patients gave negative feedback.

A summary table for positive feedback is displayed in Table 4-7. More than half of the patients (56 out of 105) stated that CR helped them to improve their physical condition; 37 patients commented that the guidance and support were very helpful during the rehabilitation; 26 patients reported their psychologically condition was improved, because they feel more confident and fearless; 22 patients mentioned they were motivated more by being in groups. In addition, 17 of them also liked the fact that they were able to share their feelings with people who had a similar experience. It is worth noting that two patients reported they stopped smoking during their CR.

Table 4-7: Key words used by patients to give a positive feedback

Key words	N
Improved physical condition	56
Guidance/Support is good	37
Better psychological condition (feeling confident, less fear, etc)	26
Like group motivation/pressure	22
General/overall organised well	19
Share feeling/able to communicate	17
Friendly Staff	8
Good Monitoring	7
Help me to change my lifestyle (e.g. stop smoking)	2
Programme adapted to individual capacity	1

Patients who completed the programme: negative feedback

Out of the 39 patients with negative feedback:

- 6 patients were not satisfied with the equipment in the CR centre;
- 6 patients commented that it was difficult to access the rehabilitation centre because of distance and/or transportation;
- 5 patients stated that the level of exercise was too intensive;
- 5 patients stated the time of rehabilitation was not flexible enough (especially those patients who worked);
- 3 patients pointed out that the health professionals were inexperienced and did not understand the needs of elderly patients;
- 2 patients reported that the group size was too large to work efficiently;
- patients also mentioned a lack of improvement in their physical condition, the group pressure, an overall dissatisfaction, a lack of guidance.

Feedback from the patients who did not complete the programme

Initially, only the patients who completed their rehabilitation were asked to give feedback. However 15 patients who stopped rehabilitation also provided positive and negative feedback. Most of them were positive: 11 patients thought the 'guidance and support' were good during the rehabilitation, 9 patients claimed they improved their physical condition and a few of them commented the rehabilitation was well organized and they enjoyed being in a group. Regarding the negative feedbacks, four patients reported a problem with equipment.

4.3 SUMMARY OF RESULTS AND LIMITATIONS OF THE SURVEY

The objective of the survey was to analyse the reasons for (non)-participation in a CR programme in Belgium. The paragraphs below summarize these reasons and the limitations of the survey. The discussion of the results in light of the literature will be integrated in the general discussion (see next chapter).

4.3.1 Main results

The four most frequently reported reasons for not accepting a proposed CR programme (n=37) were:

- The perception of the distance to CR centre (43%)
- Belief they can handle their own problem (27%)
- No time (24%)
- Transportation problems (24%)

The four most frequently reported reasons for not completing the entire CR programme (n=37) were:

- Other physical problems (32%)
- Belief they can handle their own problems (24%)
- Cost of rehabilitation (22%)
- Work obligations (19%)
- The perception of the distance to the CR centre (19%)

More than half of the patients who provided positive feedback responded that their physical conditions were improved as a result of their participation in a rehabilitation programme, the guidance provided at the rehabilitation centres was good and they psychologically felt better.

4.3.2 Limitations of the survey

4.3.2.1 *Small sample size in spite of adaptations of the protocol*

The recruitment of the patients was a major issue. The initial aim was to recruit 399 patients with equal numbers of patients in relation to their disease profile (surgery, AMI, PCI). However, the final number of patients was 226 (57% of the target).

At the beginning of the study, only patients who underwent one of the three predefined cardiac events between July 2008 and December 2008 were enrolled in the survey. The recruitment period had to be extended to June 2009. Moreover, specific difficulties with recruiting AMI patients (without intervention) were reported by the investigators and more patients from the other groups were recruited. Finally, the deadline for returning the questionnaires was extended twice.

4.3.2.2 *Biases*

The results are of interest for the enrolment and compliance of cardiac patients in Belgium. However the representativity of the sample should be put in question given the recruitment procedure and difficulties. The study most probably suffers from biases: the proportion of patients who received the offer of CR was indeed very high and few of them refused the CR.

The first bias might be due to the recruitment of the patients by the cardiologists themselves. Secondly, only 15 centres out of the 126 invited centres agreed to participate and patients from rural areas could differ from patients in urban areas. Moreover most of these participating centres had CR facilities, so probably more compliant patients. It can also be assumed that the cardiologists who returned the survey questionnaires were the most motivated ones hence more keen to prescribe CR. Finally, there might be a response bias from the patients themselves.

4.3.2.3 *Recall bias*

Another potential bias in this study is the “recall bias” where it might have been difficult for patients to recall the proposal of CR, the initial reasons to reject or stop the proposed CR programme.

5 GENERAL DISCUSSION AND CONCLUSIONS

The scope of this report was a review of the evidence on multidisciplinary CR (CR), the CR utilisation in Belgium and the reasons of (non) compliance of the patients.

5.1 DEFINITIONS OF MULTIDISCIPLINARY REHABILITATION

WHO defines multidisciplinary CR as “the sum of activities required to influence favourably the underlying cause of the disease, as well as to ensure the patients best possible physical, mental and social conditions so that they may, by their own efforts, preserve, or resume when lost, as normal a place as possible in the life of the community.”¹.

The European Association of Cardiovascular Prevention and Rehabilitation recently defined the services provided as a part of CR as patient assessment, physical activity counselling, exercise training, diet/nutritional counselling, weight control management, lipid management, blood pressure monitoring, smoking cessation, and psychosocial management¹²¹.

The Belgian description of the multidisciplinary CR stipulates the disciplines that have to perform the screening of the patient and to take part to the multidisciplinary treatment (even though each session does not need to be multidisciplinary). The disciplines involved depend on the decision of the centre that provides the treatment¹⁰

5.2 EVIDENCE ABOUT EXERCISE AND MULTIDISCIPLINARY CARDIAC REHABILITATION INCLUDING EXERCISE

The components of multidisciplinary CR vary between the studies. The consequence is that it is difficult to identify which component(s) specifically explain the outcomes of CR. The findings of the systematic literature review suggest that the exercise component of the rehabilitation proves beneficial and leads to better outcomes than standard care.

As to the currently available evidence, this positive effect is similar between multidisciplinary CR and CR programmes with exercise only. When multidisciplinary CR is directly compared to exercise therapy, no significant differences in health outcomes emerge in a mixed population of cardiac patients (inconclusive evidence for heart failure patients). The interpretation is difficult, as in exercise only programmes a reduction of other risk factors (e.g. smoking) seems to play a positive role as well¹⁸. Moreover, the search for evidence has been limited to systematic reviews and RCTs but publications of lower quality could provide more details on specific interventions. The other potential benefits of CR such as early referral, intensive surveillance of the patients and the social contact during the sessions are hard to disentangle and study individually¹²².

5.3 LACK OF PRECISION ABOUT TARGET POPULATIONS AND OTHER FEATURES OF CARDIAC REHABILITATION

The heterogeneity of study designs prevented from drawing conclusions on specific populations. The initial research question defined specific patient populations with cardiovascular disease or cardiac interventions. However, the SR pool the patient populations and the individual RCTs do not either provide any evidence for specific patient populations (except for heart failure patients). For heart failure, the conclusions of this review are in line with those of the 2008 NIHDl consensus conference¹²³. It is possible that specific populations would have a greater benefit from (multidisciplinary) CR but the analysis of the existing literature does not allow any firm conclusion. Moreover, there is hardly any information on the optimal duration and frequency of the CR as well as on the safety of the different programmes

Finally, it should be noted that, in the currently available evidence, the setting of CR (home-based versus inpatient-based) does not yield a significant difference in the outcomes for patients at moderate to low risk of further cardiac event after MI or revascularisation.

5.4 PARTICIPATION IN REHABILITATION PROGRAMMES IN BELGIUM

The initial research proposal has been triggered by concerns regarding the service provision and accessibility in Belgium (36 official CR centres) as well as the regulatory and financial arrangements enabling patients to benefit from multidisciplinary CR. A report from the Ministry of Public Health's Working Group on Rehabilitation estimated in 2004 that only 15 to 30% of patients for whom CR may be beneficial, benefit from this treatment¹¹. In the same way, two surveys carried out in European countries (in the late 90's and in 2009) concluded that fewer than half of the eligible patients participate to CR programmes in most countries^{124, 125}. For Belgium, this last study (from the CR Section of the European Association of Cardiovascular Prevention and Rehabilitation) estimated the proportion of patients participating in the early post discharge programme (Phase II) and to the long-term maintenance programme (Phase III) to be 15-20% and 5% respectively¹²⁵. A recent review by Thompson and Clark¹²² also highlights the fact that most eligible patients are not given access to CR programmes.

The findings based on the IMA database suggest that about one third (32%, Figure 3-6) of the patients do not receive any rehabilitation (or physiotherapy) session during the year after the index cardiac event. This proportion increases to more than half of the patients (55%, Figure 3-7) when only outpatient rehabilitation or physiotherapy is considered. Only 16% (Figure 3-7) of the patients continue their multidisciplinary CR post-discharge. This finding points out a problem in the continuity of care from inpatient to outpatient rehabilitation. This conclusion is identical to the one of a previous KCE report¹²⁰ which analysed the rehabilitation pathways after specific interventions.

5.4.1 Influence of patient characteristics

5.4.1.1 *Influence of the underlying disease*

Some authors claimed that CR programmes tend to focus on patients with myocardial infarction and may exclude other types of patients e.g. those with acute coronary syndrome, heart failure, cardiomyopathy^{100, 126}. This assumption could not be analysed in this study as the administrative data from IMA do not record the clinical diagnosis. However the patients were classified according to the procedure they went through i.e. percutaneous coronary interventions (PCI) or surgical procedure. The results indicate that surgery patients have a higher chance (80%, Table 3-7) of receiving multidisciplinary rehabilitation, in addition to having a longer treatment with more sessions (Table 3-9), with respect to PCI patients.

The results of the small scale survey performed among 17 cardiologists confirm that 13 of them would always prescribe CR to surgery patients and 7 of them would prescribe it to PCI patients.

5.4.1.2 *Influence of age*

The multivariate analysis performed on IMA data showed that older patients have less chance of receiving outpatient multidisciplinary CR and more chance to have no rehabilitation at all (Table 3-13). However, in the patient survey, the proportion of patients who stated that they received a proposition of rehabilitation treatment did not differ between age groups (approximately 86%). Other studies also support this finding and argue that the attendance of older people is lower than the one of younger people¹²⁷⁻¹²⁹. Tolmie et al. analysed the illness representation and CR perception of a small group of elderly patients. They concluded that CR programmes may not be suitably designed to meet the needs of the elderly in terms of risk factor reduction and programme uptake¹³⁰.

Other reasons of elderly people for not attending or stopping the treatment are also suggested in this report: physical impairment is mentioned by one third of the people who stopped whilst distance and transportation problems are more often mentioned (see below).

5.4.1.3 *Influence of gender*

Women were less likely than men to receive multidisciplinary CR after either PCI or surgery (Table 3-14). Grace et al¹³¹ identified barriers that are more common among women than among men e.g. transportation, family responsibilities, lack of CR awareness, experiencing exercise as tiring or painful, comorbidities.

5.4.1.4 *Ethnic minorities*

The literature mentions racial disparities as a challenge for the success of CR programmes^{122, 129, 132} but the influence of this variable could not be analysed in this study.

5.4.1.5 *Influence of employment, education and income status*

Employment status might also have an impact on the compliance with a CR programme. The IMA database analysis pointed out that patients who are “self-employed”, ‘Invalids and handicapped’ and ‘Unemployed’ had a lower chance of receiving multidisciplinary CR compared to ‘Workers’. The three groups also had more chance of receiving no rehabilitation at all, in particular for the group of self-employed patients (Table 3-15).

The multivariate analysis also confirmed the results of the literature i.e. that higher income^{126, 128, 132} and higher level of education^{129, 133} have a positive impact on the probability of receiving multidisciplinary CR. In the same way, patients entitled to increased reimbursement (i.e. a marker of socioeconomic difficulties) had a lower chance of following this treatment. A literature review by Witt et al confirms that unemployment, together with less education and lower socioeconomic status are associated with a reduction in participating in CR programmes¹³⁴.

5.4.1.6 *Influence of the distance to the centre*

The IMA analysis showed that the patients have a higher chance of receiving multidisciplinary CR if they live in the same “arrondissement” as an officially authorized CR centre (Table 3-16). The characteristics of the patients who answered to the survey further indicated that three quarters of them (74%, n = 130) lived within a 20 kilometres distance from the CR centre. Distance to the CR centre was the most important reason for unwillingness to accept a CR programme (43%, Figure 4-13). This was also one of the top four reasons for not completing the prescribed rehabilitation programme after starting it (19%, Figure 4-15). In the same way, transportation problems were mentioned by a quarter of the patients as a reason for refusing the CR programme (Figure 4-13). Higgins et al also found that patients who attended a CR programme had a significantly shorter travel time than the patients who did not attend¹³⁵. Other studies mention the distance and the travel time as obstacles for attending CR programmes^{126, 128, 132}. This is especially an issue for patients living in rural areas: easy access to transport and to a lesser extent family support and work flexibility were the main determinants of the attendance to CR programmes¹³⁶.

Grace et al. concluded that apart from the distance, greater strength of physician endorsement, being married and fewer perceived CR barriers are factors affecting CR enrollment¹³⁷.

5.4.1.7 *Influence of the patient co-payment*

The IMA database analysis found that patients who had multidisciplinary rehabilitation sessions had higher rehabilitation costs than the other patients. The co-payment for multidisciplinary rehabilitation is on average €191 after PCI and € 290 after cardiac surgery (Figure 3-15 and Figure 3-16). The literature indicates that the medical coverage has a significant impact on CR participation rates^{122, 126, 132}.

The fact that patients entitled to an increased reimbursement are less likely to attend multidisciplinary CR in the IMA data analysis may rather reflect his/her socio-demographic characteristics and worse health status. The survey also pointed out that the cost of the CR programme is one reason for not completing it (7 out of 37 patients). A study from the UK suggested that the level of funding available to the CR programmes has an impact on the uptake of CR services¹²⁸.

5.4.2 Other factors that influence the participation in cardiac rehabilitation programmes

Factors impacting CR referral can be attributed to the patient, to the physician or to the health care system^{132, 138}. Some authors concluded that the positive perception of the physician regarding the effectiveness of the CR has a crucial effect on the referral^{131, 137, 139 129}. The distance between the patient's residence and the CR site has an impact on this physicians' referral pattern.

Another essential factor is the patient's perception of his/her illness and rehabilitation programme¹³². The responses of the participants to the survey demonstrated that one main reason why patients refuse or drop out from the CR programme is their feeling that they can solve themselves their problem (24%, Figure 4-15). Redfern et al concluded that the patients not enrolling in a CR programme had more adverse risk-factor profile and a poorer knowledge of risk factors¹⁴⁰. French et al. found out that MI patients who consider their condition to be controllable, symptomatic and with severe consequences are more likely to attend the rehabilitation programme¹⁴¹.

Those findings point out the importance of raising patients' consciousness on the consequences of their illness and the benefits of CR on health outcomes and quality of life, in particular among patients with a worse cardiovascular profile.

5.4.3 Limits in the comparison between this study and the data from the literature

A few additional points have to be mentioned about comparing the general literature with the results of the IMA data analysis and patient survey. The studies on accessibility of CR did not specify components included whilst this study focused on multidisciplinary CR. Moreover, only outpatient CR was taken into consideration when running the IMA multivariate analysis. This may also lead to differences with the findings in the literature where inpatient CR is frequent. Finally, the patient population in the literature is heterogeneous (e.g. inclusion of patients having CAD and MI). In the analysis of the IMA database only patients with a cardiac procedure (PCI or surgery) were included and the grouping was not based on the initial diagnosis.

Key points: summary

- The findings of the systematic literature review suggest that the exercise component of the cardiac rehabilitation proves beneficial and leads to better outcomes than standard care for all groups of cardiac patients;
- Current evidence suggests that this positive effect would be similar for multidisciplinary CR and for CR programmes with exercise only in a mixed population of cardiac patients (inconclusive evidence for heart failure patients);
- However further research is required to make direct comparisons between both regimens;
- In Belgium, one third of the patients do not receive any rehabilitation session after PCI or surgical procedure;
- More than half of the outpatients (55%) do not receive any rehabilitation session after hospital discharge i.e. 68% of the patients with PCI and 30% of the patients with surgery;
- The main reasons refusing cardiac rehabilitation are by decreasing order: distance (half of the refusals), perception of self control of the problem, lack of time, transport;
- The main reasons to put an end to the treatment are: physical impairment, perception of self control of the problem, costs, distance and professional obligations;
- Older age, female gender, employment status (other than salaried worker), low education level, low income, distance to a cardiac rehabilitation centre are factors that decrease the compliance in this study as well as in the literature;
- The literature suggests other factors e.g. the health care organisation, the referral pattern of the physician, the perception of the patient of the illness and of the CR programme.

6 REFERENCES

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