

HORIZON 2020

Grant Agreement number: 634439-2

The (cost) effectiveness, sustainability and participation levels of current **EUropean **CA**rdiac **R**ehabilitation programmes in **E**lderly (>65 y): a prospective cohort study**



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Cardiovascular diseases (CVDs) are still the leading cause of death in Europe and a major cause of disability and loss of productivity in adults worldwide.

In Europe, CVDs cause over 4 million deaths and 1.9 million deaths in the European Union (EU).



The substantial burden of CVD is further exemplified by a huge economic strain due to significant cost.

Research showed that the annual cost of CVD in the EU is estimated to be **€169 billion a year**, with healthcare costs accounting for 54% of the costs.

Productivity losses represent 24% of the costs and 22% of the costs are related to informal care of people.



Cardiac rehabilitation is considered a **cost-effective intervention** following an acute coronary event

reducing morbidity, mortality and recurrent hospitalisation

improving risk factor management, and is strongly recommended in numerous national guidelines





AHA/ACCF Guideline

AHA/ACCF Secondary Prevention and Risk Reduction Therapy for Patients With Coronary and Other Atherosclerotic Vascular Disease: 2011 Update

A Guideline From the American Heart Association and American College of Cardiology Foundation

Endorsed by the World Heart Federation and the Preventive Cardiovascular Nurses Association

Cardiac rehabilitation

Class I

1. All eligible patients with ACS or whose status is immediately post coronary artery bypass surgery or post-PCI should be referred to a comprehensive outpatient cardiovascular rehabilitation program either prior to hospital discharge or during the first follow-up office visit.^{55,154,161,163} (**Level of Evidence: A**)
2. All eligible outpatients with the diagnosis of ACS, coronary artery bypass surgery or PCI (**Level of Evidence: A**)^{55,154,155,161} chronic angina (**Level of Evidence: B**),^{161,163} and/or peripheral artery disease (**Level of Evidence: A**)^{158,164} within the past year should be referred to a comprehensive outpatient cardiovascular rehabilitation program.
3. A home-based cardiac rehabilitation program can be substituted for a supervised, center-based program for low-risk patients.^{153,159,160} (**Level of Evidence: A**)

Class IIa

1. A comprehensive exercise-based outpatient cardiac rehabilitation program can be safe and beneficial for clinically stable outpatients with a history of heart failure.^{158,159a-159c} (**Level of Evidence: B**)



European Heart Journal (2012) 33, 1635–1701
doi:10.1093/eurheartj/ehs092

JOINT ESC GUIDELINES

European Guidelines on cardiovascular disease prevention in clinical practice (version 2012)

The Fifth Joint Task Force of the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice (constituted by representatives of nine societies and by invited experts)

Developed with the special contribution of the European Association for Cardiovascular Prevention & Rehabilitation (EACPR)[†]

Recommendation for specialized prevention centres

Recommendations	Class ^a	Level ^b	GRADE	Ref ^c
All patients requiring hospitalization or invasive intervention after an acute ischaemic event should participate in a cardiac rehabilitation programme to improve prognosis by modifying lifestyle habits and increasing treatment adherence.	Ila	B	Strong	205, 250

Surveys show that only 30% participate in Cardiac Rehabilitation

EDITORIAL

Treatment of Patients With Coronary Heart Disease Fails to Meet Standards of European Guidelines: Results of EUROASPIRE Surveys

Kornelia Kotseva

Cardiovascular Medicine, National Heart & Lung Institute, Imperial College, London, United Kingdom

Rev Esp Cardiol. 2009;62(10):1095-8

Health Services and Outcomes Research

Use of Cardiac Rehabilitation by Medicare Beneficiaries After Myocardial Infarction or Coronary Bypass Surgery

Jose A. Suaya, MD, PhD; Donald S. Shepard, PhD; Sharon-Lise T. Normand, PhD;
Philip A. Ades, MD; Jeffrey Prottas, PhD; William B. Stason, MD, MSc

Circulation. 2007;116:1653-1662

A position paper from the Cardiac Rehabilitation Section of the EACPR mentions that **older cardiac patients** are often excluded from CR programmes



European Heart Journal (2010) 31, 1967–1976
doi:10.1093/eurheartj/ehq236

Secondary prevention through cardiac rehabilitation: physical activity counselling and exercise training

Key components of the position paper from the Cardiac Rehabilitation Section of the European Association of Cardiovascular Prevention and Rehabilitation

Among patients referred, many do not complete the rehabilitative programme and <50% maintain exercise regimen after Cardiac Rehabilitation programme (*Daly 2002, Moore 2003*).

This is especially the case of elderly people, as there is a lack of commitment and adherence to CR with only a minority completing the full programme.



Cardiac Rehabilitation in the Elderly

Arthur R. Menezes^a, Carl J. Lavie^{a,b,*}, Daniel E. Forman^{c,d}, Ross Arena^e,
Richard V. Milani^a, Barry A. Franklin^f



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A B S T R A C T

Coronary heart disease (CHD) is the leading cause of death worldwide. Advanced age is associated with a higher prevalence of CHD as well as increased morbidity and mortality. One key vulnerability relates to the fact that older individuals are generally among the least fit, least active cohort and at increased risk of complications after an acute cardiac event and/or major surgery. There is ample evidence to demonstrate the beneficial effects of exercised-based cardiac rehabilitation (CR) programs on improving functional capacity and other indices of cardiovascular (CV) health. **Although the predominant number of studies is in middle-aged patients, there is an escalating amount of new information that establishes the cardioprotective role of CR and, in particular, structured exercise therapy (ET) among the elderly.** The present review summarizes the current data available regarding CR and ET and its salutary impact on today's growing population of older adults with CHD.

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Why the EU-CaRE study?

Limited knowledge on effects of “real-life” cardiac rehabilitation in the elderly in Europe

What can we learn from each other?

What are the patient, provider and health system characteristics that predict successful CR uptake, completion and sustainable effects among the elderly



EU-CARE



Objective

To compare the sustainability and effectiveness of 8 European Cardiac Rehabilitation programmes in the elderly (≥ 65 years) population with respect to physical fitness, cardiovascular risk factor control, general health and utilisation of care, adherence and cost-effectiveness.

To identify the main individual and centre related predictors for sustainable and effective CR programmes, defined as lasting improvement of physical, mental and social outcomes in elderly patients (≥ 65 years).

To define the core components for effective recruitment of elderly patients (≥ 65 year) into CR programmes.

Objective 1 Investigate (sustainable) effectiveness CR programmes

The first study objective is to compare the (sustainable) effectiveness of 8 European CR programmes in the elderly population with respect to effect of rehabilitation (physical fitness, general health and utilisation of care), level of adherence and (cost-) effectiveness.

Objective 2 Identify the main predictors for sustainable effective CR programmes

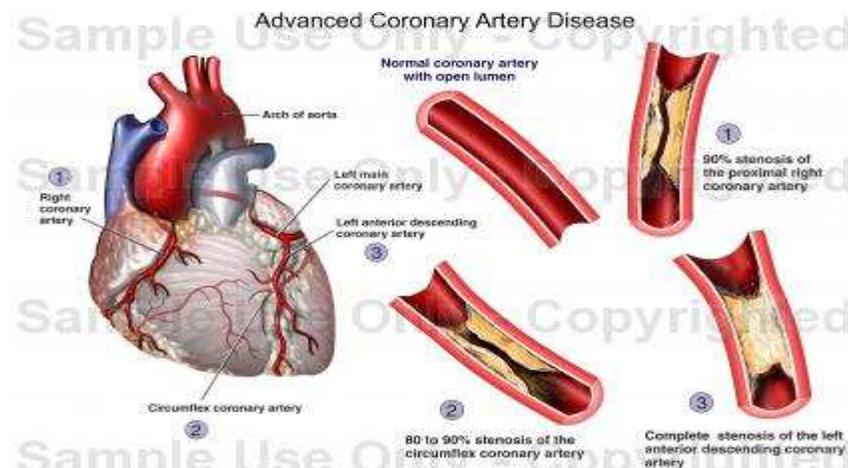
The second objective of the study is to define patient and programme characteristics and factors at the centre level which are related to sustainable effects of the CR programmes.

Objective 3 To define the core components for effective recruitment of elderly patients into CR programmes

In order to select relevant core components of recruitment into CR programmes we will perform a mixed models logistic regression analysis with participation as dichotomous outcome variables and centre and patient as random effects, and relevant patient, centre, CR programme and socio-economic characteristics as fixed effects. A two-sided p-value

Inclusion criteria

- Patients aged 65 years or older
- Patients who have accepted Cardiac Rehabilitation
- Patients who signed a written consent
- Patients who meet one of the following criteria within 3 months prior to the start of CR programme:
 1. acute coronary syndrome (ACS)
 2. underwent percutaneous coronary intervention (PCI)
 3. received coronary artery bypass grafting (CABG).



Exclusion criteria

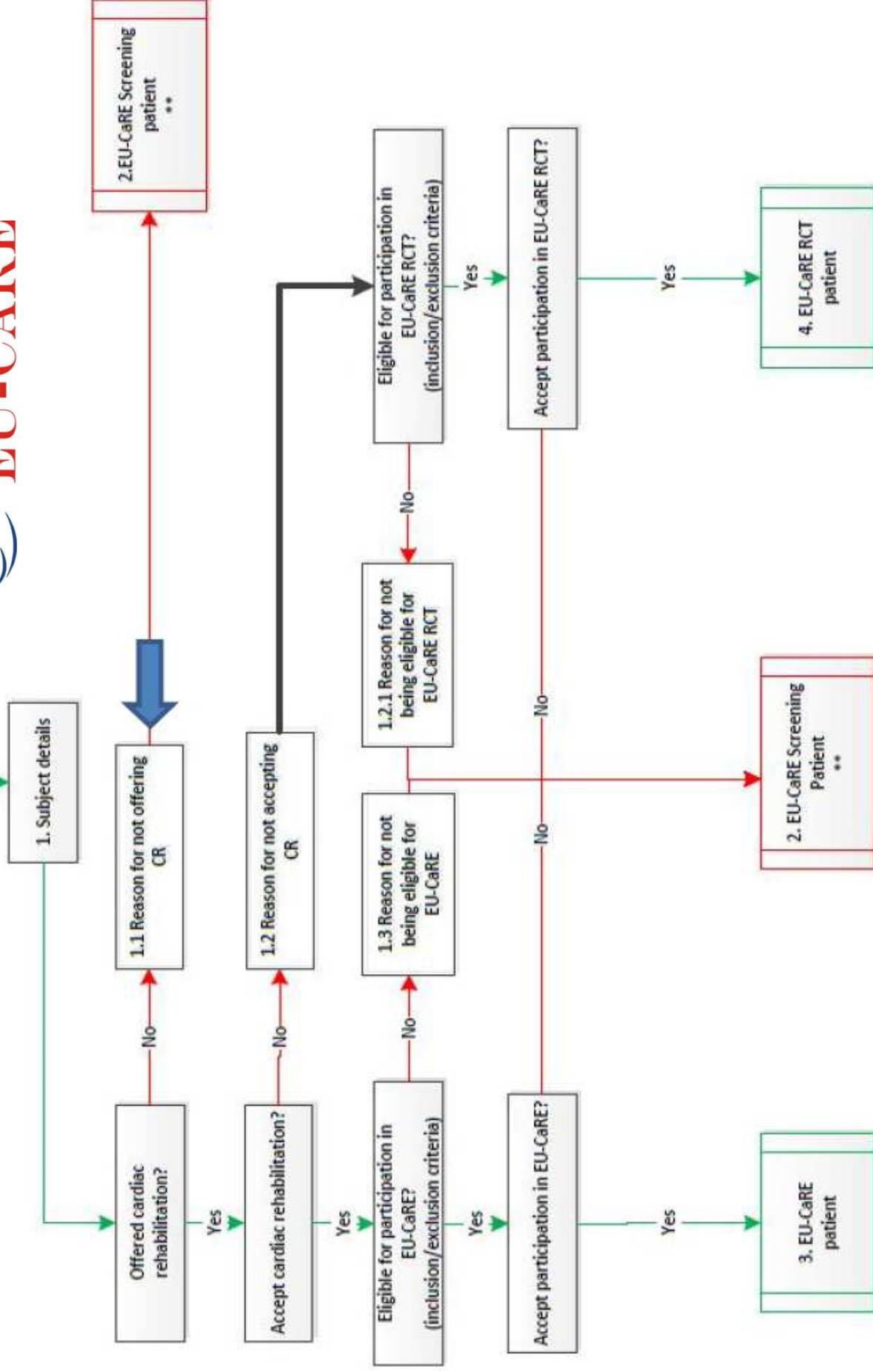
- contraindication to CR;
- mental impairment leading to inability to cooperate;
- severe impaired ability to exercise;
- signs of severe cardiac ischemia;
- insufficient knowledge of the native language;
- cardiac surgery in history prior to the last event;
- implanted cardiac device (CRT or PM dependent)



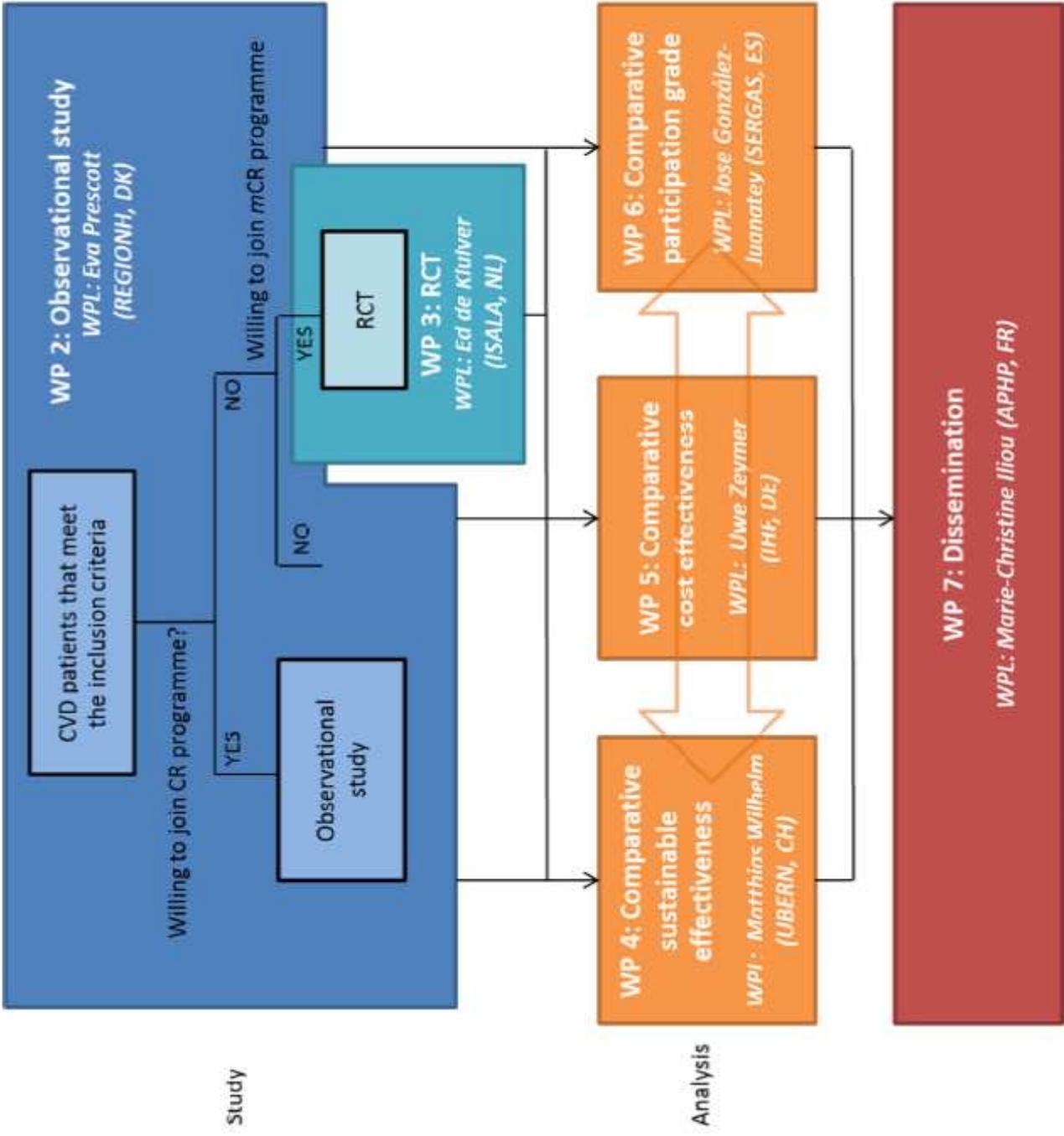
All patients (65+years)
with MI, PCI, CABG

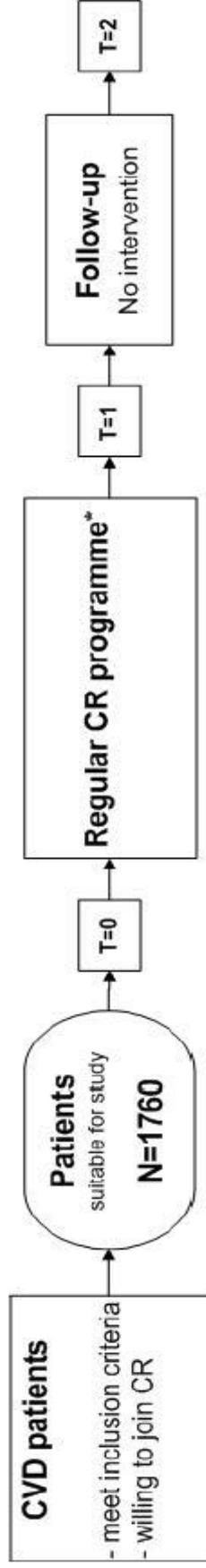


EU-CaRE



WP1: project management
WPL: Arneud van 't Hof (ISALA, NL)





* Duration of CR programme differ per participating centre

T=0 (baseline)

- Physical fitness
- Traditional risk factors
- Care utilisation
- MACE
- Questionnaires
- Patient characteristics
- Centre characteristics

T=1 (End of CR)

- Physical fitness
- Traditional risk factors
- Care utilisation
- MACE
- Questionnaires

T=2 (12 months)

- Physical fitness
- Traditional risk factors
- Care utilisation
- MACE
- Questionnaires

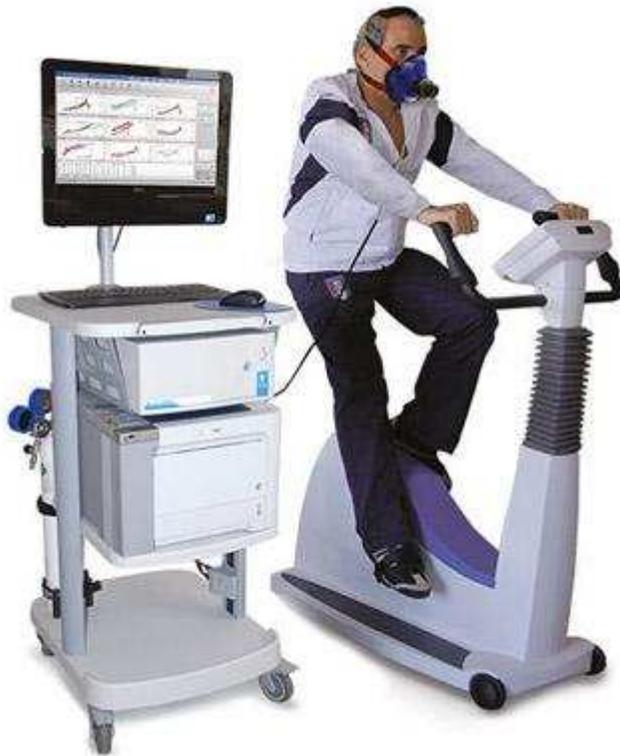
PROCEDURE / TEST	Enrollment (± 7 days)	End of CR program (T1) (± 14 days)	End of study (T2 - ± 14 days)
Patient eligibility	✓		
Patient Informed Consent	✓		
Patient characteristics:			
- Demographic	✓		
- Physical	✓		
- Medical history	✓		
- Risk factors	✓		
- Medication	✓		
- Indication for CR	✓		
Centre characteristics			
- Characteristic of CR programme	✓		
- Socio-economic characteristic	✓		
Maximal ergometer exercise test	✓	✓	✓
12-Lead ECG	✓	✓	✓
Physical examination:			
- Weight, length, BMI, lean body mass, blood pressure	✓	✓	✓
Clinical Laboratory test:			
- Lipid profile, ProBNP, renal function and HbA1C	✓	✓	✓
Questionnaires			
- SF36/RAND 36	✓	✓	✓
- PHQ-9	✓	✓	✓
- GAD-7	✓	✓	✓
Care utilisation Monitoring²	✓	✓	✓
(Serious) Adverse Events Monitoring²	✓	✓	✓



Main study endpoint

Different in peak oxygen uptake (VO_2 peak) between the start of CR programme and his end (after 6 weeks to 3 months).

VO_2 peak = functional capacity



VO2 peak increase:

Preservation of mobility, independence and mental function

Improving quality of life

Encouragement of social adaptation and reintegration

Prevention/ treatment of anxiety and depression

Enabling the patient to return to the same lifestyle as before the acute event



Secondary study endpoints/outcomers

Different in VO₂peak between 12 months (T2) e T0.

Different in VO₂peak between T2 e T1.

Traditional risks factors in cardiovascular disease.

Major Adverse Cardiovasculare Events (MACE)

General health

Care utilization

Adherence and compliance



Secondary study endpoints/outcomers

Difference in VO_{2peak} from an incremental exercise test (T2-T0, T2-T1)

Traditional risk factors:

- Changes in lipid profile (T1-T0, T2-T0)
- Changes in ProBNP (T1-T0, T2-T0)
- Changes in HbA1C (T1-T0, T2-T0)
- Changes in renal function (T1-T0, T2-T0)
- Changes in lean body mass (T1-T0, T2-T0)
- Changes in blood pressure (T1-T0, T2-T0)
- Changes in smoking habit (T2-T0)

MACE: the occurrence of events (cardiovascular (CV) mortality, all-cause mortality, near sudden cardiac death, ACS, CV intervention/surgery, CV hospital admission, CV emergency visits) as composite endpoint (T1-T2) are registered and collected by monthly telephone calls.

General health:

- Difference in depression score assessed by: PHQ-9 questionnaire (T1-T0, T2-T0)
- Difference in anxiety score assessed by GAD-7 questionnaire (T1-T0, T2-T0)
- Quality of Life: SF-36/RAND 36, difference in Physical Component Summary Score and Mental Component Summary Score (T1-T0, T2-T0)

Care utilisation as composite endpoint of: (number of) admissions, emergency visits and cardiac interventions (PCI, CABG) (T1-T2)

Adherence: the occurrence of drop-outs (including reason for drop-out) or completed CR is registered per CR programme throughout the study period.

Compliance: percentage of attended training sessions is registered per CR programme.

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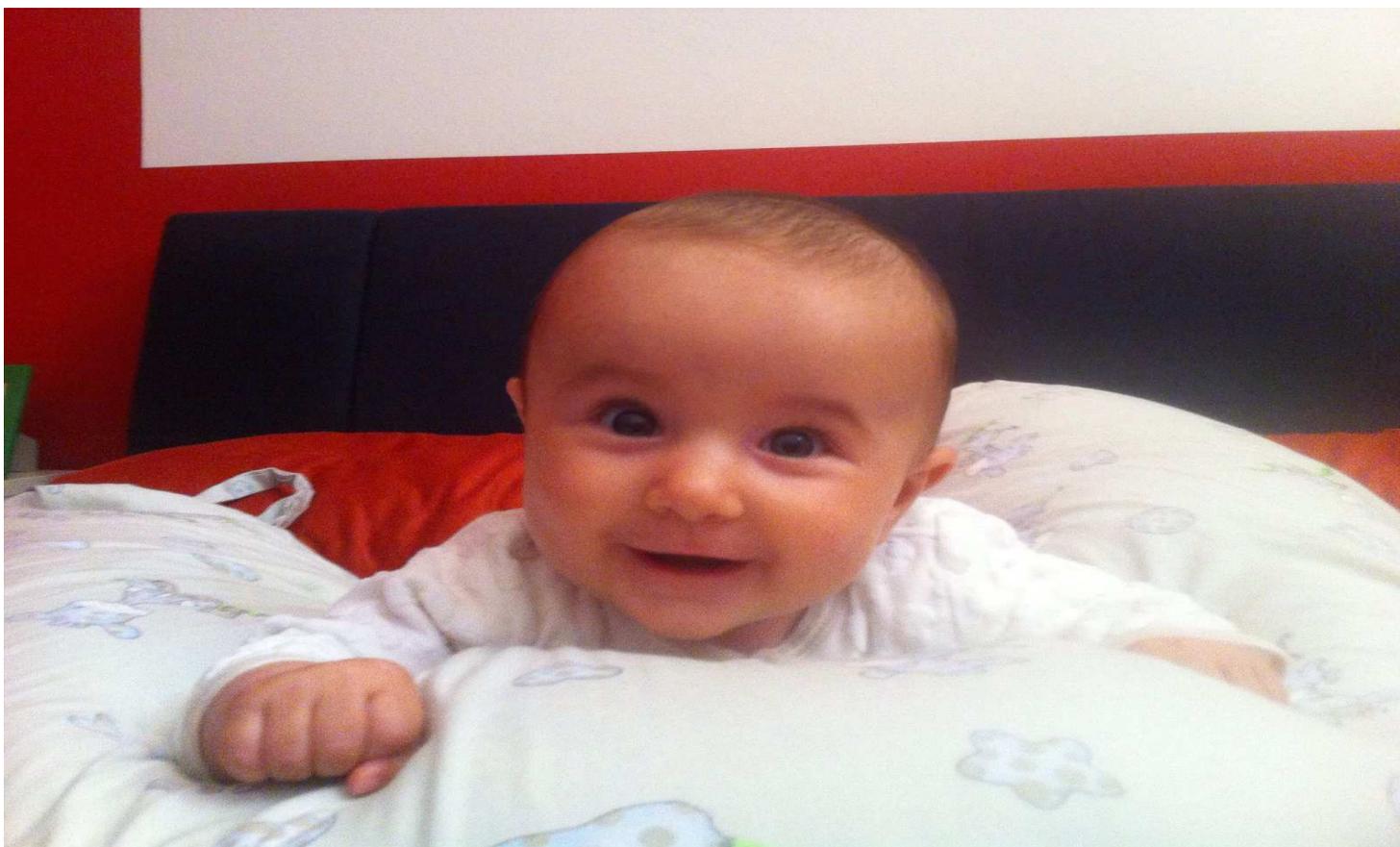


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Onlus

Responsabile Prof. Paolo Coruzzi



GRAZIE PER L'ATTENZIONE





The (cost) effectiveness, sustainability and participation levels of current **EUropean **CA**rdiac **R**ehabilitation programmes in **E**lderly (>65 y): a prospective cohort study**

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EU-CARE







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CLINICAL RESEARCH

Coronary Artery Disease

Cardiac Rehabilitation and Survival in Older Coronary Patients

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 Sharon-Lise T. Normand, PHD,‡ Donald S. Shepard, PHD*
Waltham and Boston, Massachusetts; and Burlington, Vermont

Table 2 All-Cause 5-Year Cumulative Mortality Rates for Matched Pairs of CR Users and Nonusers by Demographic Characteristics

Participant Groups	Number of Matched Pairs	Cumulative Mortality Rates		
		CR Users	Nonusers	Difference*
All matched pairs	70,040	16.3%	24.6%	8.3%
By sex and age group				
Men	44,550	18.1%	25.2%	7.1%
Age 65-74 yrs	30,003	14.2%	19.9%	5.7%
Age 75-84 yrs	13,790	24.9%	34.7%	9.8%
Age ≥85 yrs	757	47.3%	61.8%	14.5%
Women	25,490	14.2%	24.5%	10.4%
Age 65-74 yrs	15,678	11.5%	19.7%	8.2%
Age 75-84 yrs	9,135	17.2%	30.7%	13.4%
Age ≥85 yrs	677	34.4%	53.9%	19.5%
By race				
Whites	67,569	16.6%	24.9%	8.3%
Nonwhites	2,471	18.1%	26.1%	9.9%

Low participation partly due to low referral rates

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Coronary Artery Disease

Predictors of Cardiac Rehabilitation Referral in Coronary Artery Disease Patients

Findings From the American Heart
Association's Get With The Guidelines Program

Despite the proven benefits of CR and the national guideline recommendations, cardiac rehab continues to be significantly underutilized.

Table 1 Baseline Demographic and Clinical Characteristics
in the Overall Population and in Those Referred and Not Referred to CR

	Overall Population (n = 72,817)	Not Referred to CR (n = 31,843)	Referred to CR (n = 40,974)	p Value
Age (yrs)	64 (55-74)	65 (55-75)	63 (54-73)	<0.0001

OBIETTIVI:

1. Valutare **l'efficacia sostenibile** di 8 programmi europei di riabilitazione CV in pazienti con più di 65 anni. In considerazione della fitness fisica, del controllo dei fattori di rischio, dello stato di salute generale, della compliance e dell'aderenza alla terapia.
2. Identificare nei vari centri europei i principali predittori di efficacia sostenibile dei programmi di riabilitazione definiti come miglioramento degli outcome fisici, mentali e sociali.

STUDY DESIGN:

Studio prospettico di coorte.

Eva Prescott....



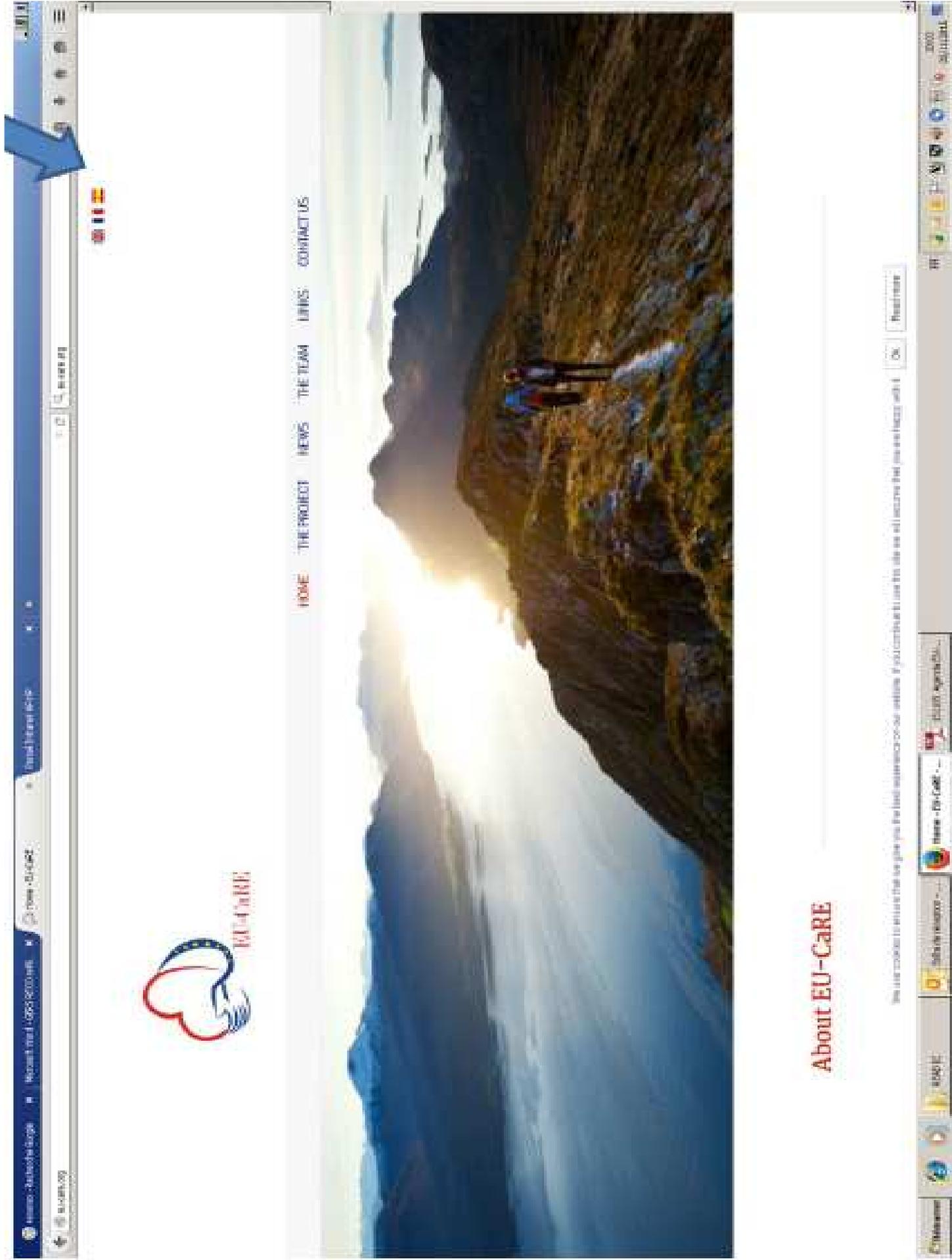
In totale 1760 pazienti arruolati in 8 centri di riabilitazione europea (220 pazienti per centro).

Main study endpoint

Difference in peak oxygen uptake (VO_{2peak}) between the end of CR programme (T1) and baseline (T0)

Secondary study endpoints/outcomes:

- Difference in VO_{2peak} between 12 months (T2) and T0
- Difference in VO_{2peak} between T2 and T1
- Traditional risk factors
- Major Adverse Cardiovascular Events (MACE)
- General health
- Care utilisation
- Costs of care utilisation
- Adherence
- Compliance



About EU-CaRE

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Team members of Preventive Cardiology & Sports Medicine, University Hospital Berne, Switzerland

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04-05-2015

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Cardiac rehabilitation should offer:

- Exercise training
- Physical activity counselling
- Diet/nutritional counselling
- Risk factor management: Weight, lipids, blood pressure, smoking cessation
- Psychosocial management
- Patient education
- Optimal medication

And is associated with:

- Reduction in cardiovascular events
- Improved survival
- Improved functional status
- Improved psychological well-being

Objective

1. to compare the **effectiveness of currently available CR programmes from 8 European institutes** in the elderly (> 65 year) population, by collecting relevant data, and analysing and reporting results.
2. to assess the effectiveness of new innovative mobile telemonitoring guided CR (*mCR*) *not opting for conventional CR*.
3. to determine the main preconditions for **sustainable and effective** CR programmes in the elderly, mainly related to lasting improvement of the physical condition, but also related to risk factors, general health (mental health and quality of life), and health care utilisation .
4. To analyse the induced and avoided costs and revenues of CR and mCR programmes to determine the cost effectiveness of different approaches .

In 1993 the World Health Organisation (WHO) offered a definition of cardiac rehabilitation that summarises very well its objectives:

“The sum of activity and interventions required to ensure the best possible physical, mental and social conditions, so that patients with chronic or post-acute CVD may, by their own efforts, regain their proper place in society and lead an active life”.

WHO Technical Report Series

831

**REHABILITATION AFTER
CARDIOVASCULAR DISEASES,
WITH SPECIAL EMPHASIS ON
DEVELOPING COUNTRIES**

Report of a
WHO Expert Committee



World Health Organization

Geneva 1993



Generalised Anxiety Disorder Assessment (GAD-7)

This easy-to-use self-administered patient questionnaire is used as a screening tool and severity measure for generalised anxiety disorder (GAD).^{[1][2]}

Generalised Anxiety Disorder Questionnaire (GAD-7)	
Over the last 2 weeks, how often have you been bothered by any of the following problems?	
Feeling nervous, anxious or on edge?	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day
Not being able to stop or control worrying?	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day
Worrying too much about different things?	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day
Trouble relaxing?	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day
Being so restless that it is hard to sit still?	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day
Becoming easily annoyed or irritable?	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day
Feeling afraid as if something awful might happen?	<input type="radio"/> Not at all <input type="radio"/> Several days <input type="radio"/> More than half the days <input type="radio"/> Nearly every day
Total=	<input type="text"/> /21



PATIENT HEALTH QUESTIONNAIRE - PHQ-9

Il presente questionario è importante perché ci consente di fornirLe la miglior assistenza possibile. Le Sue risposte ci aiuteranno a capire i problemi che Lei può avere. La preghiamo, perciò, di rispondere con la massima precisione possibile.

	Mai	Molti giorni	Più della metà dei giorni	Quasi tutti i giorni
1. Durante le ultime due settimane, con quale frequenza è stato disturbato da qualcuno dei seguenti problemi?				
a. Scarso interesse o piacere nel fare le cose	0	1	2	3
b. Sentirsi giù, depresso o disperato	0	1	2	3
c. Difficoltà ad addormentarsi o mantenere il sonno, o dormire troppo	0	1	2	3
d. Sentirsi stanco o avere poca energia	0	1	2	3
e. Scarso appetito o mangiare troppo	0	1	2	3
f. Sentirsi in colpa o di essere un fallito o di aver danneggiato se stesso o la sua famiglia	0	1	2	3
g. Difficoltà a concentrarsi sulle cose, come leggere il giornale o guardare la televisione	0	1	2	3
h. Muoversi o parlare così lentamente tanto che anche gli altri se ne accorgono o, al contrario, essere così irrequieto o agitato da doversi muovere da ogni parte molto più del solito	0	1	2	3
i. Pensare che sarebbe meglio essere morto o di farsi del male in qualche modo	0	1	2	3

2. Se ha riscontrato la presenza di qualcuno dei problemi indicati nel presente questionario, in che misura quei problemi le hanno creato difficoltà nel suo lavoro, nel prendersi cura delle cose a casa o nello stare insieme agli altri?

	Nessuna difficoltà	Qualche difficoltà	Notevole difficoltà	Estrema Difficoltà
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

QUALITY OF LIFE QUESTIONNAIRE (SF-36v2™ Health Survey)

Form # 38

This survey asks for your views about your health, how you feel and how well you are able to do your usual activities. Answer every question by checking the appropriate response. There are no right or wrong answers. If you are unsure about how to answer a question, please give the best answer you can.