

Best practice in psychological activities in cardiovascular prevention and rehabilitation: Position Paper

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Abstract

Recent guidelines on cardiovascular disease prevention suggest multimodal behavioral interventions for psychosocial risk factors and referral for psychotherapy in the case of clinically significant symptoms of depression and anxiety overall. Accordingly, psychologists of the Italian Association for Cardiovascular Prevention, Rehabilitation and Epidemiology (GICR-IACPR) have reviewed the key components of psychological activities in cardiovascular prevention and rehabilitation (CPR). The aim of this study was to elaborate a position paper on the

best practice in routine psychological activities in CPR based on efficacy, effectiveness and sustainability.

The steps followed were: i) a review of the latest international guidelines and position papers; ii) analysis of the evidence-based literature; iii) a qualitative analysis of the psychological services operating in some reference Italian cardiac rehabilitation facilities; iv) classification of the psychological activities in CPR as low or high intensity based on the NICE Guidelines on psychological interventions on anxiety and depression.

We confirm the existence of an association between depression, anxiety, social factors, stress, personality and illness onset/outcome and coronary heart disease. Evidence for an association between depression, social factors and disease outcome emerges particularly for chronic heart failure. Some positive psychological variables (*e.g.*, optimism) are associated to illness outcome. Evidence is reported on the impact of psychological activities on 'new' conditions which are now indicated for cardiac rehabilitation: pulmonary hypertension, grown-up congenital heart, end-stage heart failure, implantable cardioverter-defibrillator and mechanical ventricular assist devices, frail and oldest-old patients, and end-of-life care. We also report evidence related to caregivers. The Panel divided evidence-based psychological interventions into: i) low intensity (counseling, psycho-education, self-care, self-management, telemedicine, self-help); or ii) high intensity (individual, couples and/or family and group psychotherapy, such as stress management). The results show that psychotherapy is consisting of cognitive-behavioral therapy (mainly), interpersonal therapy, and short term psycho-dynamic therapy.

The current data further refine the working tools available for psychological activities in CPR, giving clear directions about the choice of interventions, which should be evidence-based and have at least a minimum standard. This document provides a comprehensive update on new knowledge and new paths for psychologists working in the CPR settings.

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Introduction

The aim of this position paper is to serve as a tool for consultation in order to promote best practice (based on effectiveness, efficiency and sustainability) in the daily clinical activity of psychologists working in the Cardiovascular Prevention and Rehabilitation (CPR) setting. Since the publication in 2003 of the “Guidelines for psychology activities in cardiologic rehabilitation and prevention” [1] there has been a constant growth both in the number of psychological interventions performed in the real-world of CPR [2] and in the publication of articles, meta-analyses and systematic reviews [3-8] on the association between heart disease, psychological variables and psychological interventions. Therefore, the need has emerged to update the knowledge not only as regards the traditional indications for CPR interventions - coronary heart disease (CHD), chronic heart failure (CHF) and cardiac surgery - but also concerning psychological activities in other scenarios of cardiovascular disease (CVD) where the indication for rehabilitation treatment has emerged more recently, such as pulmonary hypertension, grown-up congenital heart (GUCh), end-stage heart failure, use of implantable cardioverter-defibrillator and mechanical ventricular assist devices, frail and older/oldest patients, and end-of-life care. This document also includes an analysis of family/caregivers and their specific need for psychological interventions: in fact, numerous reports in the literature [9] now show the positive effects of good family and social support on CVD outcome in terms of better adherence and reduced readmissions, particularly in elderly patients who are increasingly referred to CPR programs and for whom the importance of a neuropsychological evaluation is also stressed.

A special feature of this paper is the introduction of a low/high intensity grade for classifying the psychological interventions, in line with the NICE guidelines on psychological interventions for anxiety and depression disorders [10]. In the nineties, in fact, the “stepped care” model was introduced [11] which envisaged the planning of clinical psychology and psychotherapy interventions at different levels of intensity and complexity (low or high) according to the results of the initial assessments carried out [12]. In 2007, the British government approved the “Improving Access to Psychological Therapies” (IAPT) Program [13] to facilitate the access of people with common emotional disorders to evidence-based psychological treatments (Care Services Improvement Partnership, 2007). This program is characterized by three steps, the first of which is related to psy-

chological evaluation and eventual monitoring over time; the second consists of low-intensity interventions suitable for patients with less severe disorders and/or of recent onset, such as education, counseling, relaxation techniques, and self-help groups; the third provides for more severe patients with high-intensity interventions, mainly psychotherapeutic treatments. The extensive and now widespread application of the IAPT model has confirmed its appropriateness, effectiveness and efficiency [14-16].

The low/high intensity classification allows the psychologist to identify and select, based on scientific evidence, interventions that can be adapted to different patients, different organizational regimes (hospitalization, day hospital, outpatient) and to the time available (full-time, part-time, or consultant psychologist). The IAPT treatment pathway is self-correcting in the sense that, if a patient with sub-threshold symptoms deteriorates over time or does not gain benefit from low-intensity treatments, he/she will go on to high-intensity treatments.

Methods

The criteria used to elaborate this position paper on best practice were based on:

- consultation of the latest international guidelines and consensus statements produced by the major scientific societies;
- identification of a reference bibliography based on evidence of effectiveness through a search of the most well-known databases (Cochrane Library, Medline, PsychINFO [2005-2017]);
- qualitative analysis of the psychological services offered in some reference cardiac rehabilitation facilities.

We did not examine in this document the psychological approach and treatments for addictions and sexuality, for which the reader should refer to the relative guidelines.

In presenting the evidence for the association between psychological variables and disease manifestation/outcome and/or for the association between psychological variables and clinical condition, the strength of evidence is graded as strong, moderate, or mild. “Onset” of a disease is defined as its occurrence, while the term ‘outcome’ refers to its clinical trend (new events, mortality). For each pathology, after a brief discussion, we provide a synthesis of the evidence of the associations between psychological variables and disease and of the psychological interventions.

The evidence-based interventions are divided into two levels according to the NICE model [10] (Table 1).

Table 1. Evidence based interventions divided into two levels according to the NICE model.

Low intensity = interventions of low complexity performed by the psychologist and/or in collaboration with the multidisciplinary team:

- Individual and/or group counseling (from single interview to motivational interview)
- Psycho-educational sessions regarding psychosocial risk factors, smoking, diet, *etc.*
- Multidisciplinary sessions regarding information and management (self-care, self-management, self-help)
- Self-help groups
- Use of self-help manuals
- Distance information and treatment programs, using the Internet
- Relaxation training
- Problem solving training

High intensity = interventions of high complexity performed by the psychologist and/or in collaboration with the multidisciplinary team:

- Psychotherapy interventions: individual, group (stress management) or family (at least 1/week)
- Multidisciplinary interventions (evidence of the need to implement a structured psychotherapeutic intervention (cognitive-behavioral therapy, motivational, mindfulness, *etc.*)

Coronary heart disease

A large body of empirical research shows that psychosocial risk factors, such as low socio-economic status, social isolation, stress, type-D personality, depression and anxiety increase the risk of incident CHD and also contribute to poorer health-related quality of life and prognosis in patients with established CHD. Psychosocial risk factors may also act as barriers to lifestyle changes and treatment adherence [4-6]. Based on epidemiological data, Rozanski recently divided the behavioral risk factors for CHD into five broad categories:

- a. Physical health behaviors, including physical inactivity, poor diet and obesity, smoking, poor or inadequate sleep, inadequate rest and relaxation
- b. Negative emotions and mental mindsets including depressive symptoms, anxiety, pessimism, anger and hostility
- c. Chronic stress, including situational stressors (work stress, marital stress, social stressors, caregiver strain, childhood and adult abuse, medical illness), and perceived stress
- d. Social isolation and poor social support
- e. Lack of sense of purpose.

Whilst psychosocial risk factors such as anxiety and depression can affect the cardiovascular system through biological and behavioral pathways, conversely CHD and its treatments can induce anxious and depressive reactions in the patient and caregiver. Depression disorder prevalence is between 15 and 20% in CHD and estimates of clinically-relevant depressive symptoms are much higher [17,18]. A recent meta-analysis indicated a 16% rate of prevalence of anxiety disorders [19]. Recently, Pedersen *et al.* [20] have provided a general overview of the prevalence of selected psychosocial risk factors, their impact on patient-reported and clinical outcomes, and biological and behavioral mechanisms that may explain the association between psychosocial factors and health outcomes.

STRONG EVIDENCE

- **Behavioral risk factors**
 - Physical inactivity, unhealthy diet, smoking [6]
 - Sleep disorders [21,22]
 - Inadequate rest and relaxation [4]
 - Consumption of 3 or more alcohol beverages per day [6]. Data are contrasting, however, regarding the moderate consumption of alcohol: positive association [23]; negative association [24,25]
 - Use of cocaine (associated with increased cardiovascular risk, *e.g.* tachycardia, arrhythmias, hypertension and vasospasm of the coronary arteries) [26].
- **Social factors**
 - Low socio-economic status, measured by educational and professional level, income, and perceived working position [27-32]. In particular, individuals after acute myocardial infarction (AMI) with low income and low education are at risk of premature mortality [33].
 - Lack of social support [31,34]. Epidemiological studies have shown that a reduced social network, poor social support and/or its perception increase the risk of cardiac events [4]. The significant role of the various social factors has been confirmed by a recent meta-analysis of 148 studies [35]. Conversely, a good social integration was associated with an almost 2-fold increase in survival.
- **Clinical depression and depressive symptoms**

Both major depression and depressive symptoms increase the risk of developing CHD and its worsening once the disease is manifest: a review of 54 studies in fact documented an approximately 2-fold

increase in risk in both primary and secondary prevention [36]. Depression is especially deleterious to cardiovascular prognosis post-AMI [17] and there does not appear to be a significant difference in prognosis between persons with pre-existing depression and those developing depression post-AMI [37].

Also the syndrome known as “vital exhaustion” increases the risk of new events [38,39].

- **Anxiety and panic**

In recent years the role of anxiety as a CHD risk factor has been clarified. Several meta-analyses have identified an increased risk associated with anxiety symptoms both in population and in patient cohorts [40,41].

Recent studies have shown that the risk of CHD events is high among patients with generalized anxiety disorder [42,43].

Among the anxiety disorders, evidence implicates generalised anxiety disorder with poorer CHD prognosis in a recent metaanalysis [44].

- **Stress**

It is widely documented that acute stress (mourning, natural disasters, terrorist attacks, football matches) can act as triggers of acute coronary syndrome [45,46]. More complex is the analysis of chronic stress related to specific situations:

- **Psychosocial characteristics of work.** The association between work stress and cardiovascular events has been further documented over the course of time. Numerous studies [47-50] have demonstrated that high demands combined with low work control produce stress, and in a recent meta-analysis a 1.23-fold increase was reported in incidence of CHD in association with job strain [48], compared with a 1.63-fold increase in mortality associated with unemployment [51].
- **Separation and divorce.** Separation and divorce are another common stressor that increase the risk of mortality; some epidemiological studies also suggest an association between marital tension and coronary events [4].
- **Negative childhood experiences.** Regarding negative childhood experiences, a large longitudinal study [52] showed that women with severe childhood abuse had an approximately 1.5-fold greater risk of early onset of cardiac events.
- **Stress associated with disease.** Diseases in themselves constitute a stress factor, often leading to depression, anxiety, social isolation and loss of self-esteem. In particular, the perception of stress can also be an important determinant of health [53,54].

- **Post-traumatic stress disorder (PTSD)**

Studies have reported the prevalence of post-AMI stress disorder and PTSD to be as high as 30% [55], although a meta-analysis of 24 observational cross-sectional studies estimated the prevalence to be 12% [56]. In any case, the rate of PTSD is much higher in cardiac patients than in the general population (10-12% in men and 5-6% in women) [57].

These patients may be prone to develop re-experiencing (*e.g.*, recalling the cardiac event or defibrillator shocks, dreams of cardiac arrest, flashbacks of the medical intervention and surgical procedure), avoidance (*e.g.*, avoiding reminders of the cardiac event such as the location of the event, the hospital, medication, situations in which heart rate increases such as exercise or sexual activity), and arousal symptoms (*e.g.*, preoccupation with heart rate or chest pain, insomnia) [58].

MODERATE EVIDENCE

- **Personality factors**

- **Anger and hostility.** Over the years it has been confirmed that there is no association between type A personality and

coronary disease onset/outcome. A meta-analysis [59] confirmed that anger and hostility are associated with increased risk of cardiovascular events both in the healthy population and in coronary patients. However, the association is less than that observed for depression and anxiety.

- **Type D personality.** A type D personality is present in about one-third of patients with CHD [60] and predicts a poorer prognosis [61-63], although some recent studies [64,65] have shown contrasting results. Type D is also associated with worsening of functional capacity and health status [66].

- **Positive psychological variables**

The role played by positive emotions (positive affect) in the development of CHD is increasingly the subject of scientific research, although it is still not completely clear [67]. Empirical evidence suggests that there is an association between positive affective states and health outcomes, including cardiovascular risk reduction and an increased resistance to infection [68]. Positive affectivity according to Steptoe [68] may be part of a broader profile of psycho-social resilience that reduces the risk of adverse outcomes of physical health.

Positive psychosocial factors also promote physiological effects, such as improvements in immune, endothelial, and autonomic functions [69,70]. Optimism is associated with a higher experience of positive emotions, enhanced social functioning, and better recovery from myocardial infarction and cardiac procedures. Recent epidemiological studies have shown that pessimism increases the risk for cardiac events, stroke and/or all-cause mortality, whereas optimism exerts a buffering role [71-74].

MILD EVIDENCE

Some studies document different psychological profiles in relation to gender and age, and there are growing data in the literature underlining the importance of psychosocial risk factors for the development of CHD in women [75-80] (Table 2).

In summary, in the opinion of the Panel, from the literature analysis there emerges:

- **strong evidence** of an association between the following variables and onset/outcome of the disease:
 - Behavioral risk factors
 - Social factors
 - Depression
 - Anxiety and panic
 - Stress
 - Post-traumatic stress disorder
- **moderate evidence** of an association between the following variables and onset/outcome of the disease:
 - Personality factors
 - Positive psychological variables

PSYCHOLOGICAL INTERVENTIONS

The position papers and psychological guidelines underline the need for an effective management of these psychosocial risk factors, including screening of psychosocial risk factors and implementation of different psychological interventions programs such as counseling, motivational interviews, health psycho-education and psychotherapy.

Pogosova *et al.* [5] suggest the need for core competencies that should include a screen for stress and psychosocial risk factors to identify clinically relevant levels of depression, anxiety, anger/hostility, relationship stress and low social support. It may be more important to teach patients how to change their existing stressors, or enhance their coping mechanisms for existing stressors, rather than to change unhealthy lifestyle habits. Therefore, it is essential to identify stressors with the patients and support them in finding ways to attenuate these stressors. This ideally should be carried out by trained personnel in dedicated sessions dealing with stress [5].

Rozanski [4] suggests some evidence-based techniques developed as management strategies for promoting healthy behaviors and the enhancement of psychosocial well-being, many of which are derived from Cognitive Behavioral Therapy (CBT): health counseling, smoking cessation, weight management, self monitoring, stress management, *etc.* A large number of “multidisciplinary” studies have been conducted to determine the effectiveness of psychosocial interventions for primary and secondary prevention but often the effects of the psychosocial components cannot be formally isolated from these studies.

The studies on psychological interventions for CHD patients have reported positive effects on quality of life, health behavior, and somatic risk profile, while others reported a protective effect on morbidity and mortality [3]. Some studies showed small-to-moderate improvements in depression and anxiety, a small reduction in cardiac mortality risk [81] and a reduction in all-cause mortality risk for men, but not for women [82]. Men appear to profit more from the interventions than women, but less studies have been performed on women than men. In particular, the meta-analysis by Whalley *et al.* [81] underlined the positive effects of psychological interventions on quality of life, depressive symptoms and anxiety, as well as an effect on cardiac mortality. Linden *et al.* [82] showed that programs which were initiated at least two months after the cardiac event showed stronger effects on the rate of future events than those initiated immediately after.

Welton *et al.* [83] carried out systematic literature searches to update an earlier Cochrane review and classified components of interventions into 6 types: usual care, educational, behavioral, cognitive, relaxation, and support. Most interventions were a combination of these components. There was some evidence that psychological interventions were effective in reducing total cholesterol and standardized mean anxiety scores, that interventions with behavioral components were effective in reducing the odds ratio of all-cause mortality and nonfatal AMI, and that interventions with behavioral and/or cognitive components were associated with reduced standardized mean depression scores.

Table 2. Evidence of association between the following variables and onset/outcome of CHD in women.

| |
|--|
| • depression [Ye S <i>et al.</i> 2012, Low <i>et al.</i> 2010, Shanmugasegaram S <i>et al.</i> 2012, Doering LV 2011, Möller- Leimkühler 2008] |
| • anxiety disorder [Doering 2011, Low <i>et al.</i> 2010] |
| • repressed anger [Low <i>et al.</i> 2010] |
| • low social support [Möller-Leimkühler 2008] |
| • stress associated with family relationships or responsibility [Low <i>et al.</i> 2010, Georgiades A 2009] |
| <i>In women, general anxiety, hostility and work-related stress are less frequently associated with CHD [Low <i>et al.</i> 2010]</i> |
| <i>Women report more stressful life events and other psychosocial risk factors in the year following discharge [Georgiades 2009]</i> |

Pogosova *et al.* [5] affirmed that stress management should be offered to patients (on an individual basis or in small groups) and that significant others should be included in the programs.

In a systematic review, Dickens *et al.* [84] sought to identify the characteristics of psychological interventions that improve depression and depressive symptoms among people with CHD. The results show that psychological interventions improved depression, although the effect was small. Problem solving, general education, skills training, CBT and relaxation had small effects on CHD patients, who were recruited irrespective of their depression status. Among high-quality trials of depressed CHD patients, only CBT showed significant, though small, effects. The systematic review of Van Dixoord [85] on the effectiveness of relaxation therapy showed positive effects on cardiovascular variables, anxiety and depression, and work reintegration. A recent review of psychotherapy interventions for patients with ischemic heart disease [86] showed positive effects on conditions of psychological distress, on the management of traditional risk factors and with respect to some cardiovascular prognostic indices. Data from the literature on the effectiveness of the above-mentioned psychological interventions and evidence-based psychotherapy are mainly based on CBT interventions; however, one can also find evidence of efficacy of interventions based on other theoretical models, though these require further confirmatory studies. Most of the studies with CBT involve individual and/or group interventions carried out in the context of research, mainly in outpatient settings - the average duration is about one year with weekly sessions in the early stages followed by monthly sessions in the second part.

Table 3 reports the major studies on CBT interventions carried out in CHD patients [87-105].

In the literature there are few reports of psychotherapeutic interventions with a non-cognitive-behavioral orientation. A randomized clinical trial conducted in 2013 by Roncella *et al.* [106] shows the efficacy of a psychoanalysis intervention (group and individual) on cardiac symptoms, quality of life, and psychological/medical outcomes at 1-year follow-up. Lesperance [107] shows the effectiveness of interpersonal psychotherapy on reducing depression in a sample of patients with CHD. However, further studies are required due to the low number of studies and short follow-up duration (1 year).

The updated Cochrane Review [7] found that for people with CHD there was no evidence that psychological treatments had an effect on total mortality, risk of revascularisation procedures, or on the rate of non-fatal AMI, although the rate of cardiac mortality was reduced and there was a reduction in psychological symptoms (depression, anxiety, or stress); however, the GRADE assessments suggest considerable uncertainty surrounding these effects. There is also considerable uncertainty about who would benefit most from treatment (*i.e.*, people with or without psychological disorders at baseline) and what the specific components of successful interventions are. For depression, psychological interventions combined with adjunct pharmacology (where deemed appropriate) for an underlying psychological disorder appeared to be more effective than interventions alone without adjunct pharmacology. For anxiety, interventions recruiting participants with an underlying psychological disorder appeared more effective than those delivered to unselected populations.

In the Panel's opinion, from the literature analysis, it can be stated that there is:

- **existence of strong evidence** for the efficacy of cognitive-behavioral interventions on the following variables:
 - depression
 - anxiety
 - stress

- **existence of moderate evidence** for the efficacy of cognitive-behavioral interventions on cardiac outcomes
- **existence of mild evidence** for the efficacy:
 - of interpersonal psychotherapy on depression
 - of short-term psychoanalytic therapy on quality of life and cardiac outcomes
 - of mindfulness interventions on anxiety, depression, stress, cardiac outcomes

Cardiac surgery

Takagi *et al.* [108] performed a systematic review and meta-analysis to determine whether perioperative depression and anxiety were associated with increased postoperative mortality in patients undergoing cardiac surgery. Neurocognitive and psychiatric complications are common following cardiac surgery and impact on the patient's quality of life, recovery, participation in rehabilitation and long-term mortality. Postoperative cognitive decline, depressive disorders, post-traumatic stress disorder and neurocognitive impairment related to silent brain infarcts have all been linked to the perioperative period of cardiac surgery, and can have potentially serious consequences. The accurate assessment of these conditions, particularly in determining the etiology, and impact on patients is difficult due to the poorly recognised nature of these complications as well as similarities in presentation to postoperative delirium [109].

MODERATE EVIDENCE

- **Anxiety and depression**
The literature search by Takagi *et al.* [108] included data on 236,595 patients undergoing cardiac surgery - coronary artery by-pass grafting (CABG), CABG with concomitant valve replacement, valve surgery - and showed that perioperative depression and anxiety may be associated with increased postoperative mortality. Depression and/or anxiety before an invasive intervention may negatively influence coping and recovery after the intervention.
- **Post-traumatic stress disorder (PTSD)**
In a narrative review, Singh [110] affirmed that PTSD has a strong association with CABG and can be a source of considerable morbidity and mortality, although the studies on which these statements are based are not recent. In primis, the study of Stoll *et al.* [111] compared patients undergoing cardiac surgery with healthy persons and those undergoing other types of surgery and noted a higher incidence of PTSD in cardiac surgery patients. The authors observed that patients after CABG with comorbid PTSD had a lower compliance with respect to use of medication, which carries the risk of an unfavorable course of the somatic disease. Also, the risk for rehospitalization after AMI is higher in patients with comorbid PTSD symptoms than in patients without.
- **Post-surgery neuropsychological disorders**
A systematic review of 2014 [112] stated that persistent cognitive impairment attributable to cardiovascular surgery in patients aged over 65 years is infrequent, and may reflect pre-existing cognitive impairment. In particular, CABG interventions seem to have modest effects in the medium and long term. Results cannot be generalized to the oldest-old, to women or to patients with pre-existing cognitive impairments. Postoperative decline appears to be associated with the presence of new ischemic lesions from emboli during surgery, but the pathogenesis seems still unclear and also hard to predict [113].

Table 3. Major studies on CBT interventions in CHD patients.

| Study | Design | Setting | Diagnosis | Patients | Mean age (years) | Follow-up (years) | Intervention | Outcomes |
|---------------------------------------|--------|---------------|--|---|------------------|-------------------|--|---|
| ENRICH (Berkman <i>et al.</i> , 2003) | RCT | Multi-center | AMI | 2481 (1397 males and 1084 females; 1238 intervention and 1243 controls) | 61 | 29 months | Group and individual cognitive-behavioral therapy, education, relaxation, and type A behavior modification for 18 contact hours. | Improvements in depression and social support. There was no benefit in terms of cardiac outcomes or mortality after follow-up. |
| Blumenthal <i>et al.</i> , 2005 | RCT | Single-center | Patients with stable ischemic heart disease (IHD) and exercise-induced myocardial ischemia | 134 patients (92 males and 42 females; 44 intervention and 42 controls 1 and 48 controls 2) | 63 | | Weekly 1.5-hour stress management training for 16 weeks. | Less emotional distress and lower levels of depression compared with usual care controls. Improved markers of cardiovascular risk more than usual medical care alone. |
| Claesson <i>et al.</i> (2005) | RCT | Single-center | Ischemic heart disease | 198 (only females; 101 intervention and controls) | 61 | 1 | Cognitive-behavioral stress management program <i>vs</i> usual care 1-year. | Both groups improved in all psychosocial variables the rate of improvement was significantly greater in the intervention group for self-rated stress behavior (P=0.006) and vital exhaustion (P=0.03). |
| McLaughlin <i>et al.</i> (2005) | RCT | Single-center | ACS | 100 (74 males and 26 females; 53 intervention and 47 controls) | 60 | | CBT, counselling, education for 8-week treatment sessions were 30 minutes and conducted by doctoral-level clinicians with telephone. | 27% improvement in depression symptoms (P=0.05), 27% in anxiety (P=0.02), and a 38% improvement in home limitations (P=0.04). |
| Michalsen <i>et al.</i> (2005) | RCT | Single-center | Stable or unstable CAD | 101 (78 males and 23 females; 48 intervention and 53 controls) | 59 | | CBT, relaxation, and type A behavior modification for 96 contact hours. | Both groups improved in QoL, and significantly greater improvements for the lifestyle group were found for physical function and physical sum score (P=0.046 and P=0.045). Depression, anxiety, anger and perceived stress were reduced similarly in both groups. Greater benefits among women in the lifestyle intervention <i>vs</i> advice group for depression and anger (P=0.025 and P=0.040), but no effects for men. |
| Sebregts <i>et al.</i> (2005) | RCT | Single-center | AMI or CABG | 204 (169 males and 35 females; 106 intervention and 98 controls) | 55 | | A combined stress management and health education program during eight weekly 2.5-h sessions. | Reduction of hostility and total Type A behavior at post intervention (P=0.01) and at 9-month. Follow-up (P=0.03). The intervention had no overall impact on vital exhaustion and depression, whereas we unexpectedly found that the percentage of patients with major depression was reduced in the control group but not in the intervention group. |
| Edelman <i>et al.</i> (2006) | RCT | Single-center | Patients with 1 or more known cardiovascular risk factors | 154 (30 males and 124 females; 77 intervention and 77 controls) | 53 | 10 | Personalized health planning (PHP): usual care associated with educational counselling and mindfulness meditation, relaxation training, stress management, motivational techniques, and health education and coaching. | Baseline 10-year risk of CHD was 11.1% for subjects randomized to Usual Care (n=77), and 9.3% for subjects randomized to PHP (n=77). Over 10 months of the intervention, CHD risk decreased to 9.8% for UC subjects and 7.8% for intervention subjects. A multidimensional intervention based on integrative medicine principles reduced risk of CHD, possibly by increasing exercise and improving weight loss. |

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Table 3. Continued from previous page.

| Study | Design | Setting | Diagnosis | Patients | Mean age (years) | Follow-up (years) | Intervention | Outcomes |
|--|-------------|---------------|--|---|--------------------|----------------------------|--|--|
| Koertge <i>et al.</i> (2008) | RCT | Single-center | AMI, PCI or CABG | 247 (only females; 119 intervention and 128 controls) | 62 | | Group cognitive-behavioral therapy, education, relaxation, and type A behavior modification for 40 contact hours. | For VITAL exhaustion, intention to treat analysis showed effects for time ($P<0.001$) and time x treatment interaction ($P=0.005$), reflecting that both groups improved over time, and that the decrease of VE was more pronounced in the intervention group. |
| Albus <i>et al.</i> (2009) | RCT | Single-center | Patients with stable CHD | 77 (67 males and 10 females; 39 intervention and 38 controls) | 54.2 +/- 6.9 years | After 1, 2, 3, and 7 years | Multimodal, behavioral intervention and relaxation training 10 sessions once a week followed by 9 subsequent sessions once a month, which included group discussions, relaxation and exercise training, which continued for a period of up to 1 year. | Improvement of miocardial perfusion. |
| Blom <i>et al.</i> (2009) | RCT | Single-center | CAD | 247 (only females; 13 intervention and 122 controls) | ≥ 75 | After 1 and 2 years | 20 (2-h group sessions) of stress management therapy. | Reduction of self-rated daily stress behavior over time compared to controls. |
| Griffiths <i>et al.</i> (2009) | Pilot study | Single-center | Diagnosed cardiac condition that required cardiac rehabilitation | 6 (5 males and 1 female) | 50 | | Mindfulness based Cognitive Therapy eight-week (two hours per week). Mindfulness-based Cognitive Therapy group developed by Segal, Williams and Teasdale (2002) adapted for a cardiac population. | Development of awareness, commitment, within group experiences, relating to the material and acceptance as central experiential themes. Absence of a control group and small sample size number is in accordance with IPA sample sizes. Interpretive phenomenological analysis (IPA) of participant experiences. |
| Neves <i>et al.</i> (2009) | RCT | Single-center | Stable or unstable CAD | 81 (69 males and 11 females; 41 intervention and 40 controls) | 60 | 2 | Group relaxation therapy for 3 months <i>vs</i> usual care. | Perceived stress declined more in the intervention group and it had significantly lower heart rate, blood pressure, and rate-pressure product values after the program ($P \leq .0001$). Relaxation therapy was associated with a positive effect on psychological stress and hemodynamic variables. No difference in the follow-up. |
| Orth-Gomér <i>et al.</i> (SWITCHD, 2009) | RCT | Multi-center | AMI, PCI or CABG | 237 (only females; 112 intervention and 125 controls) | 62 | 7 | 20 Group cognitive-behavioral therapy for 12 months. Educational group sessions were aimed at improving knowledge of the heart, healthier lifestyle, training skills, and improving mastery of marital stress, coping with serious illness, counteracting anxiety and depression, improving social relations and social support, and practicing relaxation techniques. | Women in usual care had a mortality rate of 20%, whereas those in the psychosocial intervention had a mortality rate of 7%. No women were lost to follow-up. |

To be continued on next page

Table 3. Continued from previous page.

| Study | Design | Setting | Diagnosis | Patients | Mean age (years) | Follow-up (years) | Intervention | Outcomes |
|---|---------------------|---------------|--|---|------------------|-------------------|--|---|
| Blumenthal <i>et al.</i> (2010) ENHANCED | RCT | Multi-center | CHD | 150 | ≥35 | | Stress management training (SMT) <i>vs</i> traditional exercise based cardiac rehabilitation for 12 weeks. | Cardiac rehabilitation enhanced by SMT produced significant reductions in stress and greater improvements in medical outcomes compared with standard CR. Our findings indicate that SMT may provide incremental benefit when combined with comprehensive CR. |
| Gulliksson <i>et al.</i> (SUPRIM, 2011) | RCT | Single-center | Stable or unstable CAD | 362 (277 males and 85 females; 192 intervention and 170 controls) | 62 | 7.8 | CBT 40 contact hours spanning 1 year 20 two-hour sessions of group-based stress management. The groups consisted of 5 to 9 same-sex participants, 5 key elements (education, self-monitoring, skills training, cognitive restructuring, and spiritual development) and was focused on stress reduction and management. | Group undergoing CBT had a lower rate of fatal and non-fatal first recurrent cardiac events; fewer recurrent acute myocardial infarctions and a non significant lowering of all-cause mortality. In patients with CVD an intensive 40-hour group-based CBT program decreased the risk of recurrent CVD and AMI. |
| Goodwin <i>et al.</i> (2012) | Pilot study | Single-center | Acute coronary syndrome | 16 (5 males and 11 females; all intervention) | 56.4 | | ACT four, 90-min group sessions focused on developing mindfulness and distress tolerance skills, and strengthening commitment to health-related behavior change. | Satisfaction with the intervention. Large improvements in diet and moderate increases in physical activity from pre- to post-treatment. |
| Orth Gomer <i>et al.</i> (2012) | Observational study | Single-center | Acute coronary syndrome AMI, PTCI or CABG | 30 (19 males and 11 females; all intervention) | 55.5 | 9 | CBT: ten sessions of two hours of stress management program. | No gender differences but discussion styles varied between the women and men, Women were more open and more personal. Family issues were more frequent than job issues, although all women were employed outside their homes. Men talked about concrete and practical things, mostly about their jobs, and not directly about their feelings. Daily stresses of life decreased significantly for both men and women, but more so for women. Depressive thoughts were low at baseline, and there was no change over time. In contrast, anxiety scores were high at baseline and decreased significantly, but more so for women than for men. |
| Murphy <i>et al.</i> (2013) | RCT | Multi-center | AMI, PTCI or CABG | 275 (238 males and 37 females; 139 intervention and 136 controls) | 59 | 2 | “Beating Heart Problems” cognitive-behavioral therapy and motivational interviewing program <i>vs</i> usual care. | Compared with the C group patients, intervention group patients tended toward greater reduction in 2-year risk of cardiac event, at both the 4- and 12-month follow-up. Significant benefits in dietary fat intake and functional capacity were also evident. |
| Parswani <i>et al.</i> (2013) | RCT | Single-center | CHD | 30 (only males; 15 intervention and 15 controls) | 48.5 | 3 months | Mindfulness-Based Stress Reduction (MBSR) program. | Significant reduction in symptoms of anxiety and depression, perceived stress, blood pressure and body mass index in patients of the MBSR group after the completion of intervention assessment. At 3-month follow-up, therapeutic gains were maintained in patients of the MBSR group. |

In a long-term study with a median follow-up of 11 years in patients following cardiac surgery, cognitive dysfunction present at 6 months was associated with increased long-term mortality [114], further demonstrating that the consequences of postoperative cognitive dysfunction are likely to have long-term implications that are more significant than simply that of a 'transient postoperative state'. Cognitive functions were reported to be mildly or not significantly impaired after transcatheter aortic valve implantation (TAVI) [115]. Postoperative delirium is associated with increased anxiety and depression at 6 to 9 months, and future investigation should seek to evaluate the utility of screening programs for affective disorders in those individuals who develop delirium in the postoperative period [116].

In summary, in the opinion of the Panel, from the literature analysis there emerges:

- **moderate evidence** of an association between the following variables and clinical condition
 - Anxiety and depression
 - Post-traumatic stress disorder
 - Post-interventions neuropsychological disorders

PSYCHOLOGICAL INTERVENTIONS

A literature concerning specific psychological interventions can not be found.

Suarez-Bagnasco [117] suggests that the study of psychological issues in these cardiac diseases is relevant and could provide information about specific needs requiring psychological interventions as well as be useful for the design of specialized care training and practice. A good practice intervention is recommended.

Chronic heart failure

The European guidelines [118] underline that CHF is a common chronic disease with poor prognosis and significant quality of life limitations. Patients are required to follow a complex regimen of self-care behaviors including medication, self-monitoring of symptoms, diet and exercise. Mental comorbidities such as depressive and anxiety disorders are common in patients with CHF. Depressive comorbidities are present in about 20% of patients, anxiety comorbidities in up to 40% [119].

STRONG EVIDENCE

- **Behavioral risk factors**
Obesity, sedentary lifestyle, smoking, and cocaine and alcohol use are independent predictors of CHF [118,120-122]. Goel *et al.*, however, show that light to moderate alcohol intake has been associated with lower risk of heart failure [25].
- **Depression**
A systematic review and meta-analysis suggests that depression is an important and independent predictor of all-cause mortality among CHF patients, while anxiety does not appear to have a strong effect [100].
- **Anxiety**
The above-mentioned systematic review and meta-analysis [100] showed that anxiety does not appear to have as strong an effect as depression in predicting all-cause mortality among CHF patients, but anxiety is negatively associated with self-care behavior. However, this effect disappears behind the stronger influence of depression on self-care. It is important to consider mental comorbidities in patients with CHF [123].

MODERATE EVIDENCE

- **Social factors**
Low socio-economic status (SES) as well as immigrant status are independent predictors of CHF [124,125]. Social instability and poor social support, instability and precariousness of affective/interpersonal relationships, not being married, living alone, some social and environmental factors such as immigrant status, distance from the hospital and precarious housing conditions negatively affect the outcome [124-127].
- **Personality factors**
Type D personality. Data in the literature are contradictory and inconclusive [61,128-132].
- **Positive psychological variables**
Positive psychological well-being improves the outcome in terms of quality of life and disease management [133,134].
- **Neuropsychological disorders**
Mild cognitive impairment (MCI) is common in HF and impacts on patients' engagement in self-care, yet it is frequently not detected.[135].
- **Sleep disorders**
Sleep disorders and apnea influence the outcome [136,137].

In summary, in the opinion of the Panel, from the literature analysis there emerges:

- **strong evidence** of an association between the following variables and disease onset/outcome:
 - Behavioral risk factors, in particular alcohol and cocaine use
 - Depression
 - Anxiety
- **moderate evidence** of an association between the following variables and disease onset/outcome:
 - social factors
 - personality factors (type D)
- **moderate evidence** of an association between the following variables and outcome of the disease:
 - positive psychological variables
 - neuropsychological disorders
 - sleep disorders

PSYCHOLOGICAL INTERVENTIONS

The analysis of the literature [138-141] shows that it is fundamental to treat patients with CHF from the perspective of a chronic and progressive disease, during which they are called upon to put into action cognitive, emotional and behavioral resources that will allow them to live with the disease, adhere to complex therapeutic regimens and maintain a reasonable level of quality of life. The changes of role in the personal, family, and social/work context involve problematic emotional states; moreover, adherence to prescriptions is often conditioned by the complex pharmacological therapy, by the need to monitor physiological parameters and symptoms, and by food restrictions (salt consumption, intake of liquids, abstention from alcohol).

From the literature and from clinical experience it emerges that *interventions* to optimize the CHF treatment, reduce hospitalizations and mortality, and improve quality of life and management of the disease, carried out during the stay in hospital or at home with telemedicine methods or face-to-face interventions, are linked to two key aspects: i) self-management and adherence [142-147]; ii) depression and anxiety [148-150].

Self-management should be promoted right from the outset, maintained throughout the course of the illness, and sustained in the

phases of instability, in the transition from hospital to home and in the terminal phases [139,145,151-153]. Interventions to improve self-management do not affect the emotional structure [153]. In a recent review [154] on the effectiveness of psychological interventions on self-care, and on psychological and health outcomes in patients with CHF, the authors showed that nurses play an important role in patient education and secondary prevention. Compared to other professionals, nurses have more patient contact opportunities and are more holistic in all aspects of disease management; therefore, more nurses can be trained to incorporate the brief psychological techniques (such as motivational interviews and CBT) to maximize the intervention's effectiveness. The main limitation of the review is the moderate-to-high level of heterogeneity among the included studies, which could partially undermine the reliability and reproducibility of the results. Due to the heterogeneity of the studies, no definitive conclusions on the optimal format and forms of intervention could be drawn. Replication of the studies is required in the future to isolate the active component of the interventions and identify the ideal format and dosage of interventions.

An improvement of adherence is achieved through effective communication and by defining with the patient an interactive therapeutic plan aimed at the respect, recognition, correction and management of these aspects:

- Psychosocial: psychological problems, neuropsychological deficits and poor socio-family support [155,156].
- Cognitive behavioral: cognitive distortions about awareness, self-management of the disease at home and self-efficacy [156-158].
- Communications: [159, 146].

In published reports, details on specific counseling or psychotherapeutic interventions (cognitive therapy and stress management) for patients with CHF are often lumped together as part of the group of non-pharmacological approaches (including physical activity and dietary prescriptions) or are included in the global rehabilitation treatment or as part of the multidisciplinary hospital interventions [160-167], so it is difficult to document their specific effectiveness.

Psychological interventions can be performed to address dysfunctional aspects (cognitive, emotional or behavioral) in the management of the disease, or to provide counseling to optimize coping strategies, or to provide psychological support during the stabilization phase [168].

Many reports focus on depression and the provision of emotional support or counseling in order to understand the patient's needs, manage their emotional response to the disease, improve quality of life and optimize the physical outcomes of the therapeutic interventions.

In a recent systematic review and meta-analysis [169], a CBT intervention on depression, quality of life, hospitalizations and mortality in CHF patients was associated with a greater improvement, compared to usual care, in depression scores both at the end of the CBT program and 3 months later. Greater improvement in quality of life scores was evident for the CBT group initially after CBT sessions, but there was no difference at 3 months. Hospital admissions and mortality were similar in the two treatment groups. CBT may be more effective than usual care at improving depression scores and quality of life for heart failure patients initially following CBT and for depression at 3 months. The authors suggest larger and more robust randomized controlled trials (RCTs) to evaluate the long-term clinical effects.

There are also specific interventions based on specific theoretical health models [170] or therapies associated with positive psychology [171] and with the most recent CBT therapy [172-174].

Telerehabilitation may serve as a helpful strategy for continuing at a distance the monitoring and management of a patient, allowing face-to-face interventions, including with the patient's family. To date, only a small number of studies have been dedicated to studying the psycho-

logical aspects of telerehabilitation [175]. These patients could receive parallel psychological support and tele-assistance from the telemonitoring team (nurse, physician, physiotherapist). In any case, telemedicine interventions can provide benefits to heart failure patients only as part of a shared and integrated multidisciplinary and multi-professional 'chronic care model' [176].

In this context, one can envisage:

- interventions aimed at self-management based on brief psychological techniques (such as motivational interviews and CBT) performed by healthcare operators, especially nurses, trained by psychologists
- psychological/psychotherapeutic interventions carried out by psychologists/psychotherapists, of a prevalently cognitive-behavioral type
- telemedicine interventions, performed by healthcare operators, especially nurses, which should be trained by psychologists

In the Panel's opinion, from this analysis of the literature there emerges moderate evidence of efficacy

- for cognitive-behavioral interventions
- for psychoeducational and disease management interventions.

Heart transplantation

The specific Guidelines [177,178] affirm that the psychologist should routinely assess all patients being considered for heart transplantation (HT), before wait-listing for transplantation. Evaluation should include an assessment of the patient's ability to give informed consent and comply with instructions, including drug therapy, as well as assessment of the support systems in place at home or in the community. This assessment focuses on the following: i) social support and the ability of the social support network to cope with the stressors of HT care; ii) patient understanding of the requirements, risks and benefits of HT; iii) adherence to the medical care plan; iv) psychopathology; v) cognitive assessment. The literature on psychological comorbidity [177,179,180] shows a high incidence of anxiety-depressive disorders (30%) pre-transplantation, which tends to decrease in post-transplantation. Psychological/psychiatric contraindications are first reviewed by the psychologist and, where necessary, a psychiatrist is consulted for further assessment and/or a second opinion.

STRONG EVIDENCE

• Behavioral risk factors

The presence of substance-related disorders, personality disorders or a history of medication non adherence are powerful predictors of failure to comply with the medical regimen and, therefore, are associated with increased morbidity and mortality in HT patients [180-182].

• Depression

Major depression pre-transplant is a negative prognostic factor especially if associated with poor social support [183,184]. It adversely affects adherence to exercise and participation in daily life activities [185].

Its incidence was 7.9% for severe or moderate depression [186] and 33-69% for the less severe levels [187,188]. If the depressive symptomatology is treated pharmacologically, symptoms can be reduced and the health status improved post-transplant [189]. A recent systematic review indicated that depression increases the risk of post-transplant mortality [190]. The presence of depression post-transplantation is frequent [191], equal to 41%. Grandi *et al.* [192] reported that demoralization in combination with depres-

sion predicted more acute rejection episodes in the 6-year period post-transplant than either variable considered independently. Major depression prior to heart transplantation is a risk factor for post-transplant malignancies and PTSD symptoms are a predictor of post-transplant poor adherence [191].

MODERATE EVIDENCE

- **Social factors**

The presence of poor social support post-transplantation is correlated to a worse quality of life [193] as is low socio-economic status, living in an urban reality [182] and having a caregiver with anxious-depressive symptoms [194,195]. Conversely, high education level and a medium-high economic status are predictive of greater survival [182,196,197]. Any patient for whom social supports are judged to be insufficient to ensure care compliance in the outpatient setting may be regarded as having a relative contraindication to HT [178].

- **Anxiety**

In the recent systematic review cited above, anxiety was not associated with the risk of post-transplant mortality and morbidity [190]. However, anxiety appears to be present in the pre-transplant waiting-list phase [179,180,198]. Anxiety negatively affects the psychophysical health status [199].

- **Stress**

HT is a very stressful experience for heart transplant candidates, and recipients and patients have to cope with significant medical and emotional challenges related to the workup they must undergo for listing, waiting for a donor heart to become available, undergoing surgery and post-operative recovery, and adjustment to life with a transplanted organ [180].

At 5 and 10 years after HT, the most bothersome stressors regard work, school, and financial issues. Patients at 10 years after transplant reported less stress, similar stress intensity, and less use and perceived effectiveness of negative coping than patients at 5 years after transplant. In the long-term after transplant, demographic characteristics, psychologic problems, negative coping, and clinical factors were related to stress frequency and/or intensity [200]. HT-related stress occurs in the long-term after surgery. Types of transplant-related stress and factors related to stress confirm the importance of ongoing psychologic and clinical support after HT [200].

- **Post-traumatic stress disorder**

Its incidence in transplanted patients is 12%. In a study [191], the estimated frequency of psychiatric diagnoses after HT was 12% for transplantation-related PTSD and 41% for major depression. The presence of an episode of major depression prior to HT is a significant independent risk factor for post-transplant malignancies. Age, post-transplant malignancies and poor adherence are significant predictors of mortality in the survival analyses. Mortality was significantly higher in patients with HT-related PTSD comorbidity, possibly as a result of the lower compliance in these patients or the fact that PTSD itself is predictive for poor health status.

- **Personality factors**

Neuroticism [179,180] is correlated to anxiety and depression, thus constituting a predictive factor of psychopathology 12 months after HT. High levels of hostility are an independent predictor of subsequent mortality. Part of post-transplant nonadherence seems also to be determined by personality. Personality traits refer to a dimensional taxonomy created to understand normal personality functioning, and do not necessarily reflect psychopathology. Patients with low conscientiousness may be criticized for their carelessness, negligence, and failure to stay within the lines, while patients with high conscientiousness are disciplined, organized,

goal-oriented, and have a high need for structure, *i.e.* all characteristics that may help people in treatment adherence [181].

- **Personality factors**

Type D is a predictor of morbidity and mortality [201,202].

- **Disease management**

Different studies have found that HT candidates use positive coping strategies more frequently than maladaptive coping strategies such as denial, avoidance or disengagement [197,203]. Consistent with the results obtained by the group of Burker [197,203], maladaptive coping styles (including disengagement dimension and some help-seeking traits such as venting of emotions or seeking emotional support) were associated with the presence of psychiatric symptoms in a group of patients [179], also after a follow-up of 12 months [180]. Adherence was poor post-transplantation [204,205]. Prognostically favorable factors for adherence were high education level and having a female caregiver or being a female [205].

- **Positive psychological variables**

The state of psychophysical wellbeing, optimism and the perception of exercising active control over the disease are prognostically favorable indicators for the outcome [206,207].

- **Neuropsychological disorders**

They have an incidence in the pre-transplant phase that ranges from 15 to 59% [187], while other studies show an incidence equal to 86% in particular in the executive functions [208]. There are no indications for excluding from the list for HT patients with mental retardation and specific cognitive deficits [187,208,209]. A substantial proportion of long-term survivors of HT might be cognitively impaired. The level of impairment appears comparable to what is defined in the literature as mild cognitive impairment [210]. The benefit of HT in patients with severe cognitive-behavioral disabilities or dementia (*e.g.* self-injurious behavior, inability to understand and cooperate with medical care) has not been established; on the contrary, it has the potential for harm and, therefore, HT cannot be recommended for this subgroup of patients [178].

In summary, in the opinion of the Panel, from the literature analysis there emerges:

- **strong evidence of an association between the following variables and the conditions of pre- and post-transplant:**
 - Behavioral risk factors
 - Depression
- **moderate evidence of an association between the following variables and the conditions of pre- and post-transplant:**
 - Social factors
 - Anxiety
 - Stress
 - Post-traumatic stress disorder
 - Personality factors
 - Disease management
 - Positive psychological variables
 - Neuropsychological disorders

PSYCHOLOGICAL INTERVENTIONS

Psychotherapeutic interventions

A recent systematic review recommends, as good practice, psychotherapeutic interventions of a cognitive-behavioral type, stress management strategies and relaxation techniques as a means to reduce the state of psychological distress and promote improved quality of life. In post-transplantation, also psycho-social support interventions carried out telematically via the Internet have shown to be effective [211]. The use of mindfulness training (mindfulness-based stress re-

duction, MSBR) lasting 8 weeks was effective in reducing symptoms of anxiety, depressive symptoms and sleep disorders post-transplant [212]. Observational studies recommend the practice of individual psychotherapeutic interventions aimed not only at the patient but also at the caregiver and the healthcare team [213].

Management interventions

The patient's adherence to treatment, psychophysical wellbeing and quality of life are better if the healthcare team has developed adequate interpersonal relationship skills and uses strategies of motivational counseling [214]. Management models that include educational interventions, periodic monitoring and telematic support extended to caregivers in the months following the transplant event are predictive of good adherence to treatment [215,216]. It is also recommended to provide interventions for the prevention of relapse in smoker patients [217].

In summary, in the opinion of the Panel, from the literature analysis there emerges:

- **Strong evidence** for the efficacy of cognitive-behavioral interventions in reducing the state of psychological distress
- **Moderate evidence** for the efficacy of psychoeducational and management interventions

Mechanical ventricular assist devices

Currently there are not many studies that have investigated the psychological aspects, and the number of patients examined is very modest. Two systematic reviews investigated the impact of left ventricular assist device (LVAD) implantation on psychological variables [218,219], and showed an improvement in the state of psychophysical health, depression and anxiety scores in patients after LVAD implantation. Factors contributing to changes in depression and anxiety after the LVAD implant could be related to the improvement in acute heart failure symptoms, functional capacity, and quality of life [220].

MODERATE EVIDENCE

- **Acute and chronic stress**
The immediate post-operative period is associated with an increase in negative emotions (fear of the outcome of the interventions and of hospitalization) [221].
- **Depression**
Depression is particularly present in the post-implantation period [222-226].
- **Anxiety**
Anxiety is frequent in patients with LVAD [222-226].
- **Psycho-physiological sleep disorders**
After LVAD implantation there are problems in the area of sleep that correlate with the presence of anxiety and depression [219,227,228].
- **Neuropsychological disorders**
In patients with LVAD implantation, cognitive dysfunctions may be present, but they are mainly found in older patients and in those with LVAD as destination therapy [229]. In general, the LVAD implant seems to arrest the cognitive decline [230] and, in the space of 24 months, there is an improvement in cognitive functions with respect to patients with advanced heart failure [231-233].

In summary, in the opinion of the Panel, from the literature analysis there emerges **moderate evidence** for an association between implanted LVAD and the following variables:

- Depression
- Anxiety
- Acute and chronic stress
- Psycho-physiological sleep disorders
- Cognitive deficits

PSYCHOLOGICAL INTERVENTIONS

To date, there are no RCTs on large populations able to demonstrate the efficacy of a specific psychological intervention on patients with LVAD. There are indications that patients who undergo, post-LVAD implantation, a course of treatment including psycho-education, re-education in physical activity and self-care, as well as psychological support to the patient and caregiver, show greater functional improvement in depression [234-239], in maintenance of a correct diet and in maintenance of adequate physical activity [240].

In the opinion of the Panel, from the analysis of the literature there emerges:

- **mild evidence** for the efficacy of cognitive-behavioral interventions in reducing the state of psychological distress
- **mild evidence** for the efficacy of psychoeducational and management interventions

Implantable cardioverter-defibrillator (ICD)

The acceptance of the ICD appears to be influenced by a number of variables such as psychological morbidity, advanced age, severity of the disease, onset of anxious or depressive symptoms, type D personality, worry about the ICD implantation, and understanding of the benefits and disadvantages of the ICD, which would seem to impact on the perceived quality of life [241-244].

MODERATE EVIDENCE

- **Depression**
The frequency and severity of depressive symptoms would appear to increase in relation to the severity of the underlying CHF [245,246].
- **Anxiety and fear**
Catastrophic thoughts underlying the manifestation of anxiety provoke in the patient the avoidance of daily, physical and sexual activities [242,247] or the presence of anticipatory anxiety in relation to random stimuli such as, for example, increased heart rate during moderate physical activity [248]. In particular, higher levels of anxiety emerged in young patients [249] and in women especially as regards body image [250,251]. The results of the PainFree SST Clinical Trial [252] showed that ICD shocks have a long-lasting, adverse impact on both objective, device-measured physical activity and subjective patient-reported outcomes of quality of life and shock anxiety. Shock anxiety increased in shocked patients and remained significantly elevated at 24 months, regardless of whether the shock delivery was appropriate or inappropriate. Successful management of ICD patients requires attention to clinically relevant behavioral and psychological outcomes to speed their recovery and return to activities of daily living.
- **Post-traumatic stress disorder**
In a narrative review, Sears [253] found that patients under the age of 50 years, female, with psychiatric pre-morbidity, poor social support and less than 5 discharges (appropriate or inappropriate) were at higher risk of PTSD. Furthermore, the presence of PTSD

appears to be associated with a greater percentage of shock experiences and mortality at 5 years after implantation compared to patients who did not develop PTSD [253].

- **Type D personality**
Patients with type D personality are more likely to develop depression or anxiety disorder pre-implant because they are more exposed to psychological distress, morbidity and mortality [254,255]. Patients with a younger age, increased depression score at baseline, and Type D personality were especially prone to experience PTSD and anxiety symptomatology at 12 months follow-up [244].
- **Positive psychological variables**
In the WEBCARE study [256], optimism was found to be associated with less distress, and possibly it helps safeguard mental health in ICD patients. Increasing optimism might be the way forward to reduce long-term distress and impaired health status.
- **Neuropsychological disorders**
These deficits are more present in ICD patients who have experienced appropriate shocks. Difficulties emerged in the ability to concentrate, visual attention capacity and short-term memory independently of age and cultural level. Patients with pre-implant cognitive deficits have a lower probability of survival [257,258].

In summary, in the opinion of the Panel, from the literature analysis there emerges moderate evidence of an association between ICD wearers and the following variables:

- Depression
- Anxiety
- Post-traumatic stress disorder
- Type D personality
- Cognitive deficits

PSYCHOLOGICAL INTERVENTIONS

The detection of elements of psychological involvement and daily clinical practice both make it clear that there is a pressing need for psychological treatments for these patients. The literature indicates the effectiveness of:

- **Psycho-educational interventions:**
Evidence from the literature shows that there is a substantial consensus among different researchers on the importance of intervening at a first level with education on the nature, modes and goals of action of the device [242,259]
- **Individual psychotherapy, in particular CBT:**
This is identified as elective treatment and as having a greater degree of efficacy in the treatment of psychopathological symptoms related to the ICD device [260-262]
- **Psychotherapy based on mindfulness:**
It can increase self-monitoring capacities, metacognitive skills and body awareness [263]
- **Techniques of muscle relaxation and yoga (if associated with CBT):** [264]
- **Support groups and psychological support interventions:**
These are effective in reducing anxiety-depressive symptoms [265], in reinforcing coping strategies and in appropriately recognizing physical signals [266].
- **Web-based behavioral intervention:**
In a clinical trial of a Web-based behavioral intervention for ICD patients, the Web-based treatment was not superior to usual care on the long-term regarding patient reported outcomes. Future studies are warranted to examine the applicability of blended-care models and focus on further personalizing the program in order to increase adherence and improve outcomes. [267].

In the Panel's opinion, from the literature analysis there emerges:

- strong evidence for the efficacy of psychotherapeutic interventions, prevalently cognitive-behavioral, integrated with techniques of mindfulness and relaxation
- moderate evidence for the efficacy of psycho-educational interventions, support group interventions and psychological support interventions

Pulmonary hypertension

Living with a serious illness such as pulmonary hypertension can be a continuous challenge and requires cognitive, emotional and behavioral adaptation [268,269]. The uncertainty of the disease and the resulting disability can have a profound impact on quality of life [270], in particular on relationships with others, on cognitive abilities, emotions and on spirituality. The experience of the disease leads to a reformulation of the self, that the person is not always aware of. Anxiety, depression, panic attacks [268, 271-273] and sleep disorders [274] are the most common disturbances. In these patients, often of a young age, there is also an overlap with issues related to pregnancy.

The analysis of the scant literature available to date permits only to presume moderate evidence for the association between the following variables and clinical condition:

- Depression
- Anxiety/panic
- Psychophysiological sleep disorders

PSYCHOLOGICAL INTERVENTIONS

These include the treatment of anxiety, depression, and panic attacks, where needed. Verma *et al.* [273] suggest a combination of pharmacotherapy and psychotherapy, in particular CBT. There exist few studies on psychological interventions in pulmonary hypertension [275-277]. In particular, attention is focused on the teaching of relaxation and slow breathing techniques [275,277].

ECS/ERS guidelines [278] affirm that psychosocial support should be offered to patients with PAH (level I-C recommendation).

The Panel retains that at present there is no clear evidence of the efficacy of specific psychological interventions.

Grown-up congenital heart (GUCH)

There is no specific literature on CPR in GUCH patients. Recent reports [279,280] indicate the need for psychosocial support and for the inclusion of adult congenital cardiac patients in traditional cardiologic rehabilitation programs, and most studies indicate that there is no relation between diagnosis, physical function or presence of residual symptoms and worse psychological functioning [281-283].

MODERATE EVIDENCE

- **Social factors**
Loneliness and absence of social support [281,284], and perceived economic difficulty [284] are associated to a larger extent with symptoms of anxiety and depression than the health condition itself.
- **Depression and anxiety**
Most studies indicate the absence of a relationship between diagnosis, physical function or presence of residual symptoms and anxiety/depression [281,284-287]; nevertheless GUCH patients wearing an ICD show higher levels of anxiety [288] and in some studies

using psychiatric interviews previously undetected disorders of anxiety and depression emerged [285,287]. Furthermore, in heart disease patients with a high level of anxiety - but only in these patients - a greater vulnerability has been found for an exaggerated perception of cardiac symptoms [289].

- **Knowledge, representation, and awareness of the disease**
The conceptualization and the severity of the disease are difficult to understand on account of the multifactorial nature of the disease [290]. Patients generally present a good awareness of treatment and of the need for follow-up. There are, however, difficulties of understanding related to: the anatomy of the heart defect, factors contributing to the onset of endocarditis, the impact of smoking and alcohol, the inheritance of a heart condition [291]. Furthermore, the perceived state of health [281,292] and the imposition of limits more than the disease condition itself are related to depressive symptoms, to the psychological well-being pre-intervention and to emotional and behavioral problems.
- **Disease management and positive psychological variables**
There are no significant differences in terms of psychological functioning between normal healthy subjects and patients with GUCH - on the contrary, in some cases with GUCH there is a better functioning [282,285,293]. Possible explanations could be related to a greater sense of coherence in GUCH patients [294] or to the fact that negation and high achievement motivation could influence patients in self-report questionnaires to present an image of themselves that is socially more desirable [293].
- **Gender**
Women show greater emotional and behavioral problems than men in regard to the presence of a surgical scar and in relation to problems associated with pregnancy [295].

In summary, in the opinion of the Panel, from the literature analysis there emerges moderate evidence for an association between the following variables and GUCH:

- Social factors
- Depression
- Anxiety
- Knowledge, representation, awareness of the disease

PSYCHOLOGICAL INTERVENTIONS

Concerning psychological interventions in GUCH patients there are few specialized programs [296] and no published data on psychological interventions [297,298]. In a recent article analyzing the psychological needs of patients referred to a psychology service [296], the main psychological concerns were: generalized anxiety, heart condition-related anxiety, low mood tone, and difficulty in managing a medical condition. On average, patients received 8 sessions of psychotherapy which consisted of cognitive therapy, relaxation techniques and training in communication skills: 88% of the patients reported a reduction or absence of psychological distress at the end of the sessions.

The Panel believes that at present there is no clear evidence of the efficacy of specific psychological interventions.

Older/oldest patients (≥75 years)

The extreme variability of the aging process makes the applicability of EBM in patients over 75 years of age complex. Moreover, in the clinical trials conducted so far, the number of patients in this age-group is always very modest and, moreover, their clinical features are poorly representative of the elderly people in the real world. In fact, they are patients with a single pathology and who do not show significant cog-

nitive deficits or significant functional limitations. In the real world, on the other hand, more than 50% of people over 75 years are affected by a combination of three or more chronic diseases in heterogeneous patterns, the cumulative effect of which is different for each one. It is therefore essential that the approach to the elderly patient maintain always a high degree of flexibility with respect to the Guideline recommendations available [299].

In particular, in inpatients aged over 75 years undergoing cardiac rehabilitation, the rate of prevalence of frailty varies from 10 to 60% depending on the weight of the cardiovascular disease [300], and a recent update of the AHA/ACC has stressed that frailty is a crucial factor both in prognosis and in planning of the rehabilitative intervention, in that, if present, it calls for a utterly specific approach with patient-centered and carefully calibrated interventions, so as to maximize the benefits and minimize the risk of adverse events [301].

Hence, the core element indispensable for a correct approach to the cardiac patient over 75 years is the distinction between an elderly cardiac patient and a 'frail' elderly cardiac patient. There are several interpretative models of frailty but the most convincing for clinical practice is that developed by Fried [302] from which stems a working definition of frailty as an organic syndrome that reflects a condition of reduced physiological reserve and of high vulnerability to stressors [303]. The stressors can be determined by the disease condition, acute or chronic, or they can be iatrogenic, *i.e.* secondary to the different interventions, not only surgical and/or pharmacological but also interventions on lifestyle and on the environment [304]. A recent meta-analysis highlights how frail cardiac patients, when exposed to such stressors, are at risk of marked and often disproportionate adverse events, complications, functional decline, disability and death [305].

Frailty, closely related to comorbidity and disability, is characterized in its physical component by three or more of the following elements: muscle weakness, weight loss, slowed gait, fatigue and low levels of physical activity [302], but it can also be conditioned by problems of the psychic sphere (*e.g.*, cognitive deficits or depressive symptoms) which can be associated to specific alterations of many physiological and biological variables, such as markers of inflammation, coagulation and metabolism.

STRONG EVIDENCE

- **Depression**
Depression is a consolidated independent risk factor for cardiovascular disease in the elderly population. A systematic review [306] and data obtained from the Health and Retirement Study [307] support a bidirectional association between depression and frailty which appears to be greater, though not significantly, in women.
- **Cognitive deficits**
Cognitive impairment, even without reaching the diagnostic criteria of dementia, is high among patients with heart disease aged over 75 years, and the results from a prospective study based on the AHA Life's Simple 7 and incident cognitive impairment [308] show an association with cardiovascular disease and more generally with an incorrect lifestyle. However, the cause-effect relationship between cardiovascular disease and cognitive impairment is very complex in the over-75 age-group, especially if the patient is frail, and therefore a highly cautious approach, as personalized as possible, is necessary for the assessment and intervention.

MODERATE EVIDENCE

- **Anxiety**
A prospective cohort study conducted on 148 elderly patients [309] underlined the negative prognostic role of a high preoperative level of anxiety on postoperative mortality and morbidity. Older patients

generally tend to report less symptoms of anxiety; however, when these symptoms are present, age does not appear to act as mediator between level of anxiety and increased risk of death due to a cardiac event [304].

- **Stress**

A recent cohort study with control group [310] highlighted an association between death of the partner and a cardiovascular event in the immediate weeks and months following.

- **Social factors**

In the frail elderly patient, the data available on the protective action of psycho-social resources are still controversial: the results of the Longitudinal Aging Study Amsterdam [LASA], a population study conducted on 1665 subjects aged 55 to 85 years, highlighted an absence of significant interaction between frailty and psycho-social resources, understood as self-efficacy, emotional and instrumental support, with respect to functional decline and mortality at 3 years [311]. These findings suggest that only in the initial stages of frailty do psycho-social resources exert a protective effect, which is then lost when the functional decline is very advanced.

MILD EVIDENCE

- **Personality factors**

The results of a systematic review [312] are interesting regarding the association between hostility and cardiovascular risk: in patients aged over 75 years, hostility is not frequent but when it is present it appears significantly associated with greater body weight, greater anxiety and depression, a higher tendency to somatization and a lower quality of life. This pattern appears to be particularly sensitive to rehabilitation.

- **Health literacy**

The AHA statement on secondary prevention in elderly cardiac patients [304] emphasized the association between health literacy and clinical condition. In patients over 75 years old, especially if frail, a careful assessment of the costs and benefits of each single intervention is necessary: communication with the patient and caregiver must be as effective as possible and the information must be given in a manner appropriate to their level of health literacy. The communication style with patients aged over 75 years must also take into account that aging is usually associated with sensory impairment (sight, hearing) and cognitive deficits and also the caregiver of an elderly patient, if the spouse, may be affected by sensory impairment [313].

In summary, in the opinion of the Panel, from the literature analysis there emerges an association between the following variables and cardiac disease in patients aged over 75 years:

- **strong evidence:**
 - Depression
 - Cognitive deficits
- **moderate evidence:**
 - Anxiety
 - Stress
 - Social factors
- **mild evidence:**
 - Personality factors
 - Health literacy

PSYCHOLOGICAL INTERVENTIONS

The limited literature available on patients of this age-group makes it very hard to define the specific psychological interventions carried out as part of the rehabilitation program, since the scant available evi-

dence support the global efficacy of cardiac rehabilitation regarding both the various psycho-social risk factors and the cognitive sphere. The essential requirement of each intervention is a systematic approach to the patient, so as to incorporate the full complexity related to advanced age in every decision made, even if there are no signs of frailty [301]. Identifying which interventions should not be started or should be interrupted can be extremely complicated in this patient population, even for the psychologist. Factors to be considered include quantification of the benefit in terms of reduction of baseline risk compared to the outcome considered, risk of adverse events, and assessment of the expected benefits with respect to life expectancy [299].

Several studies with moderate evidence report comprehensive cardiac rehabilitation to be effective in reducing depression and of anxiety [312]. In order to understand the depression/frailty relationship, it is necessary to weigh carefully the depressive symptoms in terms of their biological or clinical (cognitive-behavioral) structure: major depression, strongly biological, is an independent risk factor; a depressive syndrome, on the contrary, could be the manifestation of difficulty in adapting to the loss of functional autonomy and/or the age-related decline [306]. In the latter case, frailty may have caused the depressive syndrome and then become further aggravated by it. The evidence in support in this regard has important implications for the selection of the screening tools, formulation of a correct diagnosis and then planning of the intervention.

The Update of the 2013 ACCF/AHA Guidelines [301] underlines the limited emphasis given so far in the various guidelines to the need to extend educational interventions, which are defined as extremely relevant, also to patients aged over 75 years, actively involving also their caregivers. Finally, it should be underlined that the data from a recent RCT support the effectiveness of cardiac rehabilitation, especially the physical exercise component, in improving the cognitive profile of patients over 75 years old, even in the presence of initial decline [314].

In the panel's opinion, from the literature analysis, as yet still limited, there emerges:

- **moderate evidence** for the efficacy of interventions of support for depression;
- **moderate evidence** for the efficacy of psycho-educational and management interventions.

Cardiac patients in palliative care

Recently the concept of “managed death” has replaced that of “good death” and this important change of paradigm requires all health professionals to have a precise orientation and adequate knowledge [315]:

- End of life refers to patients who may die within 12 months, which ranges from an imminent death perspective (a matter of hours, or days) to a prolonged terminal condition, which in cardiovascular terms essentially concerns advanced CHF.
- End of life care includes care provided to family members after the patient dies.
- In prolonged terminal conditions, there is not always a clear distinction between being sick and dying.
- The transition to end of life care must take place when treatments are no longer effective, the burden of symptoms is extremely heavy and it is necessary to evaluate eventual “disease-exchanging therapies”, *i.e.* a remodulation of treatments in order to allow greater therapeutic investment in the more functional aspects in line with the patient's preferences.

In the cardiovascular field, the natural history of CHF is characterized by a gradual decline in functional capacity, interrupted by acute episodes of instability which further worsen the trend. In ad-

vanced CHF, or phase D according to AHA, the high rate of mortality is hard to modify, the symptoms are disabling and the quality of life heavily compromised; nevertheless, the prognostic stratification still remains very difficult. Therefore, selecting patients with advanced CHF and a high risk of mortality at 1 year, to shift, at the right time, the goal of treatment from maintenance of life at all costs to alleviation of symptoms and possible improvement in the quality of life requires an integrated approach that takes into account not only the risk scores but also the clinical opinion of all members in the team.

These patients, characterized by complicated symptoms refractory to treatment, by a high level of psychological distress, and by a stringent need to reach shared decisions with their caregivers and family, can benefit greatly from a palliative care approach. [316,317]. In the advanced phase of illness, the patient experiences a marked reduction in their quality of life: from a physical point of view, the symptoms most frequently perceived are fatigue, dyspnea and edema in the limbs. From a psychological point of view, uncertainty and fear and a general sense of imminent death prevail. The sense of threat together with the loss of their family and social role, the physical limitation and the restriction of will and freedom determine profound existential changes. From the awareness of imminent death to the actual death itself, patients go through a series of phases, whose temporal succession varies from individual to individual, during which they pass from the acute crisis of realization to possible acceptance until the final phase of withdrawal into themselves [318].

In the panel's opinion, from the literature analysis, there emerges:

- **strong evidence** for an association between the following variables and palliative care in cardiac disease:
 - Depression
 - Distress
- **moderate evidence** for the association with:
 - Anxiety
 - Social factors
- **mild evidence** for the association with:
 - Personality factors

PSYCHOLOGICAL INTERVENTIONS

The statement published in 2012 by the AHA was a real 'call to action' on the need to promote a shared decision-making process with the patient suffering from advanced heart failure [318]. The document illustrates a sort of road map to guide all team members in the activation of a shared decision-making process, precisely during the transition phase, *i.e.* when the context is increasingly characterized by uncertain prognosis, different outcomes often "competing" with each other, and communication barriers. It is necessary to maintain attention on the clinical evolution of the disease, to adjust expectations and to promptly guide decisions; all the same, uncertainty is unavoidable and needs to be included in discussions with patients and family members. Discussions with patients must take into account all the outcomes, not only that of survival but also those of major adverse events, the burden of symptoms, functional limitations, loss of independence, quality of life and constraints on caregivers.

In the panel's opinion, from the literature analysis, as yet still limited, there emerges strong evidence for:

- Interventions of shared decision making with the patient and family members
- A palliative care approach

Patient caregiver

In dealing with the topic of caregiving, it is necessary to distinguish between objective and subjective burden. The objective burden is as-

sociated with the patient's level of dependence during the different stages of the disease, the caregiver's numerous duties, the frequency of hospital admissions, the need to use devices and/or new equipment [320]. The subjective burden refers to the management of all the negative emotions that the activity of caregiving elicits and is produced by the interaction between the characteristics of the patient's illness and inherent characteristics of the caregiver. In the acute phase of hospitalization, the cardiac event is experienced by the family in a traumatic way, in that the family members, including for the most part the spouse, experience a breakdown of their normal way of life and the loss of physical integrity of their loved one. The dominant feelings are fear, anxiety, uncertainty, impotence and loss of control. In the phase of chronicization of the disease and then in the terminal phase, family members tend to neglect their own state of health in devoting themselves to that of the patient and coping with all the other daily needs.

In all phases of the diseases, the following scenarios represent serious challenges:

- the patient's neuro-cognitive symptoms create an added burden for the spouse [321]
- the disease can disturb the couple's sexuality [322]
- if the caregiving spouse is of a young age, the burden can be worse due to the greater number of duties and responsibilities towards other family members, *e.g.* children and/or parents, and towards work activity, compared to elderly and retired caregivers [321]
- anxiety, depression and the feeling of loss of control of the family member hinder the patient's psychosocial adaptation to the disease [321]
- the personality traits of low optimism and high neuroticism in the spousal caregiver are associated with major depressive symptoms in the patient
- a low level of mutuality in the couple [321] is associated with a high burden of the family member, negatively affecting the caregiving, and with a worse health status of the patient
- lack of social support and the presence of economic problems increase the caregiver's burden [323-325]

Protective factors in all phases of the disease are:

- perception of control and good communication with the healthcare team [326];
- optimism and marital satisfaction and a supportive coping style of the partner [327];
- the possibility of having good social support, possibly sharing the care of the patient with another family member [324, 328];
- the possibility for the couple to receive informative and educational interventions regarding the area of sexuality, to increase their knowledge, well-being and help them maintain an intimate relationship [329].

Below are presented the issues related to the burden in the different phases of illness.

1) Acute phase of the disease (family caregivers of an ischemic and/or CABG patient)

Caregiver burden may be due to the demand on time (objective time spent) and difficulty with caregiving activities (subjective perceived stress) [330]

- CABG caregivers have reported feeling unprepared for their role and thus are at risk of caregiver burden. Compared to females, male CABG caregivers had totally different challenges and perceived the organizing of care as more demanding than females. All male caregivers have higher demand (time spent), difficulty (level of stress) and overall burden compared to female caregivers [330]
- Older CABG caregivers (>70 years) are also at risk of greater burden [330]

- symptoms of PTSD (alarm, hypervigilance, confusion, derealization) in the family caregiver have negative effects on the patient's disease management [331]

Psychological interventions aimed at ischemic patients and their partners improve, in the spouse, the anxiety, knowledge, and satisfaction about care [332]. Family members, particularly wives, young caregivers and with a high educational level, request to participate actively, together with the patient, in the interventions of secondary prevention and in the decision-making processes regarding drug treatment and the change of lifestyle. It is therefore necessary to have interventions of support centered on the person but aimed at the couple in order to reduce anxiety and improve communication and coping skills [326]. These interventions must also be focused on topics such as communication, care, vigilance but also respect for autonomy (family members frequently assume a 'controlling' attitude towards the patient and an attitude of 'neglect' regarding their own needs), changes in family roles and perspectives/expectations regarding the future [331,333].

In order to change lifestyle, the usefulness of motivational interviews with the couple is pointed out - they are effective in identifying processes that perpetuate dysfunctional behaviors, in exploring possible alternatives, and in determining the motivation for change, helping the couple to reflect on the modes of communication ('supportive' vs 'controlling') and promoting the use of 'supportive' communication strategies, with positive effects on the change of risk behaviors for health [334].

2) Chronic phase of illness (family caregivers of a patient with CHF)

Considering caregiving factors together with patient factors significantly increases our understanding of patient clinical events risk in CHF [335]. The influence of an effective caregiver on CHF patient outcomes has been shown in improved quality of life, lower hospitalization rates [335] and reduced mortality. Psychological distress of the spouse increases the symptoms of heart failure, regardless of the stress perceived by the patient and/or NYHA class [336]. However, providing regular care to a CHF patient can lead to deficits in the caregiver's own health and quality of life. Studies have shown that HF caregivers experience a similar level of burden as caregivers of patients with advanced cancer and chronic obstructive pulmonary disease [Humphrey 2013]. The assistance and care of patients with heart failure is perceived as demanding and characterized by a strong emotional distress with feelings of insecurity and uncertainty, by less personal freedom, experience of solitude, social isolation and often by economic problems [325,337]. The literature indicates that the burden is worse in the presence of certain individual factors and external factors [324].

The main individual dimensions that make caregivers particularly vulnerable are:

- female gender [324]. Female partners of patients with heart failure have a lower quality of life compared to male caregivers and a lower level of well-being in general compared to female partners of healthy people;
- a low perception of control [324,337,323];
- a low quality of life regarding the physical component [338]: caregiving worsens the physical health status of family members with pre-existing health problems.

The main external factors that increase the burden are:

- poor physical and mental health of the patient [324,337,338], frequent emergency hospitalizations [323,324,338], and difficulty in managing symptoms and therapies [338]. The most difficult tasks related to caregiving (monitoring of symptoms, managing medication and behavioral and food indications) contribute significantly to worsening the caregiver's physical health.

The literature regarding interventions for caregivers of patients with heart failure has focused on management, communication and relational aspects to improve the patient's health conditions, as well as on the disease management, but also on the burden of the caregiver. There are different modes of intervention according to the different goals:

- interventions involving patients, family and physicians aimed at improving the patient's disease management in terms of self-care, symptoms monitoring and taking of medications [339].
- interventions focused on the family and on reducing the caregiver's burden aimed at improving the physical and mental health of the patient and relational aspects [340].
- interventions of 'telehealth care' and 'telephone coaching' aimed at improving management of the transition phase to home [341] and at increasing the perceived caregiver mastery [342].

3) Family caregivers of patients undergoing heart transplantation

Relatives take on great responsibilities during patients' heart or lung transplant process and an understanding of their situation is required. Any patient for whom social supports are considered insufficient to achieve compliant care in the outpatient setting may be regarded as having a relative contraindication to transplant [178]. Research has shown that relatives of patients wait-listed for HT worry about a rapid disease progression and death while the patient is waiting for new organs. Most relatives suffer from uncertainty, fear and stress. These emotions persist after the transplantation, during the recovery period, and in some cases for years because of the risk of acute or, in the longer term, chronic organ rejection and death [178]. Poor physical health in the caregiver at 12 months after transplantation results in a lower patient survival during the next seven years [343]. After HT, considering the consequences on the psychophysical health and socio-economic level of caregivers, some authors have identified the need for psychological support to the family [344] and for psychotherapeutic interventions addressed to the family [345]; others, focusing on potential conflicts in the marital relationship, suggest the utility of psychosocial interventions of counseling addressed to the couple [346,347].

4) Family caregivers of patients undergoing implantation of a device

During the implantation phase, the family lives in a condition of distress characterized by a physical and emotional burden linked to the sense of responsibility, fear, anxiety, and loss of freedom and independence [348,349]. There is a higher level of anxiety in the family members than in the patients themselves and about 23% of caregivers manifest PTSD, which is not found in patients [350]. If the LVAD implant was done in an emergency and, therefore, caregivers and patients could not receive adequate information, the anxiety and fear remain, especially for caregivers, even in the period after the implant itself [349].

5) Family caregivers of patients in the terminal phase

There are few systematic studies on the families of cardiac patients in the terminal phase of illness [351]. The experience of burden appears to be relatively stable over time, without much differentiation between the phase of chronic disease and the terminal phase, but in the terminal phase the family caregiver of a cardiac patient appears to be characterized by specific needs for information and communication regarding palliative care and decisions on the end of life. Some studies point out that caregivers complain about a lack of information from care personnel regarding the treatment of symptoms, and of prognostic information about the future development of the disease, including end of life issues (e.g., disactivation of ICD), and hence a lack of planning of the timing and services that can support the patient and caregiver in

the terminal phase of illness [352]. From the literature there emerges a sense of frustration regarding the use, in this phase and by the doctors, of technical jargon difficult to understand [353]. From the analysis of the literature, some considerations emerge:

- young age, female sex and persistent family conflicts are factors associated with greater emotional stress experienced by caregivers [354];
- a fatalistic/anxious coping style [355] of the family caregiver worsens the burden;
- poor social support [354,356], poor help in managing daily activities [357], and family economic problems [355] worsen the patient's disease management;
- an inadequate knowledge/awareness of the terminal status on the part of the family caregiver interferes with the patient's disease management [353];
- the progression of the disease severity increases the limitations in the social relationships of patient and family and aggravates the communication difficulties between the partners [353].

Family members of terminal cardiac patients display similar needs to family members of patients with other terminal diseases; therefore, it is necessary to extend to this group of patients and families the use of specialized palliative care services with a multidisciplinary approach, which must include interventions of psychosocial support and on end-of-life management of the patient aimed at family members [352,357].

6) Family caregivers of patients over 75 years

The caregivers of patients aged ≥ 75 years are mostly older women, wives, often also affected by multiple physical age-related disorders and they are distinguished from other groups of caregivers by their older age and consequently greater need for help in daily living activities [358,359]. The burden in these caregivers means they have need for help in daily tasks, need for emotional support and a general need for greater communication with both the patient and the doctors [358]. The experience of burden seems to depend mostly on characteristics of the caregiver, highlighting their ability to adapt to their own role, their ability to cope and the quality of the previous relationship with the patient [360]. Because family members of patients >75 years are often elderly, the main problems are:

- insufficient knowledge/awareness of the patient's illness due to lack of communication with the doctors [358];
- low socio-economic status, poor social support and social isolation [361].

It is essential to focalize interventions on the caregiver in order to provide them with more information and increase their communication with healthcare staff and with the patient [362], promote the pres-

ence of an emotional and social support network, increase their capacity of adaptation to the caregiver role through specific interventions that increase the caregiver's own coping strategies and make them more effective [356]. Indeed, some studies have shown that the experience of caregiving can be experienced not only as a source of stress but also as a positive experience [359], especially when the communication between patient and caregiver is improved, with positive effects on both the management of the disease and on the quality of life of both partners [363], placing at the center of interest the concept of the patient-caregiver dyad [364].

Best practice in psychological activities in CPR

Best practice is defined as those interventions, programs, or strategies that have, through multiple implementation, demonstrated a high impact (positive changes related to the desired goals, high adaptability, *i.e.* successful adaptation and transferability to different settings) and high quality of evidence (excellent quality of research/evaluation methodology, confirming the intervention's high impact and adaptability evidence). Best practice is one that is most suitable given the available evidence and particular situation or context. In health promotion, such practices are used to demonstrate what works for enhancing health-related outcomes of individuals and communities, and how and why they work in different situations and contexts [from *Canadian Best Practice Portal*; accessed on 11 December 2017].

The process of evaluating the goodness of a practice is particularly critical. The approaches and methodologies can be many and various, but there will nevertheless always be a component of subjectivity.

The Panel referred to the following factors of relevance:

- **performance** = ability of a practice to achieve the objectives (based on data from the literature);
- **efficiency and sustainability** = ability of a practice to base itself on existing resources and to make efficient use of these resources;
- **transferability/reproducibility** = exportability of the practice to different contexts;
- **learning and relationships** = ability of the practice to create relationships and contexts of interdisciplinary learning and collaboration.

By best practice we thus mean a series of general indications of support for each decision-making node in the assessment and intervention, transversal to the different pathologies, based on analysis of the evidence as well as on considerations of a legal and deontological nature (Figure 1).

Best practice

It is necessary to:

- assess the possible presence of psychopathological aspects in the medical history and consider referring the patient to local community services
- investigate the possible presence of previous cognitive deficits
- evaluate the possible presence of depression and anxiety, either reactive or related to the clinical condition
- evaluate the presence/absence of social support
- evaluate the knowledge, awareness, acceptance and management of the disease
- take into account sex, age and ethnic minorities
- evaluate positive, personal and environmental resources and construct interventions aimed at reinforcing them
- evaluate the level of health literacy of the patient and caregiver in order to personalize the informative, educational and communication intervention
- design psychological interventions of low/high intensity based on the problems detected and the working and organizational resources present
- provide counseling to caregivers where problems are detected and/or their need emerges from the patients themselves, the family and/or the multidisciplinary team
- provide counseling on sexuality, where problems arise
- structure all of the psychological activity within the multidisciplinary intervention and in synergy with the team

Figure 1. General indications of support for each decision-making node in the assessment and intervention, transversal to the different pathologies.

Following the literature analysis, we were able to define recommendations, according to the grade of evidence: strong (+++), moderate (++), mild (+), of low and high intensity evidence based psychological/psychotherapeutic interventions (Figure 2).

The figure 3 contains operational cards summarizing the assessment and intervention recommendations, disease by disease, according to the grade of evidence: strong (+++), moderate (++), mild (+).

A flow chart is provided showing the path from selection to patient discharge. The selection phase initiates the care process and fea-

tures the choice of the service by the user or person referring. The definition of some strategies by the psychologist allows to then guide the requests of the user or person who has referred the patient, especially in terms of appropriateness of access to the process of care (Figure 4).

The figure 5 contains a checklist for the selection of patients to be referred to the psychologist.

The figure 6 lists the recommended psychological and neuropsychological tests.

| Pathologies | Coronary heart disease | Cardiac surgery | Chronic heart failure | Heart transplantation | L-VAD | ICD | GUCH | Pulmonary hypertension | Older/oldest patients | Cardiac patients in palliative care |
|--|------------------------|-----------------|-----------------------|-----------------------|-------|-----|------|------------------------|---|-------------------------------------|
| Interventions | | | | | | | | | | |
| LOW | | | | | | | | | | |
| Individual and/or group counseling (from single interview to motivational interview) | +++ | ♥ | +++ | +++ | ♥ | +++ | ♥ | ♥ | ♥ | ♥ |
| Psycho-educational sessions regarding psychosocial risk factors, smoking, diet, etc. | +++ | | ++ | | + | ++ | | | Only with costs and benefits evaluation | |
| Multidisciplinary sessions regarding information and management (self-care, self-management, self-help, telemedicine) | +++ | | +++ | + | | ++ | | | Only with costs and benefits evaluation | |
| HIGH | | | | | | | | | | |
| Psychotherapy interventions: individual, group (stress management) or family (at least 1/week) * | +++ | + | ++ | ++ | + | +++ | ♥ | ♥ | ♥ | ♥ |
| Multidisciplinary interventions: evidence of the need to implement a structured psychotherapeutic intervention (cognitive-behavioral therapy, motivational, mindfulness, etc.) | +++ | | ++ | | | ++ | | | ♥ | |
| ♥ Good practice, as suggested by the Panel ; +++, strong evidence; ++, moderate evidence; +, mild evidence; *Italian LEA (essential levels of assistance) (at least 1 / week) which may include short (within 8 sessions), medium (within 16), long (from 16 to 30). | | | | | | | | | | |

Figure 2. Low and high intensity evidence based psychological/psychotherapeutic interventions in the different cardiac pathologies.

CORONARY HEART DISEASE

| | | RECOMMENDATIONS |
|--------------------------------|---|--|
| ASSESSMENT | +++ Behavioral risk factors Social factors Depression Anxiety and panic Stress Post traumatic stress disorder | <ul style="list-style-type: none"> It is necessary that the psychologist carefully assesses the possible presence of risk behaviors, [acute and chronic stress, including the psychosocial characteristics of work], depression, lack of social support, anxiety and panic, post-traumatic stress disorder, hostility and type D personality, in all ischemic patients. |
| | ++ Personality factors (Type D) Positive psychological variables | <ul style="list-style-type: none"> It is important to identify patients at high risk [presence of multiple risk factors, young people, women, elderly people, ethnic minorities] and implement personalized and tailored psychological interventions. |
| INTERVENTION | | |
| CAREGIVERS INTERVENTION | +++ Cognitive behavior therapy (depression, anxiety, stress management) | <ul style="list-style-type: none"> It is necessary to implement multimodal and multi-professional interventions aimed at health education and risk factor management. |
| | + Interpersonal psychotherapy on depression Short term psychoanalytic therapy Mindfulness interventions | <ul style="list-style-type: none"> It is necessary to implement psychotherapeutic interventions mainly cognitive behavioral, individual and/or group [anxiety, depression, relaxation, stress management], contextualizing the interventions [low intensity/high intensity] in relation to the severity of the problems and the type of hospitalization [ordinary, outpatient, day/hospital]. |
| | + Psychological support and psycho-educational sessions for the partner/spouse/caregiver | <ul style="list-style-type: none"> The psychologist should consider the presence of burden in the spouse or caregiver, the possibility of problems in the relationship and evaluate when it is appropriate to proceed with an intervention or a referral. |

CARDIAC SURGERY

| | | RECOMMENDATIONS |
|--------------------------------|--|---|
| ASSESSMENT | ++ Anxiety and depression Post traumatic stress disorder Post intervention neuropsychological disorders | <ul style="list-style-type: none"> It is advisable to evaluate the possible presence of anxiety, depression, Post-Traumatic Stress Disorder and the opportunity to implement low and / or high intensity psychological and / or psychotherapeutic interventions. The possible presence of cognitive deficits should be investigated, through neuropsychological evaluation. |
| | INTERVENTION | |
| CAREGIVER INTERVENTIONS | Literature concerning specific psychological interventions was not found. | <ul style="list-style-type: none"> A good practice intervention is suggested |
| | | |

Figure 3. Operational cards.

To be continued on next page

CHRONIC HEART FAILURE

| | | RECOMMENDATIONS | |
|-------------------------|---|---|---|
| ASSESSMENT | +++ Depression Addiction alcohol and cocaine Anxiety | <ul style="list-style-type: none"> It is necessary that the psychologist carefully assess the possible presence of depression, anxiety, the abuse of cocaine or alcohol in remote and / or recent anamnesis, the lack of socio-family support, low SES and the immigrant status. | |
| | ++ Social factors Personality factors (type D) Neuropsychological disorders Sleep disorders Disease management Positive psychological variables | <ul style="list-style-type: none"> Cognitive deficits in the elderly and severely compromised patients should be investigated by neuropsychological evaluation The psychologist should evaluate the levels of health literacy, adherence and self-management skills of the disease to optimize the outcome, prevent relapse and avoid rehospitalization. Evaluation of the presence of Type-D personality is not recommended routinely | |
| | INTERVENTION | ++ Cognitive-behavioral interventions Psychoeducational and disease management interventions (self care) Telemedicine | <ul style="list-style-type: none"> Both multidisciplinary and nursing management and telemedicine intervention programs must be structured with cognitive-behavioral techniques, since they reduce the number of hospitalizations and the mortality for SCC [low intensity] Psychological interventions are necessary in the presence of depression, anxiety and lack of emotional support [high intensity] It is necessary for the psychologist to consider when it is appropriate to make a referral to the social worker. |
| | | ++ Psychological support and psycho-educational interventions in family members Caregiver burden interventions | <ul style="list-style-type: none"> Psychological intervention should optimize management treatment, encourage self-management resources and improve adherence to prescriptions. Health education should be directed to self-management of the SCC not only in terms of behavioral changes, but also changes in personal beliefs to achieve long-term lasting changes. |
| CAREGIVERS INTERVENTION | ++ Psychological support and psycho-educational interventions in family members Caregiver burden interventions | <ul style="list-style-type: none"> The psychologist should consider the presence of burden in the spouse or caregiver, the possibility of problems in the relationship and evaluate when it is appropriate to proceed with an intervention or a referral. In order to encourage and maintain knowledge and mastery in the management of the disease, psychological, psychoeducational and behavioral interventions are needed on the family members | |

HEART TRANSPLANTATION

| | | RECOMMENDATIONS | |
|-------------------------|--|--|--|
| ASSESSMENT | +++ Behavioral risk factors Depression | <ul style="list-style-type: none"> For all cardiac transplant patients, a psychodiagnostic and psychosocial investigation is required to identify the possible presence of prior psychiatric pathology, stress, anxiety and reactive depression and psychosocial distress. | |
| | ++ Social Factors Anxiety Stress Post traumatic stress disorder Personality factors Disease management Positive psychological variables Neuropsychological disorders | <ul style="list-style-type: none"> If clinically indicated, in cardiac transplant patients, it is necessary to perform a neuropsychological assessment of cognitive deficits, that are possible contraindications to transplantation [with particular attention to the executive functions involved in the decision making process]. It is necessary a careful assessment of behavioral risk factors (alcohol, tobacco, obesity), possible contraindications to transplantation. | |
| | INTERVENTION | +++ Cognitive-behavioral interventions | <ul style="list-style-type: none"> It is necessary to structure a psycho-educational program aimed at facilitating the understanding and adherence to clinical, pharmacological, behavioral prescriptions and substances de-addiction, in the pre and post-transplant phase. |
| | | ++ Psycho-educational and management interventions | <ul style="list-style-type: none"> It is necessary to implement low and / or high intensity psychological and / or psychotherapeutic interventions in relation to the severity of the problems emerging and of the hospitalization regimen [ordinary, outpatient, day / hospital, both in the pre-transplant and in the post-transplant phases. |
| CAREGIVERS INTERVENTION | ++ Psychological support and psycho-educational interventions in family members Caregiver burden interventions | <ul style="list-style-type: none"> The psychologist should consider the presence of burden in the spouse or caregiver, the possibility of problems in the relationship and evaluate when it is appropriate to proceed with an intervention or a referral. | |

Figure 3. Continued from previous page.

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MECHANICAL VENTRICULAR ASSIST DEVICES

RECOMMENDATIONS

| | | |
|--------------------------------|---|---|
| ASSESSMENT | ++ Depression Anxiety Acute and chronic stress Psychophysiological disorders of sleep Cognitive deficits | <ul style="list-style-type: none"> • It is necessary that the psychologist carefully assesses the possible presence of anxiety, depression, distress, sleep disorders, in the pre and post-implantation phases of L-VAD. • The possible presence of cognitive deficits should be investigated through neuropsychological evaluation. |
| INTERVENTION | + Cognitive-behavioral interventions Psycho-educational and management interventions | <ul style="list-style-type: none"> • It is important to promote psycho-educational interventions to increase awareness and the ability to manage L-VAD both in patients and in their caregivers. • It is necessary to implement low and / or high intensity psychological and / or psychotherapeutic interventions in relation to the severity of the emerging problems and of the hospitalization regimen [ordinary, outpatient, day / hospital, both in the pre-implant and in the post phases. |
| CAREGIVERS INTERVENTION | + Psychological support and psycho-educational interventions in caregiver | <ul style="list-style-type: none"> • The psychologist should consider the presence of burden in the spouse or caregiver, the possibility of problems in the relationship and evaluate when it is appropriate to proceed with an intervention or a referral. |

IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

RECOMMENDATIONS

| | | |
|--------------------------------|--|---|
| ASSESSMENT | ++ Depression Anxiety Post-traumatic stress disorder Type D personality Cognitive deficits | <ul style="list-style-type: none"> • It is necessary to evaluate the presence of post-traumatic stress disorder [PTSD] • An evaluation of patients who experienced shock [appropriate and inappropriate] is recommended. |
| INTERVENTION | +++ psychotherapeutic interventions, mainly cognitive-behavioral, integrated with mindfulness and relaxation techniques ++ psychoeducational interventions psychological support | <ul style="list-style-type: none"> • Psychoeducational interventions are recommended [low intensity) • It is necessary that patients with ICD, in which psychopathological symptoms have emerged, are supported with psychotherapeutic interventions (high intensity), mainly cognitive behavioral ones, integrated with mindfulness and relaxation techniques. • Information on the possibility of disabling the ICD should be shared with patients |
| CAREGIVERS INTERVENTION | | <p>A good practice intervention is suggested</p> |

Figure 3. Continued from previous page.

To be continued on next page

PULMONARY HYPERTENSION

RECOMMENDATIONS

ASSESSMENT

++
 Depression
 Anxiety / Panic
 Psychophysiological disorders of sleep

- It is necessary to evaluate the possible presence of anxiety, depression and sleep disorders associated with the clinical condition

INTERVENTION

there are no studies indicating efficacy of psychological interventions

- A good practice intervention is suggested
- The implementation of low and / or high intensity psychological and / or psychotherapeutic interventions in relation to the severity of the emerging problems and the hospitalization regimen [ordinary, outpatient, day / hospital] is suggested

CAREGIVERS INTERVENTION

- Counseling for family caregivers is suggested.
- It is necessary to provide psychological counseling on the issue of pregnancy

GROWN-UP CONGENITAL HEART

RECOMMENDATIONS

ASSESSMENT

++
 Social factors
 Depression
 Anxiety
 Knowledge, representation, awareness of the disease

- Assessment and psychological interventions would be desirable in the grown-up congenital heart patients in rehabilitation
- It is necessary to check if the surgical scar has caused problems for the patient [especially in the female population].

INTERVENTION

+
 emerges mild evidence of efficacy (a single psychological intervention)

there are no studies indicating efficacy of psychological interventions

- A good practice intervention is suggested
- It is necessary to provide psychological counseling on the issue of pregnancy

CAREGIVERS INTERVENTION

Figure 3. Continued from previous page.

To be continued on next page

OLDER/OLDEST PATIENTS

| | | | |
|--------------------------------|---|---|---|
| ASSESSMENT | +++ Depression Cognitive deficits | RECOMMENDATIONS | <ul style="list-style-type: none"> • It is necessary to carefully evaluate frailty as the strongest prognostic marker, the presence of depression and to structure a support intervention • It is necessary to evaluate the presence of cognitive deficits |
| | ++ Social Factors Stressful events Anxiety | | |
| | + Personality factors Health literacy | | |
| INTERVENTION | + cognitive-behavioral interventions psycho-educational and management interventions | <ul style="list-style-type: none"> • The cost-benefit of lifestyle intervention must be weighed carefully for each patient | |
| | + psychological support and psycho-educational interventions in the caregiver Interventions on the caregiver burden | | <ul style="list-style-type: none"> • It is necessary to evaluate the possible presence of psycho social problems (caregiver / family burden, poor social support, low socio-economic level) in order to consider the possibility of referrals to the territorial psychosocial services • It is advisable to promote the knowledge and management of the disease with psychoeducational interventions for both the patient and family dyad |
| CAREGIVERS INTERVENTION | | | |

CARDIAC PATIENTS IN PALLIATIVE CARE

| | | | |
|--------------------------------|---|---|---|
| ASSESSMENT | +++ Depression Distress | RECOMMENDATIONS | <ul style="list-style-type: none"> • It is necessary to evaluate the symptoms of psychological distress and the presence of clinical depression as they are factors which are capable of influencing the psychological response to the disease • It is advisable to evaluate the information needs of the individual patient in order to avoid that an excess of information which could cause emotional distress and worsen the outcome. |
| | ++ Social Factors Anxiety | | |
| | + Personality | | |
| INTERVENTION | +++ Activate a shared decision process considering all the outcomes, not only the survival but also the weight of the symptomatology | <ul style="list-style-type: none"> • Shared decision making with the patients and also their caregivers and other family members is necessary. | |
| | + Psychological support and psycho-educational interventions in the caregiver Interventions on the caregiver burden | | <ul style="list-style-type: none"> • It is necessary to assess the presence of caregiver burden, social isolation and any socio-economic problems • It is necessary to evaluate the informative needs of the family members |
| CAREGIVERS INTERVENTION | | | |

Figure 3. Continued from previous page.

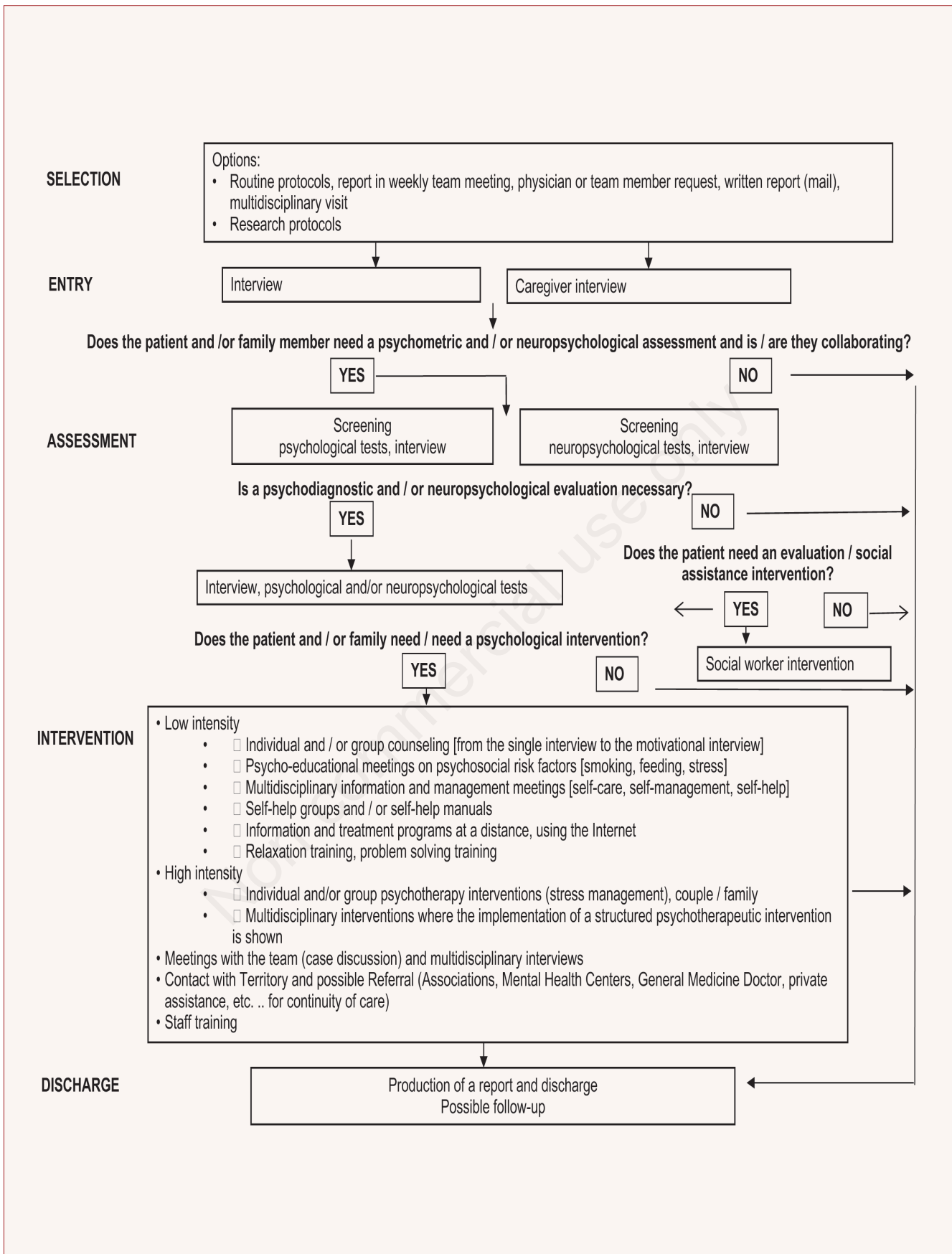


Figure 4. Flow chart showing the path from selection to patient discharge.

SELECTION CHECKLIST For each area, assess the presence/absence of the listed problems: it is sufficient to find only one element to make the psychological intervention necessary.

| | | |
|---|-------------------------------------|------------------------------------|
| 1) PSYCHOLOGICAL COMORBIDITIES | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| <ul style="list-style-type: none"> ✓ Depression (during the last month the patient felt down and hopeless? he lost interest and pleasure in life?) Anxiety (during the last month the patient has had sudden fears or panic? is frequently unable to stop or control worrying?) ✓ Post-traumatic stress disorder (during the last month the patient has been exposed to a traumatic event? he suffers from nightmares or intrusive thoughts?) ✓ Type D personality factors, Hostility (in general the patient feel anxious, irritable, or depressed? he tends to avoid sharing his thoughts and feelings with other people?) | | |
| 2) SPECIFIC PSYCHOLOGICAL ISSUES | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| <ul style="list-style-type: none"> ✓ Neuropsychological disorders (the patient is cognitively impaired?) ✓ Acute or chronic mental stress (the patient refers defeat or other serious life events?) ✓ Chronic stress at work (the patient refers long working hours, extensive overtime work, high psychological demands, unfairness and job strain?) ✓ Problems regarding the area of sexuality | | |
| 3) DISEASE MANAGEMENT / SOCIAL ISSUES/ CAREGIVER NEEDS | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| <ul style="list-style-type: none"> ✓ Inadequate awareness and acceptance of the disease, inadequate treatment adherence (the patient has impaired illness awareness and treatment related prejudices?) ✓ Social isolation and low socio-economic status (the patient is living alone, in a poor residential area? is isolated and disconnected from others? He has a low educational level, a low income?) ✓ Caregiver needs / burden (the caregiver needs information, emotional support? The care of patients is perceived as demanding and characterized by a strong emotional distress and by economic problems?) | | |

Figure 5. Checklist for the selection of patients to be referred to the psychologist.

Psychological and neuropsychological screening tests. References and description of the tools are available in www.gicr.it in the psychological area-tools section

- Anxiety and Depression-Revised [AD-R]
- Hospital Anxiety and Depression Scale [HADS]
- Beck Depression Inventory-2 [BDI-2]
- Patient Health Questionnaire 9 [PHQ-9]
- Generalized Anxiety Disorder 7 [GAD-7]
- Mini Mental State Examination [MMSE]
- Montreal Cognitive Assessment [MoCA]
- Addenbrooke's Cognitive Examination Revised [ACE-R]
- Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM)
- Distress Scale [DS14, Type D personality]
- Magerl CaRdiac preventiOn-Questionnaire [MICRO-Q]
- Adherence Schedule in Heart Disease–Brief [ASHiD-R]
- Family Strain Questionnaire [FSQ]
- Disease Impact On Caregiver [DIOC]

Figure 6. Psychological and neuropsychological tests.

Conclusions

This paper aims to support all psychologists working with CPR patients in identifying good practice and disease-specific models of intervention. There is, however, a need to develop new models of research that ‘photograph’ the real world of patients (registers, *etc.*), often quite different from the selected populations present in clinical trials. Some recommendations can be made for future research:

- to use and develop new validated “cross cultural” instruments;
- to promote observational studies (registers) that reflect the ‘real world’;
- to develop RCTs, robustly designed and with adequate follow-up, to evaluate the efficacy of the psychological/psychotherapeutic therapies described in this position paper on psychological and cardiovascular endpoints, focused on specific patient groups (in particular, women and the elderly);
- to develop research on cardiac patients in palliative care;
- to promote studies to evaluate the dedicated caregiver program with a large, representative, diversified sample that incorporates information and resources tailored to the specific concerns and needs of caregivers, in various age and gender cohorts.

Future research should validate concerns in more diverse samples so that interventions can be targeted to better support male and female caregivers in the various age-groups.

According to Richards [7], future large-scale trials testing the effectiveness of psychological therapies are required due to the uncertainties within the evidence. Future trials would benefit from testing the impact of specific (rather than multifactorial) psychological interventions on patients with CHD, and testing the targeting of interventions to different patient populations (*i.e.*, people with CHD, with or without psychopathologies).

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