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# Clinical and subclinical distress, quality of life and psychological well-being after cardiac rehabilitation

Sara Gostoli<sup>1</sup>, Renzo Roncuzzi<sup>2</sup>, Stefano Urbinati<sup>2</sup>, Chiara Rafanelli<sup>1</sup>

<sup>1</sup> Department of Psychology, University of Bologna, Bologna (Italy)

<sup>2</sup> Division of Cardiology, Bellaria Hospital, Bologna (Italy)

Corresponding Author:

Sara Gostoli, PhD

Department of Psychology, University of Bologna

Viale Berti Pichat, 5 - 40127 Bologna (Italy)

Tel.: +39 051 2091847

Fax: +39 051 24308

Email: sara.gostoli2@unibo.it

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## ABSTRACT

Background: Literature outlined positive effects of cardiac rehabilitation (CR) on clinical psychological distress (DSM depression and anxiety) and quality of life (QoL). In cardiac settings, also sub-clinical distress (subthreshold depressive and anxious symptomatology) and psychological well-being showed relevant clinical implications. This research explored these psychological variables, their changes over time and cardiac course of CR patients. Methods: Clinical and subclinical distress, QoL and psychological well-being were assessed in 108 consecutive patients undergoing CR, at baseline and up to 12 months after program's completion. Results: Of all patients, 25.9% showed high distress with a DSM diagnosis, 31.5% high distress without a DSM diagnosis, 42.6% low distress. Comparing these subgroups, worse QoL and psychological well-being were significantly linked not only to clinical but also subclinical distress. After CR completion, a significant reduction of DSM diagnoses was observed, whereas there were no positive effects on subclinical distress, QoL and well-being, or when initially occurred, they were not long lasting. Moreover, only the subgroup with high distress without a DSM diagnosis was at greater risk for adverse cardiac outcomes, showing worse scores on items of contentment. Conclusions: These findings confirm data on clinical distress reduction after CR completion. However, a great amount of relevant subclinical distress remains and predicts adverse cardiac events.

Keywords: Cardiac rehabilitation; clinical psychological distress; sub-clinical psychological distress; psychosomatic syndromes; psychological well-being; quality of life.

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# INTRODUCTION

Cardiac rehabilitation (CR) is a structured set of secondary prevention services aiming to enhance patient's functioning and quality of life, and to relieve physical symptoms (World Health Organization, 1993). The European Association of Cardiovascular Prevention and Rehabilitation (Pogosova et al., 2015) strongly recommends the assessment of psychosocial factors and provision of behavioral interventions for CR participants. In these patients, literature showed in particular the presence of clinical distress, such as depression and anxiety according to standard nosography such as DSM (Gellis & Kang-Yi, 2012; Rutledge, Redwine, Linke, & Mills, 2013; Stauber et al., 2013). Some studies, however, pointed out the presence of subclinical distress as well (Glazer, Emery, Frid, & Banyasz, 2002; Vigorito, Incalzi, Acanfora, Marchionni, Fattirolli, & Gruppo Italiano di Cardiologia Riabilitativa e Preventiva, 2003; Scholz, Knoll, Sniehotta, & Schwarzer, 2006; Milani & Lavie, 2007), intended as subthreshold psychological symptoms.

Only few findings on the progress of clinical distress after CR are available. Some studies show great improvements of clinical psychological distress, such as depression and anxiety, among CR patients who both attended programs including structured mental health interventions (Rutledge et al., 2013), and who do not (Gellis & Kang-Yi, 2012; Stauber et al., 2013). Other studies, however, point out contrasting findings (Pogosova et al., 2015) or related to gender in specific sub-groups of patients (Linden, Phillips, & Leclerc, 2007). Some research showed a reduction of depressive symptoms (Glazer et al., 2002; Vigorito et al., 2003; Scholz et al., 2006; Milani & Lavie, 2007) after program completion. However, among the cited studies, some did not include pre-CR (Scholz et al., 2006) or follow-up evaluations (Glazer et al., 2002; Milani & Lavie, 2007) that could have determined the entity of symptoms' improvement and its maintenance over time, other only focused on specific subgroups of patients (Vigorito et al., 2003), such as the very elderly.

In addition, with regard to the course of CR, there are many studies on the improvement of quality of life (Shepherd & While, 2012), whereas research on psychological well-being is lacking. The latter is a qualitatively different and more complex concept than quality of life. It is close to individual disposition and resilience, and connected to the potentialities of human beings and positive mental functioning (Ryff & Singer, 1996; Ryff et al., 2006). The lack of psychological well-being appeared to be a vulnerability factor for illness (Ryff & Singer, 1996), due to its connection to biological alterations (Ryff et al., 2006).

There is a paucity of studies specifically focusing on the prognostic role of clinical and/or subclinical distress in CR setting. In certain studies, clinical distress seems to predict early dropouts among patients attending CR (Yohannes, Yalfani, Doherty, & Bundy, 2007; Swardfager et al., 2010) and mitigates improvements in clinical outcomes (Swardfager et al., 2010). For what concerns subclinical distress, instead, it has been demonstrated that specific depressive symptoms influence adherence to CR (Glazer et al., 2002), whereas a reduction of depressive symptoms after program completion is linked to a reduction of their associated mortality as well (Milani & Lavie, 2007). To the best of our knowledge, there are no studies investigating the prognostic role of clinical and subclinical distress on patients' survival after CR completion.

Since the need to include clinimetric consideration of patients' function in daily life, performance of social roles, intellectual capacity, emotional stability, well-being, lifestyle and stress, has emerged as a crucial part of clinical investigation and patient care (Fava & Sonino, 2009), the present research established its theoretical foundation over clinimetric criteria for measures selection.

On the basis of these considerations, the aims of the present study were to evaluate, by means of reliable measures: 1) clinical (DSM-IV-TR depressive disorders and anxiety) and subclinical distress (sub-threshold self-reported depressive and anxious symptoms), and their association with health-related quality of life and psychological well-being; 2) the change of clinical and subclinical

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psychological distress, quality of life and well-being over a period of 12 months after the end of the rehabilitation program; 3) the potential association between clinical and/or subclinical distress and adverse cardiac outcomes. The length of the follow-up was chosen on the basis of previous research on similar populations (Griffo et al., 2012).

### **METHODS**

### Sample

CR patients (N=108) were approached consecutively during CR program at Bellaria Hospital (Bologna), over a period of twelve months. They were evaluated at the beginning of CR (baseline, T1), at the end of the program (T2), after 6 (T3) and 12 (T4) months from the program completion. At baseline, all patients were informed about the general aim of the study and asked to participate by the clinical psychologist involved in the research. All the participants underwent psychological assessment at the Cardiology Division facilities of Bellaria Hospital. Patients were then reached by phone again after one (T2), six (T3) and twelve (T4) months from the initial evaluation, in order to schedule follow-up appointments and repeat the psychological assessment at Bellaria Hospital. All patients who attended the CR program during the recruitment period were considered to be eligible to participate, provided that written informed consent was given. None of the patients refused to join the research and they did not receive any payment for the enrollment. The Local Ethic Committee approved the study.

#### Cardiac rehabilitation protocol

CR protocol at Bellaria Hospital consists in a four-week, daily program, addressed to outpatients and delivered by a multidisciplinary team (i.e. nurses, dietitian, physiotherapists, and psychologist). It

follows national guidelines (Kotseva, Wood, De Bacquer, Heidrich, & De Backer, 2004) procedures including prognostic stratification, i.e. risk stratification; personalized rehabilitative cycle

including prognostic stratification, i.e. risk stratification; personalized rehabilitative cycle programming, with daily supervised physical training and vital signs monitoring, floor exercises, use of ergo-meter. In addition the following additional sessions are provided: promotion of weight loss and diabetes management, physical activity prescriptions and health education, anti-smoking status program, optional group meetings on nutritional education and stress management, at least one brief psychological counselling meeting based on behavioural indications without any specific interventions addressed to mental health improvement, management of comorbidities, final evaluation and scheduled follow-up. As stated by international guidelines (Kotseva et al., 2004; Smith et al., 2006), patients who are eligible for CR are those undergone coronary artery bypass grafting (CABG), valvular heart disease surgery or heart transplant, those with stable angina, poor left ventricular ejection fraction (LVEF) or a low ischemic threshold. In addition, patients with ischemic heart disease, who are symptoms-free after angioplasty, or with silent ischemia, are included in CR. Generally, the former kind of patients (who undergone open-heart surgery) should be referred to CR with priority (Vigorito et al., 2003).

#### Assessment

The assessment included both observer- and self-rated measures. Patients took about 50-60 minutes to complete the whole evaluation at each time point.

*Socio-demographic data*. Standard socio-demographic data (i.e., age, sex, marital status, level of education and current occupation) were collected.

*Medical data: baseline profile and cardiac outcomes.* Data concerning baseline main cardiovascular diseases (acute myocardial infarction - AMI, instable angina, congestive heart failure, valvulopathy), medical procedures (percutaneous angioplasty, bypass and/or valve surgery), Body Mass Index

(BMI), and cardiac risk factors (smoke, low left ventricular ejection factor [LVEF≤40], hypertension, hypercholesterolemia, dyslipidemia, family history of CVD, diabetes mellitus, overweight/obesity [BMI≥25]) were recorded during the first assessment. Information about main CVD, medical procedures, risk factors and adverse cardiovascular events during the follow-up period (rehospitalization for worsened cardiac conditions, relapses and/or cardiac death), were extracted from medical records by the nurses of the CR Division of Bellaria Hospital.

*Clinical distress.* The Structured Clinical Interview for DSM-IV-TR (SCID) Axis I Disorders, Research Version (First, Spitzer, Gibbon, & Williams, 1994), was used in order to assess depressive (modules A and D) and anxious (module F) disorders according to DSM-IV-TR criteria (American Psychiatric Association, 2000).

Subclinical distress. Kellner's Symptom Questionnaire (SQ) (Kellner, 1987) is a 92-item self-report questionnaire, which yields 4 main scales: "depression", "anxiety", "hostility-irritability" and "somatization". Each scale is in turn subdivided into a symptom (N=17 items) and a well-being subscale (N=6 items) (respectively "depressive symptoms and contentment", "anxiety symptoms and relaxation", "anger-hostility symptoms and friendliness", "somatic symptoms and somatic wellbeing"). For the purpose of the present research, we used "depression" and "anxiety" scales only. Answers are dichotomous and each symptoms scale score may range from 0 to 23; the higher the total score, the higher the psychological distress. SQ was applied in many clinical investigations and it was found to be able to discriminate between patients with different medical disorders (Mastrogiacomo, Fava, Fava, Kellner, Grismondi, & Cetera, 1982; Kellner, 1987). Literature showed that SQ depression scale correlates positively with the Hamilton Rating Scale for Depression (+0.66) and anxiety dimension with the Hamilton Anxiety Rating Test (+0.69) (Kellner, 1987). SQ also showed good correlations with the Hopkins Symptom Checklist for corresponding scales (+0.63 for anxiety and +0.86 for depression; *p* values ranging from <.002 to <.001) (Mastrogiacomo et al., 1982).

*Quality of life*. MOS 36-item Short-Form Health Survey (SF-36) (Ware, Snow, Kosinski, & Gandek, 1993) was designed to be used in clinical practice and research, health policy evaluations, and general population surveys. The SF-36 yields psychometrically-based physical and mental health summary measures of health-related quality of life. It can be administered in 5-10 minutes with a high degree of acceptability and data quality (Ware et al., 1993).

*Psychological well-being*. Psychological Well-Being scales (PWB) (Ryff & Singer, 1996), an 84item questionnaire with a multidimensional structure, were used to evaluate the six main psychological well-being dimensions conceptualized by Ryff (autonomy, environmental mastery, personal growth, positive relationships, purpose in life, self-acceptance). Each item is defined in terms of high or low agreement on a 6-point *Likert* scale and each scale score may range from 14 to 84, higher scores corresponding to better psychological well-being. The instrument showed good internal consistency and test-retest reliability coefficients after a period of six weeks (Ryff & Singer, 1996).

#### Statistical analyses

Data analysis was performed using the IBM Statistical Package for Social Science (SPSS), version 19.0. The significance level (*p*) was set to .05, two-tailed.

Descriptive analyses were run to describe the sample. In order to identify sub-clinical psychological distress of the sample, the scores of both SQ dimensions were dichotomized on the basis of the mean scores of the general population (Kellner, 1987). If the score exceeded 1 standard deviation (SD), then it was categorized as high subclinical psychological symptomatology. Patients' subclinical distress was identified as having high subthreshold psychological symptomatology (1 SD over general population's mean score) in at least one of two SQ subscales (anxiety or depression). Thus, the sample was divided into 3 subgroups: "LOW DISTRESS" (N=46, 42.6%), "HIGH DISTRESS WITH A DSM DIAGNOSIS" (N=34, 31.5%) and "HIGH DISTRESS WITH A DSM

DIAGNOSIS" (i.e., those having at least one DSM diagnosis, N=28, 25.9%). Discrete variables at baseline (i.e. socio-demographic and medical variables, cardiac risk factors and psychiatric diagnoses) were analyzed and compared between these 3 subgroups by means of Pearson  $\chi^2$  test applied to contingency tables, while continuous variables (i.e. age, quality of life, and psychological questionnaires mean scores) by means of multivariate Analysis of Variance (ANOVA).

To evaluate the modification of the psychiatric diagnoses (i.e., DSM depression and anxiety) over time, McNemar's approximation applied to contingency tables was used.

The modification of quality of life and psychological questionnaires scores over time (from T1 to T2, T3 and T4) was examined by means of Repeated Measures ANOVA.

By means of Log-Rank test, Kaplan-Meier survival analysis was used to compare the survival curves of patients with "low distress", "high distress without a DSM diagnosis" and "high distress with a DSM diagnosis".

#### RESULTS

Description of the sample at baseline (Aim 1)

*Table 1* shows the socio-demographic and medical profile of the study population. The age ranges from 40 to 88 years old and the sample consists mainly of males (67.6%) and married people (75%). The plurality of the patients attended primary school or less (34.3%) and was already retired from work (72.2%).

CR participants mainly suffered from valvulopathy (43.5%) and most of them underwent an invasive surgery (73.1%) (*Table 1*). With regard to cardiovascular risk factors, the most common were hypertension (68.5%) and overweight (67.9%) (*Table 1*).

Of the total sample, 25.9% showed at least one DSM-IV-TR diagnosis. Anxiety was the most represented cluster (20.4%) (*Table 1*) and, in particular, generalized anxiety disorder was the most frequent diagnosis (11.1%). Among depressive disorders (12%) (*Table 1*), 9.3% of the sample showed major depression.

Comparing the 3 subgroups of patients, those with high distress without a DSM diagnosis showed worse scores on SQ depression sub-dimension of "contentment", whereas poorer levels of health-related quality of life and psychological well-being were more likely to be significantly linked to high distress, both with or without a DSM diagnosis (*Table 1*).

Going into details, patients with high distress without a DSM diagnosis showed worse scores on SQ depression sub-dimension of "contentment" than "low distress" (p<.001) and "high distress with a DSM diagnosis" (p=.012) subgroups. Moreover, patients with high distress, with or without a DSM diagnosis, showed lower scores of physical (respectively p=.003 and p=.008), mental (respectively p=.001 and p<.001) and total health-related quality of life (both p=.001), and no significant difference between each other. Similarly, concerning psychological well-being, both subgroups showed lower scores of "environmental mastery" (respectively p<.001 and p=.001) and "purpose in life" (respectively p=.004 and p=.021) than patients with low distress. Pertaining to "positive relationships" dimension, instead, only "high distress with a DSM diagnosis" subgroup showed worse mean scores than patients with low distress (p=.052), whereas on "self-acceptance" (p<.001) dimension "high distress without a DSM diagnosis" subgroup reported lower levels than those with low distress (Table 1).

Change of clinical and subclinical distress, quality of life and well-being (Aim 2) Of the total sample, only 5 patients (4.6%) did not complete any of the follow-up evaluations. The mean attrition rate was 17.9%: 10.2% at T2, 23.1% at T3 and 20.4% at T4 (some patients missed one

of the intermediate follow-up and then underwent the following). Compared to participants who underwent all the follow-up assessments, both patients who missed all the 3 follow-up evaluations and those who missed only one or two of them, did not show any significant difference on demographics (i.e., age, sex, marital status, occupation and level of education).

*Clinical distress.* Pertaining to DSM diagnoses, we found an overall significant decrement of depression (p=.016) and anxiety (p=.006) cases, from baseline to the end of the rehabilitation program (T2). The frequencies of both clusters then did not significantly vary anymore across the subsequent follow-ups.

Subclinical distress. With regard to Symptom Questionnaire, Repeated Measures ANOVA showed significant changes of the whole sample mean scores over time in both "anxiety" (F=6.79, p<.001) (*Graph 1a*) and "depression" (F=4.78, p=.003) dimension (*Graph 1b*). Pertaining to "anxiety", the mean score of the entire sample significantly decreased from baseline to the end of the CR program (p<.001), remaining then stable after 6 months. At 12-month follow-up, however, the mean score did not show difference with the baseline score anymore (*Graph 1a*). Concerning the three subgroups, patients with "high distress with a DSM diagnosis" showed the same pathway, with a significant mean scores difference between T1 and T2 (p=.01), but then no difference between baseline and 1-year follow-up mean scores. Patients with "high distress without a DSM diagnosis", instead, reported a significant mean scores reduction between T1 and T2 (p<.001) and successively an increment between T3 anT4 (p=.006) (*Graph 1a*).

"Depression" dimension showed the same pathway: the baseline mean score significantly decreased from T1 to T2 (p=.004), remaining stable until T3, but at T4 it did not significantly differ from baseline anymore (*Graph 1b*). With regard to the three subgroups, patients with "high distress with a DSM diagnosis" did not show significant mean scores changes over time, whereas those with "high

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distress without a DSM diagnosis" a significant mean scores reduction between T1 and T2 (p<.001), but at T4 the mean score did not significantly differ from baseline anymore (*Graph 1b*).

*Quality of life*. Pertaining SF-36, Repeated Measures ANOVA showed significant changes of the mean scores over time in all its domains (physical QoL: F=52.5, p<.001; mental QoL: F=45.22, p<.001; total QoL: F=69.16, p<.001) (*Graph 2*).

Baseline "physical quality of life" mean score significantly and progressively improved at T2 (p<.001) and T3 (p<.001); however, starting from 6-month follow-up it decreased again (p=.016) (*Graphs 2*). Similarly, the initial mean score of "mental quality of life" significantly and progressively improved at T2 (p<.001) and T3 (p<.001), then remaining stable at 1-year follow-up (*Graphs 2*), whereas "total quality of life" baseline score significantly and progressively improved at T2 (p<.001), decreasing again from T3 to T4 (p<.001) (*Graphs 2*).

*Psychological well-being.* Concerning PWB, Repeated Measures ANOVA showed significant changes of the mean scores over time in all dimensions (autonomy: F=9.65, p<.001; environmental mastery: F=4.66, p=.004; personal growth: F=8.02, p<.001; positive relationships: F=63.51, p=.016; purpose in life: F=3.9, p=.012; self-acceptance: F=5.14, p=.002) (*Graphs 3*).

Baseline mean score of "autonomy" significantly increased after the end of CR (p=.004) and remained stable at 6-month follow-up; however, it significantly decreased again from T3 to T4 (p=.003) (*Graph* 3). The initial mean score of "environmental mastery" significantly decreased from 6- to 12-month follow-up (p=.002) (*Graph* 3). "Personal growth" mean score was significantly lower at 1-year follow-up (p=.027) than baseline, with a significant decrement beginning from T3 (p=.005) (*Graph* 3). Concerning "positive relationships" mean score, it showed a significant decrement from the end of CR to 12-month follow-up (p=.004) (*Graph* 3). "Purpose in life" mean score showed an initial significant improvement from baseline to 6-month evaluation (p=.042), followed by a significant decrement from T3 to T4 (p=.007) (*Graph* 3). Finally, baseline "self-acceptance" mean score

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significantly increased at the end of CR (p=.019) but then it decreased again from 6- to 12-month follow-up (p=.032) (*Graph 3*).

#### Survival analysis (Aim 3)

In terms of cardiac outcomes, 29 adverse events among CR patients were registered (mean time of survival= 10.8±4 months). Comparing the 3 subgroups' survival curves by means of Kaplan-Meier analysis, patients with "high distress without a DSM diagnosis" showed a significantly different survival curve from the other 2 subgroups (Log-Rank test:  $\chi^2_{(2)}$ =9.42, *p*=.009), being associated with a significant higher rate of adverse outcomes (*Graph 4*). This subgroup reported the 51.7% (N=15) of the whole amount of cardiac events.

#### DISCUSSION

The present study allowed a better understanding of psychological profile, in terms of clinical and subclinical distress, quality of life and psychological well-being changes, of patients who attended a program of cardiac rehabilitation without a structured psychological intervention.

As literature confirms, a significant percentage of patients satisfying criteria for clinical and subclinical distress at baseline was found. With regard to clinical distress, we detected a high prevalence of anxiety diagnoses (20.4%) and fewer cases of depressive disorders (12%). These data are partially in line with literature showing a greater prevalence of anxiety, ranging from 27.8% to 45% (Serber, Todaro, Tilkemeier, & Niaura, 2009; Balestroni & Giannuzzi, 2010), and a similar frequency of clinical depression, ranging from 10% to 20% (Serber et al., 2009; Balestroni & Giannuzzi, 2010). Pertaining to subclinical psychological distress, we found that more than one fourth of the sample reported baseline depressive and anxious scores exceeding more than 1 standard

deviation of the general population mean (Kellner, 1987), even in absence of a formal psychiatric diagnosis.

CR attendance seems to be associated with a significant and stable reduction of clinically relevant depressive and anxiety disorders. These findings are in line with the literature supporting CR effectiveness on depression and anxiety improvement (Kreikebaum, Guarneri, Talavera, Madanat, & Smith, 2011; Rutledge et al., 2013). Most of the mentioned studies, however, included structured psychological interventions, specifically aimed to reduce depression and anxiety. On the contrary, in our study CR program included only one or two psychological counseling meetings focused on the behavioral management of the psychological effects of the cardiac disease, without a specific target on anxiety or depressive symptomatology. The promising findings regarding the reduction of clinical distress, even in the absence of any structured psychological interventions, seem to be linked to the secondary effect of being taken in charge by a multidisciplinary team. The constant medical support and the focus on physical symptoms, at least for a month, might lead to a reduction of the psychiatric diagnoses, which might be regarded as a psychological reaction to the cardiac event, rather than a stable way of perceiving. Non-specific therapeutic effects, indeed, may emerge as the result of providing a conceptual framework to explain symptoms, psycho-education, encouragement and support by the medical team, fostering patients' confidence in the therapeutic ability of experts in the field and/or in the ability of drugs to be therapeutic, and offering frequent and repeated opportunities to discuss one's symptoms (Fava, Evins, Dorer, & Schoenfeld, 2003). Unfortunately, we do not have any information about psychological treatments or psychotropic medications taken by the study population during follow-up. This represents one of the limits of the study.

With regard to subclinical distress or sub-threshold psychological symptomatology of anxiety and depression, literature showed that CR may improve psychological conditions – especially among elderly patients – by reducing depressive, anxious, hostile and somatization-related symptoms

(Glazer et al., 2002; Vigorito et al., 2003; Scholz et al., 2006; Milani & Lavie, 2007). Results of our study are partially in line with findings in literature. We found an improvement of levels of depressive and anxious symptoms after the end of CR program. However, these improvements seem to be not maintained and returned to the initial level after one year. Even though we cannot exclude that these differences with previous research could be due to different methodology or psychological distress measures used, the lack of sharp changes on subclinical psychological symptoms highlights the need of more specific intervention strategies addressing these sub-clinical distress when planning CR programs. Frequently, indeed, patients with affective disorders, even though effectively treated by psychotherapy or medications, continue to present high sub-clinical symptomatology and impaired levels of psychological well-being compared to healthy subjects (Rafanelli, Park, Ruini, Ottolini, Cazzaro, & Fava, 2000), which could lead to psychiatric relapses or a worse clinical course of the medical illness (Howland et al., 2008), as highlighted in our study by survival analysis outcome. Paradoxically, only subclinical distress not associated with psychiatric diagnoses - predicted a worse survival of patients after CR, as highlighted by previous studies focused on other kinds of cardiac patients (Rafanelli, Roncuzzi, & Milaneschi, 2006; Rafanelli, Milaneschi, & Roncuzzi, 2009). In the present study, we found specific qualitative differences in subclinical distress presented by patients who showed a comorbid psychiatric diagnosis and those who did not. Depressive symptomatology being equal in quantity, patients with only high distress without a DSM diagnosis were more prone to report less contentment-related symptoms (i.e., not feeling cheerful, happy, well, contented, enjoying themselves, looking forward the future) than those diagnosed with DSM depression and/or anxiety. These findings, on one hand let us hypothesize that certain kinds of symptoms could be more dangerous and "cardiotoxic" for cardiac prognosis than others and, among these, anhedonia itself has been found to be more harmful than cognitive symptoms (Rafanelli, Sirri, Grandi, & Fava, 2013). On the other hand, they suggest relevant clinical implications and pave the ground for possible future

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interventions, especially for what concerns contentment. Indeed, it could be hypothesized that high distress patients, who seem to show the lowest levels of contentment and the poorest cardiac outcomes in the survival analysis, could benefit of interventions aimed to promote acceptance and adaptation to stressful conditions, thus enhancing psychological flexibility. The latter, indeed, was found to be highly related to quality of life and adaptation in different medical settings, especially among patients with chronic conditions (Wicksell, Olsson, & Hayes, 2010; Kamody et al., 2017).

CR patients' health-related quality of life mean scores seem to improve over time, at least up to the 6-month follow-up, in line with previous studies (Shepherd & While, 2012; Kang, Gholizadeh, Inglis, & Han, 2016). CR patients baseline mean score of physical health-related QoL was more than a standard deviation lower than that of the general population (Apolone & Mosconi, 1998), becoming then similar at T3. Even if it could be hypothesized that the improvement of quality of life may be mediated by enhancement of healthier lifestyles (Miller, Balady, & Fletcher, 1997), a systematic review (Taylor et al., 2004) focused on a rehabilitation program based only on physical exercise, found no differences between CR and a control group in quality of life improvement could be only the psychosocial components of rehabilitation programs, even if not structured, as in our study. This could also explain why the positive effects on quality of life of some CR a-specific elements tend to lessen after one year.

Pertaining to psychological well-being, we found that CR patients self-reported better-improved levels of "autonomy", "purpose in life" and "self-acceptance" after the end of the program; however, these positive effects did not last over time, worsening after 6 months instead. Moreover, the other 3 PWB dimensions ("environmental mastery", "personal growth" and "positive relationships") did not change initially, then worsening after the end of the program. As Ryff and Singer (1998) argued, having a purpose in life and a sense of personal growth helps to preserve physical health over time

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through optimal allostasis, immune competence, and asymmetric brain activation, while good levels of personal growth positively influences the implementation of healthy behaviors such as exercise, diet and quality of sleep (Ryff & Singer, 1998), supporting the need to address this issue when planning CR programs. Moreover, it has been found a positive correlation between personal growth and the level of HDL cholesterol and negative with total cholesterol (Ryff et al., 2006), and a protective effect of purpose in life against myocardial infarction among older adults with coronary heart disease (Kim, Sun, Park, Kubzansky, & Peterson, 2013). In wider terms, given the ascertained link between psychological well-being and biological aspect (Ryff et al., 2006), it would be desirable to plan interventions focused on the promotion and restoring of well-being.

Finally, findings of this study support the hypotheses that not only overt DSM-IV-TR psychopathology, but also sub-threshold psychological symptomatology is associated with poor quality of life and impaired psychological well-being, as highlighted by previous studies (Nierenberg et al., 2010).

This research presents some limits that should be discussed. First, as already mentioned, we do not have any information about possible psychological and pharmacological treatments for depression and anxiety patients received during the study. Second, we cannot figure out the longitudinal courses of clinical and subclinical distress, especially for what concerns the anamnesis. We are not allowed to characterize better the onset of potential prodromal symptoms or to establish if subclinical symptoms constitute residual symptoms of a previous psychiatric disease (in which subclinical is strictly related to clinical distress), or, on the contrary, if their onset was independent, which would represent another qualitatively different psychological picture. Third, it includes a small sample size that may not be representative and may limit the power to detect significant differences.

In conclusion, although CR mainly focuses on exercise and lifestyle modification, the findings of this study suggest possible secondary positive effects exerted by cardiac rehabilitation on specific

psychological aspects, such as depression and anxiety, even in absence of specific psychological interventions. Thus, all CR specialists should be aware of the possible benefits and encourage patients to attend such programs. However, CR had no effects on subthreshold symptomatology. Subclinical psychological conditions, associated with specific impairments in psychological well-being, could represent a key risk factor either for the exacerbation of an overt psychiatric disorder (Cuijpers & Smit, 2004) or a negative clinical course of the cardiac illness, as demonstrated by our findings. A poor prognosis or mortality (De Schutter, Lavie, & Milani, 2011) could be the result of patients' non-adherence to drug treatment (Wang, Bohn, Knight, Glynn, Mogun, & Avorn, 2002). Further studies with longer follow-ups focused on the clinical course of cardiac illnesses in CR patients with high subclinical distress, even in the absence of DSM diagnoses, are needed.

#### **Disclosure of interest**

The authors declare that they have no competing interest.

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#### Table 1

Baseline description of the overall sample (CR group) and comparison of sub-groups of patients based on the presence of low and high psychological distress, without or with a DSM diagnosis (DSM-IV-TR depression and/or anxiety)

	CR GROUP (N=108)	LOW distress (N=46)	HIGH distress WITHOUT a DSM diagnosis (N=34)	HIGH distress WITH a DSM diagnosis (N=28)		
		Mean ± SD				
Age	69.41±9.77	68.02±8.86	72.53±8.45	67.89±11.91	0.05	2.61
		N (%)			ES	$\chi^2$
Sex						
Male	73(67.6)	28(60.9)	26(76.5)	19(67.9)	0.14 a	2.17
Female	35(32.4)	18(39.1)	8(23.5)	9(32.1)	0.14	2.17
Marital status						
Single	13(12)	4(8.7)	6(17.6)	3(10.7)		
Married	81(75)	36(78.3)	24(70.6)	21(75)		
Separated	2(1.9)	1(2.2)	1(2.9)	0(0)	0.28 <sup>a</sup>	8.26
Divorced	2(1.9)	0(0)	0(0)	2(7.1)		
Widower/Widow	10(9.3)	5(10.9)	3(8.8)	2(7.1)		
Level of education	25(24.2)	10(00.0)				
Elementary	37(34.3)	13(28.3)	16(47.1)	8(28.6)		
Junior High School	28(25.9)	14(30.4)	9(26.5)	5(17.9)	0.29 <sup>a</sup>	9.31
Senior High School	31(28.7)	16(34.8)	6(17.6)	9(32.1)		
College	12(11.1)	3(6.5)	3(8.8)	6(21.4)		
Occupation	25/22 1	10/01 7	7(00 ()			
Employed	25(23.1)	10(21.7)	/(20.6)	8(28.6)		
Unemployed	1(0.9)	1(2.2)	0(0)	0(0)	0.14 <sup>a</sup>	2.11
Retired	/8(72.2)	33(/1./)	26(76.5)	19(67.9)		
Homemaker	4(3.7)	2(4.3)	1(2.9)	1(3.6)		
Cardiovascular Pathology	22(20.0)	15(22.0)	10/20 4)	7(25)		
AMI	32(29.6)	15(32.6)	10(29.4)	7(25)		
valvulopatny	47(43.5)	24 (52.2)	14(41.2)	9(32.1)		
Instable angina	9(8.3)	2(4.3)	3(8.8)	4(14.3)	0.20.3	15.00
AMI + instable angina	8(7.4)	2(4.3)	2(5.9)	4(14.3)	0.38 "	15.89
AMI + valvulopathy	0(5.0)	1(2.2)	4(11.8)	1(3.6)		
Congestive heart failure	4(3.7)	2(4.3)	1(2.9)	1(3.6)		
Valvulopathy + instable angina	2(1.9)	0(0)	0(0)	2(7.1)		
Meaical Proceaure	70(73.1)	32(60,6)	28(82 1)	10(67.0)		
Angioplasty or no procedure	79(75.1)	32(09.0) 14(30.4)	28(82.4)	9(32.1)	0.14 <sup>a</sup>	2.17
Cardiovascular Pisk Factors	29(20.9)	14(30.4)	0(17.0)	9(32.1)		
Left Ventricular Ejection						
Fraction≤40	18(17)	7(15.2)	8(23.5)	3(10.7)	0.14 <sup>a</sup>	1
Hypertension	74(68.5)	30(65.2)	25(73.5)	19(67.9)	0.08 a	0.63
Dyslipidemia	67(62)	29(63)	17(50)	21(75)	0.2 <sup>a</sup>	4.11
Type 2 diabetes mellitus	23(21.3)	11(23.9)	8(23.5)	4(14.3)	0.1 <sup>a</sup>	1.11
Family history of CVD	21(19.6)	9(19.6)	6(18.2)	6(21.4)	0.03 <sup>a</sup>	0.1
Smoke habit (current or past)	57(52.8)	27(58.7)	16(47.1)	14(50)	0.1 <sup>a</sup>	1.18
Body Mass Index≥25	72(67.9)	32(72.7)	22(66.7)	18(69.2)	0.06 <sup>a</sup>	0.34
DSM	10/10			10/15 1	0.62.0	10.00
Depression	13(12)	0(0)	(0)	13(46.4)	0.63 *	42.23***

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Anxiety		22(20.4)	0(0)	0(0)	22(78.6)	0.86 <sup>a</sup>	78.94***
	score range		Mean	ES	F		
Symptom Questionnaire							
Anxiety	0-23	$5.47 \pm 4.43$	$2.26 \pm 1.98$	$7.91 \pm 3.28$	$7.79 \pm 5.22$	0.4	34.22***
anxious symptoms	0-17	$3.95 \pm 3.76$	$1.43 \pm 1.72$	$5.44 \pm 3.22$	$6.29 \pm 4.39$	0.34	27.39***
relaxation	0-6	$1.44{\pm}1.53$	0.83±1.16	2.21±1.59	$1.5 \pm 1.6$	0.15	9.21***
Depression	0-23	$5.56 \pm 3.88$	$2.59{\pm}1.5$	$8.29 \pm 2.65$	$7.14 \pm 4.51$	0.45	43.52***
depressive symptoms	0-17	$3.28 \pm 2.77$	$1.41 \pm 1.11$	$4.53 \pm 2.74$	$4.82 \pm 2.96$	0.34	27.23***
contentment	0-6	$2.29{\pm}1.96$	$1.17 \pm 1.22$	3.76±1.6	$2.32 \pm 2.18$	0.32	24.72***
MOS Short Form Survey							
Physical health-related QoL	<b>0</b> -100	$44.04{\pm}16.82$	50.87±16.09	$38.52 \pm 15.79$	$38.96 \pm 15.47$	0.13	7.62**
Mental health-related QoL	<b>0</b> -100	51.78±18.6	60.43±16.95	$46.09 \pm 18.75$	43.69±14.94	0.17	10.65***
TOTAL health-related QoL	<b>0</b> -100	47.15±17.65	55.2±16.4	$41.48 \pm 17.36$	$40.12 \pm 14.6$	0.16	10.03***
Psychological Well-Being scale							
Autonomy	<b>14</b> -84	$66.9 \pm 8.97$	66.69±8.41	$66.25 \pm 10.58$	$68 \pm 8.04$	0.01	0.29
Environmental mastery	<b>14</b> -84	66.3±11.6	71.87±7.93	62.13±11.7	62.11±12.96	0.18	10.8***
Personal growth	<b>14</b> -84	59.73±12.03	62.87±10.8	57.12±12.86	57.68±12.19	0.05	2.78
Positive relationships	<b>14</b> -84	67.62±9.53	70.24±8.4	66.38±8.36	64.82±11.54	0.06	3.33*
Purpose in life	<b>14</b> -84	$59.99 \pm 12.68$	64.89±8.57	$55.78 \pm 12.26$	56.93±16	0.11	6.58**
Self-acceptance	<b>14</b> -84	$67.04{\pm}11.08$	71.24±7.75	61.81±10.94	66.25±13.24	0.13	7.76**

<sup>a</sup>= phi coefficient

\*= p < .05; \*\*= p < .01; \*\*\*= p < .001

AMI= Acute Myocardial Infarction; CR= cardiac rehabilitation; CVD= cardiovascular diseases; ES= effect size; QoL= quality of life; SD= standard deviation. *Note*: bolded numbers represent the worst or poorest scores

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Graph 1a

Subclinical distress (anxiety) estimated marginal means of the whole sample and its 3 subgroups, at baseline (T1) and one (T2), 6(T3) and 12 months (T4) after the end of cardiac rehabilitation.





#### Graph 1b

Subclinical distress (depression) estimated marginal means of the whole sample and its 3 subgroups, at baseline (T1) and one (T2), 6 (T3) and 12 months (T4) after the end of cardiac rehabilitation.



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Graph 2

Quality of life marginal means of the whole sample, at baseline (T1) and one (T2), 6 (T3) and 12 months (T4) after the end of cardiac rehabilitation.





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#### Graph 3

Psychological well-being marginal means of the whole sample, at baseline (T1) and one (T2), 6 (T3) and 12 months (T4) after the end of cardiac rehabilitation.





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Graph 4

Survival curves of patients with "low distress", "high distress without a DSM diagnosis" and "high distress with a DSM diagnosis".



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