ALMA MATER STUDIORUM –UNIVERSITÀ DI BOLOGNA

DOTTORATO DI RICERCA IN SCIENZE PSICOLOGICHE

Ciclo XXXI

Settore Concorsuale: 11/E4

Settore Scientifico Disciplinare: M-PSI/08

Psychological assessment in Primary Care: A comparison of different strategies

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Esame finale anno 2019

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Acknowledgments

I would like to express my sincere gratitude to my supervisor Prof. Giovanni Andrea Fava for the support of my Ph.D study and related research, for his patience, encouragement and great knowledge. His guidance helped me throughout my research and writing of this thesis. I could not imagine having had a better mentor for my Ph.D program.

Beside my supervisor, I would like to thank Dr Jenny Guidi for sharing her expertise and insights that supported the development of my research skills and project in its various phases.

My sincere thanks also go to Professor Monica Rubini for her support as Ph.D program coordinator.

I am deeply thankful to the medical staff of the Primary Care Unit in Ravenna, Dott.ssa Carmen Dradi and Dott.ssa Ivonne De Portu.

Finally, I would like to express my gratitude to Alessia, without her this project would have not been possible.

Abstract

Introduction: Primary Care Psychologists make use of psychiatric classifications for the assessment of patients in general practice. However, customary psychiatric diagnoses, such as the DSM category of somatic symptoms and related disorders (SSD), have shown limited clinical utility in medical settings. There is currently need to develop and evaluate alternative assessment strategies to appropriately characterize psychosocial factors in primary care.

Aims: The aim of this study was to evaluate the incremental information provided by the Diagnostic Criteria for Psychosomatic Research (DCPR), in addition to the DSM-5 and compared to the SSD, in primary care.

Methods: Two hundred participants, recruited in a primary care practice, were administered the Structured Clinical Interview for DSM-5, the Structured Interview for DCPR revised and Paykel's Clinical Interview for Depression. Subjects also completed the Short Form Health Survey, the Psychosocial Index and the Illness Attitude Scales. Sub-groups comparisons and hierarchical regression analyses were performed to evaluate the associations of DCPR and DSM-5 diagnoses with psychological measures.

Results: DCPR identified psychological distress in the proportion of 4:1 as compared to the SSD. The percentage of patients with at least 1 diagnosis rose from 23%, when using solely the DSM-5, to 46% when integrating the DCPR. The DCPR showed a greater number of significant predictions of dimensional measures of quality of life, well-being, stress, psychological distress and illness behavior, compared to SSD. Psychosomatic syndromes had a large effect size over and above that of DSM-5.

Conclusions: The DCPR are superior to the SSD in evaluating psychosocial factors in primary care patients. Integration of DCPR in the psychological assessment in primary care enhances the clinical utility of the DSM-5.

CHAPTER 1

Introduction

1.1 Rationale for Primary Care Psychology

Psychological problems are highly prevalent in primary care settings (Toft et al., 2005; Menchetti et al., 2007; Roca et al., 2009), with an estimated rate of approximately 25-30% (Ustun & Sartorius, 1995; Serrano-Blanco et al., 2010). The majority of these patients are managed solely by General Practitioners (GPs) and there is evidence that patients with mental disorders have a significantly higher rate of contacts with their GPs than those affected only by medical disorders (Goldberg & Houxley, 1992; Zantinge et al., 2005). Hence, the management of psychological problems represents a significant burden on GPs' workload (Zantinge et al., 2005).

However, psychological problems in primary care remain undertreated and underdiagnosed (Van der Brink et al., 1991; Unutzer et al., 1999). Several limitations of GPs' care for mental disorders, such as lack of specific skills and time available per patient, have been highlighted (Zantinge et al., 2005). The diagnosis is a major problem as in many patients mental health problems manifest themselves in the form of somatic complaints, distracting GPs from recognizing psychological problems (Van der Brink et al., 1991; Unutzer et al., 1999; De Waal et al., 2004; Löwe et al., 2008). When identified, few patients are referred to secondary care services; of those referred for mental health treatment, about one-third fails to make the first appointment (Zivin et al., 2009), resisting GPs' referral (Nutting et al., 2002).

Various investigations have indicated that a small portion of patients who are treated for mental disorders in primary care receive guideline-concordant treatment (Gonzalez et al.,

2010). Most of these patients receive only pharmacological therapy, characterized by inadequate doses and poor compliance (Nutting et al., 2002; Gonzalez et al., 2010). Additionally, patients are often reluctant about taking drug treatments and psychological therapy is generally preferred (Van Schaik et al., 2006).

Difficulties in delivering effective treatments may lead to a worsening of mental disorders and a further increase of economic costs due to inappropriate use of healthcare resources such as GP consultations, drug prescriptions, medical testing and emergency services (Bower & Rowland, 2006; König et al., 2009).

Thus, the current mental health system in primary care fails at multiple levels: identifying patients with mental health problems, referring them for appropriate care, assuring follow-through, and achieving desired outcomes (Thielke, Vannoy & Unutzer, 2007; Mojtabai et al., 2011).

1.2 Principles of Primary Care Psychology

The evidence from the literature has shown that usual mental health care implemented in general practice has been far from optimal. For this reason, in the recent years, there has been an increasing demand across the world for addressing the needs of patients in primary care by including psychologists in the provision of integrated services (McDaniel & deGruy, 2014).

Primary care has been defined as "*the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community"* (Institute of Medicine, 1994).

Primary care for mental health refers specifically to services that are integrated into health care at a primary care level. The World Health Organization defines primary care psychology as "*the provision of basic preventive and curative mental health care at the first point of contact of entry into the health care system*" (WHO, 2001).

This type of care is thus concerned with the application of psychological principles to common physical and mental health problems experienced by patients and presented in primary care (McDaniel et al., 2014). Essential services at the primary care level include early identification and treatment of mental disorders, management of chronic psychiatric conditions, referral to other services when required, attention to the mental health needs of people with physical health problems and mental health promotion and prevention (WHO, 2008).

In the provision of integrated services central is the bio-psychosocial model of health and disease, which recognizes the complexity of addressing all dimensions of health and illness (Engel, 1977). Integrating mental health into general practice includes a person-centered and holistic approach, meeting the mental health needs of people with physical disorders, as well as the physical health needs of those affected by mental disorders (WHO, 2008).

Another core feature of integrated primary care is the inter-professional approach to care (Derksen, 2009). Primary care psychologists work with physicians and other health professionals in a collaborative and coordinated manner, delivering services such as health promotion, acute care, chronic disease management and mental health, with the formulation of joint treatments and objectives (Croghan & Brown, 2010; Collins et al., 2010; McDaniel & deGruy, 2014). Psychologists in primary care contribute from a preventive perspective and adopt a community approach to the provision of mental health care.

Integrating mental health services into primary care may be beneficial for several reasons. Mental health services at the primary care level are generally the most accessible, affordable and acceptable for communities. Thus, primary care psychology represents an opportunity for

reducing the gap between people affected from mental disorders and those receiving psychological treatment (Kohn et al., 2004) by increasing access to mental health services close to people homes and by providing a continuity of care.

1.3 Role and duties of Primary Care Psychologists

As McDaniel and de Gruy pointed out (2014), psychologists are in the vanguard for being called to take on new roles in primary care; the changes in the field thus open new opportunities.

The contribution of primary care psychologists is wide and aimed at the promotion of health. PC psychologists may be involved in the management of mental disorders, but also in addressing health behavior change associated with chronic diseases, or tracking progress in the care plan (McDaniel & deGruy, 2014).

An element of characterization of the work of the PC psychologists is the context in which he/she operates. Primary care setting is fast moving (short time visits), chaotic (frequent changes of schedule), concerned with health and illness, complicated (different health problems managed concurrently), team-based (close cooperation with other primary care providers) and multimodal (McDaniel & deGruy, 2014). These distinct elements of primary care settings, including the diversity of patients with a varied range of problems and their bio-psychosocial nature, shape the activities of a PC psychologist.

With a limited time available per patient, the PC psychologists provides immediate, brief and directive support, making use of diagnostic and assessment tools, together with short-term interventions (Derksen, 2009).

The PC psychologist, like the family physician, is a generalist and thus focuses more at gatekeeping for the provision of care, whereas the specialist is focused more at the alleviation of symptoms. As to the assessment, the clinical psychologist evaluates the symptomatology more precisely, whereas the PC psychologist addresses also the healthy aspects in a global point of view.

With regards to the provision of psychological support, the PC psychologist applies particular techniques within a very short period of time, drawing upon different therapeutic orientations (McDaniel et al., 2014) and using a stepped care approach. This entails the adjustment of the care strategy along the intervention, starting with minimal interventions and scaling up to referral to secondary services (Derksen, 2009). Being responsible for the overall psychological care means that, after referral for secondary or tertiary care, the patient may return to the PC psychologist for follow-up evaluation. The PC psychologist thus serves family psychologist and is thus comparable with the family physician for somatic care (Derksen, 2009).

1.4 Behavioral Health

Addressing both physical and mental health problems in primary care allows monitoring the patient's overall health status rather than specific symptoms, fostering preventive interventions. In light of this consideration, bringing the general population to healthy lifestyles would represent an important form of prevention for most prevalent conditions (Stone, 2004; Djoussè, Driver & Graziano, 2009 Forman, Stampfer, & Curhan, 2009; Tomba, 2012).

Health-related behavior (e.g. overweight, obesity, poor diet and physical activities) is an

important determinant of chronic diseases, such as cardiovascular problems and diabetes, with a high impact on the course of medical diseases (Yusuf et al., 2004; de Waure et al., 2013). Patients with chronic disease are the most frequent conditions typically seen in general practice settings. Nonetheless, it has been showed that there is a significant gap between physicians' knowledge and their practices regarding evidence-based recommendations for health promotion and disease prevention (Arndt et al., 2002; Brotons et al., 2005).

Recently, there has been a growing interest in integrating lifestyle counseling and behavior change into primary care (Dysinger, 2013; Clarke & Hauser, 2016). It has been theorized that, since many patients in primary care present physical symptoms affected by stress, problems maintaining healthy lifestyles or a psychological disorder. Therefore, it could be clinically effective and cost-effective to make behavioral counseling a core feature of primary care psychology (McDaniel et al., 2014).

A recent systematic review of the literature (Melvin et al., 2017) has highlighted that lifestyle and behavioral counseling interventions in primary care were effective in improving weight and physical activity-related outcomes, among diverse populations. As to weight loss, also web-based and computer-based interventions, which allow patients to have a self-manageable and tailored weight loss plan, proved to yield significant effects as compared to usual care (Bennett et al., 2010). As to physical activity, counseling studies achieved significant outcomes when interventions offered more versus less frequent sessions (Volger et al., 2013). This review further underlined that no significant effects were found with regards to the outcomes associated with diet modification (Melvin et al., 2017).

Recent effort focuses on using behavioral counseling to identify healthy behaviors and lifestyle changes that patients are capable of making within their community context, including their social and economic resources.

1.5 Models of mental health care in general practice

The discussion in the scientific literature regarding the implementation of psychological services in primary care has included the different types of models that might be used for this purpose.

For example, Blount (2003) identifies different types of relationships between mental health and medical providers in primary care. The author proposes to distinguish services that are coordinated, co-located, and services that are integrated.

Mental health and primary care providers may work in an independent but coordinated care. When services are coordinated, specific information is exchanged on a routine basis when patients are in treatment in both settings (Blount, 2003). Furthermore, another designated staff member, such as a mental health care manager, might serve as the responsible agent both for following up with patients and for communicating between primary care and mental health providers (Thielke, Thompson & Stuart, 2011).

When services are co-located behavioral health and medical services are located in the same site sharing office staff and facilities. Co-location indirectly encourages communication between behavioral health and medical providers, enhancing the process of referrals. With this model, the problem of patients failing to keep behavioral health appointments is improved but not eliminated (Blount, 2003).

Integrated care refers to a more structured program for interaction between primary care and mental health providers. In particular, integrated care describes care in which there is one comprehensive treatment plan with behavioral and medical elements. This model usually

makes use of shared formal data tracking systems, monitoring patient symptoms and treatments, care plans, and communications with patients and between providers (Thielke et al., 2011).

An example of integrated care is the Patient-Centered Medical Home (PCMH). PCMHs represent a transition toward an innovative approach of care that is patient and family oriented, comprehensive (integrating both behavioral and physical health needs), coordinated across providers and easy to access. In 2010, the government of the U.S. passed into legislation the Patient Protection and Affordable Care Act (ACA), with the aim of ensuring general access to quality, affordable and integrated healthcare. This legislation fostered an organizational structure built upon inter-professional healthcare practice, termed the PCMH (Kaslow et al., 2015). Psychologists have been called to play an important role in PCMH team (McDaniel & deGruy, 2014). However, evidence showed that less than 50% of PCMHs include a psychologist in the provision of services (Kessler et al., 2014). For this reason, the Working Party Group on Integrated Behavioral Health Care (Baird et al., 2014) recognized that comprehensive whole-person care was not being achieved and thus called for a greater integration.

In the Netherlands, since 1970 psychologists started working in collaboration with general practitioners. From 2008, the government recognized the professional figures of PC psychologists. A total of eight consults is reimbursed as part of every basic health insurance policy for every Dutch inhabitant, which might be increased up to 12 consults (Derksen, 2009). The PC psychologist is a certified health psychologist, working as a generalist with specialized primary care skills. In particular, the PC psychologist is able to assess and manage in collaboration with the GP a full range of psychological and behavioral problems occurring in individuals and families. The PC psychologist usually practices in the same setting with one or more family physicians (Derksen, 2009).

In the Italian context, the Primary Care Psychologist is not a recognized profession. According to the literature, there have been few initiatives, at the local level, which aimed at implementing some types of psychological service in general practice settings. The most notable intervention has been carried out by Solano (2011) in Rome. The service, which has been active for more than ten years, consists of a co-presence of both the medical practitioner and the psychologist in the same office, twice a week.

1.6 Prevalence of psychological distress in primary care

The evidence from the literature indicates that mental and behavioral disorders are common among patients attending primary health care settings.

The large cross-cultural study conducted by WHO in 14 countries (Üstün & Sartorius 1995) showed that, although the prevalence of mental disorders across the sites varied considerably, an average of 24% of all patients in these settings had a mental disorder. Prevalence ranged from 7.3% in China to 52.5% in Chile; the most frequent diagnoses were depressive, anxiety, and substance-related disorders.

King and colleagues (2008) assessed major depression, panic syndrome and other anxiety syndromes in general practice of 6 different European countries. The results showed that prevalence of major depression, other anxiety syndrome and panic syndrome in people attending their general practitioners was high but varied significantly between countries, with the highest prevalence in the UK and Spain, and lowest in The Netherlands and Slovenia.

A cross-sectional study carried out in Denmark (Toft et al., 2005) found a very high prevalence of ICD-10 mental disorders in primary care among patients consulting for a new

health problem, reaching about 50% at inclusion. Somatoform disorder (36%) was the most prevalent group of disorders. Similarly, a large study epidemiological study in primary care carried out in Spain (Roca et al., 2009) found a prevalence of psychiatric disorders of 53.6%. This prevalence was higher than in most of the studies, especially with regard to major depressive disorder, with a prevalence of 29%.

In Italy, a lower prevalence of mental disorders has been reported in comparison to other countries. The studies have reported a prevalence of around 12% for formal psychiatric disorders and a range from 11% to 18% for sub-threshold disorders (Menchetti et al., 2007). These disorders, primary depressive and anxiety disorders, were not associated with physical or medical conditions but mainly with disabilities and socio-economic problems.

1.3 Efficacy and cost-effectiveness of psychological treatment in primary care

Different studies have been carried out in order to evaluate the efficacy and cost-effectiveness of psychological treatments in primary care. With resources being limited, psychological therapy provided within primary care settings for mental disorders is brief, often consisting of less than ten sessions (Cape et al., 2010). Randomized controlled studies in primary care have targeted depression and anxiety as the main focus of psychological interventions, being the most common mental disorders. These studies have included guided self-help interventions (i.e. bibliotherapy and computerized treatments) and brief therapies such as counseling (a generic approach used to develop self-knowledge, emotional acceptance and

growth), problem-solving and cognitive behavioral therapies – CBT. All treatments proved to obtain a significant reduction in symptoms of depression and anxiety in the short term, as measured by standardized tests, in comparison to GPs' usual care or no care (Bower, Richards & Lovell, 2001; Bortolotti et al., 2008; Cape et al., 2010; Høifødt et al., 2011; Wells et al., 2018). Furthermore, these treatments were generally found to produce approximately equal benefits and no particular approach significantly outperformed any other (King et al., 2008; Cape et al., 2010; Høifødt et al., 2011).

These interventions seem to be effective when supported by either healthcare workers such as general practitioners and primary care staff (e.g. nurses) or psychologists and accredited counselors (Høifødt et al., 2011). However, a meta-analysis on the treatment of medically unexplained symptoms in primary care found that psychological interventions delivered by psychotherapists had larger effects than those provided by GPs (Gerger et al., 2015).

General short-term positive effects of brief psychological treatment have been confirmed by different meta-analysis (Bortolotti et al., 2008; Cujipers et al., 2009; Cape et al., 2010). The effect size found for such treatments were relatively smaller compared to the results of treatments carried out in other settings such as specialized mental health care, involving a longer duration of psychological therapies (Cujipers et al., 2009; Cape et al., 2010). This difference could be due to the less severe conditions presented by primary care patients, compared to those in secondary care, which would therefore limit the potential effect size (Cape et al., 2010).

Evidence about the long-term efficacy is more equivocal. Different studies found a lack of significant difference between the brief psychological therapy groups and usual care at 12 months or more (King et al., 2000; Simpson et al., 2000; Barrowclough et al., 2001; Murray et al., 2003). However, some studies found that the effects of brief therapy, such as counseling,

were maintained in the long period, up to two years (Gordon & Graham, 1996; Baker et al., 1998). A meta-analytic review by Bortolotti and co-workers (2008) did report significant short-term and long-term significant differences between psychological interventions and usual care in reducing symptoms of depression. Furthermore, psychological treatments appeared to be equivalent to antidepressants both in the short and long-term. King (2000) showed that in his study the lack of a significant difference between the treatment groups in the long-term resulted from greater improvement of patients in the GP care group between the 4 and 12-month follow-ups. Hence, the continuation of GPs usual care, unlike the psychological intervention that is interrupted, could have a role in the differences observed in the long-term. Such evidence points out the need for further research on long-term efficacy of brief psychological therapies before conclusions can be drawn (Bower and Rowland, 2006).

Given that mental health problems are related to an increased use of primary medical care services, it has been suggested that the implementation of psychological interventions might result in an overall decrease in medical care costs and cost offset (Bower and Rowland, 2006). This might include fewer referrals to psychiatric services, reduction of drug prescriptions and less GP and hospital consultations. A review by Bower and Rowland (2006) suggested that counseling in primary care was associated with a reduction in health service utilization, especially GP consultations, in comparison to usual care. The overall costs of the two treatments were similar. Thus, it seems that the addition of psychological interventions in primary care does not increase health care costs.

CHAPTER 2

Psychological assessment in primary care

2.1 Introduction

The prevalence of mental illnesses, their manifestations and their comorbidity are a major issue in primary care. The responsibility for the initial diagnosis of mental disorders falls on primary care, the first point of contact for patients within the health system (Roca et al., 2009).

Furthermore, psychological assessment in primary care should include evaluation of psychosocial factors such as lifestyle behaviors, social support and stress (Derksen, 2009). Thus, a comprehensive assessment of psychosocial distress in primary care patients is a core aspect of the work of a PC psychologist (Bower & Gilbody, 2005; McDaniel et al., 2014).

The assessment process may be undertaken by the PC psychologist after screening from the GP and should rapidly provide the information needed to identify the patient's concerns (Derksen, J. 2009; McDaniel et al., 2014). According to Derksen (2009), the PC psychologist can generally treat with success those conditions where the relevant complaints have appeared for the first time, have not existed for a long period of time, have shown an acute emergence, have appeared as a reaction to an identifiable stressor, and have not been diagnosed in conjunction with a severe personality disorder. When the intake shows one or more of the aforementioned criteria to not be met or an unclear situation to present itself, then more extensive psychodiagnostic screening may be undertaken by the PC psychologist. Based on

these clinical indications, the psychologist should develop a plan to address the patient's needs (e.g. determine whether short-term assistance or referral to a specialist is appropriate) (Derksen, 2009; McDaniel et al., 2014).

To examine the patient, the PC psychologist may draw upon a broad range of assessment strategies, such as non-structured clinical interviews and administration of psychological tools. Examples of tests that are frequently used include the Minnesota Multiphasic Personality Inventory (MMPI-2), the Millon Clinical Multiaxial Inventory (MCMI-III), the Rorschach inkblot test, and instruments to assess specific types of complaints, such as the Beck Depression Inventory (BDI) (Kush, 2001; Derksen, 2009).

Additionally, in the diagnostic process PC psychologists make particular reference to psychiatric classifications such as the Diagnostic and Statistical Manual of Mental Disorders- DSM, now fifth edition (Derksen, 2009; APA, 2013). The DSM is specifically used in clinical practice to discern, in the clinical reasoning, between complex and less complex disorders, in order to decide for a referral to secondary service or a management of the condition in primary care (Derksen, 2009).

Due to the under-detection of mental disorders in primary care, a significant amount of attention has been paid by research studies to enhance recognition of psychiatric disorders among patients. Tools that have been developed for this purpose include the Patient Health Questionnaire- PHQ (Spitzer et al., 1994; Spitzer et al., 1999), the General Health Questionnaire- GHQ (Goldberg, D. 1972) and the Symptom Check-list- SCL-90 (Derogatis, 1977). These questionnaires screen the symptoms that are the basis of DSM criteria and once an appropriate cut-off point has been chosen, they can be used as screening devices for the detection of psychological distress. Generally, these tools have proved to be valid instruments to detect mental disorders in primary care (Schmitz et al., 1999; Spitzer et al., 1999).

However, an assessment based solely on instruments that refer to psychiatric

psychopathology has the potential risk of neglecting psychosocial factors, which are functional to a comprehensive psychological assessment and consistent with the philosophy of integrated primary care.

2.2 Limitations of the DSM-5

In the last years, there have been increasing concerns regarding the clinical utility of DSM in clinical practice (Guidi et al., 2013; Cosci & Fava, 2016).

A major limitation of the DSM-5 is that it fails to appropriately detect mild mental disturbances and sub-threshold symptoms, which are often expressed in the form of somatic complaints (Fink et al., 2005; Hanel et al., 2009).

Previously, these complaints were addressed by the DSM in the category of somatoform disorders. In the last years, the issue of physical versus psychiatric has given rise to an important debate (Sykes, 2006; Rief & Isaac, 2007) and a group of experts (Bass, Preveler & House, 2001) have proposed abolishing the whole category of somatoform disorders from the DSM-IV. Others have underlined its inadequacy for primary care use (Fink et al., 2005; Rosendal et al., 2005).

In the new DSM-5, the category of somatoform disorders has been changed into the category called “somatic symptom and related disorders” (APA, 2013). This category includes the diagnoses of somatic symptom disorder, illness anxiety disorder, conversion disorder, psychological factors affecting other medical conditions, factitious disorder, other specified somatic symptom and related disorder, and unspecified somatic symptom and related disorder. According to the DSM-5, these disorders share as a common feature the prominence of somatic symptoms associated with significant distress and impairment.

Cosci and Fava (2016) have highlighted specific limitations that each of these singles rubrics entail.

The main diagnosis, somatic symptoms disorder, requires one or more distressing somatic symptoms and excessive thoughts, feelings, and behaviors related to these symptoms or associated health concerns (APA, 2013). However, medically unexplained symptoms do not necessarily involve excessive anxiety about the seriousness of symptoms but might induce demoralization and irritability (Cosci & Fava, 2016).

The diagnosis of illness anxiety disorder is concerned with the preoccupation of having or acquiring a serious illness, without the presence of high intensity somatic symptoms and maladaptive health-seeking behavior (APA, 2013). The potential problem, in this case, is the overlapping criteria with the category of somatic symptom disorder (Cosci & Fava, 2016).

In conversion disorder, the essential feature is neurological symptoms that are incompatible with neurological pathophysiology (APA, 2013). However, about 30% of outpatients who attend neurological facilities have symptoms not explained by medical findings (Stone et al., 2009).

The essential feature of psychological factors affecting other medical conditions is the presence of clinically significant psychological or behavioral factors that adversely affect a medical condition by increasing the risk for suffering, death, or disability (APA, 2013). These factors are poorly specified and add little to the diagnostic process.

As Cosci and Fava (2016) pointed out, in addition to the ambiguities of these single diagnostic rubrics, there are additional limitations that may result in misleading clinical indications. One is concerned with the use of the term “somatic symptom”, which reflects the fact that anything that cannot be explained by organic causes will fall within the domains of somatization. Thus, the DSM-5 maintains the dichotomy organic/functional, which is based on the assumption that if somatic symptoms cannot be explained by organic factors, there should

be psychiatric reasons explaining this symptomatology.

Another major flaw of the DSM-5 is that this customary taxonomy does not include important clinical information such as severity and pattern of symptoms, aspects of daily life (e.g. well-being, quality of life and stress) and illness behavior (i.e. the ways in which individuals experience, perceive, evaluate and respond to their own health status) (Mechanic & Volkart, 1960; Fava, Rafanelli & Tomba, 2012; Cosci & Fava, 2016).

2.3 The DCPR: an alternative categorical classification for primary care

It has been proposed that the assessment of psychosocial distress in medical settings such as primary care could benefit from the refinement of diagnostic instruments with high sensitivity, able to reveal sub-threshold symptomatology and to identify patterns of illness behaviors (Fava et al., 2007; Sirri et al., 2011; Fava, Sonino & Wise, 2012).

The Diagnostic Criteria for Psychosomatic Research- DCPR (Fava et al., 1995; Cosci & Fava, 2016) may represent an example of such tools. The DCPR are a set of syndromes that allows translation of the spectrum of manifestations of illness behavior and sub-threshold distress in clinical terms and can be applied to both psychiatric and medical illnesses (Cosci & Fava, 2016).

Recently, the DCPR have been presented in the revised version (Fava et al., 2017). They now include 14 psychosomatic syndromes. One is concerned with stress (allostatic overload), two with personality (Type A behavior and alexithymia), eight of them refer to the concept of abnormal illness behavior (persistent somatization, conversion symptoms, anniversary reaction, disease phobia, thanatophobia, health anxiety, illness denial and hypochondriasis) and three

syndromes (i.e. demoralization, irritable mood and secondary somatic symptoms) can be considered psychological manifestations of affective disturbances. Table 1 outlines the new DCPR criteria as presented by Fava and colleagues (2017).

Allostatic overload occurs when the cost of chronic exposure to stress-related fluctuating and heightened neural or neuroendocrine responses exceeds the coping resources of an individual (Fava et al., 2010). It is characterized by fatigue, psychic anxiety, irritability, and initial insomnia.

Type A behavior is the other DCPR irritability syndrome that has been recognized in those at risk of coronary heart disease (Friedman & Rosenman, 1974) but was also found in 10.8% of patients with non-cardiac diseases, suggesting the need to extend its assessment to other medical settings (Sirri et al., 2012). Type A behavior may share some features with hypomania, cyclothymia, and hyperthymic temperament which frequently results in an overoptimistic view of one's own ability to cope with a stressful situation (as is a life-threatening disease) and in the minimization of vulnerability to future difficulties (e.g. medical complications) (Wang et al., 2011).

Alexithymia characterizes patients who have difficulties in describing feelings and differentiating them from bodily sensations, a poor fantasy life, and an "operative" way of thinking.

The diagnosis of hypochondriasis was retained from the DSM-IV classification, as psychotherapeutic strategies had been developed and validated in randomized controlled trials (Fava et al., 2000; Barsky & Ahern, 2004) to address resistance to reassurance, which is the key characteristic of hypochondriasis.

Health anxiety includes a wide range of worries towards illness and pain, which are less specific than hypochondriasis and disease phobia and respond to medical reassurance.

Thanatophobia and disease phobia may be components of a hypocondriacal syndrome,

yet they may also occur independently. Disease phobia differs from hypochondriasis for the specificity, longitudinal stability and quality of the phobia, which concerns a specific disease, it is unlikely to be moved on another disease and tend to manifest itself in attacks rather than in constant worries. Both disease phobia and health anxiety were found to be prevalent in consultation-liaison psychiatry patients (Galeazzi et al., 2004; Porcelli et al., 2009).

Persistent somatization refers to patients in whom somatic symptoms have clustered. It may occur regardless of the functional/organic dichotomy and may be associated to a variety of medical disorders (Porcelli and Guidi, 2015).

The DCPR defined conversion symptoms were formulated according to Engel's (1970) criteria. In a sample of patients from various medical settings, DCPR conversion symptoms were found in 4.5% of subjects, while DSM-IV conversion disorder in only 0.4% (Porcelli et al., 2012).

The anniversary reaction is a special form of somatization or conversion where symptoms are related to the occurrence of the anniversary of a meaningful event the person's life. This diagnosis showed a prevalence of 3.6% in patients from different medical settings (Porcelli et al., 2012).

Illness denial includes patients who do not acknowledge the presence or the severity of their illness. In healthy subjects, illness denial may concern one's own vulnerability to life-threatening diseases, resulting in unsafe health habits or non-attendance to preventive screenings (Fava et al., 2017). DCPR illness denial was found in 9% of women with breast cancer (Grassi et al., 2005) and in 5% of subjects who underwent heart transplantation (Grandi et al., 2011).

The definition of demoralization integrates Frank's (1961) demoralization syndrome and Schmale and Engel's (1967) giving up–given up complex. According to de Figueiredo (2013) demoralization results from the convergence of psychological distress (helplessness and

hopelessness) and subjective incompetence (being unable to cope with a stressful situation).

The syndrome of irritable mood is based on Snaith and Taylor's (1985) definition. It is characterized by a feeling state that might be experienced as brief episodes or be prolonged and generalized, or need an increased effort of control over irritability. The experience of irritability is always unpleasant for the individual, and its overt manifestation lacks a cathartic effect (Snaith & Taylor, 1985).

The syndrome of functional somatic symptom secondary to a psychiatric disorder concerns the hierarchical relationship between functional somatic symptoms and psychiatric disorders. Symptoms of autonomic arousal may be a consequence of psychiatric disorders (Fava et al., 2017).

According to a recent review (Porcelli & Guidi, 2015), the DCPR can be clinically useful for different reasons.

Sub-typing medical patients: DCPR syndromes may be used for sub-typing patients who are characterized by distinct psychological profiles, even though present with the same diagnosis. Sub-typing helps clinicians to tailor different decision and interventions based on the psychological characteristics of a given individual (Porcelli & Guidi, 2015). DCPR were useful for sub-typing patients with a psychiatric diagnosis (Fava et al., 2012) or a medical disease, such as hypertension (Rafanelli et al., 2012).

Identifying sub-threshold or undetected syndromes: DCPR allows identification of psychopathological conditions that either have subclinical manifestations not meeting diagnostic criteria for psychopathology or are completely ignored by traditional nosography.

Evaluating the burden of somatic syndromes: Psychopathology and psychosocial distress increase the burden of illness in the medically ill. The DCPR system has been used in a variety of medical settings, giving clinicians the possibility to identify the patients at a higher risk of distress because of their elevated burden of disease.

Predicting treatment outcomes and identifying risk factors: identifying the psychosocial variables influencing the treatment outcome is useful in clinical practice because it may help the identification of patients who are more likely to not respond to standard medical treatment. In patients with moderate-to-severe functional gastro-intestinal disorder, nonresponse to treatment was significantly and independently predicted by the DCPR syndromes of alexithymia and persistent somatization, while improvement after treatment was predicted by DCPR health anxiety (Porcelli, De Carne & Todarello, 2004).

The DCPR have been compared to the DSM-5 in few studies. In a study on patients with congestive heart failure, Guidi and co-workers (2013) demonstrated that the DCPR-based proposal allowed a significant higher identification of psychological factors meaningful for the illness course when compared with the newly proposed DSM-5 diagnostic criteria for somatic symptom disorders. Furthermore, the DCPR predicted a worse psychosocial functioning, in psychiatric patients, compared to the DSM-5 (Porcelli et al., 2009).

The clinical utility of DCPR for primary care practice is yet to be fully understood. A study by Ferrari and co-workers (2008) found a greater severity of DCPR syndromes (number of syndromes a patient has) among frequent attenders in primary care, compared to average attenders, suggesting a mediating role of DCPR syndromes in promoting this behavioral pattern. There is currently need to evaluate the ability of DCPR to detect and characterize psychosocial distress and global functioning in primary care.

Table 1. Revised DCPR Criteria (Fava et al., 2017)
Allostatic overload: presence of a current identifiable source of distress in the form of recent life events and/or chronic stress; the stressor is judged to tax or exceed the individual's coping skills when its full nature and circumstances are evaluated. The stressor is associated with 1 or more of the following 3 features, which have occurred within 6 months after the onset of the stressor: (1) At least 2 of the following symptoms: difficulty falling asleep, restless sleep, early morning awakening, lack of energy, dizziness, generalized anxiety, irritability, sadness, demoralization. (2) Significant impairment in social or occupational functioning. (3) Significant impairment in environmental mastery (feeling overwhelmed by the demands of everyday life)
Type A behavior: At least 5 of the 9 following characteristics should be present: excessive degree of involvement in work and other activities subject to deadlines; steady and pervasive sense of urgency; display of motor-expressive features (rapid and explosive speech, abrupt body movements, tensing of facial muscles, hand gestures) indicating a sense of being under pressure of time; hostility and cynicism; irritability; tendency to speed up physical activities; tendency to speed up mental activities; high desire for achievement and recognition; high competitiveness.
Alexithymia: At least 3 of the following 6 characteristics are present: inability to use appropriate words to describe emotions; tendency to describe details instead of feelings; lack of a rich fantasy life; thought content associated more with external events than with fantasy or emotions; unawareness of the common somatic reactions accompanying the experience of a variety of feelings; occasional but violent and often inappropriate outbursts of affective behavior.

Hypochondriasis: Fears of having, or the idea of having, a serious disease based on misinterpretation of bodily symptoms. The preoccupations persist despite adequate medical evaluation and reassurance, with opportunity for discussion and clarification. The duration of the disturbance is at least 6 months. The preoccupations cause marked distress and/or impairment in social and occupational functioning.
Disease phobia: A persistent, unfounded fear of suffering from a specific disease, with doubts remaining despite adequate examination and reassurance. Fears tend to manifest themselves in attacks rather than in chronic worries as in hypochondriasis; panic attacks may be associated. The object of fears does not change with time. Duration of symptoms exceeds 6 months.
Thanatophobia: At least 2 attacks in the past 6 months of impending death and/or conviction of dying soon, without being in a threatening situation or in real danger; adequate appraisal of the situation and management to be followed (if any) has been provided by a physician, with an opportunity for discussion and clarification. Marked and persistent fear and avoidance of news that reminds of death (e.g. funerals, obituary notices); exposure to these stimuli almost invariably provokes an immediate anxiety response Avoidance, anxious anticipation, and distress interfere markedly with the level of functioning.
Health anxiety: Generic worry about illness, concern about pain and bodily preoccupations, tendency to amplify somatic sensations of less than 6 months' duration. Worries and fears readily respond to appropriate medical reassurance, even though new worries may ensue after some time.
Persistent somatization: Functional medical syndromes (fibromyalgia, chronic fatigue, esophageal motility disorders, nonulcer dyspepsia, irritable bowel syndrome, atypical chest

pain, overactive bladder) whose duration exceeds 6 months causing distress and/or seeking medical care and/or resulting in impaired quality of life. Symptoms of autonomic arousal involving other organ systems (e.g. palpitations, tremor, flushing, sweating) and/or exaggerated side effects from medical therapy, indicating low threshold of pain sensation and/or high suggestibility.
Conversion symptoms: One or more symptoms/deficits affecting voluntary motor/sensory function, characterized by lack of anatomical or physiological plausibility; and/or absence of expected physical signs or laboratory findings; and/or inconsistent clinical characteristics. If symptoms of autonomic arousal or a functional medical disorder are present, conversion symptoms should be prominent, causing distress or repeated medical care or impairing quality of life. At least 2 of the following features are present: ambivalence in symptom reporting; histrionic personality features; precipitation of symptoms by psychological stress, the association of which the patient is unaware; history of similar physical symptoms experienced by the patient or observed in or wished on someone else.
Anniversary reaction: Symptoms of autonomic arousal (e.g. palpitations, tremor, flushing, sweating) or functional syndromes (e.g. irritable bowel syndrome, fibromyalgia, atypical chest pain) or conversion symptoms causing distress and/or seeking medical care and/or impaired quality of life Appropriate medical evaluation uncovers no organic pathology to account for physical symptoms. Symptoms began when the patient reached the age, or on the occasion of the anniversary, when a parent or very close family member developed a life-threatening illness and/or died; the patient is unaware of such association.
Illness denial: Persistent denial of having a physical disorder and needing treatment (e.g. lack of compliance, delayed seeking of medical attention for serious and persistent symptoms, counterphobic behavior) as a reaction to the symptoms, signs, diagnosis, or medical treatment

of a physical illness. The patient has been provided with an adequate appraisal of the medical situation and management (if any) to be followed, with opportunity for discussion and clarification.
Demoralization: A feeling state characterized by the perception of being unable to cope with some pressing problems and/or of lack of adequate support from others (helplessness); the individual maintains the capacity to react The feeling state is prolonged and generalized (duration of at least 1 month). A feeling state characterized by the consciousness of having failed to meet expectations associated with the conviction that there are no solutions for current problems and difficulties (hopelessness).
Irritable mood: A feeling state characterized by irritability which may be experienced as brief episodes (in particular circumstances) or may be prolonged and generalized; it requires an increased effort of control over temper or results in irascible verbal or behavioral outbursts The experience of irritability is always unpleasant, and overt manifestations lack the cathartic effect of justified outbursts of anger.
Somatic symptoms secondary to a psychiatric disorder: Somatic symptoms that cause distress and/or seeking medical care and/or impaired quality of life Appropriate medical evaluation uncovers no organic pathology to account for the physical complaints. A psychiatric disorder (which includes somatic symptoms within its manifestations) preceded the onset of somatic symptoms (e.g. panic disorder preceding cardiac symptoms).

2.4 Psychosomatic assessment

In light of the need to promote integrated primary care principles, the psychosomatic perspective might represent an important opportunity to foster this new paradigm in primary care.

Psychosomatic medicine is an interdisciplinary field that is concerned with the interaction of biological, psychological and social factors in the regulation of the balance between health and disease (Lipowski, 1986; Fava & Sonino, 2000; Fava & Sonino, 2005; Fava & Sonino, 2010). It is characterized by a personalized and holistic approach to the patient, with the addition of psychosocial assessment to the standard medical examination; a multidisciplinary organization of health care that overcomes the boundaries of traditional medical specialties; a focus on the role of psychosocial factors affecting individual vulnerability, course, and outcome of any type of medical disease (Fava et al., 2017).

Assessment of psychosocial factors potentially influencing individual vulnerability to illness is often omitted by the primary care physician or the medical specialist (Fava & Sonino, 2010). Moreover, these psychosocial factors are neglected by customary psychiatric taxonomy, which tends o rely exclusively on 'hard data', excluding 'soft information' (Sonino & Fava, 2007). For this reason, the notion of psychiatric disturbance is not representative of the complexity of the problems encountered in clinical practice (Fava et al., 2004).

Psychosocial variables affecting illness vulnerability may encompass factors such as psychological distress, stress, illness behavior, well-being and quality of life.

The notion of stress allows the identification of temporal relationship between life events, chronic conditions and symptom onset or relapse. Indeed, daily life stresses may be experienced by the individual as taxing or exceeding his/her coping skills. Stress may result in responses mediated by a variety of neurotransmitters, proinflammatory cytokines, and

hormones (Grippo & Sotti, 2013; Nemeroff, 2016).

Illness behavior is a core characterization in psychosomatic medicine and provides an explanatory model for clinical phenomena that do not find room in customary taxonomy (Cosci & Fava, 2016). Illness behavior refers to the different ways individuals respond to bodily indications, monitor internal states, define and interpret symptoms, utilize various sources of informal and formal care (Mechanic, 1995).

Psychological well-being is another crucial factor and several studies have suggested that positive affect plays a buffering role in coping with stress and has a favorable impact on disease course (Pressman & Cohen, 2005; Ryff et al., 2014). Frederickson and colleagues (2015) showed that individuals with high psychological well-being presented reduced gene expression of conserved transcriptional response to adversity, suggesting a potential protective role of psychological well-being in a number of medical disorders.

Quality of life and patient reported outcomes (any report coming directly from patients about how they function or feel in relation to a health condition or its therapy) concern the functional status of the individual and the patient's appraisal of his/her own health. Measures of disease status alone are insufficient to describe the burden of illness whereas subjective health status is as valid as that of the clinician when it comes to evaluating outcomes (Topp et al., 2015; Rodriguez-Urrutia et al., 2016).

The psychosomatic evaluation of these important psychosocial variables stems from clinimetric principles (Fava, Tomba & Sonino, 2012; Tomba & Bech, 2012; Grassi et al., 2015; Bech, 2016; Piolanti et al., 2016). The term 'clinimetrics' was introduced by Alvan R. Feinstein to indicate a domain concerned with indexes, rating scales, and other expressions that are used to describe or measure symptoms, physical signs, and other clinical phenomena (Feinstein, 1987). The aim of clinimetrics was to provide a home for a number of clinical phenomena which did not find room in customary clinical taxonomy (Feinstein, 1987). The customary

taxonomy does not include patterns of symptoms, severity of illness, effects of comorbid conditions, timing of phenomena, rate of progression of illness, functional capacity and other clinical features that demarcate major prognostic and therapeutic differences among patients who otherwise seem deceptively similar, because they have the same diagnosis (Feinstein, 1983).

The need to include clinimetric consideration of psychosocial factors has emerged as a crucial part of clinical investigation and patient care (Feinstein, 1994). This information may be crucial in managing patients with unexplained somatic symptoms (Katon & Walker, 1998) or with difficult patient-doctor relationships (Hahn et al., 1994). A comprehensive psychological assessment in primary care should thus include a clinimetric evaluation of these psychosocial factors.

2.5 Clinimetric methods and indexes

Clinimetric principles should guide the selection of methods to be used for a specific assessment and the modalities in which the assessment unfolds (Fava, Tomba & Sonino, 2011).

Standardization and sensibility are both related to the quality of clinical measurements (Feinstein, 1987). Standardization refers to the reliability and validity of an index. Reliability has an external part (observer variability in using the index, such as inter-rater agreement) and an internal part (consistency). Validity, on the other hand, reflects the accuracy with which the phenomenon under observation is measured with a standard reference procedure, or gold standard (Feinstein, 1987). An index is valid if it measures what it is supposed to measure.

Furthermore, Feinstein (1987) formulated the concept of sensibility. An essential

requisite for sensibility of an index is its discrimination properties, which means that it should be able to detect clinically relevant changes in health status over time (Husted et al., 2000; Fava & Belaise, 2005). Sensibility thus appears an important concept for developing and selecting indexes to monitor changes in clinical trials. As important is the clinimetric concept of incremental validity, that refers to the unique contribution (or incremental increase) in predictive power associated with a particular assessment procedure in the clinical decision process (Sechrest, 1963). Accordingly, each distinct aspect of measurement should deliver a unique increase in information to qualify for inclusion. In clinical research, several scales are often used under the misguided assumption that nothing will be missed. On the contrary, violation of the concept of incremental validity leads to conflicting results (Fava & Belaise, 2005).

A unique feature of clinimetric tools is to provide a broad global rating of clinical phenomena. Although the sensitivity of these methods is acknowledged in drug trials, where they often yield the most sensitive discrimination between drug and placebo effects (Fava, Rafanelli & Tomba, 2011), their value in clinical practice is currently underestimated.

Another key characteristic is the collaboration of the patient. This is particularly true in the psychosocial domain, where many observer and self-rating scales have been developed. Although observer-rated methods make full use of the clinical experience and comparison potential of the interviewer, self-rating methods allow a more direct assessment of the patient subjective perceptions, such as quality of life.

Several clinimetric instruments have been developed for the psychological assessment in medical settings (Fava, Tomba & Sonino, 2012; Sirri et al., 2008; Piolanti et al., 2016; Fava et al., 2017) and might result particularly useful for Primary Care Psychologists.

CHAPTER 3

Study

3.1 Rationale

The current psychiatric taxonomy applied in primary care has limited clinical utility, as it fails to detect sub-clinical distress and neglect important psychosocial information necessary for the clinical process of medical decisions. In particular, the DSM-5 category of somatic symptoms and related disorders has been deemed inadequate for clinical practice use.

The assessment of psychosocial distress in medical settings such as primary care may benefit from the use of the DCPR, allowing the PC psychologist to sensitively reveal sub-threshold symptomatology. The fact that DCPR may be used for sub-typing medical patients, identifying sub-threshold or undetected syndromes, evaluating the burden of somatic syndromes, predicting treatment outcomes and identifying risk factors, could enhance the clinical utility of the current psychiatric assessment applied in primary care.

The use of rating scales in primary care represents another major issue. Beside general recommendations about available tools to be used in primary care, no studies have been conducted to identify a systematic strategy of assessment. The use of self-rating dimensional measures of psychosocial factors such as stress, well-being, illness behavior and quality of life may provide important information for the process of clinical reasoning.

Given this background, it is imperative to develop an alternative psychological assessment strategy of psychosocial factors for primary care settings.

3.2 Aims and objectives

The current study has the main aim to develop and evaluate an alternative psychological assessment strategy to appropriately characterize psychosocial factors in primary care patients. In particular, this project will attempt to provide an answer for the following research question: "Can the DCPR help the psychologist providing appropriate feedback and clinical indications in primary care, in conjunction with the DSM-5?".

This aim will be subdivided into the following specific objectives:

1. Report the prevalence of psychosomatic (DCPR) and psychiatric (DSM-5) diagnoses in primary care.
2. Compare DCPR and DSM-5 diagnostic sub-groups with unaffected patients as to observer-rated measures of affective symptoms and self-rating dimensions of distress, stress, well-being, illness behavior and quality of life.
3. Evaluate and compare the incremental validity of DCPR and SSD in addition to the DSM-5 with regards to self-rated psychological variables.

3.3 Hypotheses

1. We hypothesize to find prevalence rates of mental disorders similar to those reported in the literature. As to the DCPR, we hypothesize that these psychosomatic syndromes will allow a sensitive identification of psychological sub-threshold distress.

2. We hypothesize to find significant higher associations between patients affected by a mental or psychosomatic syndromes and dimensional measures of psychosocial factors, compared to the unaffected patients.
3. We hypothesize to find a better prediction of self-related measures of psychosocial variables by using the DCPR-based categorization, than the category of somatic symptoms disorders, in addition to the DSM-5 diagnostic criteria.

3.4 Methods

This study received approval from the ethics boards of the University of Bologna.

3.4.1 Participants

Patients were consecutively recruited in a primary care practice in Ravenna, located in Northern Italy. Subjects were provided with a detailed explanation of the study and subsequently invited to take part as volunteers in the research.

Patients were excluded if < 18 or > 70 years old, had cognitive impairments, refused to cooperate, did not give written informed consent, presented with psychotic or significant pain symptoms.

After signing the informed consent form patients were invited for a single clinical interview within the primary care practice, carried out by a trained clinical psychologist.

3.4.2 Assessment

Participants underwent three detailed clinical interviews and completed three self-rating questionnaires for the assessment of psychopathology and psychosocial functioning:

1. ***Structured Clinical Interview for DSM-5, SCID-5*** **(First et al., 2015)**

   The SCID-5 is a semi-structured interview for obtaining DSM-5 diagnoses. The interview covers the following diagnoses: depressive and bipolar disorders; schizophrenia spectrum and other psychotic disorders; substance use disorders; anxiety disorders; obsessive-compulsive disorder; post-traumatic stress disorder; somatic symptom and related disorders; attention-deficit/hyperactivity disorder; and adjustment disorder.

2. ***The Semi-Structured Interview for Diagnostic Criteria for Psychosomatic Research – Revised version (DCPR-R)*** **(Fava et al., 2017)**

   This interview was developed based on the previous interview for DCPR (Porcelli et al., 2007), integrating the revised version of DCPR criteria, as outlined by Fava and colleagues (2017). Compared to the first version (Fava et al., 1995) the DCPR-R includes two additional syndromes (allostatic overload and hypochondriasis, which was retained from DSM-IV (APA, 2000)) and allows differentiation between helplessness and hopelessness in demoralization. Items of the interview for DCPR are scored through a yes/ no response format evaluating the presence of 14 psychosomatic syndromes: alexithymia, type A behavior, irritable mood, demoralization, disease phobia, thanatophobia, health anxiety, illness denial, functional somatic symptoms

secondary to a psychiatric disorder, persistent somatization, conversion symptoms, anniversary reaction, allostatic overload and hypochondriasis. The interview for DCPR (Porcelli et al, 2007) had shown excellent inter-rater reliability, construct validity and predictive validity for psychosocial functioning and treatment outcome (Galeazzi et al., 2004). Diagnoses were formulated independently from the DSM.

3. Clinical Interview for Depression – CID (Paykel, 1985; Guidi et al., 2011)

The CID is an observer-rated dimensional assessment tool for assessing a wide range of affective symptoms, consisting of an expanded version of the Hamilton Rating Scale for Depression (Hamilton, M. 1967). The CID covers 36 symptom areas rated on 7-point scales with specification of each anchor point based on severity, frequency and/or quality of symptom. The CID has been used extensively as an outcome measure in several controlled clinical trials and follow-up studies of pharmacotherapy and psychotherapy of affective disorders (Fava & Kellner, 1991; Fava et al., 1994). Furthermore, the CID has been shown to be a valid and reliable tool with good clinimetric characteristics as well as high sensitivity to change in the broad evaluation of affective symptomatology (Guidi et al., 2011).

4. *PsychoSocial Index – PSI* (Sonino & Fava, 1998; Piolanti et al., 2016)

The PSI is a 55 – item self- rating scale based on clinimetric principles tailored for busy clinical setting.

The PSI covers the following clinical domains:

(a) *Socio-demographic and clinical data:* this part includes largely routine information about medical and psychiatric history, the patient's family, employment and habits. It may alert clinicians to some threats to health, such as alcohol or drug use.

(b) *Stress:* this section is an integration of both perceived and objective stress, life events and chronic stress. It consists of 17 questions with a total score ranging from 0 to 17. These questions contain essential information for case identification of allostatic overload

(c) Well-being: this section covers different areas of well-being, i.e., positive relations with others, environmental mastery and autonomy, with a score ranging from 0 to 6.

(d) *Psychological distress:* this section consists of a checklist of symptoms addressing sleep disturbances, somatization, anxiety, depression and irritability. The total score may range from 0 to 45.

(e) *Abnormal illness behavior:* it allows the assessment of hypochondriacal beliefs and bodily preoccupations. The total score may range from 0 to 9.

(f) *Quality of life* (item 55): a simple direct question on quality of life is included. The score ranges from 0 to 4.

The items of the PSI were derived from the Screening List for Psychosocial Problems - SLP (Kellner, 1991), the Wheatley Stress Profile (Wheatly, 1990), Ryff's Scale of Psychological Well-being (Ryff, 2014) and Kellner's Illness Attitude Scales (Kellner, 1987; Sirri et al., 2008), all validated instruments. Some questions involve specific responses, most require a yes/no answer, while others are rated on a Likert 0–3 scale (from 'not at all' to 'a great deal'). The PSI has been employed in various clinical populations in different countries and showed high sensitivity, discriminating varying degrees of psychosocial impairment in different populations (Piolanti et al., 2016). In this study, items concerning illness behavior were scored with the IAS.

5. *12-item Short Form Health Survey– SF-12* (Ware, Kosinsky & Keller, 1996)

The SF-12 is a self-report questionnaire, derived from the SF-36 (Ware, 1993) and

designed to measure a person's perceived quality of life. The SF-12 surveys eight domains of health with answers to each question being scored on a 5-point Likert scale: physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems and mental health (psychological distress and psychological well-being). An algorithm is used to transform the eight raw scores into norm-based scores. The SF-12 provides two aggregate summary measures of psychosocial functioning: the Physical Component Summary (PCS) and the Mental Component Summary (MCS). The SF-12 has been extensively validated and proved to be useful in comparing patient groups known to differ or to change in terms of the presence and seriousness of physical and mental conditions, acute symptoms, age and aging, self-reported 1-year changes in health, and recovery from depression (Ware et al., 1996).

6. ***Illness Attitude Scales – IAS*** **(Kellner, 1987; Sirri et al., 2008)**

The IAS consist of nine self-report scales concerning: (1) Worry about Illness (WI; general worry about having a serious illness), (2) Concern about Pain (CP; concerns that physical pain experiences may be indicative of an underlying disease), (3) Health Habits (HH; avoidance of behaviors that may be harmful to one's health), (4) Hypochondriacal Beliefs (HB; belief in the existence of a disease which physicians have failed to diagnose), (5) Thanatophobia (TH; fear of death), (6) Disease Phobia (DP; worries about having specific diseases), (7) Bodily Preoccupations (BP; a sensitivity to bodily sensations which may be indicative of illness), (8) Treatment Experiences (TE; how frequently a person has sought medical treatments) and (9) Effects of Symptoms (ES; the extent to which bodily symptoms interfere with general

functioning).

Each scale contains three items rated on a 5-point Likert scale ranging from “no” to “most of the time”. For each scale, the score may range from 0 to 12, with higher scores corresponding to more severe hypochondriacal symptoms. The IAS scores showed both high discriminant validity in differentiating hypochondriacal patients from normal controls, family practice patients and non-hypochondriacal psychiatric patients and sensitivity to changes after treatment of hypochondriasis (Sirri, L. 2014; Weck, Bleichhardt & Hiller, 2010)

3.4.3 Data analysis

Data were entered into SPSS for Windows 20.0 (SPSS Inc., Chicago, IL, USA). The quality of data collection was monitored regularly to assure accuracy and completeness of data.

Descriptive statistics were used to analyses socio-demographic/medical variables and to generate frequencies of psychiatric/psychosomatic diagnoses.

Subgroup comparisons between DCPR/DSM-5 and unaffected groups, with regards to psychological measures of distress, stress, quality of life and illness behaviors were evaluated with the univariate analyses of variance using the general linear model (GLM), after controlling for socio-demographic and medical variables. DSM-5 and DCPR systems were examined separately and sub-groups were selected according to the most frequent diagnostic clusters.

The distinct role played by DCPR and SSD in predicting psychological variables, in adjunction to DSM-5 diagnoses (not including SSD), was evaluated with a series of hierarchical regressions, controlled for socio-demographic and medical variables.

The extent to which DCPR syndromes, SSD and DSM-5 diagnoses were distinctly associated with psychosocial variables was evaluated with effect sizes by using Partial Eta Squared value (ηp). This measure was provided by the univariate analyses of variance using the general linear model. A standardized effect size of 0.01 is considered as small, 0.06 as medium and 0.14 as large (Levine & Hullet, 2002).

3.5 Results

3.5.1 Patients' characteristics

533 patients were approached to take part in the study. Of these, 256 (47.5%) declined to participate (main reason being lack of time), 8 (1.5%) were older than 70 years old and 3 (0.5%) had a psychotic disorder. Sixty-six (13.3%) subjects who agreed to participate did not attend psychological interview. Totally, the non-participants sample included 339 subjects (62.9%): 192 (56.7%) were females and 147 (43.3%) were males. Because of refusal to participate, clinical problems or not meeting the inclusion criteria, 200 patients (37.2%) entered the study and underwent psychological interview. Figure 1 shows the study flow-chart.

In the study sample, there were 132 females (66%) and 68 males (34%), the mean age was 46.5 years (SD = 14.5), 129 patients (64.5%) were employed and 95 (47.5%) were married (Table 2). Out of the total sample, 82 (41%) patients had an active medical disease, mostly cardiac (19%), endocrine (12.5%) or pain disorders (7.5%). Twenty-two (11%) patients were taking psychiatric medications at the time of assessment, 111 (55.5%) acknowledged drinking alcohol, 50 (25%) smoking cigarettes and 11 (5.5%) using recreational drugs.

Figure 1. Study flow-chart

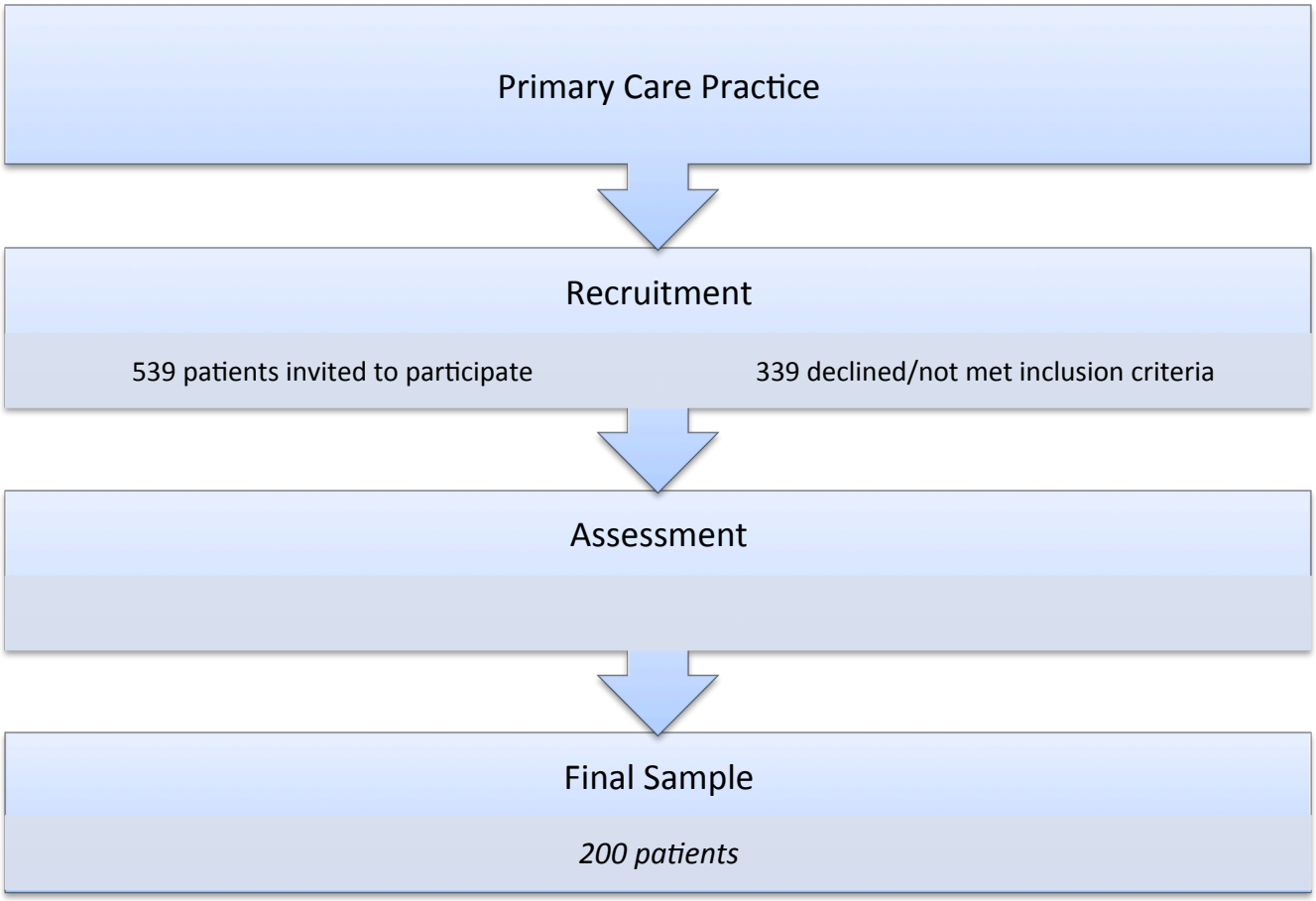


Table 1: Patients characteristics

	n (200)	%
Sex		
Male	68	34
Female	132	66
Employment status		
Employed	129	64.5
Unemployed	18	9.0
Retired, housewife, student	53	26.5
Marital Status		
Single	78	39
Married	95	47.5
Divorced/widowed	25	12.5
Active Medical Disease	82	41
Medical diagnostic groups		
Cardiology	38	19
Endocrinology	25	12.5
Pain	15	7.5
Pulmonary	6	3
Gastroenterorology	5	2.5
Others	9	4.5
Smoking	50	25
Alchool use	111	55.5
Substance use	11	5.5
Psychiatric medication	22	11

3.5.2 Prevalence of DCPR and DSM-5 diagnoses

Overall, 93 (46.5%) patients received at least 1 psychiatric (DSM-5) or psychological (DCPR) diagnosis (Figure 2). Forty-one patients (20,5%) had a diagnosis of both DCPR and DSM-5, 47 (23,5%) had a diagnosis of DCPR without DSM and 5 (2,5%) a diagnosis of DSM without DCPR.

In total there were 46 patients (23%) with at least one DSM-5 diagnosis. Twelve (4.8%) patients received more than 1 DSM diagnosis. The most frequent diagnostic clusters were somatic symptom and related disorders (10%), mood disorders (8%) and anxiety disorders (7.5%) (Figure 3).

As to mood disorders, 14 (7%) patients had major depression, 1 (0.5%) persistent depressive disorder and 1 (0.5%) bipolar disorder, type II. As to anxiety disorders, 5 (2.5%) patients had panic disorder, 5 (2.5%) agoraphobia, 1 (0.5%) social anxiety, 2 (1%) specific phobia and 2 (1%) generalized anxiety disorders. Five (2.5%) patients received a diagnosis of somatic symptom disorder, 11 (5.5%) illness anxiety and 4 (2.5%) psychological factors affecting medical conditions. Finally, 2 (1%) patients were diagnosed with eating disorder, 3 (1.5%) with adjustment disorder and 2 (1%) with substance use disorder.

Using DCPR criteria, 88 patients (44%) suffered from at least 1 DCPR syndrome (Figure 4). Of these, 51 (25.5%) presented with more than 1 DCPR diagnosis. Thirty-one patients (15.5%) had allostatic load, 26 (13%) demoralization, of which 9 (4.5%) with hopelessness, 27 (13.5%) had alexithymia, 23 (11.5%) irritable mood, 17 (8.5%) health anxiety, 16 (8%) persistent somatization, 12 (6%) type A behavior, 11 (5.5%) secondary somatic symptoms, 7 (3.5%) illness denial, 5 (2.5%) thanatophobia, 4 (2%) disease phobia, 1 (0.5%) patient had hypochondriasis, 3 (1.5%) conversion symptoms and 2 (1%) anniversary reaction.

Figure 2. Prevalence of DSM-5 and DCPR diagnoses

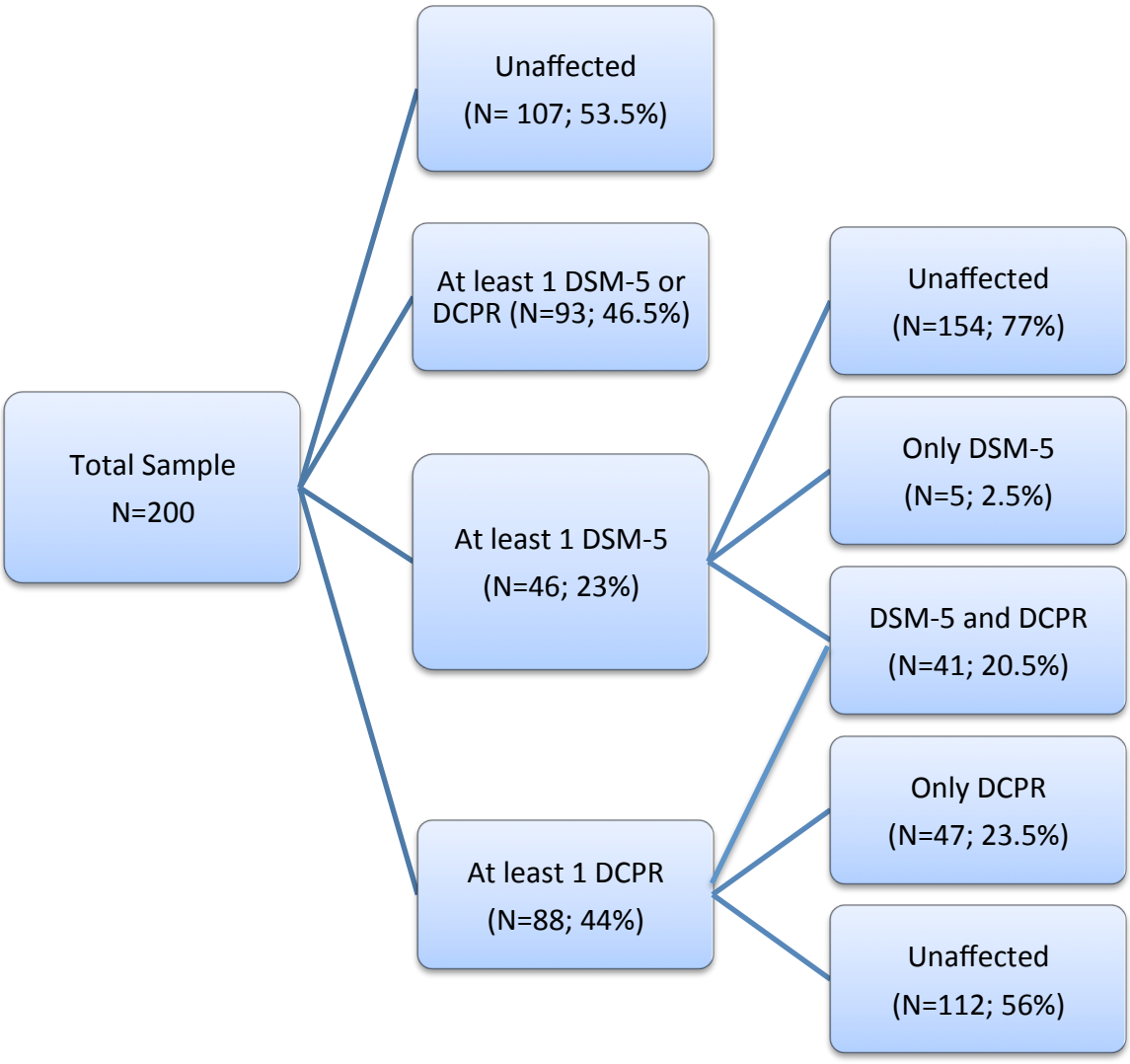


Figure 3. DSM-5 clusters

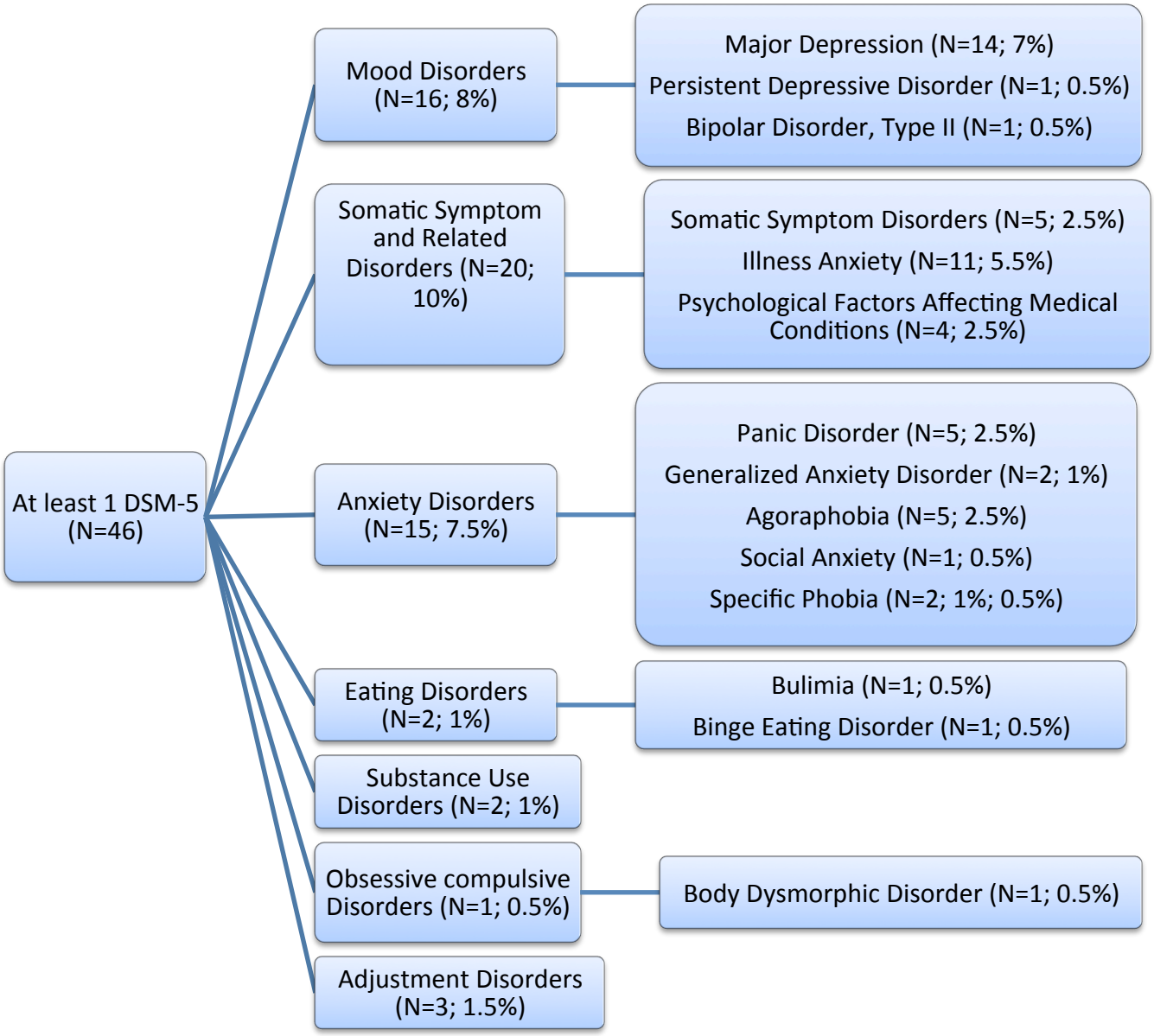
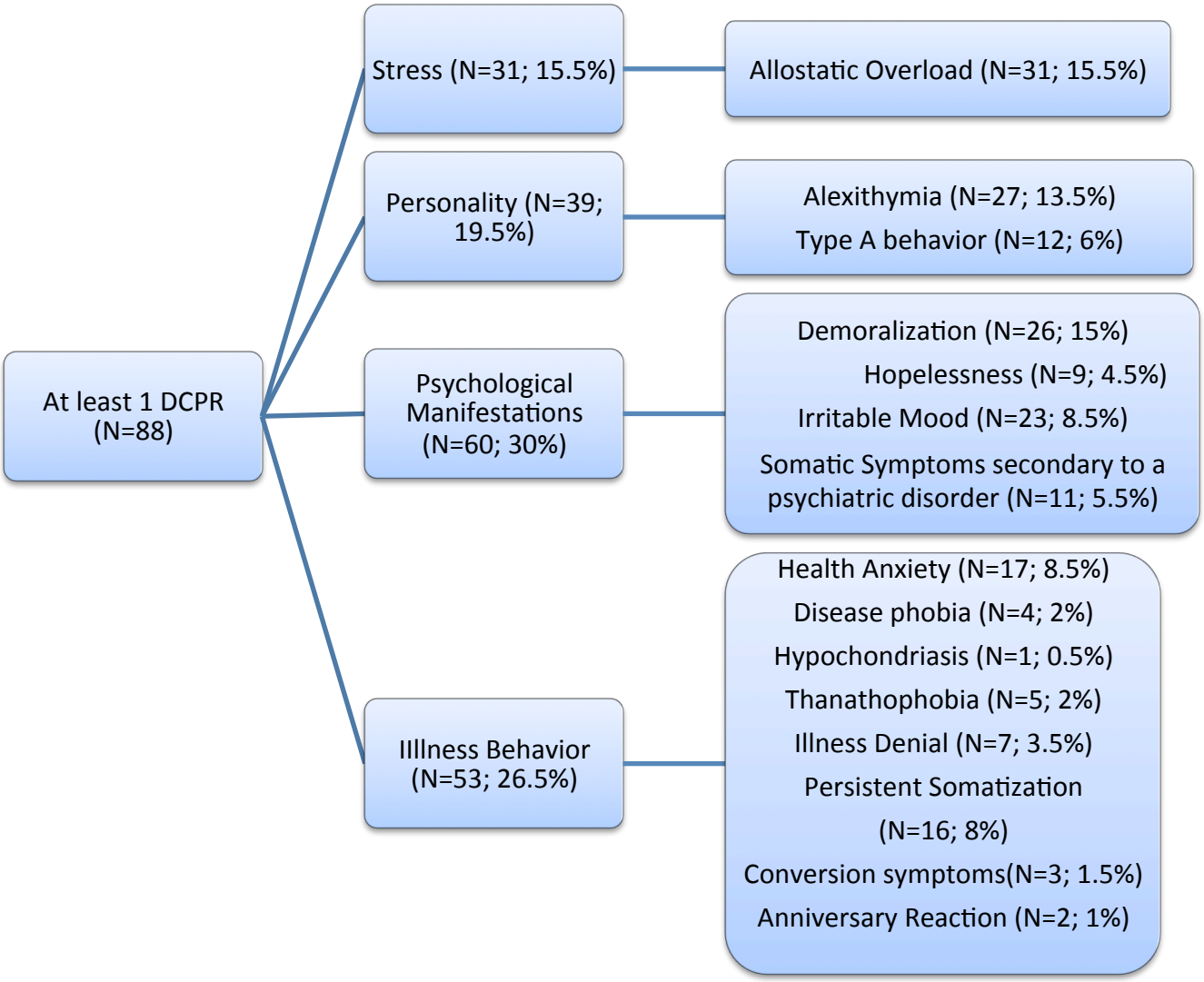


Figure 4. DCPR clusters



3.5.3 Between-groups comparisons

1. DSM-5

- At least one DSM-5 diagnosis

Table 2 displays the differences in PSI, SF-12, IAS and CID scales' scores of patients with at least 1 DSM diagnosis compared to those who had none (this group included subjects with no diagnosis and patients with DCPR diagnoses).

One can observe how patients meeting DSM criteria showed significantly higher scores at PSI distress [F(1,195)=47.29; P<.001] and PSI stress [F(1,195)=5.08; P<.05], and significantly lower scores at PSI well-being [F(1,195)=22.40; P<.001], PSI quality of life [F(1,195)=21.24; P<.001] and SF-12 mental health component of quality of life [F(1,195)=25.30; P<.001], compared to the control group. No differences were observed at the SF-12 measure of the physical component of quality of life.

As to the IAS, patients with at least 1 DSM diagnosis reported significantly higher scores at worry about illness [F(1,195)=9.47; P<.01], concerns about pain [F(1,195)=19.63; P<.001], hypochondriacal beliefs [F(1,195)=8.51; P<.01], thanathophobia [F(1,195)=16.97; P<.001], disease phobia [F(1,195)=14.63; P<.001], bodily preoccupations [F(1,195)=12.76; P<.001] and effects of symptoms [F(1,195)=20.80; P<.01] scales. No differences were observed at the health habits and treatment experience scales.

Concerning the CID, the DSM-5 group reported significantly higher score at anxiety [F(1,195)=72.06; P<.001], depression [F(1,195)=59.51; P<.001] and total score scales [F(1,195)=98.70; P<.001], compared to the unaffected group.

Table 2: Sub-group comparison of patients with and without* DSM-5 diagnoses at PSI, SF-12, IAS and CID controlled for age, gender and active medical diseases

	DSM (+) N= 46	DSM (-) N= 154	F (1,195)	p
	Estimated marginal means (SE)	Estimated marginal means (SE)		
PSI distress	14.57 ± 6.98	7.31 ± 5.17	47.29	<.001
PSI stress	4.26 ± 2.74	3.19 ± 2.37	5.08	<.05
PSI well-being	3.67 ± 1.55	4.84 ± 1.31	22.40	<.001
PSI quality of life	1.98 ± 0.93	2.64 ± 0.72	21.24	<.001
SF-12 PCS	47.84 ± 10.23	48.89 ± 8.51	0.03	NS
SF-12 MCS	38.32 ± 10.45	47.82 ± 10.02	25.30	<.001
IAS Worry about illness	6.87 ± 3.33	5.25 ± 2.62	9.47	<.01
IAS Concerns about pain	6.33 ± 2.90	4.42 ± 2.28	19.63	<.001
IAS Health habits	7.11 ± 3.33	6.91 ± 2.83	0.03	NS
IAS Hypochondriacal beliefs	2.04 ± 2.47	1.03 ± 1.88	8.51	<.01
IAS Thanatophobia	5.61 ± 3.78	3.13 ± 3.12	16.97	<.001
IAS Disease phobia	3.46 ± 3.20	1.76 ± 2.05	14.63	<.001
IAS Bodily preoccupations	4.61 ± 2.83	3.01 ± 2.26	12.76	<.001
IAS Treatment experience	5.48 ± 2.56	4.40 ± 2.38	3.43	NS
IAS Effects of symptoms	3.93 ± 3.34	1.69 ± 2.27	20.80	<.001
CID anxiety	8.65 ± 2.72	5.53 ± 1.74	72.06	<.001
CID depression	17.37 ± 5.49	12.36 ± 2.56	59.51	<.001
CID total	63.91 ± 11.59	47.83 ± 7.62	98.70	<.001

*Includes patients with no diagnosis and those with only DCPR diagnoses

- Mood disorders

Table 3 displays the differences of patients with mood disorders compared to unaffected ones. This latter group excludes patients with other types of DSM-5.

Patients with mood disorders showed significantly higher levels of psychological distress [F(1,165)=33.45; P<.001] and stress [F(1,165)=7.71; P<.01] and significantly lower scores of well-being [F(1,195)=12.36; P<.01], quality of life [F(1,165)=24.57; P<.001] and mental health quality of life [F(1,165)=19.07; P<.001].

Few significant differences were found at IAS scales. Patients with DSM-5 mood disorders reported significant higher scores at treatment experience [F(1,165)=6.92; P<.01] and effect of symptoms [F(1,165)=19.30; P<.001] scales. Furthermore, they showed significant higher scores at anxiety [F(1,165)=11.05; P<.01], depression [F(1,165)=104.25; P<.001] and total score [F(1,165)=84.52; P<.001] scales of the CID.

Table 3: Sub-group comparison of patients with and without* mood disorders diagnoses at PSI, SF-12, IAS and CID controlled for age, gender and active medical diseases

	Mood disorder (+) N= 16	Mood disorder (-) N= 154	F (1,165)	p
	Estimated marginal means (SE)	Estimated marginal means (SE)		
PSI distress	16.56 ± 7.50	7.31 ± 5.17	33.45	<.001
PSI stress	5.00 ± 2.58	3.19 ± 2.37	7.71	<.01
PSI well-being	3.44 ± 1.67	4.84 ± 1.31	12.36	<.01
PSI quality of life	1.56 ± 1.20	2.64 ± 0.72	24.57	<.001
SF-12 PCS	42.65 ± 12.07	48.89 ± 8.51	3.86	NS
SF-12 MCS	35.83 ± 10.50	47.82 ± 10.02	19.07	<.001
IAS Worry about illness	5.88 ± 3.20	5.25 ± 2.62	0.62	NS
IAS Concerns about pain	5.00 ± 2.8	4.42 ± 2.28	0.99	NS
IAS Health habits	6.25 ± 3.27	6.91 ± 2.83	2.23	NS
IAS Hypochondriacal beliefs	1.81 ± 2.2	1.03 ± 1.88	1.32	NS
IAS Thanatophobia	4.56 ± 4.08	3.13 ± 3.12	3.11	NS
IAS Disease phobia	2.94 ± 2.59	1.76 ± 2.05	2.46	NS
IAS Bodily preoccupations	3.44 ± 2.52	3.01 ± 2.26	0.26	NS
IAS Treatment experience	6.56 ± 2.30	4.40 ± 2.38	6.92	<.01
IAS Effects of symptoms	5.06 ± 3.35	1.69 ± 2.27	19.30	<.001
CID anxiety	7.44 ± 2.47	5.53 ± 1.74	11.05	<.01
CID depression	16.56 ± 5.70	12.36 ± 2.56	104.25	<.001
CID total	5.00 ± 13.59	47.83 ± 7.62	84.52	<.001

*Includes patients with no diagnosis and those with only DCPR diagnoses

- Anxiety disorders

Table 4 displays the differences of patients with anxiety disorders compared to unaffected ones. The unaffected group includes subjects with no diagnosis or with only DCPR diagnosis.

Patients diagnosed with anxiety disorders reported significantly higher scores at PSI distress [$F(1,163)=11.88$; $P<.001$] and significantly worse physical [$F(1,163)=6.14$; $P<.05$] and mental [$F(1,163)=9.59$; $P<.01$] quality of life, as assessed by the SF-12, compared to the unaffected group. No significant differences were reported at PSI stress, well-being and quality of life.

At IAS, they reported significantly higher scores of thanathophobia [$F(1,163)=4.46$; $P<.05$].

Concerning the CID, patients diagnosed with anxiety disorders reported significantly higher score at anxiety [$F(1,163)=67.70$; $P<.001$], depression [$F(1,163)=4.07$; $P<.05$] and total score scales [$F(1,163)=27.09$; $P<.001$].

Table 4: Sub-group comparison of patients with and without* anxiety disorders diagnoses at PSI, SF-12, IAS and CID controlled for age, gender and active medical diseases

	Anxiety disorder (+) N= 15	Anxiety disorder (-) N= 154	F (1,163)	p
	Estimated marginal means (SE)	Estimated marginal means (SE)		
PSI distress	12.60 ± 4.03	7.31 ± 5.17	11.88	<.001
PSI stress	3.60 ± 2.50	3.19 ± 2.37	0.27	NS
PSI well-being	4.40 ± 1.35	4.84 ± 1.31	0.88	NS
PSI quality of life	2.33 ± 0.61	2.64 ± 0.72	1.97	NS
SF-12 PCS	54.33 ± 3.63	48.89 ± 8.51	6.14	<.05
SF-12 MCS	38.53 ± 10.52	47.82 ± 10.02	9.59	<.01
IAS Worry about illness	5.93 ± 2.54	5.25 ± 2.62	0.36	NS
IAS Concerns about pain	5.47 ± 2.56	4.42 ± 2.28	1.90	NS
IAS Health habits	6.47 ± 3.72	6.91 ± 2.83	0.88	NS
IAS Hypochondriacal beliefs	1.80 ± 2.93	1.03 ± 1.88	2.00	NS
IAS Thanatophobia	5.33 ± 4.03	3.13 ± 3.12	4.46	<.05
IAS Disease phobia	2.53 ± 2.74	1.76 ± 2.05	1.49	NS
IAS Bodily preoccupations	4.27 ± 1.94	3.01 ± 2.26	3.41	NS
IAS Treatment experience	4.00 ± 1.69	4.40 ± 2.38	0.89	NS
IAS Effects of symptoms	2.33 ± 2.25	1.69 ± 2.27	0.87	NS
CID anxiety	9.73 ± 2.71	5.53 ± 1.74	67.70	<.001
CID depression	14.07 ± 2.89	12.36 ± 2.56	4.07	<.05
CID total	59.40 ± 7.10	47.83 ± 7.62	27.09	<.001

*Includes patients with no diagnosis and those with only DCPR diagnoses

- Somatic symptom and related disorders

Table 5 displays the differences of patients with somatic symptoms and related disorders compared to unaffected ones. This latter group excludes patients with other types of DSM-5 diagnoses.

Patients identified in the category of somatic symptoms and related disorders reported significantly higher levels of psychological distress [F(1,169)=32.43; P<.001] and significantly lower scores of well-being [F(1,169)=14.55; P<.001], PSI quality of life [F(1,169)=11.59; P<.01] and SF-12 mental health quality of life [F(1,169)=16.63; P<.001], compared to the control group.

As to the IAS, they reported significantly higher scores at health habits [F(1,169)=18.72; P<.001], concerns about pain [F(1,169)=16.63; P<.001], hypochondriacal beliefs [F(1,169)=30.27; P<.01], bodily preoccupations [F(1,169)=26.50; P<.01], disease phobia [F(1,169)=9.99; P<.001], effects of symptoms[F(1,169)=17.53; P<.001] and treatment experience [F(1,169)=27.26; P<.001].

As to the CID, the somatic symptoms and related disorders group reported significantly higher score at anxiety [F(1,169)=54.44; P<.001], depression [F(1,169)=47.23; P<.001] and total score scales [F(1,169)=78.17; P<.001].

Table 5: Sub-group comparison of patients with and without* somatic symptom and related disorders (SSD) diagnoses at PSI, SF-12, IAS and CID controlled for age, gender and active medical diseases

	SSD (+) N= 20	SSD (-) N= 154	F (1,169)	p
	Estimated marginal means (SE)	Estimated marginal means (SE)		
PSI distress	15.35 ± 8.77	7.31 ± 5.17	32.43	<.001
PSI stress	4.05 ± 3.31	3.19 ± 2.37	1.83	NS
PSI well-being	3.55 ± 1.76	4.84 ± 1.31	14.55	<.001
PSI quality of life	2.00 ± 1.02	2.64 ± 0.72	11.59	<.01
IAS Worry about illness	47.05 ± 10.06	48.89 ± 8.51	0.42	NS
IAS Concerns about pain	37.78 ± 11.85	47.82 ± 10.02	16.63	<.001
IAS Health habits	8.20 ± 3.90	5.25 ± 2.62	18.72	<.001
IAS Hypochondriacal beliefs	7.60 ± 3.15	4.42 ± 2.28	30.27	<.001
IAS Thanatophobia	7.25 ± 3.09	6.91 ± 2.83	0.08	NS
IAS Disease phobia	2.55 ± 2.78	1.03 ± 1.88	9.99	<.001
IAS Bodily preoccupations	7.00 ± 3.69	3.13 ± 3.12	26.50	<.001
IAS Treatment experience	4.75 ± 3.69	1.76 ± 2.05	27.26	<.001
IAS Effects of symptoms	5.50 ± 3.34	3.01 ± 2.26	17.53	<.001
CID anxiety	9.00 ± 2.92	5.53 ± 1.74	54.44	<.001
CID depression	17.80 ± 6.29	12.36 ± 2.56	47.23	<.001
CID total	66.45 ± 14.07	47.83 ± 7.62	78.17	<.001

*Includes patients with no diagnosis and those with only DCPR diagnoses

2. DCPR

- At least one DCPR diagnosis

Table 6 displays the differences in PSI, SF-12, IAS and CID scales' scores of patients with at least 1 DCPR diagnosis compared to those who had none (this group also include patients with only DSM diagnosis).

It can be observed that patients meeting DCPR disorders criteria showed significantly higher scores at PSI distress [F(1,195)=67.91; P<.001] and PSI stress [F(1,195)=34.25; P<.001], and significantly lower scores at PSI well-being [F(1,195)=62.04; P<.001], PSI quality of life [F(1,195)=42.03; P<.001] and SF-12 mental health component of quality of life [F(1,195)=67.40; P<.001], compared to the unaffected group. No differences were observed at the SF-12 measure of the physical component of quality of life.

As to the IAS, patients with at least 1 DCPR diagnosis reported significantly higher scores at worry about illness [F(1,195)=17.46; P<.001], concerns about pain [F(1,195)=17.80; P<.001], hypochondriacal beliefs [F(1,195)=8.91; P<.01], thanathophobia [F(1,195)=28.92; P<.001], disease phobia [F(1,195)=14.72; P<.001], bodily preoccupations [F(1,195)=16.59; P<.001], treatment experience [F(1,195)=7.79; P<.01] and effects of symptoms [F(1,195)=25.90; P<.001] scales. No differences were observed at the health habits scale.

Concerning the CID, the DCPR group reported significantly higher score at anxiety [F(1,195)=85.01; P<.001], depression [F(1,195)=60.78; P<.001] and total score scales [F(1,195)=111.66; P<.001].

Table 6: Sub-group comparison of patients with and without* DCPR diagnoses at PSI, SF-12, IAS and CID controlled for age, gender and active medical diseases

	DCPR (+) N= 88	DCPR (-) N= 112	F (1,195)	p
	Estimated marginal means (SE)	Estimated marginal means (SE)		
PSI distress	12.86 ± 6.58	5.92 ± 4.25	67.91	<.001
PSI stress	4.56 ± 2.67	2.55 ± 1.94	34.25	<.001
PSI well-being	3.75 ± 1.48	5.22 ± 1.05	62.04	<.001
PSI quality of life	2.08 ± 0.82	2.80 ± 0.66	42.03	<.001
SF-12 PCS	48.39 ± 9.59	48.86 ± 8.39	0.002	NS
SF-12 MCS	39.15 ± 10.41	50.72 ± 8.18	67.40	<.001
IAS Worry about illness	6.63 ± 2.99	4.84 ± 2.52	17.46	<.001
IAS Concerns about pain	5.74 ± 2.76	4.41± 2.28	17.80	<.001
IAS Health habits	7.07 ± 3.21	6.87 ± 2.73	0.008	NS
IAS Hypochondriacal beliefs	1.75 ± 2.51	0.88 ± 1.55	8.91	<.01
IAS Thanatophobia	5.18 ± 3.51	2.54 ± 2.90	28.92	<.001
IAS Disease phobia	2.94 ± 2.78	1.53 ± 1.99	14.72	<.001
IAS Bodily preoccupations	4.23 ± 2.79	2.71 ± 1.99	16.59	<.001
IAS Treatment experience	5.32 ± 2.53	4.13 ± 2.28	7.79	<.01
IAS Effects of symptoms	3.34 ± 3.14	1.31 ± 1.91	25.90	<.001
CID anxiety	7.81 ± 2.55	5.02 ± 1.32	85.01	<.001
CID depression	15.90 ± 4.25	11.63 ± 2.66	60.78	<.001
CID total	59.41 ± 10.53	45.34 ± 6.52	111.66	<.001

*Includes patients with no diagnosis and those with only DSM-5 diagnoses

- Allostatic overload

In Table 8 are reported the difference of patients diagnosed with allostatic overload (AO) compared to unaffected ones at PSI, SF-12, IAS and CID. The unaffected group includes subjects with no diagnosis and patients with only DSM-5 disorders, excluding patients with other types of DCPR disorders.

Compared to the unaffected group, patients with AO reported significantly higher scores of distress [$F(1,138)=43.32$; $P<.001$] and stress [$F(1,138)=33.37$; $P<.001$], and significantly lower scores of well-being [$F(1,138)=31.50$; $P<.001$] and quality of life, measured at PSI [$F(1,138)=13.97$; $P<.001$] and SF-12 [$F(1,138)=53.84$; $P<.001$].

As to the IAS, the AO group reported significantly higher scores at thanathophobia [$F(1,138)=4.97$; $P<.05$], disease phobia [$F(1,138)=4.73$; $P<.05$], bodily preoccupations [$F(1,138)=6.59$; $P<.05$] and effects of symptoms [$F(1,138)=7.66$; $P<.01$] scales.

Furthermore, they displayed significantly higher score at anxiety [$F(1,38)=80.19$; $P<.001$], depression [$F(1,138)=51.66$; $P<.001$] and total score scales [$F(1,138)=111.27$; $P<.001$].

Figure 5 and Figure 6 show the comorbidity of AO with DSM or other DCPR diagnoses. Approximately 60% of patients diagnosed with AO did not meet any DSM criteria. Furthermore, the majority of them (68%) had comorbidity with other DCPR syndromes.

Table 8: Sub-group comparison of patients with and without* allostatic load (AO) diagnoses at PSI, SF-12, IAS and CID controlled for age, gender and active medical diseases

	AO (+) N= 31	AO (-) N= 112	F (1,138)	p
	Estimated marginal means (SE)	Estimated marginal means (SE)		
PSI distress	13.03 ± 5.00	5.92 ± 4.25	43.32	<.001
PSI stress	5.00 ± 2.14	2.55 ± 1.94	33.37	<.001
PSI well-being	3.81 ± 1.32	5.22 ± 1.054	31.50	<.001
PSI quality of life	2.26 ± 0.68	2.80 ± 0.66	13.97	<.001
SF-12 PCS	51.66 ± 6.32	48.86 ± 8.39	2.82	NS
SF-12 MCS	37.10 ± 9.04	50.72 ± 8.18	53.84	<.001
IAS Worry about illness	6.00 ± 2.92	4.84 ± 2.52	2.62	NS
IAS Concerns about pain	5.13 ± 2.93	4.417± 2.28	1.92	NS
IAS Health habits	7.06 ± 3.02	6.87 ± 2.73	0.21	NS
IAS Hypochondriacal beliefs	0.84 ± 1.77	0.88 ± 1.55	0.19	NS
IAS Thanatophobia	4.39 ± 3.73	2.54 ± 2.90	4.97	<.05
IAS Disease phobia	2.77 ± 2.78	1.53 ± 1.99	4.73	<.05
IAS Bodily preoccupations	4.10 ± 2.79	2.71 ± 1.99	6.59	<.05
IAS Treatment experience	4.90 ± 2.15	4.13 ± 2.28	0.59	NS
IAS Effects of symptoms	2.71 ± 2.31	1.31 ± 1.91	7.66	<.01
CID anxiety	8.23 ± 2.40	5.02 ± 1.3	80.19	<.001
CID depression	16.03 ± 2.54	11.63 ± 2.66	51.66	<.001
CID total	61.77 ± 8.25	45.34 ± 6.50	111.27	<.001

*Includes patients with no diagnosis and those with only DSM-5 diagnoses

Figure 5. AO comorbidity with DSM diagnoses

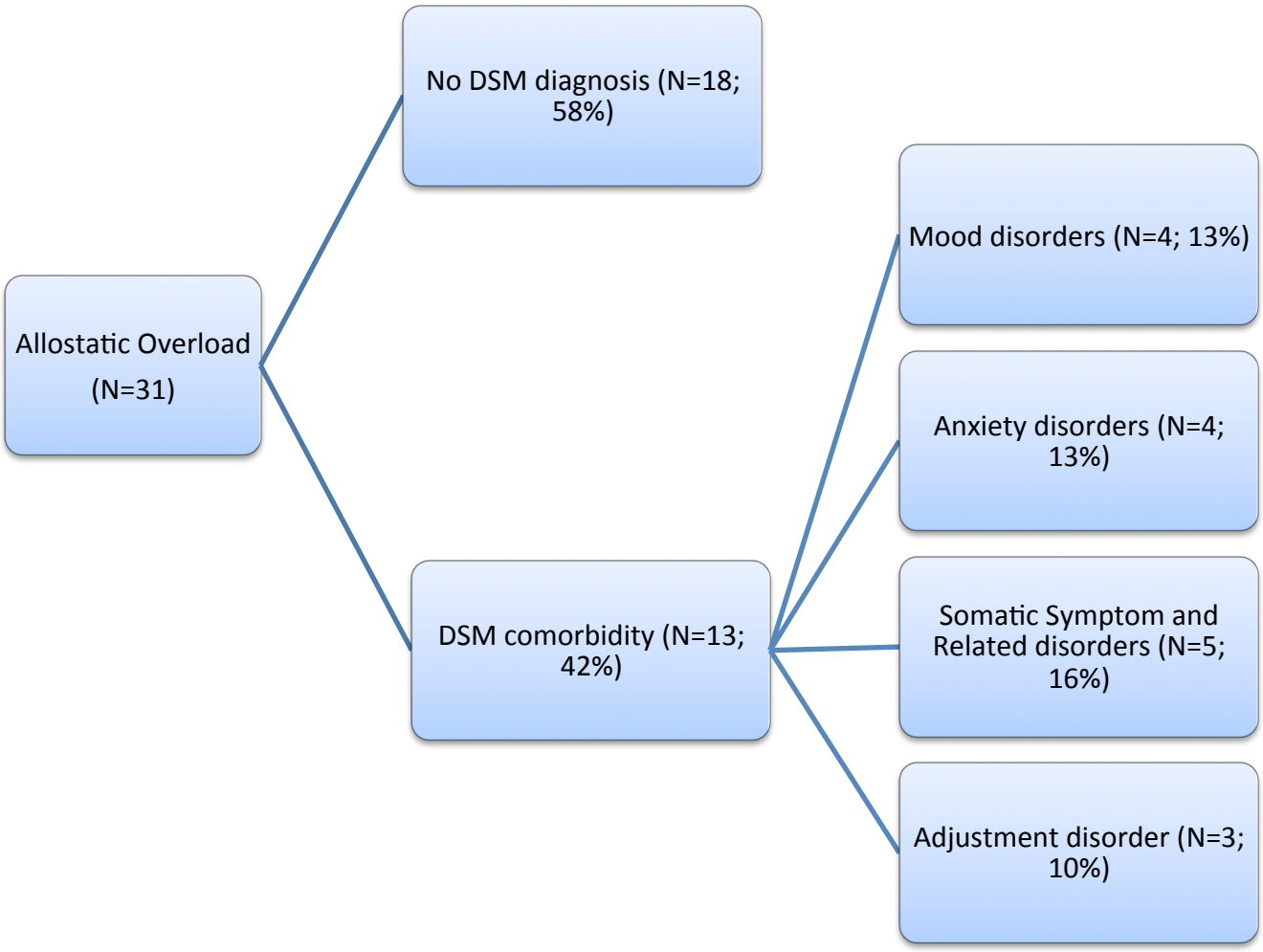
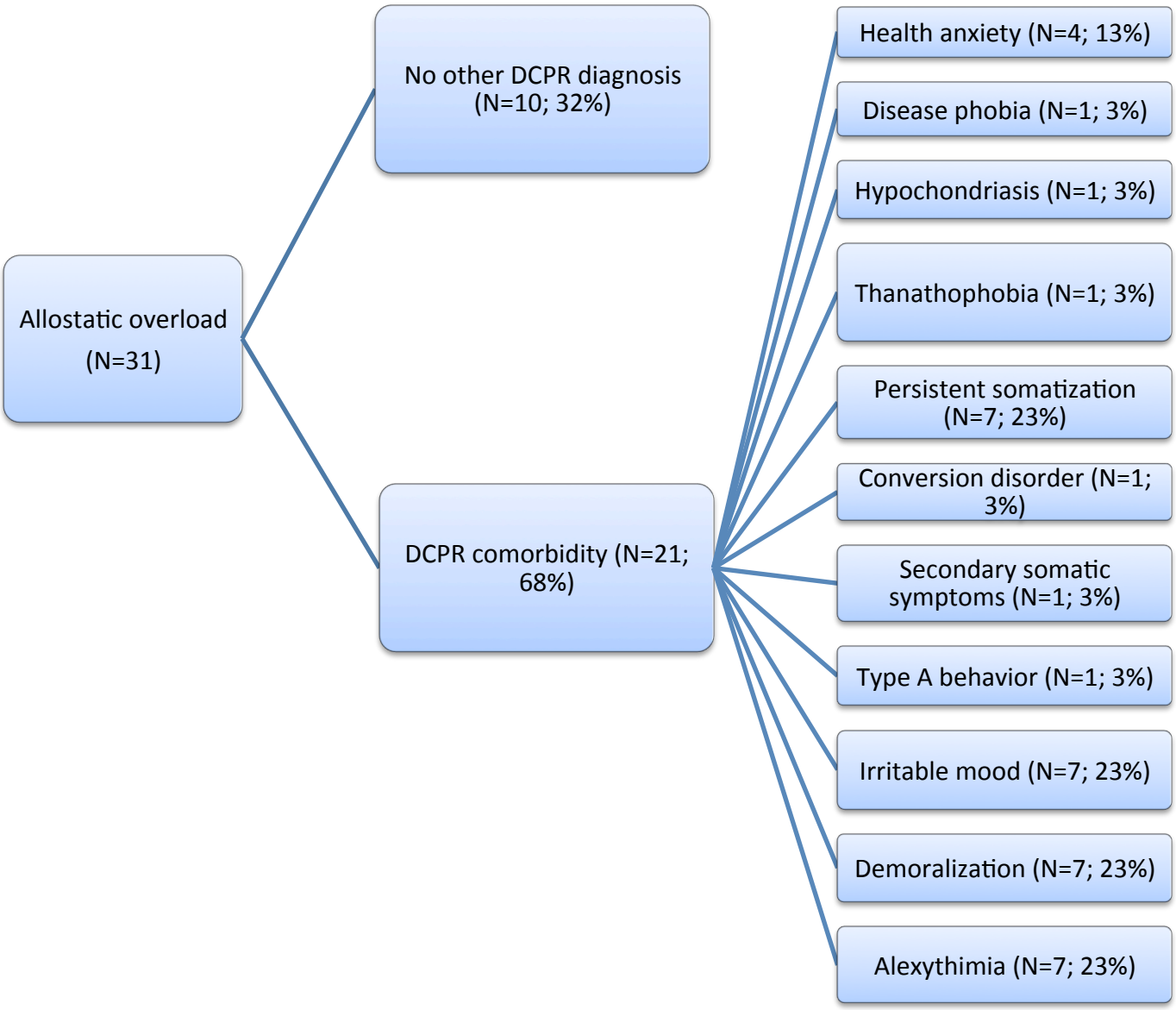


Figure 6. AO comorbidity with other DCPR diagnoses



- Demoralization

Table 7 displays the differences in PSI, SF-12, IAS and CID scales' scores of patients diagnosed with demoralization compared to non-cases. This latter group excludes patients with other types of DCPR disorders.

Patients meeting demoralization criteria reported significantly higher scores of distress [F(1,133)=47.87; P<.001] and stress [F(1,133)=59.28; P<.001], and significantly lower scores of well-being [F(1,133)=51.09; P<.001] and quality of life, measured at PSI [F(1,133)=48.11; P<.001] and SF-12 [F(1,133)=69.19; P<.001], compared to the other group.

Furthermore, they reported significantly higher scores at concerns about pain [F(1,133)=11.21; P<.01], hypochondriacal beliefs [F(1,133)=8.12; P<.01], thanathophobia [F(1,133)=13.50; P<.001], disease phobia [F(1,133)=6.39; P<.01], bodily preoccupations [F(1,133)=9.37; P<.01], treatment experience [F(1,133)=8.50; P<.001] and effects of symptoms [F(1,133)=26.51; P<.001] IAS scales.

Concerning the CID, the demoralization group reported significantly higher score at anxiety [F(1,33)=44.62; P<.001], depression [F(1,133)=103.38; P<.001] and total score scales [F(1,133)=101.41; P<.001].

As shown in Figure 7, half of the patients diagnosed with demoralization were not identified by any DSM criteria. Of those identified, 35% had a diagnosis of mood disorders in comorbidity. The majority of diagnoses of demoralization (73%) had comorbidity with other DCPR diagnoses (Fig. 8), in particular with irritable mood (31%).

Table 7: Sub-group comparison of patients with and without* demoralization diagnoses at PSI, SF-12, IAS and CID controlled for age, gender and active medical diseases

	Demoralization (+) N= 26	Demoralization (-) N= 112	F (1,133)	p
	Estimated marginal means (SE)	Estimated marginal means (SE)		
PSI distress	14.42 ± 8.18	5.92 ± 4.25	47.87	<.001
PSI stress	5.96 ± 2.66	2.55 ± 1.94	59.28	<.001
PSI well-being	3.31 ± 1.56	5.22 ± 1.054	51.09	<.001
PSI quality of life	1.65 ± 1.01	2.80 ± 0.66	48.11	<.001
SF-12 PCS	47.27 ± 10.76	48.86 ± 8.39	0.26	NS
SF-12 MCS	34.80 ± 9.87	50.72 ± 8.18	69.19	<.001
IAS Worry about illness	5.88 ± 3.92	4.84 ± 2.52	2.60	NS
IAS Concerns about pain	5.92 ± 3.05	4.417± 2.28	11.21	<.001
IAS Health habits	5.92 ± 3.64	6.87 ± 2.73	3.79	NS
IAS Hypochondriacal beliefs	2.15 ± 2.89	0.88 ± 1.55	8.12	<.01
IAS Thanatophobia	5.19 ± 4.21	2.54 ± 2.90	13.50	<.001
IAS Disease phobia	2.88 ± 2.71	1.53 ± 1.99	6.39	<.05
IAS Bodily preoccupations	4.31 ± 3.23	2.71 ± 1.99	9.37	<.01
IAS Treatment experience	6.00 ± 2.82	4.13 ± 2.28	8.50	<.01
IAS Effects of symptoms	4.31 ± 3.86	1.31 ± 1.91	26.51	<.001
CID anxiety	7.54 ± 2.43	5.02 ± 1.3	44.62	<.001
CID depression	19.31 ± 5.03	11.63 ± 2.66	103.38	<.001
CID total	64.12 ± 12.40	45.34 ± 6.50	101.41	<.001

*Includes patients with no diagnosis and those with only DSM-5 diagnoses

Figure 7. Demoralization comorbidity with DSM diagnoses

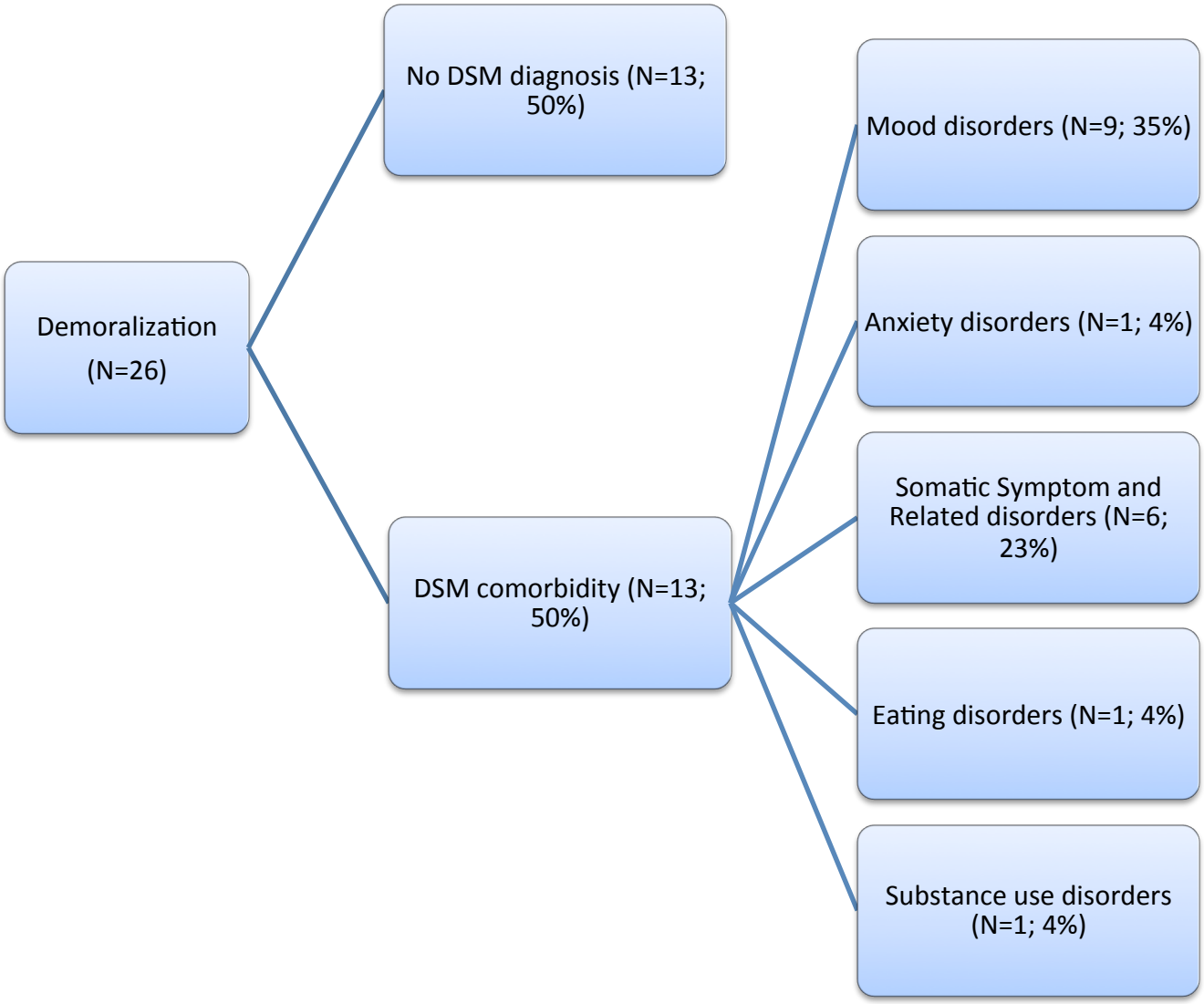
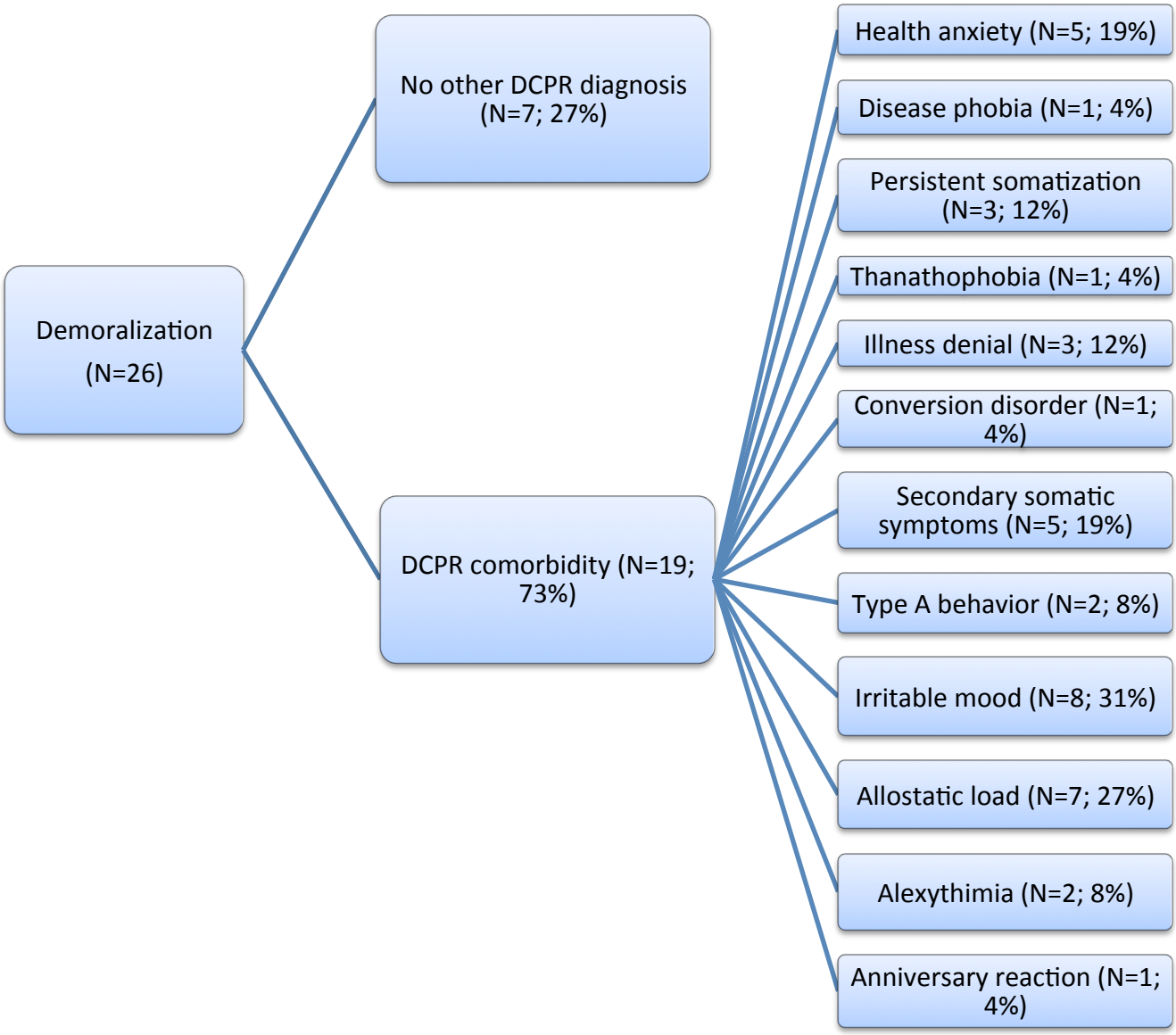


Figure 8. Demoralization comorbidity with other DCPR diagnoses



- Illness behavior

Table 9 displays the differences at PSI, SF-12, IAS and CID of patients with a diagnosis of illness behavior compared to those who had none. This latter group excludes patients with other types of DCPR.

One can observe how patients diagnosed in the DCPR cluster of illness behavior showed significantly higher scores at PSI distress [F(1,147)=57.70; P<.001] and PSI stress [F(1,147)=21.14; P<.001], and significantly lower scores at PSI well-being [F(1,147)=55.14; P<.001], PSI quality of life [F(1,147)=31.10; P<.001] and SF-12 mental health component of quality of life [F(1,147)=42.96; P<.001]. No differences were observed at the SF-12 measure of the physical component of quality of life.

As to the IAS, they reported significantly higher scores at worry about illness [F(1,147)=32.07; P<.001], concerns about pain [F(1,147)=33.65; P<.001], hypochondriacal beliefs [F(1,147)=15.77; P<.001], thanathophobia [F(1,147)=34.31; P<.001], disease phobia [F(1,147)=21.19; P<.001], bodily preoccupations [F(1,147)=23.85; P<.001], treatment experience [F(1,147)=13.93; P<.001] and effects of symptoms [F(1,147)=35.39; P<.001] scales. No differences were observed at the health habits scale.

Concerning the CID, the group of patients with anxiety disorders reported significantly higher score at anxiety [F(1,147)=112.01; P<.001], depression [F(1,147)=49.77; P<.001] and total score scales [F(1,195)=110.06; P<.001], in comparison to the unaffected group.

As shown in Figure 9, more than 60% of patients with a DCPR diagnosis of illness behavior received a DSM diagnosis. The majority of them (43%) had a diagnosis of somatic symptom and related disorders in comorbidity.

Table 9: Sub-group comparison of patients with and without* illness behavior diagnoses at PSI, SF-12, IAS and CID controlled for age, gender and active medical diseases

	Illness behavior (+) N= 40	Illness behavior (-) N= 112	F (1,147)	p
	Estimated marginal means (SE)	Estimated marginal means (SE)		
PSI distress	14.15 ± 7.71	5.92 ± 4.25	57.70	<.001
PSI stress	4.63 ± 2.91	2.55 ± 1.94	21.14	<.001
PSI well-being	3.47 ± 1.51	5.22 ± 1.05	55.14	<.001
PSI quality of life	1.97 ± 0.94	2.80 ± 0.66	31.10	<.001
SF-12 PCS	46.36 ± 10.58	48.86 ± 8.39	1.56	NS
SF-12 MCS	39.11 ± 11.10	50.72 ± 8.18	42.96	<.001
IAS Worry about illness	7.70 ± 3.13	4.84 ± 2.52	32.07	<.001
IAS Concerns about pain	6.70 ± 2.90	4.417± 2.28	33.65	<.001
IAS Health habits	7.27 ± 3.12	6.87 ± 2.73	0.40	NS
IAS Hypochondriacal beliefs	2.28 ± 2.65	0.88 ± 1.55	15.77	<.001
IAS Thanatophobia	6.05 ± 3.42	2.54 ± 2.90	34.31	<.001
IAS Disease phobia	3.75 ± 3.41	1.53 ± 1.99	21.19	<.001
IAS Bodily preoccupations	4.98 ± 3.06	2.71 ± 1.99	23.85	<.010
IAS Treatment experience	6.00 ± 2.50	4.13 ± 2.28	13.93	<.001
IAS Effects of symptoms	4.23 ± 3.43	1.31 ± 1.91	35.39	<.001
CID anxiety	8.48 ± 2.46	5.02 ± 1.32	112.01	<.001
CID depression	16.55 ± 4.8	11.63 ± 2.66	49.77	<.001
CID total	62.52 ± 11.8	45.34 ± 6.50	110.06	<.001

*Includes patients with no diagnoses and those with only DSM-5 diagnoses

Figure 9. Illness behavior comorbidity with DSM diagnoses

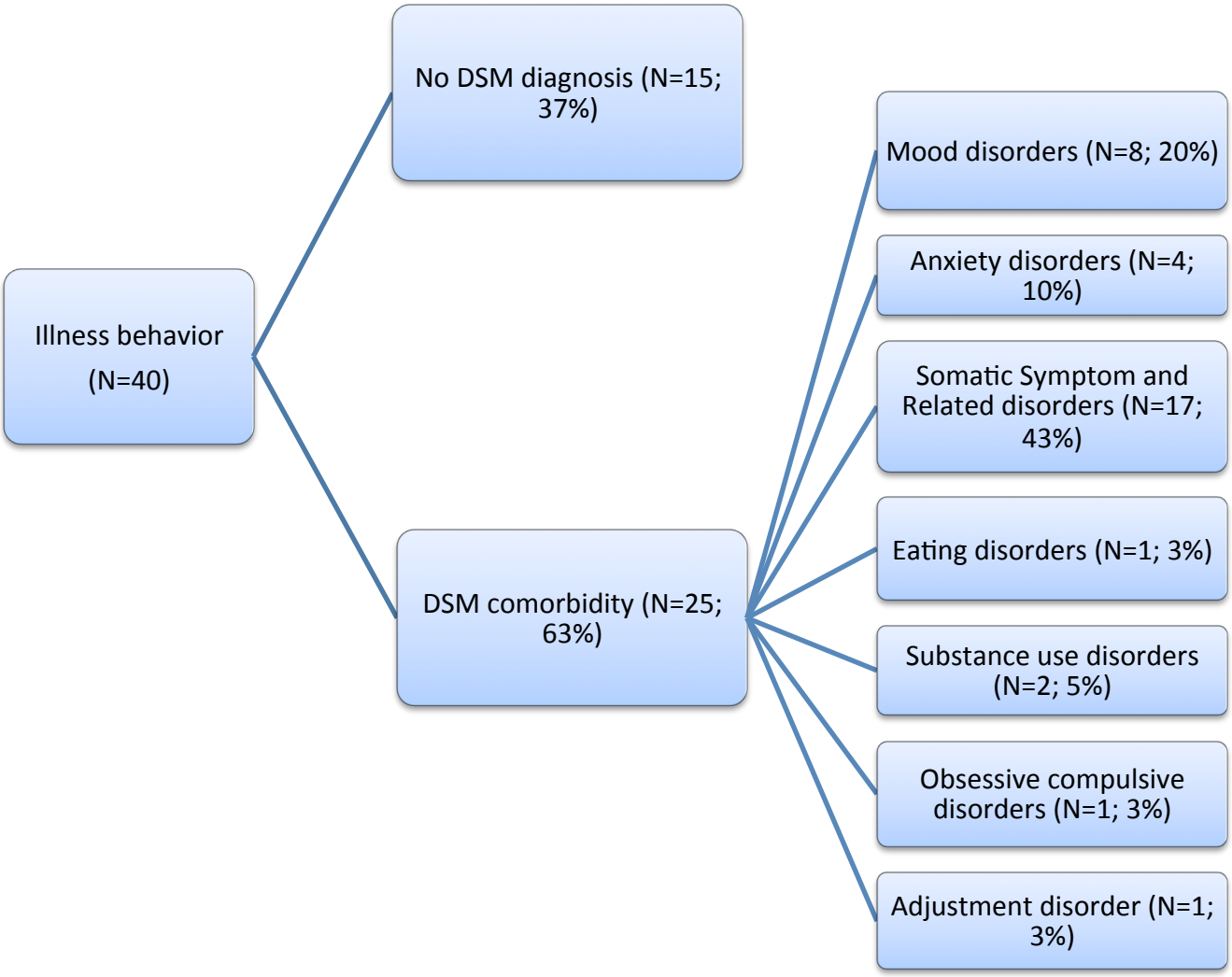
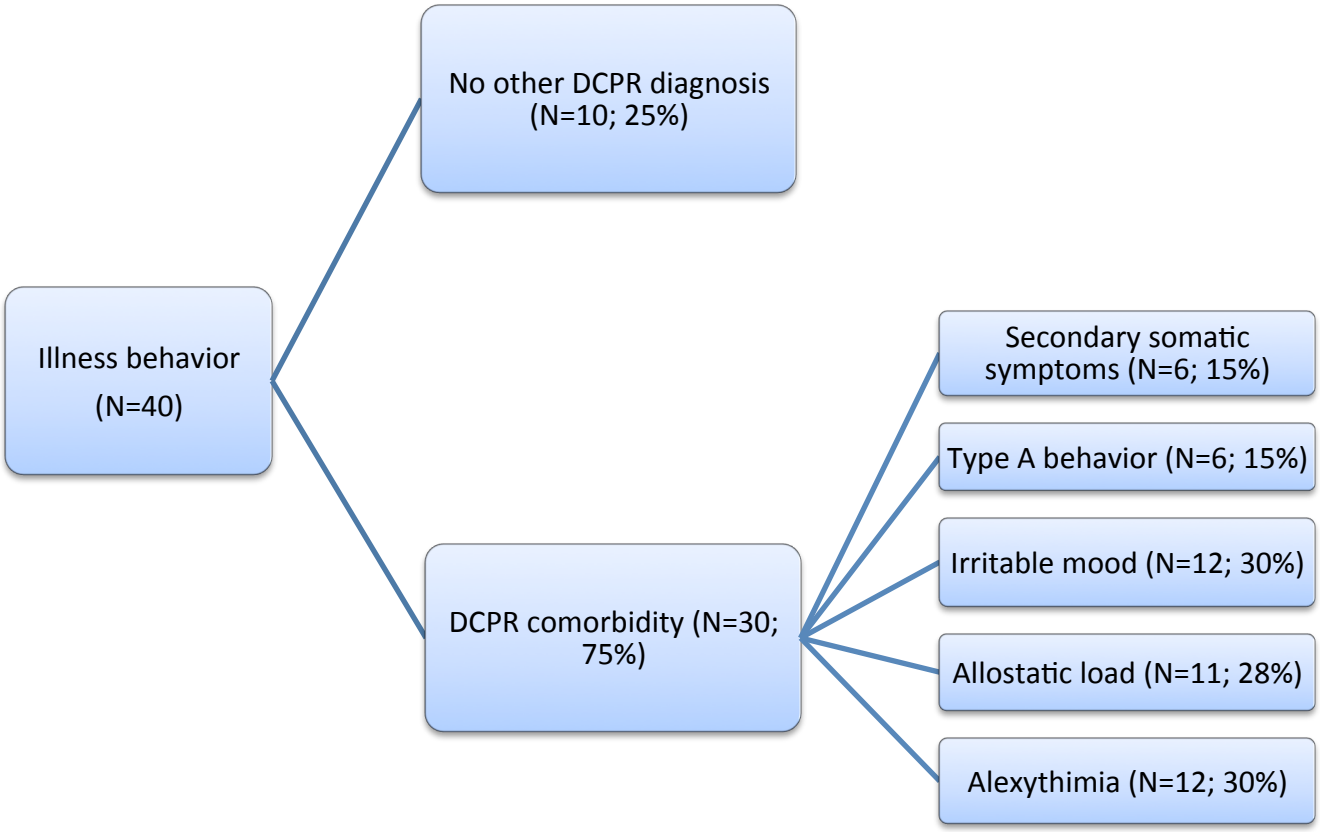


Figure 10. Illness behavior comorbidity with other DCPR diagnoses



- Alexithymia

Table 10 displays the differences in PSI, SF-12, IAS and CID scales' scores of patients with alexithymia compared to those who had none. This latter group includes patients with no diagnosis and patients with DSM-5 disorders.

Patients with alexithymia scored significantly higher at PSI distress [F(1,134)=39.78; P<.001] and PSI stress [F(1,134)=10.94; P<.01], and significantly lower at PSI well-being [F(1,134)=27.49; P<.001], PSI quality of life [F(1,134)=24.57; P<.001] and SF-12 mental health component of quality of life [F(1,134)=29.40; P<.001], compared to the non-cases group. No differences were observed at the SF-12 measure of the physical component of quality of life.

Furthermore, these patients reported significantly higher scores at IAS worry about illness [F(1,134)=16.71; P<.001], concerns about pain [F(1,134)=11.86; P<.01], hypochondriacal beliefs [F(1,134)=9.91; P<.01], thanathophobia [F(1,134)=16.16; P<.001], disease phobia [F(1,134)=14.22; P<.001], bodily preoccupations [F(1,134)=8.93; P<.01] and effects of symptoms [F(1,134)=13.89; P<.001] scales. No differences were observed at the health habits and treatment experience scales.

As to the CID, the alexythimia group reported significantly higher score in the anxiety [F(1,134)=83.20; P<.001], depression [F(1,134)=23.85; P<.001] and total score scales [F(1,134)=63.74; P<.001].

Figure 11 and Figure 12 show the comorbidity of alexythimia with DSM or other DCPR diagnoses. More than half of the patients diagnosed with alexythimia (56%) met criteria for a DSM diagnosis. The majority of them (30%) had a diagnosis of somatic symptoms and related disorders in comorbidity. As to the comorbidity with DCPR, the vast majority of patients with alexythimia (89%) met the criteria for other DCPR syndromes.

Table 10: Sub-group comparison of patients with and without* alexithymia diagnoses at PSI, SF-12, IAS and CID controlled for age, gender and active medical diseases

	Alexithymia (+) N= 27	Alexithymia (-) N= 112	F (1,134)	p
	Estimated marginal means (SE)	Estimated marginal means (SE)		
PSI distress	12.74 ± 6.49	5.92 ± 4.25	39.78	<.001
PSI stress	4.11 ± 2.96	2.55 ± 1.94	10.94	<.01
PSI well-being	3.85 ± 1.58	5.22 ± 1.05	27.49	<.001
PSI quality of life	2.04 ± 0.75	2.80 ± 0.66	24.57	<.001
SF-12 PCS	48.53 ± 8.99	48.86 ± 8.39	0.001	NS
SF-12 MCS	40.10 ± 11.60	50.72 ± 8.18	29.40	<.001
IAS Worry about illness	7.11 ± 2.40	4.84 ± 2.52	16.71	<.001
IAS Concerns about pain	5.85 ± 2.39	4.417± 2.28	11.86	<.01
IAS Health habits	7.19 ± 3.30	6.87 ± 2.73	0.19	NS
IAS Hypochondriacal beliefs	2.11 ± 2.53	0.88 ± 1.55	9.91	<.01
IAS Thanatophobia	5.22 ± 3.16	2.54 ± 2.90	16.16	<.001
IAS Disease phobia	3.41 ± 2.85	1.53 ± 1.99	14.22	<.001
IAS Bodily preoccupations	4.22 ± 2.97	2.71 ± 1.99	8.93	<.01
IAS Treatment experience	5.22 ± 2.88	4.13 ± 2.80	3.01	NS
IAS Effects of symptoms	3.19 ± 3.05	1.31 ± 1.91	13.89	<.001
CID anxiety	8.41 ± 2.70	5.02 ± 1.32	83.20	<.001
CID depression	15.00 ± 4.01	11.63 ± 2.66	23.85	<.001
CID total	58.85 ± 10.85	45.34 ± 6.50	63.74	<.001

*Includes patients with no diagnoses and those with only DSM-5 diagnoses

Figure 11. Alexythimia comorbidity with DSM diagnoses

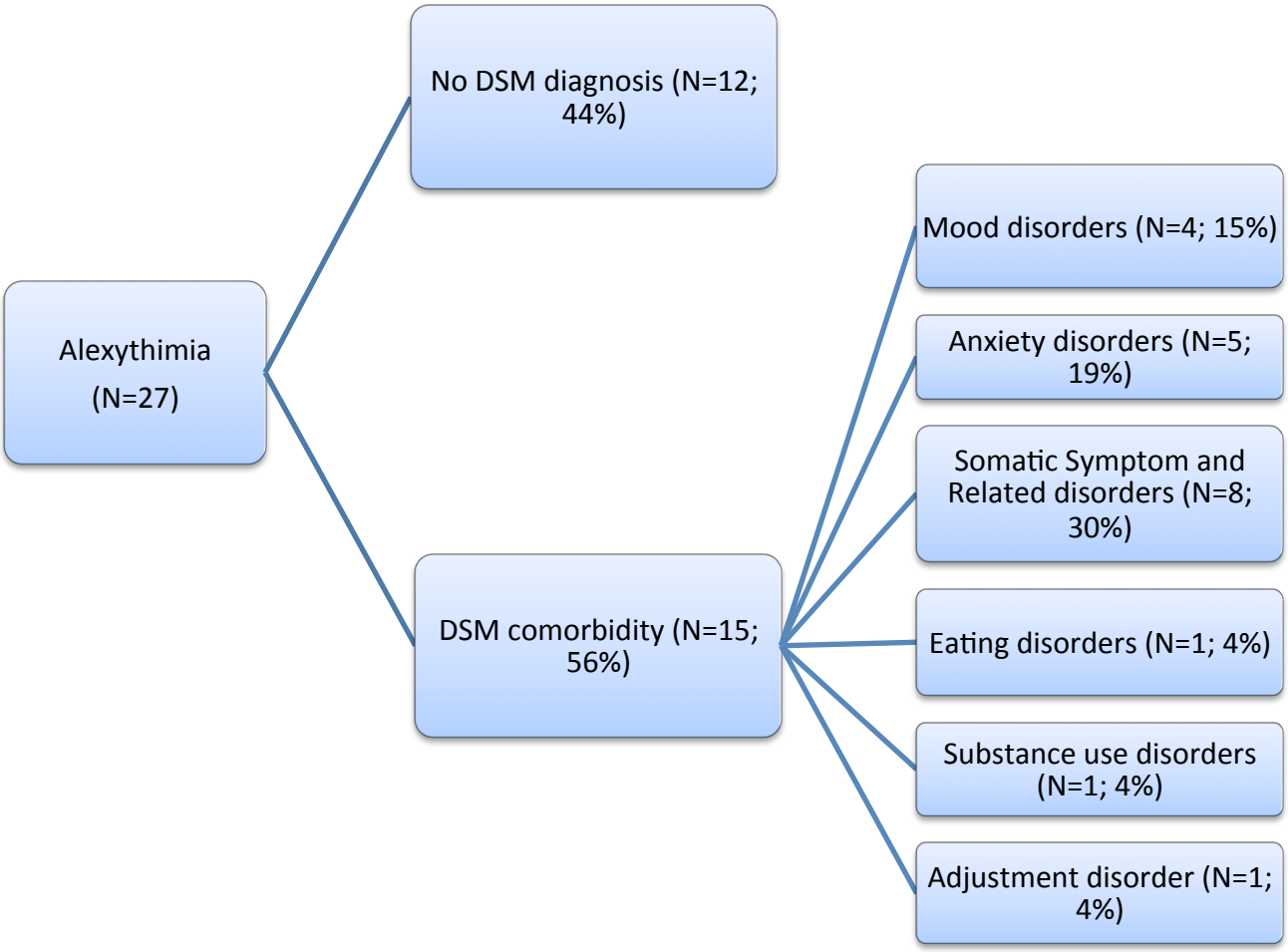
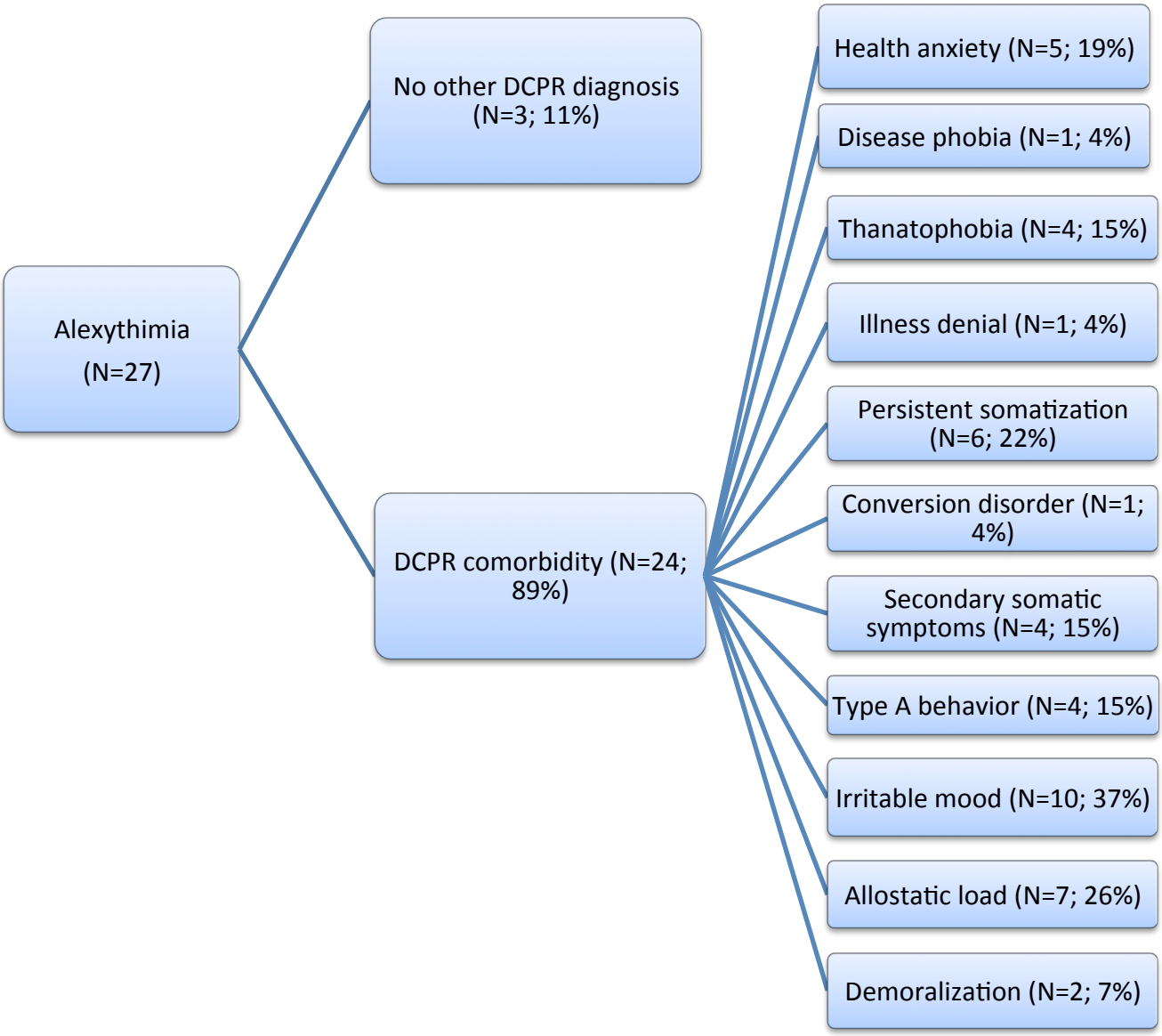


Figure 12. Alexythimia comorbidity with other DCPR diagnoses



3.5.3 Predicting psychosocial variables from DCPR and SSD in adjunction of DSM-5 diagnoses (not including SSD)

In order to evaluate and compare the predictive contribution of DCPR and SSD in addition to DSM-5 diagnoses, a series of hierarchical regression models were used with PSI, SF-12 and IAS scales as dependent variables. For all models, forced-entry variables in the first block were age, gender, presence of a medical disease and presence of any DSM-5 diagnoses (not including SSD). The second block was constituted by the presence of DCPR and presence of SSD diagnoses.

Test for Multi-collinearity

The analysis revealed that a very low level of multi-collinearity was present. VIF scores were 1.211 for DSM-5, 1.323 for DCPR and 1.147 for SSD.

- **Psychosocial Index (PSI)**

Variables included in the first block explained a significant portion of the variance of the distress, stress, well-being and quality of life scales. Presence of any DSM-5 (not including SSD) in the first model was a significant predictor for all PSI measures expect of stress. Addition of DCPR and SSD variables in the second block significantly improved prediction of psychological distress [R2 change=0.17; F(2,193)=18.62; P <.001], stress [R2 change=0.13; F(2,193)=7.69; P<.001], well-being [R2 change=0.19; F(2,193)=11.59, P<.001] and quality of

life [R2 change=0.11; F(2,193)=13.98; P<.001]. DSM-5, DCPR and SSD were all significant factors in the prediction of psychological distress. Effect size was large for DCPR (β=0.38; P<.001; ηp=0.15), medium for DSM-5 and (β=0.20; P<.001; ηp=0.05) small for SSD (β=0.14; P<.05; ηp=0.03). With regards to quality of life, only DSM-5 (β=0.19; P<.01; ηp=0.03) and DCPR (β=0.35; P<.001; ηp=0.11) were significant predictors. Furthermore, only DCPR showed a significant effect in the prediction of the well-being (β=0.45; P<.001) and stress scales (β=0.41; P<.001), with a large effect size.

Table 11: Hierarchical regression analyses predicting PSI measures of psychological distress, stress, well-being and quality of life from psychosomatic syndromes (DCPR) and Somatic Symptoms and Related Disorders (SSD) in adjunction to psychiatric diagnoses (DSM-5 not including SSD), controlled for age, gender and active medical diseases

PSI		β	p	ηp	R^2	R^2 change	d.f	F	F change	p
Psychological distress	Model 1				0.19		(4,195)	11.45		<.001
	Any DSM*	0.36	<.001	0.13						
	Model 2				0.36	0.17	(2,193)	18.62	26.89	<.001
	Any DSM*	0.20	<.001	0.05						
	Any DCPR	0.38	<.001	0.15						
	Any SSD	0.14	<.05	0.03						
Stress	Model 1				0.06		(4,195)	3.26		<.05
	Any DSM*	0.12	NS							
	Model 2				0.19	0.13	(2,193)	7.69	15.58	<.001
	Any DSM*	0.00	NS							
	Any DCPR	0.41	<.001	0.13						
	Any SSD	0.06	NS							
Well-being	Model 1				0.07		(4,195)	3.75		<.01
	Any DSM*	0.23	<.01	0.05						
	Model 2				0.26	0.19	(2,193)	11.59	25.38	<.001
	Any DSM*	0.07	NS							
	Any DCPR	0.45	<.001	0.17						
	Any SSD	0.06	NS							
Quality of life	Model 1				0.11		(4,195)	6.61		<.001
	Any DSM*	0.31	<.001	0.09						
	Model 2				0.20	0.11	(2,193)	13.98	9.64	<.001
	Any DSM*	0.19	<.01	0.03						
	Any DCPR	0.35	<.001	0.11						
	Any SSD	0.03	NS							

*DSM-5 diagnoses not including SSD

- **Short-Form health survey (SF-12)**

The Mental Component of quality of life (MCS) was significantly predicted by the variables included in the first block [R2=0.17; F(4,195)=10.047; P<.001]. In this model, the presence of any DSM-5 was a significant predictor (β=0.32; P<.001) with a large effect size (ηp=0.10). Addition of DCPR and SSD variables significantly improved prediction [R2 change=0.16; F(2,193)=16.57, P<.001]. However only DCPR, not SSD, was found to significantly predict MCS (β=0.43; P<.001) showing a large effect size (ηp=0.17). In this model, DSM-5 remained significant (β=0.16; P<.01)], with a medium effect size (ηp=0.03).

The Physical Component of quality of life (PCS) was not significantly predicted by any models. Neither DSM-5, DCPR nor SSD were significantly related to PCS.

Table 12: Hierarchical regression analyses predicting Sf-12 Mental (MCS) and Physical Component (PCS) of quality of life from psychosomatic syndromes (DCPR) and Somatic Symptoms and Related Disorders (SSD) in adjunction to psychiatric diagnoses (DSM-5 not including SSD), controlled for age, gender and active medical diseases

SF-12		β	p	ηp	R^2	R^2 change	d.f	F	F change	p
MCS	Model 1				0.17		(4,195)	10.04		<.001
	Any DSM*	0.32	<.001	0.10						
	Model 2				0.34	0.16	(2,193)	16.57	24.73	<.001
	Any DSM*	0.16	<.01	0.03						
	Any DCPR	0.43	<.001	0.17						
	Any SSD	0.05	NS							
PCS	Model 1				0.03		(4,195)	1.95		NS
	Any DSM*	0.00	NS							
	Model 2				0.04	0.00	(2,193)	1.37	0.23	NS
	Any DSM*	0.00	NS							
	Any DCPR	0.02	NS							
	Any SSD	0.05	NS							

*DSM-5 diagnoses not including SSD

- **Illness Attitude Scale (IAS)**

Variables included in the first model significantly predicted the IAS measures of worry about illness, thanathophobia, bodily preoccupations, treatment experience and effect of symptoms. In this model, presence of any DSM-5 (excluding SSD) showed a significant effect only in the hypochondriacal beliefs and effect of symptoms scales. Addition of DCPR and SSD factors yielded a significant increase in the prediction of all scales except of health habits.

Both DCPR and SSD were significant factors in the prediction of worry about illness [(β=0.23; P<.01; ηp=0.5) and (β=0.23; P<.01; ηp=0.05)], concerns about pain [(β=0.19; P<.05; ηp=0.03) and (β=0.28; P<.001; ηp=0.08)], thanathophobia [(β=0.28; P<.001; ηp=0.07) and (β=0.22; P<.01; ηp=0.05)], disease phobia [(β=0.17; P<.05; ηp=0.02) and (β=0.28; P<.001; ηp=0.07)] and bodily preoccupations [(β=0.21; P<.01; ηp=0.04) and (β=0.20; P<.01; ηp=0.04)]. However only DCPR was found to significantly predict the treatment experience (β=0.16; P<.05) and effect of symptoms scales (β=0.27; P<.001), with a small (ηp=0.02) and medium (ηp=0.06) effect size, respectively.

Table 13: Hierarchical regression analyses predicting Illness behaviors (IAS) from psychosomatic syndromes (DCPR) and Somatic Symptoms and Related Disorders (SSD) in adjunction to psychiatric diagnoses (DSM-5 not including SSD), controlled for age, gender and active medical diseases

IAS		β	p	ηp	R^2	R^2 change	d.f	F	F change	p
Worry about illness	Model 1				0.06		(4,195)	3.11		<.05
	Any DSM*	0.03	NS							
	Model 2				0.18	0.12	(2,193)	7.39	15.05	<.001
	Any DSM*	0.09	NS							
	Any DCPR	0.23	<0.1	0.50						
	Any SSD	0.23	<0.1	0.05						
Concerns about pain	Model 1				0.04		(4,195)	2.26		NS
	Any DSM*	0.13	NS							
	Model 2				0.18	0.13	(2,193)	7.19	16.36	<.001
	Any DSM*	0.01	NS							
	Any DCPR	0.19	<.05	0.03						
	Any SSD	0.28	<.001	0.08						
Health habits	Model 1				0.03		(4,195)	1.60		NS
	Any DSM*	0.09	NS							
	Model 2				0.03	0.00	(2,193)	1.11	0.18	NS
	Any DSM*	0.10	NS							
	Any DCPR	0.01	NS							
	Any SSD	0.03	NS							
Hypochondriacal beliefs	Model 1				0.03		(4,195)	1.76		NS
	Any DSM*	0.17	<.05	0.03						
	Model 2				0.07	0.04	(2,193)	2.73	4.55	<.05
	Any DSM*	0.10	NS							
	Any DCPR	0.13	NS							
	Any SSD	0.14	NS							
Thanathophobia	Model 1				0.08		(4,195)	4.34		<.01
	Any DSM*	0.13	NS							
	Model 2				0.22	0.14	(2,193)	9.52	18.35	<.001
	Any DSM*	0.00	NS							
	Any DCPR	0.28	<.001	0.07						
	Any SSD	0.22	<.01	0.05						
Disease phobia	Model 1				0.04		(4,195)	2.14		NS
	Any DSM*	0.12	NS							
	Model 2				0.16	0.12	(2,193)	6.43	14.41	<.001
	Any DSM*	0.01	NS							
	Any DCPR	0.17	<.05	0.02						
	Any SSD	0.28	<.001	0.07						

IAS		β	p	ηp	R^2	R^2 change	d.f	F	F change	p
Bodily preoccupations	Model 1				0.03		(4,195)	1.81		NS
	Any DSM*	0.10	NS							
	Model 2				0.13	0.10	(2,193)	5.20	11.58	<.001
	Any DSM*	0.00	NS							
	Any DCPR	0.21	<.01	0.04						
	Any SSD	0.20	<.01	0.04						
Treatment experience	Model 1				0.05		(4,195)	3.06		<.05
	Any DSM*	0.09	NS							
	Model 2				0.09	0.03	(2,193)	3.22	3.39	<.05
	Any DSM*	0.03	NS							
	Any DCPR	0.16	<.05	0.02						
	Any SSD	0.06	NS							
Effects of symptoms	Model 1				0.11		(4,195)	6.36		<.001
	Any DSM*	0.24	<.01	0.06						
	Model 2				0.19	0.07	(2,193)	7.70	9.28	<.001
	Any DSM*	0.13	NS							
	Any DCPR	0.27	<.001	0.06						
	Any SSD	0.07	NS							

*DSM-5 diagnoses not including SSD

3.6 Discussion

This study evaluated the incremental information provided by specific psychological criteria (Diagnostic Criteria for Psychosomatic Research) in addition to standard psychiatric assessments (DSM-5) and compared to the category of somatic symptoms and related disorders, in a sample of 200 primary care patients.

The results from this investigation showed that the prevalence of primary care patients with at least one psychiatric disorder as assessed by the DSM-5 was of 23%. This finding is in line with the results found in a large cross-cultural study conducted in 14 countries (Üstün & Sartorius, 1995) but higher than the prevalence found in previous studies in Italian primary care settings (Menchetti et al., 2007), which reported a prevalence of around 12%. The most frequent diagnostic clusters were somatic symptom and related disorders (10%), mood disorders (8%) and anxiety disorders (7.5%), consistent with previous epidemiological studies carried out in this setting (Üstün & Sartorius, 1995; Toft et al., 2005; Menchetti et al., 2007). As to psychosomatic disorders, the prevalence of patients with at least one DCPR diagnosis was of 44%. This is the first data concerning the occurrence of DCPR in the general population of primary care patients, showing a high prevalence of these sub-threshold conditions.

Our findings showed that the DCPR allows the identification of psychopathology in the proportion of 4:1, as compared to the SSD category, when applied to patients in primary care. All cases identified through the SSD were detected also by the DCPR, whereas 34% of patients (N=68) could not be identified as presenting psychological distress without the use of the DCPR system. Similarly, the percentage of patients with at least 1 diagnosis rose from 23%, when using solely the DSM-5 (including in this case the SSD), to 46% when integrating the DCPR. The majority of these patients were diagnosed as presenting only DCPR (23.5%) or both DCPR and DSM (20%), whereas just the 2.5% was diagnosed as presenting with only

DSM-5. These findings lend support to the hypothesis that the DCPR are more suitable for classifying psychological distress in medical settings than the criteria for somatic symptom and related disorders, as it has been previously shown in a study conducted on patients with congestive heart failure (Guidi et al., 2013). Indeed Guidi and colleagues (2013) found that the DCPR identified psychological factors meaningful for the illness course in the proportion of 3:1, as compared to the SSD in medical patients. These results confirm that the use of the DSM-5 in primary care benefits from the integration of DCPR with regards to the sensitivity in identifying sub-threshold distress (Fava et al., 2007; Fava, Tomba & Sonino, 2012).

As to DCPR, the most frequent psychosomatic syndromes were allostatic load, demoralization and alexythimia.

Allostatic overload reflects the cumulative effects of stressful experiences in daily life, which is judged as exceeding the individual's coping skills and might be associated to psychological symptoms. McEwen (2007) proposed a formulation of the relationship between stress and the processes leading to disease based on the concept of allostasis, the ability of the organism to achieve stability through change. It is a common clinical observation that stressful life events may be followed by health problems. Recently, the introduction of structured methods of data collection has allowed identification of the link between life events in the year preceding the onset of symptoms and a number of medical disorders (Fava, Cosci & Sonino, 2017). Similarly, long-standing life situations and daily life stresses may be experienced by the individual as exceeding his/her coping capacities. Integrating an evaluation of allostatic load in the psychological assessment is important because the joint presence of allostatic load and a psychiatric disorder calls for a closer monitoring of the clinical situation for the risks factors associated to this condition. Regardless of the presence of psychiatric, it has been shown that abnormalities in the biological markers associated with allostatic load increase health risk (Gruenewald et al., 2006; Ryff et al., 2006).

Demoralization results from the awareness of being unable to cope with a pressing problem and may have two different ways of expression: helplessness (the individual maintains the capacity to react but lacks adequate support) and hopelessness (when the individual feels he/she alone is responsible for the situation and there is nothing he/she or anyone else can do to overcome the problem) (Sweeney et al., 1970; Fava et al., 2017). In our sample, one patient with demoralization out of three presented with hopelessness. Hopelessness/giving up is likely to be linked to depressive illness and may provide a severity connotation to the diagnosis of major depressive disorder. The 35% of patients diagnosed with demoralization in this study had a comorbidity with mood disorders. However, demoralization and major depression may occur also independently, as major depression does not necessarily involve demoralization (Tecuta et al., 2015). According to a recent review (Porcelli and Guidi, 2015) demoralization have been found to be frequent the medically ill.

Alexithymia characterizes patients who have difficulties in describing feelings and differentiating them from bodily sensations, a poor fantasy life, and an "operative" way of thinking (Sifneos, 1973). In medical patients, the DCPR category of alexithymia was found in about one third of the cases associated with a comorbid DSM-IV mood or anxiety disorder, in another third with various forms of somatization, and in the remaining sample with no psychiatric morbidity (Porcelli et al., 2013). Alexithymia seems linked to an increased risk and a worsened outcome of several medical conditions (Porcelli et al., 2003; Lumley et al., 2007; de Vries et al., 2012).

Associations of DSM-5 and DCPR diagnoses (including allostatic load, demoralization, illness behavior and alexythimia sub-groups) with dimensional measures of psychological factors provided evidence that both classifications were able to identify cases with significantly higher levels of psychological distress, stress and maladaptive illness behaviors, as well as significantly impaired well-being and quality of life, compared to non-cases. As to

psychological symptoms of distress, significant associations were reported both at self-rated (PSI) and observer-rated (CID) scales, highlighting a convergence of the data obtained through different methodologies of assessment. Observer-rated methods make full use of the clinical experience and comparison potential of the interviewer, whereas self-rating methods allow a more direct assessment of the patient subjective perceptions (Fava, Tomba & Sonino, 2012).

With regards to the specific diagnostic clusters, we found that mood and anxiety disorders were poorly related to measures of illness behaviors (IAS). A previous study found the IAS to correlate with measure of depression and anxiety in non-hypochondriacal populations (Sirri et al., 2008) but, in case of patients with hypochondriasis or functional somatic disorders, these associations were not reported (Kellner et al., 1988). It has been thus hypnotized that abnormal illness attitudes might be particularly influenced by the absence of clear explanations and effective treatments for impairing functional symptoms, rather than a consequence of concomitant emotional disturbances (Sirri et al., 2008).

As to patients diagnosed with somatic symptoms and related disorders, they were found to display significantly higher levels of psychological distress and maladaptive illness behaviors, as well as significantly impaired well-being and mental quality of life, compared to non-cases. However, compared to the DCPR-based classification, the SSD was not significantly related to the PSI measure of stress (life events and daily hassles), suggesting the higher sensitivity of DCPR to detect exposure to environmental challenges exceeding subjects' resilience resources (Fava et al., 2010; Guidi et al., 2013).

In order to further investigate the different contribution of SSD and DCPR criteria, in addition to DSM-5, for the assessment of primary care patients, we performed a series of hierarchical regressions, controlled for the effects of socio-demographic and medical variables. The main finding was that psychosomatic syndromes as assessed by the DCPR yielded more significant associations with psychosocial factors and a higher effect size, than the SSD.

Addition of the model including SSD and DCPR to DSM-5 significantly increased prediction of all PSI scales, SF-12 Mental Component of quality life (not significant for the Physical Component) and IAS (except for hypochondriacal beliefs and health habits). However, the predictive contribution of the SSD criteria was significant only for the PSI psychological distress scales and specific measures of illness behaviors (IAS). On the contrary, the DCPR significantly and transversely contributed to the prediction of almost all the variables included in the psychological assessment. Presence of any DCPR together with any DSM-5 was the best model of fit for the prediction of psychological distress and quality of life, as assessed by the PSI and SF-12. Furthermore, the DCPR had a large effect size over and above the DSM-5. These findings are consistent with those observed by Porcelli and colleagues (2009), showing that DCPR syndromes were independent predictors of quality of life, after controlling for DSM-IV psychopathology, in consultation-liason psychiatry. The ability of DCPR syndromes to predicting psychosocial problems among medical patients is also consistent with previous studies showing a close association between DCPR and psychosocial functioning measured with a variety of instruments in endocrinology (Sonino et al., 2004), dermatology (Picardi et al., 2005) and the general population (Mangelli et al., 2006).

As to stress and well-being, DCPR was the only factor that yielded a significant contribution to the prediction model. The capacity of DCPR criteria to sensitively capture differences in measures of stress and well-being has been highlighted in diverse medical settings such as heart transplantations, cardiology and gastro-intestinal disorders (Rafanelli et al., 2003; Grandi et al., 2011; Rafanelli et al., 2012; Guidi et al., 2013). This is particularly important for the emerging area of intervention that is concerned with strategies increasing psychological well-being in all phases of medical illness, from prevention (decreased well-being has been associated with unhealthy behaviors) to rehabilitation (the process of rehabilitation requires the promotion of well-being and changes in lifestyle) (Fava, Cosci &

Sonino, 2017). Increasing well-being by Well-Being Therapy may contribute to improving health attitudes and behavior, either in combination with other therapeutic strategies or as a first-line approach (Fava, 2016).

With regards to the assessment of maladaptive illness behaviors, DCPR and SSD, not DSM-5, showed the best model of fit for the IAS. However, compared to the SSD, only the DCPR significantly predicted higher levels of physical impairment (effect of symptoms) and a higher frequency of medical treatments, examinations and visits to the doctor (treatment experience). This results underlines how the DSM-5 seems to neglect important information concerning the psychological factors affecting medical conditions and abnormal illness behaviors, such as patterns of psychosocial factors, coping strategies, burden of illness, effects of comorbid conditions, responses to previous treatments, and other clinical distinctions which are likely to influence the course, therapeutic response and outcome of a given illness (Porcelli & Guidi, 2015). On the other hand, the DCPR syndromes may broaden the clinician's perspective on patient problems by providing clinical information that does not find any space in the traditional psychiatric classification and therefore may be suggested as operative tools in psychosomatic-based outpatient services and clinics. Indeed, a previous study (Ferrari et al., 2008) showed that DCPR criteria were associated to sub-threshold psychiatric comorbidity predicting a pattern of frequent attendance in primary care. This evidence further provides ground to the hypothesis that DCPR may have a role in mediating seek of medical care (Fava et al., 2017).

Limitations

The present study has some limitations that should caution against generalizing the results. First, we found a high rate of refusal to undergo psychological assessment and the sample composition might reflect specific characteristics of patients willing to participate in the study.

Second, data might have been influenced by situational variables and the temporal stability of the associations could not be ascertained due to the cross-sectional design of this study.

3.7 Conclusions

In conclusion, this study has the merit to compare the category of somatic symptom and related disorders with an alternative classification (DCPR), with regard to prevalence rates and by examining their distinct contribution to the prediction of psychosocial measures collected by means of both interviewer-based and self-rating instruments, in addition to the DSM-5 in primary care.

Results from this investigation indicate that, in the setting of primary care, the DCPR classification is superior to the SSD category in evaluating psychosocial factors in presenting patients. A psychological assessment that includes DCPR is feasible and could expand our understanding of patients' mental health status. Our findings support the need of broadening the assessment based on psychiatric taxonomy in primary care by integrating these specific psychological criteria. Furthermore, the results corroborate the clinical utility of the DCPR classification to provide useful information regarding the evaluation of psychosocial factors in

the psychological assessment of primary care patients.

3.8 Clinical implications

The results from this investigation might have important implication for the emergent role of Psychologists in integrated primary care services. The DCPR can provide Primary Care Psychologists with a sensitive tool for a comprehensive clinical assessment that can be integrated in the customary psychiatric assessment, enhancing the clinical utility of the DSM-5. The provision of an appropriate classification for primary care settings has the potential to form the basis for appropriate referral and timely treatment of psychosocial distress in primary care, thus guiding the process of clinical reasoning and medical decisions.

3.9 Implications for future research

Current findings support the need to investigate further the role that DCPR may play in primary care patients, such as the longitudinal stability of the diagnoses over time and their associations to psychosocial variables. Moreover, an important direction of future studies should include targeting DCPR syndromes through psychological therapy, with the aim of improving the quality of life and global state of patients, while reducing the costs associated to health care utilization.

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