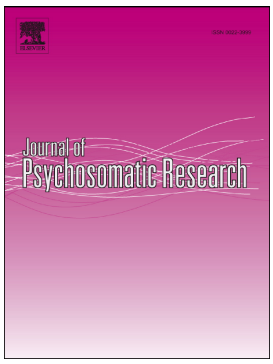

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Assessing demoralization in medically ill patients: factor structure of the Italian version of the Demoralization Scale and development of short versions with the Item Response Theory framework

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Abstract

Objective. Demoralization has been mostly investigated in oncology but is also relevant in patients with other physical illnesses. Our aims were to investigate the psychometric properties of the 24-item Italian version of the Demoralization Scale (DS-24) among medically ill inpatients and to develop shorter versions for screening.

Methods: Four-hundred and seventy-three participants were recruited from medical wards of the University Hospital of Ferrara. Patients were assessed using the Diagnostic Criteria for Psychosomatic Research-Demoralization module (DCPR/D), Demoralization Scale (DS-24), Patient Health Questionnaire-9 (PHQ-9), Brief-Symptom Inventory-18, Anxiety subscale (BSI-Anx) and EuroQol Group (EQ-5D). Confirmatory factor analyses of previous structures and exploratory factor analyses were conducted using an Item Response Theory approach, including a bifactor model.

Results: According to DCPR/D criteria, the prevalence of demoralization was 40%**.** Confirmatory analyses revealed that none out of seven factor structures from oncology studies adequately fitted data from hospital inpatients. Exploratory Item Factor Analysis uncovered a four-factor model comprising Disheartenment, Dysphoria, Sense of Failure, Loss of Meaning and Purpose, or a bifactor model, comprising similar factors with the addition of a general factor accounting for 45% of the variance. Moreover, we developed 13 and 6-item versions of the DS, both retaining high correlation with DS-24 scores (r=0.98 and r=0.95, respectively) and concordance with DCPR/D criteria (AUC-ROC 0.82 and 0.81).

Conclusion. The DS factor structure differs between general hospital and cancer patients. Differences may depend on intrinsic disease features and cultural-geographic factors. The short versions of the DS-24 may aid clinicians in identifying demoralized patients in hospital settings.

Keywords: demoralization, general hospital, distress, chronic diseases, screening, depression

Word count: 4524

1. Introduction

Demoralization has been thoroughly studied in the context of cancer and palliative care as a subjective state of existential distress affecting about 30-40% of the patients and characterized by low morale, loss of meaning and purpose in life, feelings of hopelessness and helplessness, and sense of being trapped (Clarke and Kissane, 2002; Grassi and Nanni, 2016; Nanni et al., 2018a; Robinson et al., 2015; Tecuta et al., 2015). In this population, demoralization is associated with suicidal ideation (Fang et al., 2014; Vehling et al., 2017), poorer quality of life (Grassi et al., 2004) and requests to hasten death (Robinson et al., 2017). Similar results, in terms of prevalence but not studied in terms of consequences, have been reported in few studies of patients with medical conditions that are not imminently life-threatening, such as cardiovascular, neurologic and other chronic diseases (Clarke et al., 2003; Koo et al., 2018; Offidani et al., 2018; Rafanelli et al., 2005; Tecuta et al., 2015).

Demoralization in medically ill patients may be particularly relevant as it may bring about dysfunctional illness behaviors (e.g. somatization, frequent attender behavior, illness denial), psychological suffering and lower quality of life (Grassi et al., 2017c; Tecuta et al., 2015). Of note, demoralization may not simply reflect the severity of the disease, but may also depend on illness-related disability and other contextual factors (Marchesi and Maggini, 2007). Not surprisingly, the construct of demoralization partly overlaps with that of depression, as both conditions create sadness, loss of some pleasure and other features (de Figueiredo, 1993). However, these conditions display clinical features (Bobevski et al., 2018; Mangelli et al., 2005) and correlates (Fang et al., 2014) that could justify their distinction, particularly in the choice of clinical management (Griffith and Gaby, 2005). Interestingly, in medical populations, demoralization may predict psychosocial impairment more accurately than anxiety or depressive disorders defined by DSM criteria (Porcelli et al., 2009).

Currently, few tools to identify and assess demoralization exist. Among them, the DS-24 has been widely endorsed across clinical settings, either in its original (Kissane et al., 2004) or shortened version (Robinson et al., 2016a), although it has been validated exclusively in oncology and palliative care in several languages (Grassi et al., 2017a; Hadnagy et al., 2012; Hung et al., 2010; Mehnert et al., 2011; Rudilla et al., 2016).

Therefore, since the DS-24 has not been tested among patients with physical illnesses other than cancer, despite its potential utility, and considering the need to extend our

knowledge of the clinical features of demoralization, the aims of the present study were: (i) to examine the psychometric properties of DS-24 in the general hospital setting, in comparison with an interview-based tool for demoralization; (ii) to develop shorter versions of the DS-24 that may have utility for clinical screening and research purposes; (iii) to examine the relationship of the DS-24 and its shorter versions with psychological and quality of life variables in the medically ill.

2. Methods

2.1 Participants

A convenience sample of medically ill patients was recruited from the Sant'Anna University Hospital in Ferrara, Italy. Participation was offered to individuals hospitalized in different medical wards of the hospital including internal medicine, cardiology, endocrinology, nephrology, gastroenterology, pneumology, rheumatology and oncology. Patients were eligible according to the following criteria: (1) aged 18 or older; (2) able to participate in the clinical interview; (3) absence of delirium and/or cognitive impairments; (4) fluent in the Italian language. Each patient was informed about the aim of the study, gave his/her written consent to participate, and was individually met by a research assistant who administered a semi-structured interview and a psychometric battery during a single session. The whole assessment took about one hour. The study was approved by the Ethical Committee of the Emilia-Romagna Region, "Central Emilia" area (CE-AVEC).

2.2 Measures

2.2.1 Demoralization

Demoralization was assessed using the DS-24 and the structured Interview for the Diagnostic Criteria for Psychosomatic Research (DPCR/D) (Mangelli et al., 2007).

The DS-24 (Grassi et al., 2017a) is a 24-item instrument rating on a 5 point Likert Scale (0 = never; 4 = all the time) the symptoms of demoralization during the past two weeks, The original version validated in palliative care comprises five factors, namely Loss of Meaning and Purpose, Dysphoria, Disheartenment, Sense of Failure, and Helplessness and Hopelessness (Kissane et al., 2004), whereas the Italian version validated in cancer settings consisted of four factors: Loss of Meaning and Purpose, Dysphoria,

Disheartenment and Sense of Failure (Grassi et al., 2017a) and showed good internal consistency and reliability (Nanni et al., 2018b).

The DCPR/D, is part of a larger semi-structured clinical interview (Fava et al., 1995; Mangelli et al., 2007; Porcelli and Guidi, 2015) ; According to the DCPR the presence of demoralization is defined if the following criteria are met: A) failure to meet one's own or significant others' expectations; B) inability to cope with pressing problems; C) hopelessness, helplessness or giving up; D) symptoms lasting ≥1 month (Porcelli and Rafanelli, 2010). This instrument was extensively used in the medical setting (Mangelli et al., 2005; Porcelli and Guidi, 2015) and chosen as the gold standard comparator for the DS-24, as previously done (Nanni et al. 2018).

2.2.2 Other assessment instruments

The Patient Health Questionnaire-9 (PHQ-9), (Spitzer et al., 1999) in its Italian version (Rizzo et al., 2000) was used to establish the presence of major depression according to DSM–IV criteria over the past two weeks. The instrument has good psychometric properties using a cutoff score ≥10 (Kroenke et al., 2001; Spitzer et al., 1999; Thombs et al., 2014), with responses on a 4-point Likert scale. In our sample the PHQ-9 had a Cronbach α of 0.83.

The Brief Symptom Inventory-18 (BSI-18) is an 18-item questionnaire to assess symptoms of psychological distress during the past seven days. Each item is scored on a 0 to 4 Likert scale. The scale has three factors, namely somatization, depression and anxiety (Derogatis, 1983) and showed acceptable psychometric properties in Italian validation studies (Grassi et al., 2018, 2013). For the purpose of this study, only the BSI-18 anxiety subscale (BSI-Anx) was used (Cronbach α=0.85).

The EuroQol-5D, three level version (EQ-5D-3L) was used (Brooks, 1996; Euroqol Group, 1990) to assess quality of life. This scale measures general health impairment (i.e. mobility, self-care, usual activities, pain/discomfort and anxiety/depression) on three response levels. Responses to these questions were both used as raw scores and, as recommended, converted through a standardized scoring system, to a single Health State Index (HSI) (range score 0-1, higher score corresponding to better QoL). The scale showed good psychometric properties (Nanni et al., 2018a; Reed et al., 2009).

Patient's sociodemographic (age, marital status, living situation, occupation) and medical data (diagnosis) were collected from the patient's clinical charts.

2.3 Statistical analysis

To investigate the DS-24 structure, we used several methods, in particular including analyses developed under the Item Response Theory. This approach is considered more accurate than "traditional" (linear) factor analyses recovering the structure of ordinal data, since, unlike ordinary factor analyses, it models non-linear relations between item responses and latent variables (Chalmers, 2012; Kappenburg-ten Holt, 2014).

First, we estimated the fitness of available factor structures by retrieving relevant studies from the literature and conducting Confirmatory Item Factor Analyses (CIFAs). To identify available factor structures, we conducted a Pubmed search with the following terms: [demoraliz* AND scale AND "factor structure" OR factor analysis"].

Second, we sought to evaluate the factor structure of the DS-24 in our medical inpatient sample using a series of Exploratory Item Factor Analyses (EIFAs). Analyses were based on a Maximum Likelihood estimation method and Promax rotation, since we expected significant correlations between factor scores (Osborne and Costello, 2005). The optimal number of factors was established using a parallel analysis with 1000 resampling iterations, as implemented in the *fa.parallel* function of the *psych* R package. In addition, we report the features of models based on one to six factors. Both CIFAs and EIFAs were conducted with the *mirt* R package, using maximum likelihood estimation (Chalmers, 2012), the Metropolis-Hastings Robbins-Monro (MHRM) algorithm and quasi-Monte Carlo integration grids. For each model, we report Akaike's Information Criterion (AIC) and Bayesian Information Criterion (BIC) values as model selection criteria, Root Mean Square Error of Approximation (RMSEA < 0.08 is a good fit), Tucker Lewis Index (TLI ≥ 0.95 is a good fit), Comparative Fit Index (CFI ≥ 0.95 is a good fit). For each item in the models, we report factor communality estimates (h2) and the Q1 variant of the chi-squared statistic as indices of item fit (Yen, 1981).

Third, we sought to explore whether data could be also represented with a bifactor model. In bifactor models all of the scale items are loaded on a *general* factor; in addition, specific subsets of items are loaded on one or more *specific* (or group) factors, that are uncorrelated with the general factor. To estimate the structure of the bifactor model, we conducted a Pure Exploratory Bifactor Analysis (PEBI) with Robust Diagonally Weighted Least Squares (RDWLS) estimation and Robust Promin rotation, using the Factor software, 10.9 release (Ferrando and Lorenzo-Seva, 2017). Unlike other bifactor models,

the PEBI allows specific factors to be intercorrelated (Lorenzo-Seva and Ferrando, 2019). To allow comparability with other models, the fitness of the bifactor model was evaluated using a confirmatory ordinal analysis based on the *bfactor* function of the *mirt* package (Chalmers, 2012).

Fourth, we sought to construct two shorter versions of the scale performing two item selection procedures, starting from the unidimensional IRT model of the 24-item version. In each procedure, after visual inspection of item information and trace plots, we discarded items with inadequate fitness, i.e. those yielding significant χ^2 statistic, adopting a conservative threshold ($p<0.10$). Item information and trace plots of the 24-item version were obtained using the *mirt* R package (Chalmers, 2012) and are reported in the Supplement. The UniCo (Unidimensional Congruence) parameter was obtained from the Factor software (Ferrando and Lorenzo-Seva, 2017) and used to establish whether to pursue multidimensional structures in the shorter scales: values larger than 0.95 suggest an unidimensional structure (Ferrando and Lorenzo-Seva, 2018).

Fifth, we assessed the psychometric properties of the three versions of the DS-24 by calculating internal consistency (Cronbach's α with Bootstrap 95%CI based on 1000 samples), convergent validity with demoralization defined by the DCPR subscale (ROC curve analysis) and divergent validity with depression, anxiety and quality of life examining the correlations with PHQ-9, BSI-Anx and Euro-QOL scores, respectively. The overlap between demoralization and depression was estimated by analyzing the relative prevalence of demoralization and depression based on PHQ-9 definition and DS-24 cutoffs. Also χ^2 test, Student's t test, and analysis of variance were used to determine the differences in demoralization scores between groups. Pearson r correlation test was used to analyze association between variables.

3. Results

3.1 Sample characteristics

A total of 554 patients meeting the inclusion criteria were approached over the study period. Of these, 71 declined participation for several reasons (31 no interest; 22 fatigue or not in good health conditions or disease-related problems, 18 other reasons) and 10 (1.8%) had missing measures not allowing evaluation. The final sample consisted of 473 subjects with a mean age of 62.9 (±17.7) years, 54.3% were aged 65 or older; most were

females (55.1%). Most of the subjects had middle-school education level (63%), were married (56.0%) or widowed (26.0%). The majority had retired from work (59.5%), while fewer were still employed (18.9%). There were several medical diagnoses represented (cardiovascular disorders, n=83; gastroenterological diseases, n=80; infectious disease, n=57; neurological disorders, n=50; respiratory diseases, n=48; onco-hematology disorders, n=42). There were also 110 patients admitted to internal medicine units with other disorders, including non-specific symptoms (e.g. pain, general malaise, symptoms, signs, and findings not elsewhere classified), or other conditions (e.g. genitourinary conditions, endocrine and metabolic diseases, injury, medical conditions secondary to alcohol or drug use).

3.2 Prevalence of demoralization

One-hundred and eighty-nine patients (40%) (CI 95%, 35%-44%) met the DCPR/D criteria for demoralization (cases). The mean DS-24 total was 31.57 (±19.37), with higher scores among DCPR/D cases vs non-cases (44.3±17.9 vs 22.9±15.0, t= -13.52, df=470 p=0.001). Analysis of demoralization according to the medical disorders indicated no significant difference in demoralization between the groups, with the exception of patients with other disorders who showed higher scores in comparison with patients with gastroenterological or infectious disease (Table S1). The DS-24 total was significantly associated with PHQ-9 (r=0.79, df=445, p<0.001), BSI-Anx (r=0.62, df=467, p<0.001), and EQ-5D (r=-0.42, df=469, p=0.001) scores.

3.3 Confirmatory and Exploratory Item Factor Analyses

We found six studies reporting a factor structure of the DS-24, five on the 24-item and one on the 16-item versions. Studies were conducted in a palliative care and psycho-oncology setting in Australia (n=100) (Kissane et al., 2004), an advanced palliative cancer care unit (n=100) in Ireland (Mullane et al., 2009), a cancer center (n=516) in Germany (Mehnert et al., 2011), a palliative care unit (n=226) in Spain (Rudilla et al., 2016) and a cancer outpatient service (n=194) in Italy (Grassi et al., 2017a). The study reporting the structure of the 16-item versions was conducted on a palliative care sample (n=211) in Australia (Robinson et al., 2016a).

Analysis of the Mardia's multivariate asymmetry skewness and kurtosis indicated that data of the DS-24 from our sample had non-significant skewness (χ^2=6182, df=2600, p>.99) but significant kurtosis (χ^2=755, df=40, p<0.001, see Table S2). The Kaiser-Meyer-Olkin test indicated adequacy of the correlation matrix (0.94; bootstrap 95%CI 0.943 – 0.949). The UniCo value (0.776; bootstrap 95%CI: 0.736 - 0.818) was indicative of a multidimensional structure. In the CIFAs, none of the factor structures from the cancer setting demonstrated adequate fit using data from general hospital patients (all χ^2 >1000, all p <0.001, Table 1). We then conducted EIFAs on our sample. By using a IRT approach, we obtained one to six factor solutions, that explained 47.2 to 60.7% of the overall variance. Results from the parallel analysis suggested that the extraction of four factors would be optimal. This solution accounted for 56% of the overall variance and displayed adequate fitness to data. Loadings for this model are reported in Table 2, while the variance-covariance and residuals matrices are reported in the supplement (Tables S3 and S4). Items 5, 8, 9, 17 displayed significant cross-loadings (Table 2) and local dependency was found between item 2 and 3, and between item 12 and 14 (Table S4). However, removing these items in two analyses did not substantially modify the fitness indices (see Table S7).

3.4 Alternative model: bifactor structure

Data of the DS-24 was modeled with the PEBI, with one general factor and four specific factors (Table 3, diagram in Figure S2). For most items the highest loadings were observed onto the *general* factor, with the exception of items 1, 3, 11, 14, 16, 18, 19. Overall, the composition of the specific factors was similar to the model obtained with the EIFA procedure and comprised the factors *disheartenment*, *sense of failure*, *loss of meaning and purpose* and *dysphoria*. The model explained 72% of the total variance and yielded good fit indices (CFI: 0.998; RMSEA: 0.030, 95%CI: 0.011 – 0.034; BIC:1122). The inter-correlations between the specific factors were lower than in the four-factor model, but statistically significant. The model fitness was also evaluated for comparability using the IRT approach (structure reported in Table S5; residuals in Table S6) and yielded slightly better indices than the four-factor model (see Table S7 for model comparison). Overall, the CIFA explained 61.8% of the total variance. Local dependency was again observed between items 2 and 3.

3.5 Item Response Theory analyses: development of short versions

To examine the possible development of short versions of the DS-24, we selected items based on their fitness under the IRT paradigm. Information and trace line plots are reported in the supplement (Figure S1). The following items had a chi-square p value of 0.10 or less and were thus eliminated: 2, 6, 8, 10, 11, 13, 14, 15, 18, 19, and 20. Thus, the first short version comprised 13 items (DS-13; items 1, 3, 4, 5, 7, 9, 12R, 16, 17R, 21, 22, 23, 24; see Table S8). The UniCo value was indicative of a unidimensional structure (0.961; bootstrap 95%CI: 0.935 - 0.985).

At the second item selection, the following items were eliminated using the same criteria: 1, 7, 12, 17, 21, 22, 23. Although item 17 had a p value slightly above the established threshold (χ^2=31.6, df=23, p=0.11) it was eliminated in order to increase homogeneity of the scale and to ease scoring. The ultra-short version had 6 items (DS-6; items: 3, 4, 5, 9, 16, 24, Table S9). Again, the UniCo value was indicative of a unidimensional structure (0.986; bootstrap 95%CI: 0.980 - 0.994).

3.6 Psychometric properties

The three versions of the Demoralization Scale had excellent reliability (DS-24 Cronbach α: 0.938; 95%CI: 0.930-0.945; DS-13 α: 0.910; 95%CI: 0.895-0.920; DS-6 α: 0.843; 95%CI: 0.816-0.864). Table 4 reports data relative to the reliability with the DCPR/D, stable across the different scales. Also the correlations of the DS-13 and DS-6 with the DS-24 (DS-13: r=0.98, df=471, p<0.001; DS-6: r=0.95, df=471, p<0.001), PHQ9 (DS-13: r=0.77, df=445, p<0.001; DS-6: r=0.75, df=445,p<0.001), BSI-Anxiety (DS-13: r=0.58, df=467, p<0.001, DS-6: r=0.56, df=467, p<0.001), and EQ-5D (DS-13 r=-0.42, df=469, p<0.001; DS-6 r=-0.44, df=469, p<0.001) were maintained. High correlations were also found between DS-13 and DS-6 (r=0.95, df=471, p<0.001).

We examined the overlap of subjects fulfilling the PHQ-9 criteria for depression and demoralization, defined with a cutoff of 30 at the DS-24. Among 182 patients who were PHQ-9 cases of depression, 27 (14.8%) were not demoralized, whereas of those PHQ-9 non-depressed (n=265) 53 (20.0%) were demoralized, with an overlap between depression and demoralization of 34.7% (n=155). The figures were very similar using the short versions of the Demoralization Scale, as well as the DCPR/D (Table S8). In comparison with DCPR/D non-cases, DCPR/D demoralized patients reported higher

scores on both the DS-13 (25.1 ± 10.8 vs 12.4 ± 9, df=470, t=13.2, p=0.001) and the DS-6 (11.9 ± 5.7 vs 5.4 ± 4.6, df=470, t=13.5, p=0.001).

4. Discussion

This study examined the factor structure and psychometric properties of the DS-24 among medically ill patients admitted to the general hospital.

A first general result of the study was that 39.9% were found to meet the criteria for demoralization according to DCPR/D criteria. A DS-24 cut-off score of ≥30 optimized sensitivity and specificity for demoralization caseness. This finding confirms the high prevalence of demoralization in the general hospital, similar to cancer and palliative care settings (Clarke and Kissane, 2002; Grassi and Nanni, 2016). Also, in agreement with other studies carried out in oncology, demoralization was associated not only with depression and anxiety, but with lower levels of quality of life (Grassi et al., 2004).

As a more specific result, the DS-24 displayed good psychometric properties in this population, despite minor differences in its factor structure compared with those derived from cancer studies. Data obtained from exploratory analyses of the demoralization scale, developed under the IRT, yielded a four-factor structure or, alternatively, a bifactor structure (one general factor plus four specific factors), both explaining a large quota of the variance. Although we did not report results based on linear models, the IRT approach outperformed the results obtained with such approach, both in terms of explained variance and overall fitness (Kapteyn-ten Holt, 2014). However, both the four-factor and the bifactor model in our sample of general hospital patients were still largely similar to that obtained with a factor analysis of data from Italian cancer outpatients (Grassi et al., 2017a). Similarities of our results with those from the Italian cancer sample (Grassi et al., 2017a) may derive from recruitment of patients in the same catchment area, which imply a very similar cultural and social background. Moreover, our sample was largely composed of elderly participants (over half of them were 65 or older), which may have further increased similarities with the sample of the study from the cancer setting (Grassi et al., 2017a). In fact, elderly, medically ill patients may be particularly exposed to existential distress regarding the end of life, loss of social roles, frailty, dependence on caregivers, that are also common themes related to demoralization among oncological patients (Grassi and Nanni, 2016; Tecuta et al., 2015). Consistently, a positive association between

demoralization and age has been previously detected (Vehling et al., 2012), as well as a strikingly high prevalence of demoralization in elderly cancer patients (Ko et al., 2018).

Our four-factor model differed from those obtained in studies from other geographic regions: in particular “Disheartenment” was the main facets of demoralization in our models, while “Loss of meaning and purpose” were more relevant in the majority of other studies (Kissane et al., 2004; Mullane et al., 2009; Rudilla et al., 2016), even when the same number of factors was detected (Mehnert et al., 2011). Existential issues are a typical hallmark of distress in cancer patients (Kissane et al., 2019) but may have a different characterization among patients affected by medical disorders. Consistently, among medically ill patients, disability, rather than severity of the illness, was associated with demoralization (Marchesi and Maggini, 2007). Moreover, geographic variability may have played a role: individual illness behavior, explanatory models of the illness, attachment features or coping strategies may display cross-cultural variability (Grassi et al., 2017b; Hinton and Kirmayer, 2017; Kirmayer and Sartorius, 2007; Vehling et al., 2019). Lastly, differences in healthcare or welfare policies could also shape health outcomes and ultimately, demoralization (Graves, 2008; Keyhani et al., 2012; Nicholson et al., 2012).

A further significant result was that we were able to develop two shortened, but equally valid, versions of the scale. Similar to the 24-item version, both shortened versions maintained similar psychometric properties in terms of reliability with the DCPR criteria as well as correlations with depression (PHQ-9), anxiety (BSI-Anxiety), and quality of life (EQ-5D) ratings. Shorter scales seem to offer advantages in terms of acceptability and screening utility (Rolstad et al., 2011). A similar analysis was conducted by Robinson and colleagues who developed the DS-II in 211 Australian palliative care patients (Robinson et al., 2016b, 2016a), further validated in another oncology sample (Belar et al., 2019). Another short version was developed to reflect the five dimensions of demoralization from the original factor structure (Kissane et al., 2004). Despite using a different methodology, the scale nonetheless displayed adequate psychometric properties (Galiana et al., 2017). Similar to other shortened versions, discarding some reversed items may positively affect the scale quality and validity (Dalal and Carter, 2015; Galiana et al., 2017; Robinson et al., 2016a); however future studies are needed to evaluate the DS-13 and the DS-6 as screening tools in medically ill patients.

Finally, the DS-24 was also modeled as a bifactor structure, a “hybrid” between a unidimensional and a multidimensional structure (Lorenzo-Seva and Ferrando, 2019).

Thus, demoralization in hospital inpatients may largely reflect a unidimensional construct, complemented by the assessment of specific facets such as those that were identified. Secondary factors were not evident in the shorter scales, suggesting that a general demoralization factor is sufficient to maintain reliability with the DCPR construct and validity for screening purposes. Future studies may evaluate whether adopting a bifactor model of demoralization, or using other approaches such as network models (Fried et al., 2017), may improve the replicability of findings.

The findings of the present study underscore the importance and value of assessing demoralization in the general hospital, considering the relationship of this construct with abnormal illness behavior and suicidal ideation, even in the absence of clinical depression (Clarke and Kissane, 2002; Fang et al., 2014; Nanni et al., 2018a; Robinson et al., 2015; Tecuta et al., 2015; Vehling et al., 2017). Moreover, tools that facilitate the distinction between demoralization and depression may be particularly helpful in guiding clinical management, although currently few clinical trials exist indicating optimal treatment for demoralized, non-depressed patients. In the Managing Cancer and Living Meaningfully trial (CALM therapy), patients with moderate death anxiety at baseline had a significant reduction in demoralization across six months from this meaning-centered intervention (Cohen's d = 0.50, p=0.01) (Rodin et al., 2018). Other recent studies support the utility of meaning-centered psychotherapy: both cancer patients (Breitbart et al., 2018; Kissane et al., 2019) as well as individuals with cyclothymic disorder (Tomba et al., 2016) who reported demoralization, or psychological dimensions typical of demoralization (Van Der Spek et al., 2017), received significant advantage from psychological interventions. When depression is comorbid with demoralization, then the use of antidepressants is also indicated. It is urgent nonetheless to develop and test specific approaches to treat demoralization in patients affected by other medical conditions.

This study is strengthened by the use of IRT, a reliable and robust methodology for investigating the psychometric properties of assessment instruments (Thomas, 2011), an adequate sample size, and a study population that is highly representative of general hospital patients.

However, a number of limitations have to be considered. First, our study comprised a convenience sample of individuals affected by several medical disorders: examining more homogeneous populations may highlight illness-related specificities of demoralization. Second, the use of a psychiatric diagnostic interview and the complete

DCPR interview (Fava et al., 2012) would have allowed to examine the reliability of the DS-24 with other disorders (e.g. adjustment or stress-related disorders) and psychosocial conditions (Gala et al., 1999; Sirri et al., 2011). Patients with non-specific signs and symptoms or other disorders (including medical consequences of alcohol/drug use), who showed higher scores of demoralization may have influenced the analysis of our data. Third, depression was also examined with a self-rated instrument (the PHQ-9) which suggests caution in the interpretation of results on divergent validity (Thom et al., 2019).

Fourth, we used the DCPR/D criteria as a gold standard to validate the presence of demoralization, despite differences in the constructs and in the required duration of symptoms (at least one month in the DCPR/D, the two weeks in the DS-24) (Kissane et al., 2004). The DCPR have been recently revised (Fava et al., 2017), where hopelessness (criterion C: 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), is only a specifier and not mandatory for the diagnosis of demoralization. Further investigation is also necessary to examine more precisely the relationship between DCPR/D and demoralization tools (i.e. the DS-24, but also other instruments, such as the Subjective Incompetence scale) (Cockram et al., 2009) and to explore possible expansion of the DCPR/D semi-structured interview to include some aspects that, in the DS-24, are part of the demoralization syndrome (e.g., meaninglessness and dysphoria) that are not currently taken into account in the DCPR/D. Also, the exploration of demoralization and abnormal illness behavior could be interesting, as recently suggested in kidney transplant recipients (Battaglia et al., 2018).

In conclusion, the DS-24 yielded good psychometric properties among medical inpatients from the general hospital. The slight differences of the factor structure between this setting and oncology may depend on methodological, cultural-geographic factors and intrinsic clinical features. These factors may ultimately shape the experience and clinical management of patients with chronic physical illnesses. In addition, two reliable, short versions of the DS-24 were presented that may aid screening in everyday clinical practice as well as further research on this important construct.

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Table 1. Confirmatory Item Factor Analyses and Exploratory Item Factor Analyses based on Item Response Theory analyses

Confirmatory Item Factor Analyses		Factors	CFI	TLI#	RMSEA#	RMSEA IC (90%)
Kissane et al. (2004) 24 items	59.5%	5	0.851	0.830	0.118	0.112 - 0.123
Grassi et al. (2017) 24 items	57.7%	4	0.879	0.863	0.106	0.100 - 0.112
Mullane et al. (2009) 24 items	47.3%	5	0.744	0.710	0.154	0.148 - 0.159
Mehnert et al. (2011) 24 items	56.9%	4	0.870	0.853	0.110	0.104 - 0.115
Rudilla et al. (2016) 23 items	47.3%	5	0.713	0.650	0.164	0.157 - 0.170
Robinson et al. (2016) 16 items	48.8%	2	0.901	0.870	0.092	0.081 - 0.103

Exploratory Item Factor Analyses		Factors	CFI	TLI#	RMSEA#	RMSEA IC (90%)
	47.2%	1	0.931	0.921	0.080	0.086 - 0.079
	47.6%	2	0.958	0.946	0.067	0.060 - 0.073
	52.0%	3	0.980	0.969	0.050	0.042 - 0.058
	56.0%	**4**	**0.991**	**0.984**	**0.036**	**0.026 - 0.046**
	56.8%	5	0.995	0.990	0.029	0.015 - 0.040
	60.7%	6	0.997	0.992	0.026	0.001 - 0.039

Table 2. Four-factor Exploratory Item Factor Analysis of the DS-24 with Promax rotation

		F1	F2	F3	F4	H2
	Disheartenment					
5	I no longer feel emotionally in control	**-0.34**	0.29	0.01	-0.14	0.46
R6	I am in good spirits	**-0.67**	0.15	-0.23	0.17	0.61
8	I feel that I cannot help myself	**-0.37**	-0.04	-0.05	-0.33	0.45
9	I feel hopeless	**-0.47**	-0.02	-0.01	-0.46	0.75
R12	I cope fairly well with life	**-0.45**	0.05	-0.35	-0.09	0.62
18	I feel distressed about what is happening to me	**-0.98**	-0.21	0.13	-0.02	0.67
21	I feel sad and miserable	**-1.06**	0.02	0.01	0.19	0.86
22	I feel discouraged about life	**-0.86**	0.00	0.05	-0.04	0.76
23	I feel quite isolated or alone	**-0.55**	0.24	-0.06	0.03	0.52
24	I feel trapped by what is happening to me	**-0.60**	0.06	-0.05	-0.15	0.63
	Dysphoria					
7	No one can help me	0.03	**0.43**	-0.01	-0.41	0.50
10	I feel guilty	0.08	**0.72**	-0.06	0.10	0.43
11	I feel irritable	-0.21	**0.52**	0.04	0.06	0.39
13	I have a lot of regret about my life	0.27	**0.73**	0.02	-0.13	0.42
15	I tend to feel hurt easily	-0.21	**0.40**	0.25	-0.16	0.38
16	I am angry about a lot of things	-0.29	**0.47**	0.11	-0.04	0.47

	Sense of failure					
R17	I am proud of my accomplishments	0.24	**0.65**	**-0.65**	0.17	0.65
R1	There is a lot of value in what I can offer others	0.02	-0.23	**-0.63**	-0.34	0.62
R19	I am a worthwhile person	-0.05	0.01	**-0.73**	-0.03	0.60
	Loss of meaning and purpose					
2	My life seems to be pointless	0.08	0.12	-0.09	**-0.88**	0.89
3	There is no purpose to the activities in my life	0.15	0.05	0.01	**-1.00**	0.81
4	My role in life has been lost	-0.04	-0.05	0.05	**-0.88**	0.74
14	Life is no longer worth living	-0.08	0.02	-0.14	**-0.72**	0.77
20	I would rather not be alive	-0.28	0.06	-0.15	**-0.47**	0.70

eigenvalues	5.027	2.614	1.690	4.100	
Proportion var	0.209	0.109	0.070	0.171	
Cumulative var	0.209	0.318	0.389	0.560	

Inter-factor correlations	F1	1				
	F2	-0.632	1			
	F3	0.459	-0.291	1		
	F4	0.787	-0.524	0.549	1	

Table 3. Pure Exploratory Bifactor Model of the DS-24 with Promin rotation

Item	label	F1	F2	F3	F4	GF
Disheartenment						
R_DEMO6	Low_spirit_R	**0.29**	0.19	-0.02	0.19	**0.62**
demo18	Distress	**0.74**	-0.17	-0.01	-0.04	**0.55**
demo21	Sadness	**0.56**	-0.04	-0.07	0.14	**0.74**
demo22	Discouragement	**0.49**	0.07	0.06	0.09	**0.69**
demo24	Entrapment	**0.65**	-0.13	-0.03	0.03	**0.66**
Sense of failure						
R_DEMO1	No_Value_R	-0.19	**0.59**	0.48	-0.14	**0.36**
R_DEMO12	Inability_Coping_R	0.17	**0.29**	0.15	0.05	**0.62**
R_DEMO17	Lack_pride_R	-0.24	**0.37**	-0.13	0.37	**0.55**
R_DEMO19	Not_worthwile_R	-0.13	**0.56**	0.16	-0.05	**0.50**
Loss of meaning and purpose						
demo2	Life_pointless	-0.12	0.08	**0.59**	-0.09	**0.80**
demo3	Lack_purpose_activity	-0.19	-0.04	**0.74**	-0.11	**0.69**
demo4	Lack_purpose_role	-0.05	-0.02	**0.57**	-0.22	**0.73**
demo8	Cannot_help_myself	0.20	0.01	**0.25**	-0.04	**0.54**
demo9	Hopelessness	0.23	0.00	**0.39**	-0.02	**0.68**
demo14	Lack_worth_living	0.00	0.16	**0.66**	0.04	**0.59**
demo20	Rather_dead	0.12	0.15	**0.54**	0.16	**0.55**
Dysphoria						
demo5	Lack_emotion_control	0.15	-0.09	0.11	**0.23**	**0.56**
demo7	Helplessness	-0.09	-0.10	0.26	**0.31**	**0.60**
demo10	Guilt	-0.08	-0.12	-0.27	**0.36**	**0.59**
demo11	Irritability	0.19	-0.16	-0.06	**0.60**	**0.37**
demo13	Regret	-0.13	-0.18	-0.18	**0.38**	**0.52**
demo15	Easily_hurt	0.16	-0.31	0.09	**0.36**	**0.41**
demo16	Anger	0.20	-0.20	0.06	**0.55**	**0.44**
demo23	Isolation	0.02	-0.05	0.16	**0.20**	**0.71**
	Eigenvalues	1.947	1.547	1.030	0.892	11.870
	Prop. variance	0.081	0.064	0.043	0.037	0.495

		1	**2**	**3**	**4**	**GF**
Factor intercorrelations	**1**	-				
	2	0.299	-			
	3	0.554	0.205	-		
	4	0.203	0.194	0.384	-	

Table 4. Diagnostic accuracy of the three versions of the DS compared with the DCPR/D

	DS-24	DS-13	DS-6
ROC AUC (95%CI)	0.821 (0.784 – 0.858)	0.815 (0.777 – 0.853)	0.810 (0.772 – 0.849)
Cutoff	≥30	≥17	≥10
Sensitivity	76.7%	75.1%	75.7%
Specificity	72.8%	72.1%	71.7%

The authors have no competing interests to report.

- Factor structure of the Demoralization Scale has been mostly investigated in oncology;
- We conducted exploratory factor analyses using item response theory;
- The structure of demoralization was similar to that of Italian oncological patients;
- We developed reliable 13 and 6 item versions for screening purposes;

Abstract

Objective. Demoralization has been mostly investigated in oncology but is also relevant in patients with other physical illnesses. Our aims were to investigate the psychometric properties of the 24-item Italian version of the Demoralization Scale (DS-24) among medically ill inpatients and to develop shorter versions for screening.

Methods: Four-hundred and seventy-three participants were recruited from medical wards of the University Hospital of Ferrara. Patients were assessed using the Diagnostic Criteria for Psychosomatic Research-Demoralization module (DCPR/D), Demoralization Scale (DS-24), Patient Health Questionnaire-9 (PHQ-9), Brief-Symptom Inventory-18, Anxiety subscale (BSI-Anx) and EuroQol Group (EQ-5D). Confirmatory factor analyses of previous structures and exploratory factor analyses were conducted using an Item Response Theory approach, including a bifactor model.

Results: According to DCPR/D criteria, the prevalence of demoralization was 40%**.** Confirmatory analyses revealed that none out of seven factor structures from oncology studies adequately fitted data from hospital inpatients. Exploratory Item Factor Analysis uncovered a four-factor model comprising Disheartenment, Dysphoria, Sense of Failure, Loss of Meaning and Purpose, or a bifactor model, comprising similar factors with the addition of a general factor accounting for 45% of the variance. Moreover, we developed 13 and 6-item versions of the DS, both retaining high correlation with DS-24 scores (r=0.96 and r=0.95, respectively) and concordance with DCPR/D criteria (AUC-ROC 0.82 and 0.81).

Conclusion. The DS factor structure differs between general hospital and cancer patients. Differences may depend on intrinsic disease features and cultural-geographic factors. The short versions of the DS-24 may aid clinicians in identifying demoralized patients in hospital settings.