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The impact of social-emotional context in chronic cancer pain: patient-caregiver reverberations: Social-emotional context in chronic cancer pain

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(Article begins on next page)

Supportive Care in Cancer

The impact of social emotional context in chronic cancer pain: Patient-caregiver reverberations --Manuscript Draft--

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Abstract:	<p>Purpose. Pain is a multifactorial and subjective experience. Psychological and social factors can modulate it. This study analyzed whether and how prolonged cancer pain is related to the social-relational environment's characteristics. Specifically, we investigated whether the caregiver's emotional support, his/her compassion ability or, on the contrary - his/her personal distress, associates with the patient's pain level.</p> <p>Methods. The sample consisted of 38 cancer patients suffering from pain and 38 family caregivers. The patients completed the McGill Pain Questionnaire (MPQ), the Balanced Emotional Empathy Scale (BEES) referred to caregiver, and an interview concerning the patient's perception of the caregiver's compassion level. Caregivers completed the Distress Thermometer (DT), the BEES, and an interview assessment of their compassion level.</p> <p>Results. Caregiver's distress level correlated with patient's pain intensity ($r = .389$; $p = .028$). Exploratory linear regression confirmed this association ($R^2 = .151$; $F(1,30) = 5.33$; $p = .028$; $\beta = .389$). The number of problems reported by caregivers correlated with the patients' pain level ($r = .375$; $p = .020$), which was verified in a regression analysis ($R^2 = .140$; $F(1,36) = 5.88$; $p = .020$; $\beta = .375$). In particular, the caregiver's amount of emotional problems was related to patient's pain level ($r = .427$; $p = .007$); this result was reaffirmed in a regression ($R^2 = .182$; $F(1,36) = 8.03$; $p = .007$; $\beta = .427$).</p> <p>Conclusions. Our results show an association between social suffering, as indicated by the caregiver's emotional distress and the patient's physical pain. The results also highlight high distress levels and emotional problems among caregivers. The work emphasizes the need of a bio-psychosocial approach in managing cancer pain, along with the necessity to find effective interventions to fight emotional distress in family caregivers. The recovery of the caregivers' emotional resources could have beneficial implications on the patients' pain.</p>

Response to Reviewers:

Please, see the attached file "Author responses to the comments 06.08.2018".

06/08/2018

Author's responses to the comments (Minor Revisions 11.07.18)

We would like to thank the reviewers for the time spent reading the first revision of the manuscript and the useful feedback to improve it, and to the editor of Supportive Care in Cancer for considering the article for publication. We have carried out the revisions accordingly; changes are marked red in the manuscript.

Reviewer #1**Author Response 1)**

The limitations and the conclusions of the study are now addressed in two separate paragraphs in the Discussion section (Limitations: line 266 of page 10; Conclusions: line 298 of page 11). Since the order of the paragraphs changed and some sentences were added, the reference numbers have been modified too. The modified numbers are also reported in red throughout the text.

Author Response 2)

The document has been carefully edited by an expert to eliminate minor problems with the English.

Reviewer #2**Author Response 3)**

Given that the cross-sectional design allows us demonstrate association rather than causation, the words suggesting "prediction" and "contribution to explanation" have been eliminated throughout the text.

1 **The impact of social emotional context in chronic cancer pain: Patient-caregiver reverberations**

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5 **Social emotional context in chronic cancer pain**

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Abstract

Purpose. Pain is a multifactorial and subjective experience. Psychological and social factors can modulate it. This study analyzed whether and how prolonged cancer pain is related to the social-relational environment's characteristics.

Specifically, we investigated whether the caregiver's emotional support, his/her compassion ability or, on the contrary - his/her personal distress, associates with the patient's pain level.

Methods. The sample consisted of 38 cancer patients suffering from pain and 38 family caregivers. The patients completed the McGill Pain Questionnaire (MPQ), the Balanced Emotional Empathy Scale (BEES) referred to caregiver, and an interview concerning the patient's perception of the caregiver's compassion level. Caregivers completed the Distress Thermometer (DT), the BEES, and an interview assessment of their compassion level.

Results. Caregiver's distress level correlated with patient's pain intensity ($r = .389; p = .028$). Exploratory linear regression confirmed this association ($R^2 = .151; F(1,30) = 5.33; p = .028; \beta = .389$). The number of problems reported by caregivers correlated with the patients' pain level ($r = .375; p = .020$), which was verified in a regression analysis ($R^2 = .140; F(1,36) = 5.88; p = .020; \beta = .375$). In particular, the caregiver's amount of emotional problems was related to patient's pain level ($r = .427; p = .007$); this result was reaffirmed in a regression ($R^2 = .182; F(1,36) = 8.03; p = .007; \beta = .427$).

Conclusions. Our results show an association between social suffering, as indicated by the caregiver's emotional distress and the patient's physical pain. The results also highlight high distress levels and emotional problems among caregivers. The work emphasizes the need of a bio-psychosocial approach in managing cancer pain, along with the necessity to find effective interventions to fight emotional distress in family caregivers. The recovery of the caregivers' emotional resources could have beneficial implications on the patients' pain.

Keywords. Cancer pain · Emotional support · Empathy · Compassion · Personal Distress · Caregiver · Bio-Psychosocial Model

142 Introduction

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544 Cancer patients often experience pain. According to the National Institutes of Health, **between 14% and 100%** of the
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745 patients feel pain [1]. Higher prevalence rates are reported among patients under active treatments (50-70%) and among
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946 patients in advanced stage of disease (60-90%) [2]. **The experience of pain** is complex and multifactorial; it cannot be
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1147 reduced to the perception of sensory qualities of the nociceptive stimulus. Psychological factors modulate pain and
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1348 make it a strictly subjective event. Some of the most important cognitive and emotional aspects affecting pain are: stress
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1549 level, anxiety, and depression [3, 4]; emotion awareness and expression [5]; evaluative processes, beliefs, and coping
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1750 strategies [6-8]; expectancy and motivation [9-10]. **The social and relational environment** influence pain too, **whereby**
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1951 important factors are *social connection* and *support*. *Social connection* is a fundamental human need and contributes to
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2152 maintaining health and wellness [11]. Moreover, **relational** bonds play a critical role in mitigating the effects of life's
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2353 most stressful experiences [8]. According to Zautra (2013), individual resilience depends on relations: the primary
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2554 sources of positive emotions in **the face** of difficult events are beneficial social interactions [12]. *Social support* is
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2755 defined as the degree of perceived satisfaction with social relationships [13] or as the resources, effective or perceived
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2956 as being available, from others in **the** social network [14]. It is categorized **into** emotional, tangible, informal, and
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3157 companionship support. Emotional support, specifically, is the offering of empathy, concern, affection, love, trust,
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3358 acceptance, encouragement, and caring [15]. Some studies show how social support, ranging from tangible aid to
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3559 emotional connection, has a positive influence on pain perception and adaptation. For example, a randomized factorial
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3760 mixed design study by Montoya and colleagues (2004) showed that individuals with chronic pain report less severe pain
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3961 and show less activation of the central nervous system under painful conditions when they are in the presence of their
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4162 significant other [16]. A cross-sectional study with the applications of structural equation modeling (SEM) reports that
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4363 chronic pain patients receiving higher levels of social support not only **exhibit decreased depressive symptomatology,**
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4564 **but also pain intensity,** which, in turn, decreases functional impairment and increases functional status [14]. Social
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4765 support has both direct effects **on pain** and health outcomes, **as well as** indirect effects that protect individuals from the
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4966 negative influence of stress-related biological processes [e.g. 17, 18]. Conversely, the lack of social connection and
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5167 caring may feel "painful" [19, 20]. Recent **evidence suggests** that social pain – the painful feelings following events of
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5368 "social disconnection" **such as** rejection, isolation, social loss, or lack of support – and physical pain are processed, in
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5569 part, by the same neural circuitry [20]. As **a** consequence of this physiological similarity, these two types of pain
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5770 experience can influence each other: experimental and longitudinal studies have demonstrated that **feelings of social**
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171 pain can increase physical pain sensitivity [21, 22], while physical pain can **exacerbate feelings of** social rejection, even
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 372 without **actual** experiences of exclusion [23].
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573 On **the other side**, however, providing a suffering person with social support can be a very demanding task. Family
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 774 caregivers, people who take care of the patient for most of the time, **assume increasingly more responsibility** and
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 975 frequently take on burdens **for which** they are not prepared. As **a** consequence, they often develop physical and
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 1176 emotional illnesses [24]. A recent review **suggests** that the most prevalent physical problems among caregivers include
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 1377 sleep disturbance, fatigue, pain, loss of physical strength, loss of appetite, and weight loss [25, 26]. However, the
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 1578 detrimental physical effects are generally less intensive than the psychological ones [27]. Emotionally, **cancer patient**
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 1779 caregivers **face** symptoms of anger, depression, mood disturbances, and anxiety [24, 25, 28]. Besides, caregivers often
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 1980 experience empathy through which they share pain and suffering with the patient. **Evidence from** experimental studies
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 2181 shows that empathizing with somebody else's pain activates brain regions involved in the first-hand experience of pain
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 2382 [29] and can also increase pain sensitivity in the observer [30]. Some research groups point out that **the** empathic
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 2583 involvement with another person's suffering **evokes** primarily two kinds of **responses** in the observer: *compassion*,
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 2784 which is also referred to as empathic concern or sympathy, **or empathic distress**, also called personal distress [31, 32].
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 2985 *Compassion* is conceived as a feeling of concern for another person's suffering, which is associated with approach,
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 3186 prosocial motivation **and behavior**. *Empathic distress*, on the other hand, refers to a **self-focused**, strong aversive
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 3387 **affective reaction** to the suffering of **another**, accompanied by the desire to withdraw from **the** situation in order to
 34
 3588 protect oneself from excessive negative feelings, **thereby decreasing the likelihood of prosocial behavior** [32]. The term
 36
 3789 "compassion fatigue" is also used to refer to this state of distress, strain, and weariness **from** caring for another person's
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 3990 physical or emotional suffering [33]. Thus, individuals who experience high levels of empathy and involvement towards
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 4191 **the** patient's pain are vulnerable **to the development** of psychological symptoms such as distress, fatigue, and even an
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 4392 increased pain sensitivity. These disturbances also affect caregivers' emotional resources to support and connect with
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 4593 the patient.
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 4894 **To build upon previous work**, the **primary purpose of this study** was **therefore** to **assess** the contribution of **the** social
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 5095 emotional dimension on prolonged pain in cancer patients. **More specifically**, we investigated whether and how **the**
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 5296 caregiver's emotional support, effective (**the** caregiver's actual compassion ability or, on the contrary, his/her personal
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 5497 distress level) or perceived (**the** patient's perception of emphatic concern received by **the** caregiver), **was related to the**
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 5698 patient's pain level. **Additionally**, this study investigated potential factors **associated with** "caregiver's burden" among
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 5899 the respective family caregivers.
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101 **Methods**

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103 **Sample**

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105 Participants were recruited between October 2016 and December 2016 at Clinical and Oncological Psychology and
 106 Medical Oncology Units of San Giovanni Hospital “Molinette” in Turin. Each participant was tested with the Mini-
 107 Mental State Examination (MMSE) to assess his/her cognitive capacity to provide informed consent and to complete
 108 the questionnaires. The inclusion criteria were: 1) being diagnosed with cancer; 2) age > 18 years; 3) **compliance** with
 109 the basic criterion of chronic pain definition, **which**, according to the International Association for the Study of Pain
 110 (IASP) Task Force for the Classification of Chronic Pain in ICD-11, **is**: “Persistent or recurrent pain lasting longer than
 111 3 months” [34]; 4) being accompanied by the main family caregiver, **who was** also willing to participate in the research.
 112 Exclusion criteria were a score **lower or equal to 19 on** the MMSE and **the presence of** psychotic mental disorders.

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114 **Procedure**

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116 The researchers approached potential participants in the waiting rooms of the aforementioned **healthcare** units, **with an**
 117 initial screening question: “Are you experiencing pain daily or almost daily for at least three months?”. Respondents
 118 who answered ‘yes’ were considered compliant with the basic criterion of chronic pain and were consequently included
 119 in the study. Patients and caregivers were asked to read and complete two different **test** batteries **independently**. They
 120 **were offered** the possibility to **fill out** the tests in loco or at home. Participants **were encouraged** to ask questions in case
 121 of **doubt about any of the items** or otherwise. Finally, **participants** were **briefed** that all **gathered data will** be used for
 122 research purposes **only** and **will be kept** anonymous. Participants provided written informed consent **following the**
 123 protocols admitted by Ethics Committee of the City of Health and Science University Hospital of Turin that approved
 124 **this** study.

125 We asked a total of 85 cancer patients to participate; **35 were deemed ineligible for the study and were therefore**
 126 **excluded**. Specifically, 18 cancer patients **did not pass** the screening question, **i.e., reported no** chronic pain; 12 patients
 127 did not have a caregiver; 5 patients had a caregiver **who refused** participation. Therefore, 50 patients with a primary
 128 caregiver **were** recruited. **During the study, additional** 5 dyads agreed to participate **by** completing the questionnaires at
 129 home **but** did not return the tests, 5 dyads withdrew **their participation** from the study, and **another** 2 patients passed
 130 away **before returning** the questionnaires. **The** final sample consisted of 38 dyads (76 participants).

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131 Screening Tools

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133 All participants completed a sheet collecting *socio-demographic information* (sex, age, marital status, children,
134 educational level, occupational status, primary caregiver, eventual psychological therapy). Patients also completed a
135 sheet collecting *clinical information* (tumor site, stage of the disease, treatment phase, type of therapy, presence of
136 second tumor site, eventual psychopharmacological treatment).

137 **The** caregivers completed three tests. The *Distress Thermometer* (DT) is a self-report measure of psychological distress
138 [35]. Responders are asked to rate their distress level using a thermometer visual analogue scale with scores ranging
139 from 0 (“no distress”) to 10 (“extreme distress”). **The** cut-off score is 4. The thermometer is accompanied by a problem
140 list, which asks subjects to identify any of 34 issues (grouped into five categories: practical, relational, emotional,
141 spiritual, and physical concerns) that have been a source of their general distress level. The *Balanced Emotional*
142 *Empathy Scale* (BEES) [36] is a 30-item instrument scored on a 9-point Likert scale, which **evaluates** the level of
143 affective empathy, i.e., the extent to which the respondent can emphatically share others’ emotions (e.g., feel others’
144 suffering or take pleasure in their happiness). Finally, to evaluate the caregivers’ actual ability to experience
145 compassion towards the patient, a brief interview of 10 questions on a 9-point Likert scale was **conducted**. The
146 interview was **based** on the questions concerning relational empathy of the *Barrett-Lennard Relationship Inventory*
147 (BLRI) – *Empathy Understanding subscale* [37]. **The** patients completed three **additional** tests. The *McGill Pain*
148 *Questionnaire* (MPQ) is a multidimensional scale designed to measure different aspects of pain experience and pain
149 intensity in adults suffering from chronic painful conditions with different etiology [38]. **The** MPQ contains 78 pain
150 descriptor items categorized into 20 subclasses that fall into **four** major subscales: sensory, affective, evaluative, and
151 miscellaneous [39]. **The** patients also completed the BEES in order to assess the perceived empathy level of **the**
152 caregiver. In this case, the **participants were instructed to read the** sentences **with reference** to their caregiver and not to
153 themselves. Finally, to investigate **the** patient’s perception of **the** caregiver’s compassion level, the same interview
154 **based** on the BLRI was used. **Similarly, the** patients **were told** that the questions were referred to their caregiver and in
155 answering **them**, they **should** think about their actual relationship with him/her.

157 Statistical Analysis

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159 Statistical analysis was executed using SPSS Statistics Version 23.0 (IBM Corp. Armonk, NY, USA). Descriptive
160 statistics including means, standard deviations, and frequencies were used to describe **the** sample’s socio-demographic

and clinical characteristics. To assess variables distributions, measures of skewness and kurtosis were used. For the multivariate analysis, we used bivariate Pearson's correlations, exploratory linear regressions, and means comparisons through independent samples T-test. None of the test assumptions were found violated. The tests were two-sided and a p-value of less than .05 was considered statistically significant.

Results

Descriptive statistics

The 38 dyads were composed by the patients and their respective primary family caregivers. As shown in Table 1, cancer patients (65% female, $n = 25$) were at an average age of 58.5 years ($SD = 13.4$; range 30-78); male and female caregivers were balanced and at an average age of 54.4 years ($SD = 14.8$; range 20-79). 78% of the patients ($n = 30$) and 63% of the caregivers ($n = 24$) were married. The majority of the patients (65%, $n = 25$) reported their spouse as their "primary caregiver"; caregivers reported their spouse as "caregiver" (44%, $n = 17$) nearly as frequently as they reported "none" (34%, $n = 13$). The majority of both patients (65%, $n = 25$) and caregivers (84%, $n = 32$) reported that they were not receiving psychological therapy. Regarding illness, the majority of patients was under active treatment (89%, $n = 34$) of chemotherapy (84%, $n = 32$). As presented in Table 2, 60% of the patients ($n = 23$) reported a mild pain level, 29% ($n = 11$) reported a moderate pain level, and 11% ($n = 4$) – a severe pain level. The mean score of total pain in the patients' group was 21.87 ($SD = 21.12$), corresponding to 28% of the maximum score of the MPQ. This value is in line with the normative mean scores across chronic painful conditions that range from 24 to 50% of the maximum score of the MPQ [40]. Hence, cancer pain falls within the category of chronic pain. Regarding the patients' perception of the caregiver's empathy, almost all patients (97%, $n = 37$) reported a medium empathy level of the caregiver, whereas half of the patients (45%, $n = 17$) reported a medium compassion level and the other half (55%, $n = 21$) – a high compassion level. With regard to caregivers' characteristics, 39% of the caregivers ($n = 15$) had a moderate distress level, 37% of them ($n = 14$) a mild distress level, and 24% ($n = 9$) – a severe one. In total, 63% of the caregivers had a distress level above the cut-off. The majority of the caregivers reported having problems in the emotional (84%, $n = 32$) and in the physical sphere (78%, $n = 30$). In particular, the most common emotional problems among caregivers were "worry" (63%, $n = 24$), "sadness" (45%, $n = 17$), "irritability" (31%, $n = 12$), and "fears" (29%, $n = 11$). Most caregivers indicated a medium empathy level (81%, $n = 31$), while half of the caregivers reported a medium compassion level (50%, $n = 19$) and the other half (50%, $n = 19$) – a high compassion level.

191 *Analysis of the associations between caregiver's emotional resources and patient's pain*

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193 **Regarding** the hypothesized contribution of **the** caregiver's emotional support **to the** patient's pain, **an initial** analysis
194 did not show a significant association of empathy level (effective or perceived) **and** compassion level (effective or
195 perceived) with patient's pain. **Nevertheless, we observed a** positive correlation between **the** caregiver's distress level
196 and **the** patient's pain, **which was** subjectively reported **in** the evaluative subscale of **the** MPQ ($r = .389; p = .028$). This
197 subscale describes the overall subjective intensity of pain experience [38]. Moreover, **the** total **amount** of problems
198 **reported by the caregiver** was positively associated with all subcategories of **the** patient's pain: total pain ($r = .375; p =$
199 $.020$), sensory ($r = .340; p = .037$), affective ($r = .326; p = .46$), evaluative ($r = .386; p = .017$), and miscellaneous ($r =$
200 $.389; p = .016$). Specifically, **we observed** a precise correlation between **the** caregiver's total quantity of emotional
201 problems and **the** patient's pain level ($r = .427; p = .007$); **crucially, the total quantities of the caregiver's** problems
202 reported in the other **domains** (practical, relational, physical, and spiritual) **were** not correlated with patient's pain level.
203 Exploratory simple linear regressions confirmed the relationship between caregiver's emotional distress and patient's
204 pain showing that **the** caregiver's general distress level was **significantly associated with the** patient's pain intensity (R^2
205 $= .151; F(1,30) = 5.33; p = .028; \beta = .389$). **The** patient's pain level also **linked to the** caregiver's total **number** of
206 problems ($R^2 = .140; F(1,36) = 5.88; p = .020; \beta = .375$), and, in particular, **to the** caregiver's **total amount** of emotional
207 problems ($R^2 = .182; F(1,36) = 8.03; p = .007; \beta = .427$).

208
209 *Analysis of the associations between caregiver's problems and distress level*

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211 To understand which factors **were related to the** caregivers' distress, **we computed the correlations** between caregiver's
212 general distress level and **number** of problems reported in different **domains** (practical, relational, emotional, spiritual,
213 and physical). Even **though marginally significant** associations were found between **the number** of relational problems
214 and general distress level ($r = .336; p = .060$), and between **the number** of relational problems and **the number** of
215 emotional problems ($r = .309; p = .059$), only **the quantity of the** caregiver's problems in the emotional sphere was
216 significantly and highly correlated with the general distress level experienced by him/her ($r = .687; p < .001$). **This**
217 **relation was further established in a** regression analysis ($R^2 = .472; F(1,30) = 26.87; p < .001; \beta = .687$). Finally,
218 analyzing emotional problems one **by one, multiple** single t-tests revealed a significantly higher distress level when **the**
219 problems "depression" ($\Delta mean = 3.56; t = -3.47; p = .002$), "fears" ($\Delta mean = 2.23; t = -3.01; p = .005$), "irritability" (Δ

mean = 2.72; $t = -3.89$; $p = .001$), “sadness” (Δ mean = 2.35; $t = 3.57$; $p = .001$), and “loss of interest in daily activities” (Δ mean = 3.13; $t = -4.36$; $p < .001$) were present compared to when these problems were not reported by caregivers.

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223 Discussion

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225 The aim of this study was to test the hypothesis that caregiver’s emotional support, effective or perceived, was
226 significantly associated with chronic cancer pain. Initially, we did not find support for the proposed hypothesis. In fact,
227 the caregiver’s effective or perceived empathy and compassion levels were not found related to the patient’s pain level.
228 These results could mean that the social-emotional support is not linked to chronic pain experience of cancer patients.

229 Another possible interpretation, which is more congruent with existing literature and with the results from our follow-up
230 analyses, is that empathy and compassion scores have been affected by social desirability and acquiescence [40].

231 Literature on the subject indeed suggests that there are substantial problems with relying solely on self-report measures
232 to estimate empathy. These measures are often convoluted by the individual’s concerns with their own evaluations or
233 those of others. In other words, the extent to which participants report how they actually feel in empathy-inducing
234 contexts cannot be disentangled from how respondents wish to be perceived in such settings on the basis of the self-
235 reports [40, 29]. Furthermore, the assessment of empathy and compassion itself could make people feel “under
236 accusation”, as if one is not compassionate or empathic enough. Participants therefore tend to answer in, what they
237 consider, the most “normal” way in order to not appear dissimilar from others. Moreover, acquiescence is a form of
238 compliance, which is observed when individuals respond positively to all questions irrespective of the content.

239 Together, these biases tend to cause average or higher scores without reflecting the actual empathy levels. Indeed, this
240 appears to be the case in this study as all empathy and compassion scores collected with self-reports were clustered in
241 the middle to high ranges of the distribution. As a consequence, it is difficult to draw conclusions about the absence of
242 the hypothesized relationships and further investigations using more objective alternative measures are required.

243 Our results show that the caregiver’s distress level, mainly pertaining to his/her emotional problems, correlates
244 positively with the patient’s pain perception. Personal distress, especially when associated with emotional problems, is
245 able to adversely influence the effective resources and the capacity of an individual to provide another one in pain with
246 compassion and prosocial behaviors, and it is often linked to fatigue and relational withdrawal [31, 32]. As a result, the
247 caregiver’s personal distress can indirectly lead to a lack of (or a worsening of the quality of) the emotional connection
248 and support of the patient and may in turn increase the patient’s perception of isolation. Thus, these data provide
249 evidence in favor of the physical/social pain overlap theory [19-23]. In fact, suffering in the patient’s relational sphere,

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as reflected by the emotional distress of caregiver in this study, is significantly correlated with the patient's physical pain level. Alleviating the suffering in the patient-caregiver social environment could therefore play an important role in the effective management of prolonged pain.

The description of the caregivers' condition in this sample was critical: more than half of the caregivers (63%) reported a distress level above the cut-off, which indicates the necessity of an intervention [35], and 84% of them reported at least one emotional problem. Furthermore, emotional problems were the main source of the caregivers' distress. In spite of this, the majority of caregivers (84%) reported that they were not receiving any psychological therapy.

These results are in line with previous literature highlighting that the role of the cancer patient caregiver satisfies all criteria for chronic stress and, as such, primarily impacts the caregiver's psychological well-being leading to the development of emotional symptoms like depression and anxiety [27, 28]. Moreover, the detected positive associations between the patient's pain intensity and the caregiver's distress level, and between the patient's pain level and the caregiver's quantity of emotional problems, conform with existing literature pointing out that anxiety, tension, and depression are significantly higher among caregivers of cancer patients in pain than among caregivers of pain-free patients [41, 42]; they are also consistent with previous work showing that the patient's perceived pain plays an independent role in affecting the caregiver's emotional burden and distress [43].

Limitations

A limitation we already discussed was the difficulty of validly assessing empathy and compassion through self-report measures. Another issue was the experimental attrition our study suffered. The sample size was based on reviews studies [44, 45, 46], describing experiments that shared sample and design characteristics with our prospective study.

The minimum reported sample size was 29 participants. Although the initial recruited sample was 50 dyads, we suffered an unforeseen participants dropout. A larger sample size would therefore yield more statistical power for assessing the presence of the hypothesized effects, which we will be opting for in future works. Third, the exclusion of the socio-demographic and clinical characteristics from the analyses. The sample was highly homogeneous in regard to patients' clinical characteristics. On the ground of this, we decided to leave aside the medical features from the analysis, assuming them as stable characteristics of the group. Regarding the socio-demographic aspects, we investigated the associations between age and pain level and between sex and pain level, but both resulted not significant. Therefore, we decided not to include these variables as co variate in the following regressions. Although this study design focused specifically on the assessment of selected social-emotional variables, we recognized that personal and medical

280 characteristics – such as cancer type, length and type of treatment, disease **stage**, cancer-related operations and/or
 281 infections, musculoskeletal complaints related to inactivity, and generalized fatigue – have an important impact on
 282 cancer pain. We **therefore** suggest a focused study analyzing **also** the contribution of these **characteristics** on chronic
 283 cancer pain in order to **build a fuller** picture of the phenomenon. **Such a study will require a more heterogeneous sample**
 284 **with respect to those variables and a greater number of participants.** Fourth, the cross-sectional design **does not allow**
 285 **for causal inference about the** relationships between the variables **of interest but provides a descriptive account of the**
 286 cancer patient-primary caregiver **dyad.** These preliminary results **thus call for replication using** more complex study
 287 designs. Longitudinal studies, for **instance**, taking multiple measures over an extended period, **can be a useful tool for**
 288 **determining** cause-effect relationships between the studied variables. Finally, **by omitting** patients without pain, we may
 289 have **left out** patients for whom the family caregivers' **support** has **had the largest** impact, **i.e.**, we **cannot assess** the
 290 **potential contributions of very strong** caregiver **emotional** support to the absence of pain in cancer patients. Future
 291 studies should **therefore consider also** patients without chronic pain in order to assess whether and how psycho-social
 292 influences contribute to the absence of pain. Moreover, having excluded patients **who were** not accompanied by their
 293 main family caregiver, this study may have excluded patients for whom caregiver support is least effective with regard
 294 to **the** amelioration of pain. **A replication** including other types of caregiver and/or patients without caregiver **would**
 295 **allow us to better** understand how **the** different social-emotional environments surrounding patients affect chronic
 296 cancer pain experience.

297 298 *Conclusions*

299
 300 This study **shows** that **the** cancer patient's physical pain is connected to his/her interpersonal sphere (**as higher patient**
 301 **pain levels were found associated with poorer caregiver** emotional well-being) and **thereby** supports the necessity of a
 302 bio-psychosocial approach **to the** treatment of prolonged cancer pain. In several healthcare settings, pain management
 303 still tends to take a biomedical approach, which often concentrates on the organic origin of pain, regarding it mostly as a
 304 potential diagnostic tool and therefore undervaluing its psychosocial and social influences [23]. **Furthermore**, several
 305 investigations **have concluded** that the bio-psychosocial model is **being adopted** only partially, with **a focus on** cognitive
 306 and behavioral factors but **without a** consideration of **the** social dimension of pain [e.g., 47]. The present work shows
 307 that **the** social-relational reality is clearly **connected to the** prolonged pain experience **by** cancer patients: the caregiver's
 308 emotional distress alone explains 18% of the variance **in** the overall patient's pain level.

Another fundamental **issue** highlighted by the results of this study is **the necessity of developing** effective interventions to **support the family caregivers**. The constant contact with suffering and pain exposes caregivers to emotional exhaustion and personal distress. Identifying those caregivers who manifest **greater emotional distress** and help them to improve their condition will be, firstly, beneficial for their psychological health and, secondly, will improve **the patient's painful experience by restoring the emotional resources that can be dedicated to the patient's support**. Some interesting studies [e.g., 31] describe a type of ability training named *Compassion Training* that could be useful in this context. It has been demonstrated that *Compassion Training*, **by** cultivating feelings of warmth and prosocial motivation, increases positive affective experiences, even in response to others' suffering, and it is associated with stronger activations in brain regions previously implicated in positive valuation, as well as love and affiliation [48, 49]. Future research could **evaluate** whether **engaging** caregivers suffering from emotional distress **in a brief training program would impact positively the caregivers'** psychological well-being and whether and how the recovery of emotional resources **would in turn benefit the** patients' pain.

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Compliance with ethical standards

Conflicts of interest The authors have no financial or other relationships that might lead to a conflict of interest.

Ethical approval All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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Manuscript Title:

Manuscript Identifying Number (if you know it):

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Are you the corresponding author? Yes No

Corresponding author's name:

Martina De Laurentis

Manuscript Title:

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Table 1 Patients' and caregivers' socio-demographic characteristics and patients' clinical characteristics.

	n (%)	M (SD) ^a
<i>Patients' socio-demographic characteristics</i>		
Sex		
Male	13 (35)	
Female	25 (65)	
Age		58.5+/-13.4
Educational level (years)		11.5 +/-3.7
Marital status		
Unmarried	3 (7.9)	
Divorced	1 (2.6)	
Partner cohabitant	2 (5.3)	
Married	30 (78.9)	
Widow	2 (5.3)	
Children		
Yes	31 (81.6)	
No	7 (18.4)	
Occupational status		
Employed	11 (28.9)	
Retired	15 (39.5)	
Student	0	
Unemployed	4 (10.5)	
Housewife	4 (10.5)	
Occasional worker	3 (7.9)	

Caregiver		
None	0	
Spouse	25 (65.8)	
Children	3 (7.9)	
Friend	1 (2.6)	
Partner	4 (10.5)	
Other relative	4 (10.5)	
Psychological therapy		
Yes	13 (34.2)	
No	25 (65.8)	
<i>Caregivers' socio-demographic characteristics</i>		
Sex		
Male	19 (50)	
Female	19 (50)	
Age		54.43+/14.84
Educational level (years)		12.6+/3.99
Marital status		
Unmarried	9 (23.7)	
Divorced	1 (2.6)	
Partner cohabitant	2 (5.3)	
Married	24 (63.2)	
Widow	1 (2.6)	
Children		
Yes	25 (65.8)	
No	13 (34.2)	

Occupational status

Employed	16 (42.1)
Retired	14 (36.8)
Student	2 (5.3)
Unemployed	3 (7.9)
Housewife	1 (2.6)
Occasional worker	0

Caregiver

None	13 (34.2)
Spouse	17 (44.7)
Children	5 (13.2)
Friend	0
Partner	2 (5.3)
Other relative	1 (2.6)

Psychological therapy

Yes	2 (5.3)
No	32 (84.2)

Patients' clinical characteristics

Tumor site

Breast	14 (31.8)
Bones	1 (2.3)
Dermatologic	1 (2.3)
Gynecologic	1 (2.3)
Gastric	9 (20.5)
Genitourinary	1 (2.3)

Head/Neck	7 (16)
Hodgkin's	1 (2.3)
Lung	6 (13.6)
Presence of second tumor site	
Yes	6 (15.8)
No	32 (84.2)
Stage of the disease	
Under active treatment	34 (89)
In remission	4 (11)
Treatment phase	
Waiting for therapy	2 (5.3)
Active treatment	34 (89.5)
Follow-up	1 (2.6)
Type of therapy	
Chemotherapy	32 (84.2)
Radiotherapy	2 (5.3)
Pharmacotherapy	3 (7.9)
Psychopharmacological treatment	10 (26.3)

^a n, cumulative absolute frequencies; %, percentage frequencies; M, means; SD, standard deviations.

Table 2 Descriptive statistics of patients' pain and patients' perception of caregiver's empathy and compassion; caregivers' distress, empathy and compassion.

	n (%)	M (SD) ^b
<i>Patients' pain</i>		
Total Pain		21.87+/-21.12
Pain subscales		
Sensory		12.68+/-11.87
Affective		3.45+/-3.89
Evaluative		1.34+/-1.59
Miscellaneous		4.39+/-5.11
Level of Pain		
Mild	23 (60.5)	7.7+/-8.32
Moderate	11 (28.9)	35.45+/-5.82
Severe	4 (10.5)	66+/-8.2
<i>Patients' perceived empathy</i>		
Total Perceived Empathy		135.86+/-13.18
Level of Perceived Empathy		
Low	0	
Medium	37 (97.4)	135.83+/-3.97
High	1 (2.6)	149.92+/-7,32
<i>Patients' perceived compassion</i>		
Total Perceived Compassion		55.53+/-9.6
Level of Perceived Compassion		
Low	0	

Medium	17 (44.7)	50.24+/-3.59
High	21 (55.3)	63.53+/-4.98
<i>Caregivers' distress</i>		
Total Distress		4.71+/-2.18
Level of Distress		
Mild	14 (36.8)	2.79+/-1.25
Moderate	15 (39.5)	5.73+/-0.88
Severe	9 (23.7)	8.67+/-1.15
Reported Problems		
In practical sphere	13 (34.2)	
In relational sphere	6 (15.8)	
In emotional sphere	32 (84.2)	
In spiritual sphere	3 (7.9)	
In physical sphere	30 (78.9)	
Emotional Problems		
Depression	3 (7.9)	
Fears	11 (28.9)	
Irritability	12 (31.5)	
Sadness	17 (44.7)	
Worry	24 (63.2)	
Loss of interest in daily activities	8 (21.5)	
<i>Caregivers' empathy</i>		
Total Empathy		145.28+/- 13.77
Level of Empathy		
Low	0	

Medium	31 (81.6)	137.73+/-4.17
High	7 (18.4)	159+/-8.97
<i>Caregivers' compassion</i>		
Total Compassion		53.78+/- 8.59
Level of Compassion		
Low	0	
Medium	19 (50)	46.5+/-4.34
High	19 (50)	60.68+/-5.15

^b n, cumulative absolute frequencies; %, percentage frequencies; M, means; SD, standard deviations.