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Research paper

The interplay between childhood trauma, hopelessness, depressive symptoms, and mental pain in a large sample of patients with severe mental disorders: A network analysis

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ABSTRACT

Background: Mental pain represents a significant risk factor for suicidal behavior in severe mental disorders. The present study aims to investigate the interplay between childhood traumatic experiences, hopelessness,

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Hopelessness
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Psychache
Severe mental illness

depressive symptoms and mental pain, using a network analysis approach in a large transdiagnostic sample of participants living in the community.
Methods: The present investigation was conducted using data gathered in a multicentric observational cross-section study organized as a joint project, including different Italian research and clinical settings. Considering the assessment tools adopted in the study, 12 different variables were included as nodes in the EBICglasso network analysis. Stability of the edges and of centrality indices were assessed using bootstrap procedures, considering case-dropping and node-dropping procedures.
Results: A total of 2147 participants were included in the analysis**.** Mental pain represents a central feature in a complex network of relationships, including traumatic experiences, hopelessness, and depressive symptoms. More in deatail, mental pain and, to a lesser extent, affective and cognitive depressive symptoms emerged as the most central and influential nodes of the network, highlighting the strong link existing between these aspects and their importance in the lives of people with mental disorders.
Conclusions: Results confirm the importance of mental pain as a transdiagnostic feature, requiring careful assessment and consideration in all patients, beyond the diagnostic categories and regardless of suicide risk. Assessing and managing the presence and severity of mental pain should be taken into account in clinical practice, in the perspective of providing significant clinical benefits, as well as relevant research insight.

1. Introduction

1.1. Background

Mental pain, also known as psychache, moral pain, psychic pain, emotional pain or psychological pain, can be defined as a condition of clinically significant distress characterized by mental suffering and inner torment (Fava et al., 2019; Pompili, 2024). In many instances, it can be considered as similar to somatic or physical pain. Still, the sensation of hurt is entirely determined by conditions that are within the mind of the individual experiencing it, such as shame, guilt, grief, humiliation, hopelessness, loneliness, sadness or anguish (Shneidman, 1999). It encompasses a wide range of subjective experiences, characterized by strong negative feelings (Orbach et al., 2003a).

Mental pain is strongly related to suicide and suicidal ideation; in fact, ending what is considered as an intolerable level of mental pain may represent one of the main drives underlying suicidal thoughts and behaviors (Orbach et al., 2003a; Shneidman, 1976, 1993). However, it carries considerable importance also beyond the field of suicidology: a considerable measure of mental pain can also be observed in individuals who do not present suicidal ideation or behaviors, and it equally requires to be addressed and treated, as highlighted and discussed in a recent review (Pompili, 2024).

Mental pain can also be considered an important patient-reported outcome, as it has to be directly reported by the patient and takes into essential account the subjective view and personal experiences (Fava et al., 2019): in this regard, it also represents a topic that is recently gaining increasing interest, as patient-reported outcomes allow for the development of more patient-centric interventions and treatments (Basch Ethan, 2017; Sartorius, 2014) and are becoming increasingly prioritized in clinical trials (Kieffer et al., 2020).

Mental pain may represent one the core features of major depressive dsorders, as the anguish and painful tension that can frequently be observed in depressive episodes are inexorably linked to this negative mental state (American Psychiatric Association, 2013; Maj et al., 2020). However, mental pain is not an exclusive feature of major depressive disorders: it can occur even in the absence of depressive symptoms and can be observed and measured in the context of other conditions, such as anxiety disorders (Guidi et al., 2019), eating disorders (Nordbø et al., 2006; Schmidt and Treasure, 2006), post-traumatic stress disorders (Monson et al., 2004), obsessive-compulsive disorders (Hezel et al., 2012), and schizophrenia spectrum disorders (Baker, 1996). People with personality disorders, in particular borderline personality disorder, may show a wide range of intense negative feelings that are all closely linked to considerable levels of mental pain (Lieb et al., 2004; Zanarini et al., 1998). In this regard, mental pain can be truly considered as a transdiagnostic feature in the field of clinical psychiatry (Fava et al., 2019).

The relationship between mental pain and other important transdiagnostic features related to suicide, such as depressive symptoms, hopelessness, and childhood traumatic experiences, is a complex and articulate one. The role of mental pain as a mediator of effect between childhood trauma (Pompili et al., 2022a), or depressive symptoms (Pompili et al., 2022b), and increased suicide risk has already been explored in recent studies.

However, the analyses conducted in these studies were based on previously formulated hypotheses. In contrast, the complex relationship between these different transdiagnostic dimensions, independently from suicide risk, remains to be investigated with approaches that do not include a-priori assumptions, such as a network analysis approach. This approach could provide further insight into the relations between these dimensions and regarding the influence of specific domains, and confirm or confute the centrality of mental pain as a transdiagnostic dimension.

1.2. Aim

The present study aims to explore the interplay between childhood traumatic experiences, hopelessness, depressive symptoms and mental pain using a network analysis approach in a large transdiagnostic sample of participants living in the community.

2. Materials and methods

2.1. Study design

The present investigation was conducted using data gathered in a multicentric observational cross-sectional study organized as a joint project, including different Italian research and clinical settings (Pompili et al., 2022a).

The study was approved by the Internal Review Board of the Sant'Andrea Hospital (approval code 4646_2017) as part of the Sapienza University of Rome, acting as the coordinating center, as well as by the internal review boards and local ethical committees of individual participating and collaborating centers. The study was conducted according to the World Medical Association Declaration of Helsinki. Each participant provided written informed consent. The recruitment process took place from December 2017 to March 2020.

More details on study procedures and participant recruitment process can be found in previous study reports (Pompili et al., 2022a, 2022b).

2.2. Participants

Participants were assessed for the presence of psychiatric diagnoses according to the criteria of the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) (American Psychiatric Association, 2013) confirmed using the Structured Clinical Interview for DSM-

IV Axis I Disorders (SCID-I), via psychiatric interviews and the administration of psychometric instruments.

Participants were included in the study if they had an age between 18 and 65 years or above 65 years, lacking medical comorbidities that could constitute significant living impairment and reduced overall quality of life, if they were willing to participate, and provided written informed consent. Exclusion criteria for the study were neurologic diseases (such as dementia, Parkinson's disease, epilepsy), cognitive impairments, and language difficulties that could limit the assessment process.

Participant data was managed using a web-based system with codes and anonymous labels devised specifically for the study. Investigators belonging to individual centers registered all data using a guided digital procedure to minimize data entry errors.

2.3. Assessments

Individual investigators from each participating center were instructed regarding the recruitment process. They were also trained to use study assessment tools and had constant contact with the coordinating center.

A dedicated form was used to collect participants' sociodemographic and clinical characteristics. Assessment tools used in the present analyses included the Beck Depression Inventory-2 (BDI-2) (Beck et al., 1996), the Beck Hopelessness Scale (BHS) (Beck and Steer, 1988), the Childhood Trauma Questionnaire (CTQ) (Bernstein et al., 1998), the Orbach & Mikulincer Mental Pain Questionnaire (OMMP) (Orbach et al., 2003b). Self-report measures were preferred to investigate patients' lived experiences (Sartorius, 2014).

The BDI-2 is a frequently used self-report instrument that evaluates the presence and severity of depressive symptoms over a period of 14 days and includes a total of 21 items (Beck et al., 1996). BDI-2 items were introduced in the network analysis according to a three-factor structure: Cognitive Factor (BDI_Cog), Affective Factor (BDI_Aff), and Somatic Factor (BDI_Som) (Huang and Chen, 2015; Manian et al., 2013).

The BHS is a self-report measure of trait hopelessness regarding the future, with higher scores showing more severe hopelessness, good psychometric properties, and composed of 20 items (Beck and Steer, 1988; Pompili et al., 2013). BHS items were introduced in the network analysis using the three-factor structure devised by the scale Authors, including the factors Expectations of Success (BHS_ES), Expectations of Failure (BHS_EF), and Future Uncertainty (BHS_FU) (Beck et al., 1974; Dyce, 1996).

The CTQ is a self-report questionnaire assessing the presence and severity of different types of trauma composed of 28 items (Bernstein et al., 1998). The scale is composed of 5 domains that were included in the network analysis: emotional neglect (CTQ_EN), physical neglect (CTQ_PN), emotional abuse (CTQ_EA), physical abuse (CTQ_PA), and sexual abuse (CTQ_SA).

The OMMP is a self-report measure of mental pain intensity composed of 44 items (Orbach et al., 2003b), that includes detailed questions on cognitive and affective elements (Pompili et al., 2008). Considering that the OMMP does not present a defined domain or factor structure (Casanova et al., 2021), the OMMP total score was included in the analysis.

2.4. Data analysis

Considering the assessment tools adopted in the study, 12 different variables were included in the network analyses.

Network plots represent the interplay among different variables, identified as nodes, with the between-variables correlations represented as edges. In the present work, blue edges have been used to identify positive correlations, while red edges to identify negative correlations, with thicker edges representing stronger correlations.

Zero-order correlations matrix and network were used to visually represent the association between variables.

An EBICglasso model, which accounts for the total covariance in the correlation matrix, was used for the final network analysis model. A conservative tuning parameter (γ) of 0.5 was adopted (Hevey, 2018).

Centrality indices of betweenness, closeness, strength and expected influence were computed to assess the relevance of each node within the network and were graphically represented with the use of centrality plots as standardized z scores.

Betweenness reflects the number of times a given node lies on the shortest path between any other two nodes. Closeness represents the inverse of the total length of the shortest paths between the considered node and all other network nodes. Strength is the total sum of correlations between a considered node and all connected nodes. Finally, expected influence is the sum of all connections of a given node, which also considers the correlation's directionality (Bringmann et al., 2019).

Robustness and stability of the network and of centrality indices were assessed using bootstrap procedures with 1000 iterations, considering case-dropping and node-dropping procedures (Epskamp et al., 2018).

Data management and descriptive statistics were performed using SPSS version 28.0.

Network analyses and plots were designed using JASP version 0.17.30.

3. Results

A total of 2147 participants were included in the original study and in the dataset used for the present network analysis.

Details regarding the sociodemographic and clinical characteristics of the sample and scores on each domain of included scales can be found in Table 1.

Network analysis plot for the EBICglasso model is reported in Fig. 1.

Nodes tended to form clusters based on the construct to which they belonged, with most variables belonging to a specific scale emerging as strongly associated between them.

In particular, both somatic and cognitive aspects of depressive symptoms were strongly linked to the affective dimension of depression and were less strongly related to each other. Cognitive symptoms were also related to emotional abuse and future uncertainty.

As regards traumatic experiences, physical and emotional neglect were strongly linked, as were physical and emotional abuse; sexual abuse was mostly linked to physical abuse and, less strongly, to emotional abuse and physical neglect. Emotional neglect was also related with a decrease in expectations of success, and emotional abuse was related to a reduction in expectations of success, as well as cognitive symptoms of depression. Hopelessness dimensions were similarly related to each other.

Mental pain represented a convergence point between depressive, hopelessness and trauma domains, having a direct correlation with all nodes in the network, except somatic aspects of depressive symptoms; stronger correlations were observed with depressive and hopelessness symptoms than with trauma domains.

Centrality indices values and plots are reported in Table 2 and Fig. 2, respectively.

Mental pain showed the highest centrality in the network, representing the node with the highest closeness and also showing high levels of betweenness, strength, and expected influence.

Emotional abuse showed high levels of betweenness; affective symptoms of depression showed high levels of strength and expected influence, but this may be related to the strong correlation between affective symptoms and cognitive and somatic symptoms of depression.

Sexual abuse represented the most peripheral node in the network, with low scores on all centrality indices. Somatic symptoms of depression and expectations of failure also showed low levels of betweenness.

The zero-order correlation matrix and the relative network plot are reported in Supplementary Table 1 and Supplementary Fig. 1,

Table 1
Socio-demographic and clinical characteristics of the sample.

Variable	mean (± SD); n (%)
Age (years)	42.87 (±15.01)
Gender	
Male	828 (38.6 %)
Female	1319 (61.4 %)
Marriage status	
Married	703 (32.7 %)
Divorced	274 (12.8 %)
Widowed	71 (3.3 %)
Unmarried	1076 (50.1 %)
Other/Did not disclose	23 (1.1 %)
Work situation	
Employed	1077 (50.2 %)
Unemployed	749 (34.9 %)
Retired	225 (10.5 %)
Other/Did not disclose	96 (4.4 %)
School Attainment	
≤ 8 years	683 (31.8 %)
= 13 years	1060 (49.4 %)
≥ 6 years	385 (17.9 %)
Other/Did not disclose	19 (8.9 %)
Recruitment setting	
Inpatient	662 (30.8 %)
Outpatient	1485 (69.2 %)
Diagnosis	
Schizophrenia Spectrum Disorders	293 (13.6 %)
Bipolar Disorder	437 (20.4 %)
Major Depressive Disorder	558 (26.0 %)
Anxiety Disorder	104 (4.8 %)
Post-traumatic Stress Disorder	101 (4.7 %)
Eating Disorder	235 (10.9 %)
Borderline Personality Disorder	76 (3.6 %)
Other Personality Disorder	100 (4.7 %)
Other	243 (11.3 %)
Substance Abuse Present	209 (9.7 %)
BDI_Cog (score)	12.18 (±7.51)
BDI_Aff (score)	9.34 (±5.58)
BDI_Som (score)	11.07 (±5.82)
BHS_ES (score)	3.75 (±2.88)
BHS_EF (score)	1.72 (±1.85)
BHS_FU (score)	2.86 (±1.52)
CTQ_EN (score)	13.05 (±5.87)
CTQ_PN (score)	8.20 (±3.17)
CTQ_EA (score)	9.36 (±4.76)
CTQ_PA (score)	6.71 (±3.32)
CTQ_SA (score)	6.67 (±3.87)
OMMP (score)	111.74 (40.59)

BDI_Cog: Beck Depression Inventory, Cognitive Factor; BDI_Aff: Beck Depression Inventory, Affective Factor; BDI_Som: Beck Depression Inventory, Somatic Factor; BHS_ES: Beck Hopelessness Scale, Expectation of Success Factor; BHS_EF: Beck Hopelessness Scale, Expectation of Failure Factor; BHS_FU: Beck Hopelessness Scale, Future Uncertainty Factor; CTQ_EN: Childhood Trauma Questionnaire, Emotional Neglect Domain; CTQ_PN: Childhood Trauma Questionnaire, Physical Neglect Domain, CTQ_EA: Childhood Trauma Questionnaire, Emotional Abuse Domain; CTQ_PA: Childhood Trauma Questionnaire, Physical Abuse Domain; CTQ_SA: Childhood Trauma Questionnaire, Sexual Abuse Domain; OMMP: Orbach & Mikulincer Mental Pain Questionnaire.

respectively; in this network, the central role of mental pain is more clearly confirmed.

Edge weight stability assessed using nonparametric bootstrapping procedures is reported in Supplementary Fig. 2. Overall, the network presented remarkable edge weight stability, with very few edges showing overlapping confidence intervals.

Centrality indices stability is reported in Supplementary Fig. 3. Centrality indices had acceptable stability; in particular, high-centrality nodes such as mental pain, affective symptoms of depression, and cognitive symptoms of depression retained valuable centrality indices.

Case-dropping bootstrap results for edges and centrality indices are reported in Supplementary Fig. 4 and Supplementary Fig. 5. The network showed remarkable stability in case-dropping bootstrap analyses.

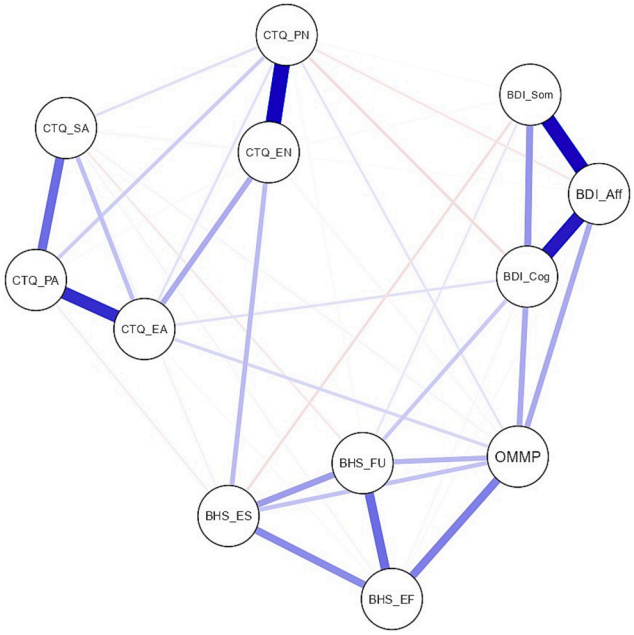

Fig. 1. Network analysis plot (EBICglasso model).
DI_Cog: Beck Depression Inventory, Cognitive Factor; BDI_Aff: Beck Depression Inventory, Affective Factor; BDI_Som: Beck Depression Inventory, Somatic Factor; BHS_ES: Beck Hopelessness Scale, Expectation of Success Factor; BHS_EF: Beck Hopelessness Scale, Expectation of Failure Factor; BHS_FU: Beck Hopelessness Scale, Future Uncertainty Factor; CTQ_EN: Childhood Trauma Questionnaire, Emotional Neglect Domain; CTQ_PN: Childhood Trauma Questionnaire, Physical Neglect Domain, CTQ_EA: Childhood Trauma Questionnaire, Emotional Abuse Domain; CTQ_PA: Childhood Trauma Questionnaire, Physical Abuse Domain; CTQ_SA: Childhood Trauma Questionnaire, Sexual Abuse Domain; OMMP: Orbach & Mikulincer Mental Pain Questionnaire.

Table 2
Centrality indices values.

Variable	Betweenness (z-score)	Closeness (z-score)	Strength (z-score)	Expected Influence (z-score)
BDI_Cog	−0.247	0.164	1.246	0.893
BDI_Aff	0.412	−0.273	1.953	1.738
BDI_Som	−1.236	−1.166	−0.445	−0.650
BHS_ES	0.247	0.952	−0.547	−0.983
BHS_EF	−0.247	0.966	−0.367	0.115
BHS_FU	−1.236	0.061	−0.450	−0.308
CTQ_EN	0.906	0.510	−0.140	0.040
CTQ_PN	−0.742	0.064	0.121	−0.633
CTQ_EA	1.730	0.073	0.123	0.549
CTQ_PA	0.412	−0.857	−0.252	−0.136
CTQ_SA	−1.236	−2.060	−2.020	−1.856
OMMP	1.236	1.565	0.779	1.232

BDI_Cog: Beck Depression Inventory, Cognitive Factor; BDI_Aff: Beck Depression Inventory, Affective Factor; BDI_Som: Beck Depression Inventory, Somatic Factor; BHS_ES: Beck Hopelessness Scale, Expectation of Success Factor; BHS_EF: Beck Hopelessness Scale, Expectation of Failure Factor; BHS_FU: Beck Hopelessness Scale, Future Uncertainty Factor; CTQ_EN: Childhood Trauma Questionnaire, Emotional Neglect Domain; CTQ_PN: Childhood Trauma Questionnaire, Physical Neglect Domain, CTQ_EA: Childhood Trauma Questionnaire, Emotional Abuse Domain; CTQ_PA: Childhood Trauma Questionnaire, Physical Abuse Domain; CTQ_SA: Childhood Trauma Questionnaire, Sexual Abuse Domain; OMMP: Orbach & Mikulincer Mental Pain Questionnaire.

Finally, node-dropping bootstrap results are reported in Supplementary Fig. 6 for edge stability and in Supplementary Fig. 7 for centrality stability.

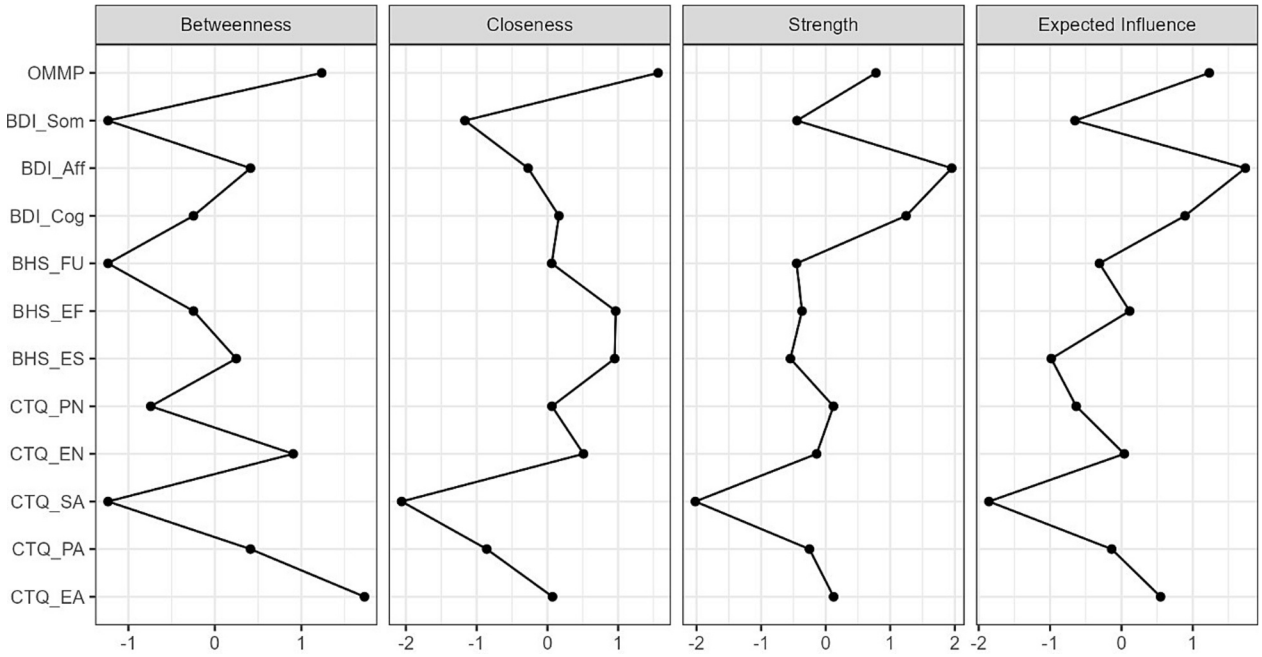

Fig. 2. Centrality indices plots.
DI_Cog: Beck Depression Inventory, Cognitive Factor; BDI_Aff: Beck Depression Inventory, Affective Factor; BDI_Som: Beck Depression Inventory, Somatic Factor; BHS_ES: Beck Hopelessness Scale, Expectation of Success Factor; BHS_EF: Beck Hopelessness Scale, Expectation of Failure Factor; BHS_FU: Beck Hopelessness Scale, Future Uncertainty Factor; CTQ_EN: Childhood Trauma Questionnaire, Emotional Neglect Domain; CTQ_PN: Childhood Trauma Questionnaire, Physical Neglect Domain, CTQ_EA: Childhood Trauma Questionnaire, Emotional Abuse Domain; CTQ_PA: Childhood Trauma Questionnaire, Physical Abuse Domain; CTQ_SA: Childhood Trauma Questionnaire, Sexual Abuse Domain; OMMP: Orbach & Mikulincer Mental Pain Questionnaire.

4. Discussion

Mental pain and, to a lesser extent, affective and cognitive depressive symptoms emerged as the most central and influential nodes of the network, highlighting the strong link existing between these aspects and their importance in the lives of people with mental disorders (Pompili et al., 2022b). These results confirm the importance of mental pain as a transdiagnostic feature, requiring careful assessment and consideration in all patients beyond the diagnostic categories and regardless of suicide risk (Fava et al., 2019; Pompili, 2024).

Sexual abuse emerged as a peripheral node in the network, showing low scores on all centrality indices: this could partly be due to frequent minimization and denial issues, as well as recall bias, regarding this particular domain (MacDonald et al., 2016; MacDonald et al., 2015).

Somatic symptoms of depression represent another peripheral node: this is in line with reports of previous studies performing factor analyses that combined affective and somatic symptoms into a single factor (Arnau et al., 2001; Beck et al., 1996; Faro and Pereira, 2020; Vanheule et al., 2008).

The present study has some considerable points of strength. To the best of our knowledge, this study represents the first transdiagnostic assessment of the interplay between trauma, hopelessness, depressive symptoms, and mental pain conducted using a network analysis approach. While the effect of trauma and depression in increasing mental pain and the consequent role of mental pain in suicide attempts has already been explored in mediation analyses (Pompili et al., 2022a), this study represents the first assessment of the relationship between these variables conducted without a-priori hypotheses regarding the centrality of specific variables.

Moreover, the large sample size allowed accurate analyses; in particular, the large number of included participants, combined with the relatively restricted number of nodes included in the analyses, provided a network with remarkable stability, particularly in case-dropping assessments. Centrality indices stability decreased significantly to the node-dropping evaluation: in fact, it is well-known that dropping nodes, particularly in models with fewer variables, can rapidly lead to very different networks and very different centrality indices; for this reason, these analyses are not always recommended and should be interpreted with care (Epskamp et al., 2018). However, the rapid decrease in centrality indices stability in node-dropping analyses could also be interpreted as showing the importance of each node in the network, highlighting how the explored model can be considered parsimonious and include only variables of interest.

Some limitations have to be taken into account. The present study included participants with several different psychiatric diagnoses, leading to a heterogeneous sample. In this regard, the findings of the present study could not be well generalized to different contexts, and the observed results could differ substantially in specific clinical populations. However, this also highlighted the transdiagnostic importance of the explored constructs. Exploring the network structure of the included variables in diagnostically homogeneous samples and comparing the networks observed in different diagnostic groups represent an interesting perspective for future research.

Finally, while mental pain is strongly related to suicide attempts, suicide-related outcomes were not included in the present work. Therefore, no information is reported one of the most important and clinically relevant correlates of mental pain; in fact, mental pain is often assessed specifically in relation to suicidal behavior and suicide attempts in clinical settings. Assessing the interaction between trauma, hopelessness, depressive symptoms and mental pain, comparing their network structure in participants with and without death thoughts, suicide ideation, and suicide attempts represents another important future study perspective.

5. Conclusions

Mental pain represents a central and relevant feature in a complex network of relationships, including traumatic experiences, hopelessness, and depressive symptoms in a large sample of patients with severe mental disorders. Assessing and managing the presence and the severity

of the mental pain dimension should be taken into account in psychiatric practice, regardless of the patient's diagnosis and suicide risk profile, in the perspective of providing significant clinical benefits, as well as relevant research insight.

CRediT authorship contribution statement

Stefano Barlati: Writing – original draft, Validation, Supervision, Methodology, Investigation, Conceptualization. **Marco Innamorati:** Writing – review & editing, Methodology, Formal analysis, Data curation. **Antonio Vita:** Writing – review & editing, Validation, Supervision, Conceptualization. **Gabriele Nibbio:** Writing – original draft, Investigation, Formal analysis, Conceptualization. **Denise Erbuto:** Writing – review & editing, Investigation, Data curation. **Salvatore Sarubbi:** Writing – review & editing, Investigation. **Valeria del Vecchio:** Writing – review & editing, Investigation. **Mario Luciano:** Writing – review & editing, Investigation. **Gaia Sampogna:** Writing – review & editing, Investigation. **Giovanni Abbate-Daga:** Writing – review & editing, Investigation. **Claudia Carmassi:** Writing – review & editing, Investigation. **Giovanni Castellini:** Writing – review & editing, Investigation. **Pasquale De Fazio:** Writing – review & editing, Investigation. **Giorgio Di Lorenzo:** Writing – review & editing, Investigation. **Marco Di Nicola:** Writing – review & editing, Investigation. **Silvia Ferrari:** Writing – review & editing, Investigation. **Arianna Goracci:** Writing – review & editing, Investigation. **Carla Gramaglia:** Writing – review & editing, Investigation. **Giovanni Martinotti:** Writing – review & editing, Investigation. **Maria Giulia Nanni:** Writing – review & editing, Investigation. **Massimo Pasquini:** Writing – review & editing, Investigation. **Federica Pinna:** Writing – review & editing, Investigation. **Nicola Poloni:** Writing – review & editing, Investigation. **Gianluca Serafini:** Writing – review & editing, Investigation. **Maria Signorelli:** Writing – review & editing, Investigation. **Alfonso Tortorella:** Writing – review & editing, Investigation. **Antonio Ventriglio:** Writing – review & editing, Investigation. **Umberto Volpe:** Writing – review & editing, Investigation. **Andrea Fiorillo:** Writing – review & editing, Validation, Supervision, Project administration, Investigation, Conceptualization. **Maurizio Pompili:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Conceptualization.

Author contributions

S.B., G.N., A.V., A.F. and M.P. prepared the study design. S.B. and G. N. prepared the manuscript's first draft. G.N and M.I. performed the data analyses. All authors contributed substantially to and approved the final version of the paper.

Ethical standards

The study was approved by the Internal Review Board of Sant'Andrea Hospital (RIF.CE: 4646_2017) as part of the Sapienza University of Rome, the study coordinator, and by the local ethics committee of the participating centers. The study was performed in accordance with the Declaration of Helsinki. All patients gave their written informed consent.

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Declaration of competing interest

The authors declare no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jad.2025.03.185.

Data availability

All the data that support the findings of this study are available within the article and its supplementary material. The ethics committee did not grant permission to share study data with third parties or upload data anonymously.

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