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Clinical staging and PID-5: a dimensional approach to diagnosis in the early stages of psychopathology

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SUMMARY

Objective

The study presents the data on the use of a dimensional model complementary to the traditional categorical diagnosis, specifically applied to the mental health of young people and to the early clinical stages of emerging psychiatric disorders and psychosis.

Methods

For this goal, the data obtained from the assessment of young users were collected; subjects recruited were the first 100 attending at the Child and Adolescent Neuropsychiatry and Psychiatry Services of the ASST Melegnano and Martesana in the period 2018-2020, and enrolled in the Regional Innovative Projects dedicated to psychic disorders at a young age. The traditional diagnosis and the assessment of the mental state at risk were compared with the PID-5 Personality Inventory indexes (version extended to 220 items), based on the alternative model for personality disorders of Section III of DSM-5; we considered Domains, Traits and the specific psychopathological indices relating to Psychoticism domain.

Results

our data show that the more one advances in the progression stage of the disease (identified by the mental state at risk), the more there is a concordance with the traditional diagnosis. The diagnostic dispersion is higher in less vulnerable group. Our findings also suggest that PID-5 facets are more articulated in less compromised subjects and more coherent in the pre- and psychotic groups.

Conclusions

The finding of transversal, polymorphic and fluid pathological traits between the different diagnostic categories, especially in subjects in which a vulnerability in the level of risk of the mental state is recognized, suggest the usefulness of a dimensional approach complementary to traditional diagnosis, at least in the early stages of psychopathology.

Key words: early interventions, PID-5, personality disorders, dimensional psychopathological models, early onset psychopathology

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Introduction

This study is based on the model of Clinical Staging in psychiatry, a relatively new proposal for an alternative heuristic approach to diagnosis, especially in the early clinical stages of emerging mental disorders [1,2].

The model, derived from other medical branches [3,4], in particular oncology, was initially proposed by Fava and Kellner [5] as a "neglected dimension of the psychiatric classification", limited to mood disorders, and systematized more extensively by McGorry's Australian research group on Early Intervention in Psychosis [1].

This area of research started from the consideration that "the diagnosis is essentially a classification with utility" [6]; clinical researchers have oriented towards the search for alternative and / or complementary heuristic models

to categorical diagnostic systems, considering that, in the latter, the first clinical forms are not differentiated from those which apparently become persistent disorders. The traditional diagnostic approach of DSM 5 and ICD 10 had an absolute merit: they created a common language in the diagnostic field for clinicians and researchers and they gave an operational description of psychiatric diagnoses; the same models have, nevertheless, a mail limitation: they are derived from samples of patients with overt and chronic pathologies, in tertiary care contexts. Therefore, this type of diagnosis can be reliably used only in contexts in which such pathologies represent a stable outcome. They are less useful tools to guide early intervention [7] or the treatment of people with disorders less severe or in an initial phase [8]. In the field of youth mental health this problem is significantly more evident. In this specific population, evolving syndromic patterns are the norm, early clinical phenotypes are fluid, dynamic and pluripotential. The urgent need for management long before a traditional diagnosis can be defined is essential to reduce the risk of developing more elaborate, persistent, recurrent and disabling syndromes.

The McGorry's group model attributes the young subjects to one of the stages of psychopathological progression: Stage 0 - asymptomatic subjects and population at risk, Stage 1a - Non-specific anxiety and depressive syndromes, Stage 1b - Attenuated psychiatric syndromes, Stage 2 - First psychotic episode, Stage 3 - Recurrence or Persistence, Stage 4 - Chronicity [8,9]. This model therefore proposes a diagnostic classification organized along a continuum, recognizing that in the general population exists a wide range of illness / mental health expressions, widespread, below the diagnostic threshold and relatively non-specific. Emphasis is placed on a wider and transdiagnostic level of preclinical manifestations or early or prodromal clinical states. These states are recognized as having a potential for suffering, dysfunctionality and need for care, which must be intercepted long before the achievement of traditional diagnostic clarity, since in this condition the recovery potential appears significantly lower (Early Intervention, EI). According to the available experimental data, the same "categorical" DSM 5, in its Section III, proposes both alternative diagnostic approaches and a more dimensional perspective [10,11]. Of particular interest for the present work are the diagnostic models of the attenuated psychosis syndrome and the alternative model for describing personality disorders, the practical utility of which will be verified in this work using the operative tool of investigation proposed by DSM 5 for personality disorders, the Personality Inventory for DSM-5, PID-5 [12,13].

Starting from this theoretical frame of reference, of great relevance in the EI panorama [14], we wanted to verify how this approach can prove to be clinically useful, in a complementary way and alongside the traditional psychiatric diagnosis. In particular, we compared and put in correlation the categorical and dimensional / stage diagnosis. The stages used in this study are not exactly superimposable to the more refined and even broader spectrum ones described by McGorry and listed above, however we describe the risk level of actual mental state according to a progressive stage model represented by Groups as below described. Furthermore, we assessed the coexistence of transversal psychopathological traits using the Personality Inventory for DSM-5, PID-5 [12,13]. It is a self-administered questionnaire, proposed in the Italian validated 220-item version [15,16]. Finally, we wanted to investigate specifically the Psychoticism Domain of the Scala and its predictivity, according to the patient's self-assessment, in the sample of CHR (Clinical High Risk) and ARMS (At Risk Mental State) subjects. In fact, these are the categories historically taken over by EI projects, before they extended to prevention in a transdiagnostic perspective.

Assuming that (a) psychotic disorders in the early stages have a multifaceted clinical presentation and (b) different mental disorders in comorbidities or co-occurrence are very often recognized, classical diagnostic stability is poor making difficult to set up an effective and early treatment plan. It therefore becomes fundamental to evaluate how much these nonspecific and fluctuating symptoms may reflect more stable psychopathological dimensions that extend beyond the traditional boundaries of the classical diagnostic classification [8]. The goal is to bring diagnostic fluidity back to a more stable dimensional system that allows a more effective diagnosis and possible interventions in the young clinical population.

Materials and methods

This research recruited the first 100 patients enrolled in the Departmental Project of the ASST Melegnano and Martesana, North Area, dedicated to Mental Health in the young age (14-24 yrs. age), over the period June 2018 - December 2020. This project integrates two Regional funded projects relating respectively to Psychiatry (Prevention and Early Intervention of psychiatric disorders in youths) and to Neuropsychiatry of Childhood and Adolescence (Adolescents with Psychiatric Disorders).

The articulated assessment, shared between the participating Services, included different Scales and Inventories:

1. PID-5 (Personality Inventory for DSM-5), in the extended form to 220 items, in its Adult (> 18 years) and Adolescents (11-17 years) versions;
2. PQ 16 (Questionnaire for prodromal symptoms);
3. SOFAS (Social and Occupational Functioning Assessment Scale);

4. GAF (Global Assessment of Functioning Scale);
5. CAARMS (Comprehensive Assessment of at-risk Mental States) in selected cases worthy of further study.

In the present study, the evaluation will be focused only on the data of the PID-5 Inventory, self-assessment form. The results were analyzed according to Krueger et al. scoring for the Adult version [15] and to the adolescent normative sample described in Fossati et al. [16]. PID-5 offers a trait assessment on a multiple psychopathological spectrum, providing a multidimensional assessment relating to both personality disorders and psychotic phenomena. The inventory is made up of 5 Domains (Negative Affectivity, Detachment, Antagonism, Disinhibition, Psychoticism) and 25 traits or facets (Anxiety, Emotional Liability, Hostility, Perseveration, Reduced Affection, Separation Anguish, Submission, Anhedonia, Depressivity, Avoidance of intimacy, Suspiciousness, Withdrawal, Attention seeking, Insensitivity, Deception, Grandiosity, Manipolarity, Distractibility, Impulsiveness, Rigid perfectionism, Tendency to take risks, Irresponsibility, Eccentricity, Perceptual dysregulation, Unusual beliefs and experiences).

The inventory is present, in its extended form used here, both as a self-assessment and as a hetero-assessment by a family member or even a clinician. Each case was also evaluated by a clinician according to traditional diagnosis (ICD-10) and attributable mental state risk, according to one of the following risk levels: Group 0 = no psychotic vulnerability, Group 1 = vulnerable subjects, Group 2 = attenuated psychosis, Group 3 = Brief Limited Intermittent Psychotic Symptoms (BLIPS), Group 4 = psychosis / antipsychotic treatment threshold.

Statistical analysis

Statistical analysis was conducted using IBM® SPSS® Statistics rel. 27. Descriptive statistics (frequencies and ranks) were used to summarize data as in tables I to VI. Due to the small number of cases and the not normal distribution of ordinal variables the authors choosed to adopt a non-parametric statistical approach. Subjects were aggregated according to different criteria (see after) and the derived groups were compared using non-parametric statistics (χ^2 statistics for frequencies distribution among groups and rank analysis with Kruskall-Wallis test for multiple independent samples for ranks distribution in the different groups).

The aggregation criteria used to constitute the comparison groups are as follows:

- mental state at risk (Group 0 = no psychotic vulnerability, Group 1 = vulnerable subjects, Group 2 = attenuated psychosis, Group 3 = BLIPS, Brief Limited Intermittent Psychotic Symptoms, Group 4 = threshold psychosis / antipsychotic treatment);
- traditional diagnostic categories according to ICD-10;
- number of pathological Domains of the PID-5 (higher than the 90th percentile);
- number of pathological Facets (above 90th percentile) of the PID-5, grouped by range (< 5, between 5 and 10, > 10);
- value in the Psychoticism domain of PID-5 according to the following operational classification: Normal (< 75th percentile), Sensitive (between 75th and 90th percentile), Pathological (above 90th percentile).

Results

The sample is composed of 100 subjects, of which 52 females and 48 males; the average age is 19.2 years (sd 2.5), in the female sample the age was slightly lower than in the male sample (18.6 sd 2.6 *vs* 19.8 sd 2.2), the difference was not statistically sound.

Table I lists the diagnoses according to the ICD-10 diagnostic macro-aggregations. The sample sees a significant prevalence of subjects belonging to the psychotic and affective spectrum and to the area of personality disorders.

Based on the at-risk mental state categorization, almost half of the sample fell within the category of vulnerable people. The most interesting finding, however, is that 39% of the sample already had clinically significant conditions (Tab. II). For subsequent analyses, due to the minimal number of Group 3 (BLIPS N = 1), the only patient in this group was aggregated to Group 4 (Threshold/Antipsychotic treatment) as the clinical picture was similar.

Furthermore, we wanted to highlight the distribution of diagnoses by diagnostic classes and of mental state at risk, grouped by sex.

Diagnoses F0, F1, F7, F8, and F9 were then grouped in a “mixed category” in order to give greater prominence to the more specific categories with respect to the project (psychotic disorders, affective disorders, personality disorders, disorders afferent to the neurotic spectrum). According to the literature data, a different distribution emerges with respect to sex: in the male sample symptoms of the psychotic spectrum occur more frequently than in the female sample, where diagnosis of neurosis and personality disorder are more represented (χ^2 = 18.68, df 4, = 0 .0009) (Tab. I).

Compared to the mental state at risk, the distribution by sex shows significant differences, males being more represented in the psychosis threshold group (31.3%, compared to 3.8% of females), and vice versa females are more represented in the no psychotic vulnerability group (38.5%, compared to 12.5% of males) (χ^2 = 15.69, df 3, p = 0.0013) (Tab. II).

Subsequently, the analysis took into consideration the data relating to PID-5, according to the following aggregation variables:

TABLE I. *Sample distribution (n = 100) according to diagnostic classes and by sex.*

ICD-10 diagnosis		Total	Female	Male
F0	Mental disorders due to known physiological conditions	1	0	1
F1	Mental and behavioral disorders due to psychoactive substance use	2	0	2
F2	Schizophrenia, schizotypal, delusional, and other non-mood psychotic disorders	21	3	18
F3	Mood [affective] disorders	10	8	2
F4	Anxiety, dissociative, stress-related, somatoform and other nonpsychotic mental disorders	23	14	9
F6	Disorders of adult personality and behavior	32	21	11
F7	Intellectual disabilities	1	0	1
F8	Pervasive and specific developmental disorders	3	1	2
F9	Behavioral and emotional disorders with onset usually occurring in childhood and adolescence	6	5	1
X	Unspecified mental disorder	1	0	1

TABLE II. *Sample distribution (n = 100) according to at-risk mental state and by sex.*

At-risk mental state		Total sample	F (% column)	M (% column)
Group 0	No psychotic vulnerability	26	20 (38.5)	6 (12.5)
Group 1	Vulnerable subjects	45	24 (46.2)	21 (43.8)
Group 2	Attenuated psychosis	11	5 (9.6)	6 (12.5)
Group 3	BLIPS	1		
Group 4	Threshold/antipsychotic treatment	17	3 (5.8)	15 (31.3)

Group 0: no psychotic vulnerability; Group 1: vulnerable subjects; Group 2: attenuated psychosis; Group 3: BLIPS ; Group 4: psychosis threshold.

- the number of domains found to be psychopathological: 37% of the sample presented 2 or more psychopathological domains above the risk threshold (Tab. III);
- the number of traits found to be psychopathological, broken down by range; 63% of the sample presented an overall number of psychopathological traits greater than 5 (Tab. IV);
- the score of the Psychoticism Domain; in this case the sample shows a trend of the indicator towards pathological values (28% can be classified in the "Sensitive" category and 17% in the "Pathological" one) (Tab. V).

Subsequent analyses focused on a possible concordance between traditional clinical diagnoses and attribution of a mental state at risk (Tab. VI). Even with the interpretative limit deriving from the high number of cells with an expected value < 5, it emerges that the more one advances in the progression stage of the disease (identified by the mental state at risk), the more there is a concordance with the traditional diagnosis. In subjects with no psychotic vulnerability there are, in fact, mainly neurotic disorders and a range of residual diagnoses (which includes "non-psychiatric diagnosis" or "childhood onset disorders"), while the dispersion of traditional diagnoses is maximum in group 1 (vulnerable subjects) where at 46.7% we find personality disorders and the range of diagnostic categories is very wide. This dispersion is reduced in group 2 (attenuated psychosis), and at minimum in group 4, in which the agreement with the traditional diagnosis of psychotic disorder is 82.2% (χ^2 = 69.965, df 12, p < 0.0001).

PID-5 was subsequently correlated (based on the number of pathological domains) with the categorization of mental states at risk (Tab. III). The simple observation of Table III allows us to highlight how the progress in the stage of progression of the disease (identified by the mental state at risk) does not uniquely correlate with the "severity" of PID-5 (according to the total number of pathological domains identified). Indeed, paradoxically, it seems that the more severe subjects have a relatively fewer pathological domains at PID-5. The sample does not show statistically significant differences nor for analysing frequencies or analysing for ranks (χ^2 = 9.96, df 15, p = 0.822; Kruskall-Wallis H = 3.622, df 3, p = 0.305).

TABLE III. *Psychopathological domains (PID-5) total and by at-risk mental state.*

Number of psychopathological domains over the threshold	Total sample	Group 0 (% column)	Group 1 (% column)	Group 2 (% column)	Group 3 and 4 (% column)
0	41	14 (53 . 8)	14 (31.1)	5 (45.5)	8 (44.4)
1	22	3 (11.5)	12 (26.7)	2 (1 8 . 2)	5 (27.8)
2	15	4 (15.4)	6 (13.3)	1 (9.1)	4 (22 . 2)
3	15	4 (15.4)	8 (17.8)	2 (18.2)	1 (5. 6)
4	6	1 (3.8)	4 (8.9)	1 (9.1)	/
5	1	/	1 (2.2)	/	/
Tot.	100	26	45	11	18

Group 0: no psychotic vulnerability; Group 1: vulnerable subjects; Group 2: attenuated psychosis; Group 3: BLIPS ; Group 4: psychosis threshold.

TABLE IV. *Psychopathological traits (PID-5) total and by at-risk mental state.*

Number of psychopathological traits	%	Group 0 (% column)	Group 1 (% column)	Group 2 (% column)	Group 3 and 4 (% column)
< 5	37	No.	No.	No.	No.
Between 5 and 10	38	13 (50)	13 (28.9)	2 (18.2)	9 (50)
> 10	25	6 (23.1)	16 (35.6)	7 (63.6)	9 (50)
Tot.	100	7 (26.9)	16 (35.6)	2 (18.2)	/
		26	45	11	18

Group 0: no psychotic vulnerability; Group 1: vulnerable subjects; Group 2: attenuated psychosis; Group 3: BLIPS ; Group 4: psychosis threshold.

The number of pathological traits of PID-5 were then analysed according to the at-risk mental state. In this case, the differences are more evident: the psychopathologically more structured conditions (groups 2 and 3-4) are associated to a "normalization" of the pathological traits of PID-5. In addition, in this case there is a paradoxical reduction of psychopathological indices in the group of subjects at higher risk. Conditions more "fluid" with respect to the risk (groups 0 and 1) present instead a more complex facets of psychopathological manifestations (χ^2 = 14.79, df 6, p = 0.022) (Tab. IV).

We analysed the concordance between the scores of the "Psychoticism" Domain (PID-5) and at-risk mental state. Also in this case we are witnessing a paradoxical "normalization" of the pathological values in the most severe group (Group 3-4) with respect to the less serious groups, where the correlation between the normal value and the absence of vulnerability is maximum (73%) and distribution of the different pathological values is large in groups 1 and 2. This trend of results, only apparently paradoxical, will be discussed in the conclusions. (χ^2 =15.769, df 6, p = 0.015) (Tab. V).

Discussion

The analysis of the data by categorizing the sample ac-

TABLE V. *Psychoticism summary score (PID-5) total and by at-risk mental state.*

Psychoticism domain	%	Group 0 (% column)	Group 1 (% column)	Group 2 (% column)	Group 3 and 4 (% column)
Normal	55	19 (73.1)	23 (51.1)	5 (45.5)	8 (44.4)
Sensitive	28	3 (11.5)	13 (28.9)	2 (18.2)	10 (55.6)
Pathological	17	4 (15.4)	9 (20)	4 (36.4)	/
Tot.	100	26	45	11	18

Group 0: no psychotic vulnerability; Group 1: vulnerable subjects; Group 2: attenuated psychosis; Group 3: BLIPS; Group 4: psychosis threshold.

TABLE VI. *Agreement between traditional diagnostic categories and at-risk mental state.*

Main diagnosis (ICD-10)	Group 0	Group 1	Group 2	Group 3 and 4
F2 Psychotic dis.	0	1	5	15
F3 Affective dis.	2	5	2	1
F4 Neurotic dis.	11	11	1	0
F6 Personality dis.	9	21	2	0
Other diagnoses	4	7	1	2

Group 0: no psychotic vulnerability; Group 1: vulnerable subjects; Group 2: attenuated psychosis; Group 3: BLIPS ; Group 4: psychosis threshold.

cording to the subgroups defined by the level of at-risk mental state showed that the largest subgroup was that of vulnerable subjects, in line with expectations, considering the age group and the mission of the Projects to which the recruited subjects belong. In fact, 45% of the sample belongs to this group; subjects with no psychotic vulnerability represent the second largest group (26%), while the other categories are represented by preclinical conditions (psychosis threshold, 17%, and attenuated psychosis, 11%).

The analysis of concordance between "classic" diagnoses and at-risk mental state confirmed the importance of assessing this state of risk in a sample of young people with so-called early onset manifestations. In fact, beyond the obvious high concordance value between the diagnosis of psychotic spectrum and the mental state of psychosis (attenuated or manifest), what we want to underline is how in other diagnostic spectra (in particular the affective ones and, above all, of the personality) the dispersion of mental states at risk is maximum. Our data emphasize once again the importance of a functional more than a categorical evaluation to favour an early interception of the disorder.

However, the most interesting data, in our opinion, comes from the evaluation by the PID-5. The results at PID-5 on the general sample reveal the importance of conducting a more in-depth evaluation at the level of the traits, compared to that of the domains alone, which the 220-item scale allows us to grasp. In fact, if the results are analysed only at the broader level of the domains, 41% of the sample reports non-psychopathological levels. This data however appears to be overrepresented, both when compared with the diagnoses, traditional and of at-risk mental state, and with respect to traits level, in which however 37% turn out to have less than 5 and another 38% between 5 and 10. Reading the level of traits therefore allows us to identify more subtle psychopathological nuances, which are often more significant and of greater interest in clinical settings, especially in the case of emerging pathologies in young people and again, as seen, in the area of vulnerability rather than frank psychopathology. The careful evaluation of the psychopathological traits allows in fact a more complete representation of the individual subject evaluated, favouring both an earlier treatment and a more individualized treatment path.

The potential of use of a multidimensional tool such as the PID-5 shows all power especially when the results are analysed not in a general sense (i.e. considering the tested subject as belonging to a generic "general sample") but correlating them to the at-risk mental state evaluation. Moreover, it also emerges that the evaluation of results at the Facets level (traits) is more useful than at the Domain level. According to our results, at the level of the Domains psychopathology is under-dimensioned in the patient's self-assessment compared with the diagnosis made by the clinician. On the contrary, the traits level of description accounts for a diversification of much broader psychopathological nuances, which allow us to intercept multiple and transversal facets pertaining to different diagnostic categories, in particular for the group where such fluidity is maximum, once again the vulnerable subjects we need to treat as soon as possible.

This observation underlines the importance of combining the staging diagnostic assessment with a multidimensional psychopathological assessment, especially in the early stages of psychopathology, the ones in which the diagnostic fluidity is maxima and the symptomatic polymorphism suggests multiple and diversified subsequent psychopathological outcomes. This polymorphism in the early stages, particularly evident in vulnerable subjects, is also supported by what emerges from PID 5, especially with an analysis that goes down to the level of traits, as presented by our data.

The evaluation of the PID-5 Psychoticism Domain deserves a particular consideration. This domain, in fact, apparently seems not very specific in identifying the manifest psychotic conditions. In fact, in our opinion, it represents a particularly sensitive and therefore important indicator to be analysed especially in conditions of medium risk (Groups 1 and 2). As expected by its construct, the score of the Psychoticism Domain is "normal" in 73.1% of subjects in Group 0 (without psychotic vulnerability), but it progressively worsens in vulnerable subjects and then in attenuated psychosis subjects. In fact, the percentages of "sensitive" and "pathological" scores increase in Groups 1 and 2, on the contrary subjects belonging to the psychosis threshold group show a prevalent "sensitive" level in the Psychoticism domain, none of them reporting "pathological" scores. The same phenomenon is however evident analysing the number of pathological traits, or the number of pathological do-

mains, as mentioned before. We can therefore hypothesize that this result is subverted in this subgroup of patients with a more advanced stage of psychopathology due to a more marked difficulty in recognize illness at this stage (fall of critic functions). An alternative explanation may be that the traits investigated are felt more egodistonic in the early stages, in which they are less integrated in the initial phases of illness and, for this reason, are well recognized and described. Worsening the clinical state, patients undergo to a sort of adaptation whereby problems are no longer critically detected.
Some limitations have to be underlined. Our results need to be replicated in a more robust sample, in order to have the possibility to have a more significant stratification of variables and have a number of alternative explicative hypothesis. Another limitation of this study is the non-availability of data regarding the ability of critic of psychotic subjects, in order to explain the "paradoxes" we found, but the results we found were somewhat unexpected. The issue needs to be better studied in a future work.

Conclusions

Despite these limitations, we can draw some concluding remarks. In line with what was expected with respect to the mission of the two Projects "Prevention and Early Intervention of Psychiatric Disorders in Youth" and "Adolescents with Psychiatric Disorders", the group of vulnerable subjects was the most numerous. The same group appears to be a fluid one, in which there are polymorphic psychopathological facets, transversal to the various traditional diagnostic categories, potentially leading to different psychopathological outcomes, stabilize or regress. According to that, we have highlighted how a trait-level analysis can be useful in setting up a specific treatment path. In a more specific way, the presented data confirm the great utility of a tool such as PID-5 in highlighting transdiagnostic psychopathological traits, especially in the earliest stages of the disease and especially in the vulnerable group. In particular, the clinical utility is evident if these symptomatic manifestations are sought at a more specific and profound level, that is, that of the Traits, or Facets.
Therefore, with respect to the usefulness of different models and approaches to diagnosis, it seems appropriate to refer to the observations that the most useful approach depends on the context in which the question is posed and each clinical decision, to treat or not, is ultimately a categorical one, even when based on a dimensional assessment of severity and impact [17].
As a final remark, we are aware that our data will not close the debate regarding the question of whether a dimensional approach can really improve our diagnostic approach, even if the latest version of the DSM-5 recognize the dimensionality of psychopathology. But at the same time, we are aware that, in particular in the field of the early clinical stages of mental disorders emerging in youth and psychosis, a dimensional approach is suggested as a complementary value in diagnostic terms [18], and our data seem to point in that direction.

Conflict of interest statement

The Authors declare no conflict of interest.

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Author contributions

SC: recruited subjects and collected data; RM, CM: contributed to recruitment; FD: reviewed and analysed data. All the Authors contributed to literature analysis and discussion of results.

Ethical consideration

This study was previously authorized by ASST Direction, according to local office of Ethical Committee, because it was an observational study, with aggregated data, and there was not any clinical experimentation necessitating a specific authorization.

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