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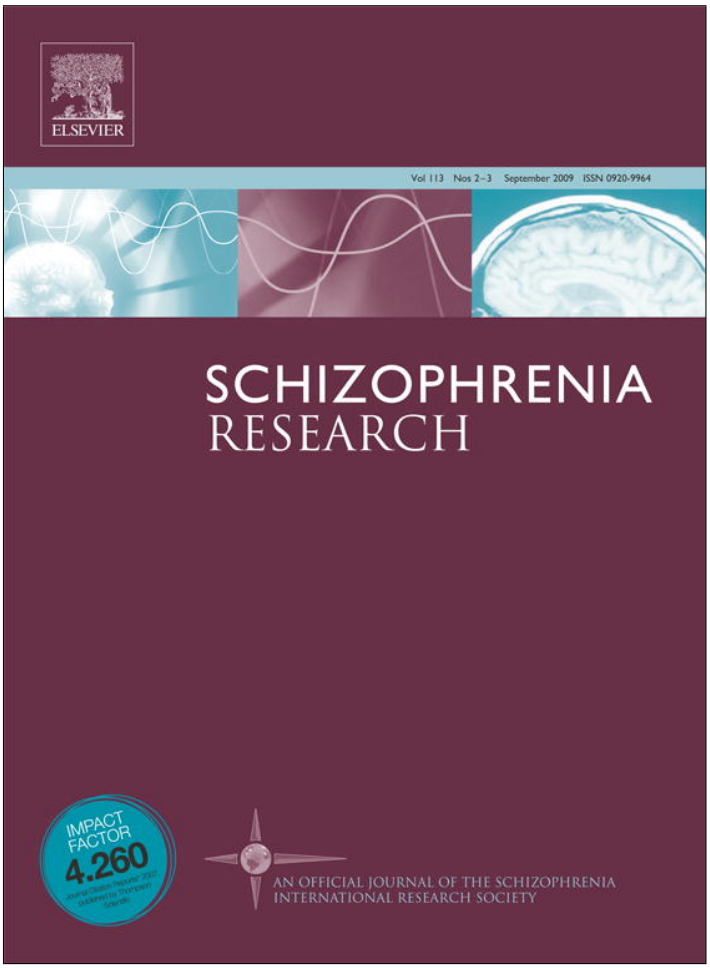

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Risk of suicide and suicidal ideation in psychosis: Results from an Italian multi-modal pilot program on early intervention in psychosis

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ABSTRACT

Suicidality is high in schizophrenia, particularly in first-episode patients. Little is known about patients with prodromal symptoms of psychosis or otherwise high-risk persons.
In a sample enrolled in an early intervention program implemented in Milan (Italy), a history of attempted suicide before enrollment was found in 6 first-episode schizophrenia (out of 87, 6.9%), and 7 high-risk of psychosis (out of 81, 8.6%) patients.
In the first-episode group, a history of suicide attempts was related to a shorter duration of untreated psychosis. In the high-risk group, a family psychiatric history in first/second degree relatives of patients and a personal history of substance abuse were both associated with an enhanced risk of attempted suicide before enrollment.
During the first year of treatment, 3 new attempted suicides were recorded among 57 (5.3%) high-risk patients, and none among first-episode patients ($n=58$) (no dropout in the sample). The levels of suicide ideation on the BPRS did not differ by group at assessment, and significantly declined from assessment at entry to 1-year follow-up, except in seven HRP patients who become positive for core symptoms of schizophrenia, as measured on the BPRS. At enrollment, patients at high risk of psychosis had the same prevalence of past suicide attempts than first-episode schizophrenia patients: since suicide attempt is the most important predictor of a future suicidal attempt, the assessment of suicide risk should be given a privileged role in patients at high risk of psychosis as well.
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1. Introduction

In schizophrenia, up to 5% of patients die by suicide (Inskip et al., 1998; Palmer et al., 2005), and 20–40% attempt suicide during the course of their illness (Harkavy-Friedman et al., 1999; Radomsky et al., 1999). Symptoms of psychosis (De Hert et al., 2001; Heila et al., 1997), male gender, depression, alcohol and substance abuse, traumatic or stress events in the preceding months, poor social support and a family history of suicide represent risk factors for suicide in schizophrenia (Fenton, 2000; Hawton et al., 2005).

The risk of suicide in schizophrenia is higher during the early phases of the illness (Nordentoft et al., 2004; Palmer et al., 2005). Indeed, 15 to 26% of patients have attempted

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suicide at least once by their first contact: an additional 2 to 11% make another attempt during the first year of treatment (Addington et al., 2004; Nordentoft et al., 2002; Verdoux et al., 2001).

Attempted suicide is the most important antecedent of completed suicide (Brown et al., 2000; Reutfors et al., 2009) and should receive special attention in order to prevent suicidal behavior later (Mann et al., 2005). The early detection of first-episode psychosis, aimed at favoring adherence to treatment, might reduce the risk of suicide. To date, few studies have explored this issue. Melle et al. (2006) found that patients coming from early-detection centers had a lower suicidal behavior than those coming from no early-detection services, particularly in terms of suicidal attempts and/or planning. Some studies found a correlation between longer duration of untreated psychosis (DUP) and suicidality prior to presentation (Altamura et al., 2003; Clarke et al., 2006; Harvey et al., 2008); however, no link to DUP was reported at assessment (Nordentoft et al., 2002) or at follow-up (Bertelsen et al., 2007) in the OPUS trial, nor in the Suffolk County Mental Health Project (Bakst et al., 2009).

Fewer data are available on patients with prodromal symptoms of psychosis or otherwise high-risk persons (Cornblatt et al., 2003; Simon et al., 2006). This is not a homogeneous group, and primarily involves young people with attenuated or transient positive symptoms who still do not meet criteria for diagnosis of psychosis but show symptoms of deterioration. Interventions aimed at reducing the risk of transition to full-blown psychosis in these samples (Olsen and Rosenbaum, 2006), should, as well, reduce their risk of suicide.

This study summarizes data from a multi-modal, comprehensive program targeted at the early detection and intervention for persons at the onset and for those with a high risk of psychosis: the Programma 2000, the first of its kind to be launched in Italy (Milan) since 1999 (Cocchi et al., 2008).

We are specifically interested in establishing: a) whether first-episode psychosis patients had higher levels of suicidality compared to high-risk patients; b) whether the socio-demographic and clinical profile at assessment was related to suicidality at assessment or at follow-up; c) whether treatment reduced the risk of suicide (both suicide ideation and occurrence of suicide attempt) in the two groups of patients in a different way.

2. Methods

Data were collected during the routine assessment of patients attending the Programma 2000. The institutional review board approved the study, and all patients gave their informed consent. The sample included 168 patients out of a catchment area catering to approximately 200,000 inhabitants.

2.1. Assessment and diagnosis

All patients referred to Programma 2000 underwent a comprehensive, multidimensional evaluation. In this study, the following standardized assessment instruments were considered: (i) a socio-demographic form; (ii) the Early Recognition Inventory Retrospective Assessment of Symptoms checklist (ERIraos-CL) (Häfner et al., 1992), a 17-item screening checklist intended to select the persons needing a more in-depth assessment; (iii) the Health of the Nation Outcome Scale (HoNOS) (Wing et al., 1998), to assess psychopathology and disability: it includes 12 five-point items to evaluate clinical and social functioning over the prior 2 weeks; (iv) the 24-item Brief Psychiatric Rating Scale (BPRS) (Overall and Gorham, 1962; Roncone et al., 1999), to assess general psychopathology; and (v) the Global Assessment of Functioning (GAF) (Moos et al., 2000).

The main criteria of enrollment were:

- patients aged 17 to 30;
- first contact with any public mental health service from the catchment area for a first episode of psychosis (with DUP $\leq$ 24 months), or being referred to Programma 2000 with a suspected psychosis.

The main criterion for the inclusion of a first-episode of psychosis (FEP) is a diagnosis of schizophrenia or related syndromes (F20-25 in ICD-10) according to both ICD-10 and DSM-IV criteria (WHO, 1992; APA, 1994). Affective psychosis (bipolar disorder, or unipolar disorder with psychotic features) is an exclusion criterion, as is a co-morbid persistent substance-use dependent disorder, while substance use/abuse without dependence is not.

As for the high-risk of psychosis (HRP) group, patients are included, after exclusion of a past or present diagnosis of psychosis in the spectrum of schizophrenia or affective disorders, when they have a score $\geq$ 12 on the ERIraos-CL and evidence of positive symptoms on the BPRS – even if in an attenuated or subthreshold form – associated to signs of social withdrawal on the GAF. A co-morbid persistent substance-use dependent disorder is an exclusion criterion. Diagnoses of any anxiety disorder or personality disorder, or any alcohol and/or substance abuse are not exclusion criteria when the main requirements are met.

2.2. Treatment protocol

All the patients who enrolled in Programma 2000 received a comprehensive, tailored and flexible intervention package, based on the assessment results (Cocchi and Meneghelli, 2004; Cocchi et al., 2008).

2.3. Measures on suicidal behavior

We defined suicide attempt as any act of purposeful self-harm with expressed suicidal intent, i.e. the wish to die, as reported by the patient at the assessment and/or by a family member consulted as a key informant (no discrepancy), or recorded during treatment, within the first year of follow-up.

To evaluate the influence of the symptoms of psychosis on suicide ideation, according to the Remission in Schizophrenia Working Group (RSWG), we considered seven items of BPRS as representative of the core symptoms of psychosis: grandiosity, suspiciousness, unusual thought content, hallucinatory behavior, conceptual disorganization, mannerism/posturing, blunted affect. These symptoms are expected to give a measure of the patient's remission, as well as the impact of core psychotic symptoms on the associated level of functioning (Lasser et al., 2007). The inter-rater reliability for the BPRS at assessment, as measured by the intra-class correlation

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coefficient, was found to be 0.86 (95% CI: 0.81 to 0.90) in the first-episode group, and 0.76 (95% CI: 0.67 to 0.83) in the high-risk group.

2.4. Statistical analyses

Data were analyzed with the Statistical Package for Social Science (SPSS) for Windows (Chicago, Illinois 60606, USA), version 13. Additional analyses were carried out with GraphPad Prism (GraphPad Software, Inc., La Jolla, CA 92037 USA). All tests were two-tailed, with $\alpha = 0.05$. Non-parametric statistics were used, due to non-normality (Kolmogorov–Smirnov, with Lilliefors significance correction, $P<0.05$ in all explorations). Categorical data were analyzed in inter-group comparisons with χ^2, or Fisher's exact test, when appropriate ($n<5$ in any cell in binary comparison). The Mann–Whitney test was used to compare the ordinal variables. The non-parametric Friedman test for repeated measures (with the Dunn multiple comparison test for further post-hoc comparisons) was used to compare the ordinal variables across time. Spearman's rho correlation coefficients were used to examine associations between two variables.

Effect sizes of statistically significant differences were expressed through the receiver operating characteristic Area Under the Curve (AUC) (95% CI) for both ordinal and binary variables: when 95% CIs were both above 0.500 (equiprobability), the effect size of the difference can be considered statistically reliable; the suggested thresholds for AUC used as effect size measure are: small = 0.556; medium = 0.638; large = 0.714 (Kraemer and Kupfer, 2006).

3. Results

The FEP group included 87 patients (male/female ratio = 4.1); age at assessment did not differ by sex (males: mean = 22.3; Standard Deviation [SD] = 3.7; females: mean = 23.7; SD = 4.3).

The HRP group included 81 patients (male/female ratio = 2.3); age at assessment did not differ by sex (males: mean = 22.0; SD = 3.7; females: mean = 23.0; SD = 3.5).

At assessment, FEP patients were more severe than HRP patients, and also scored at a lower level of functioning on the GAF, as expected on the basis of classification; however, levels of suicide ideation on the BPRS, or levels of self-harming and self-endangering behavior on the HoNOS did not differ by group (Table 1).

In the sample, 13 patients had a history of attempted suicide before enrollment, with an equal proportion between FEP ($n = 6$, 6.9%) and HRP ($n = 7$, 8.6%) patients: $\chi^2 = 0.018$, $df = 1$, $P = 0.89$.

3.1. Clinical variables associated with suicidal behavior in FEP

In FEP, women (17.6%) were more likely to have attempted suicide than men (4.3%), but the difference was not statistically significant (Fisher's exact test, $P = 0.086$). The only separated patient had attempted suicide before enrollment.

Among first-degree relatives of FEP patients, we recorded 3 cases of completed suicide (the father and two female first-degree cousins), and 4 cases of attempted suicide (in three cases, the mother; in one case, the maternal grandmother).

Table 1
Clinical characteristics at entry of the patients enrolled in the first-episode and the high-risk groups.

Variables of interest	First-episode psychosis $N = 87$	High-risk persons $N = 81$	Statistics
ERIraos-CL [a]	26.3 (8.3) 27.0	18.1 (7.6) 17.0	Mann–Whitney $U = 1441.50$, $P = 0.0001$
HoNOS	15.2 (6.7) 14.0	13.0 (4.9) 12.0	Mann–Whitney $U = 2709.00$, $P = 0.010$
BPRS, core symptoms of psychosis	17.9 (6.7) 17.0	12.2 (4.6) 11.0	Mann–Whitney $U = 1662.00$, $P = 0.0001$
GAF	43.7 (8.9) 44.0	52.9 (9.6) 51.0	Mann–Whitney $U = 1594.50$, $P = 0.0001$
Suicide ideation on BPRS	1.8 (1.4) 1.0	1.9 (1.3) 1.0	Mann–Whitney $U = 3292.00$, $P = 0.495$
Suicidal behaviour on HoNOS	0.42 (0.93) 0.0	0.38 (0.87) 0.0	Mann–Whitney $U = 3454.50$, $P = 0.762$

All data: mean (standard deviation) median.
[a] Only 77 persons in the first-episode group and 78 among those in the at-risk group underwent the ERIraos-CL evaluation.

All cases of suicidality among relatives occurred among those without a history of suicide attempt: 7 vs 0; however, a psychiatric family history was associated with an enhanced risk of attempted suicide before enrollment (8.6% vs 3.4%), but the difference was not statistically significant. Substance use or abuse, or a history of traumatic or otherwise stressful life events were not related to past suicide attempts (Table 2).

A history of suicide attempt was associated to a shorter DUP (AUC: no attempted suicide compared to attempted suicide before enrollment = 0.773, 95% CI = 0.568–0.979), but the Duration of untreated illness (DUI) was not.

At assessment, suicide ideation on BPRS was positively related to scores on the HoNOS ($n = 87$, Spearman's rho = 0.368, $P = 0.0001$), on ERIraos-CL (Spearman's rho = 0.227, $P = 0.047$), and, marginally, on the core symptoms of psychosis on BPRS (Spearman's rho = 0.208, $P = 0.053$).

As of March 2009, information on the effectiveness at the 1-year follow-up is available for 58 patients in the FEP group (no dropouts). No new suicide attempt occurred in this sample.

At the 12-month follow-up, 39 FEP patients (67.2%) were in remission according to the criteria specified by the RSWG and their levels of suicide ideation on the BPRS declined over time, from assessment until the 1-year follow-up. This change can be considered statistically significant, but smooth (Friedman test = 15.59, $df = 2$, $P = 0.0001$, but post-hoc Dunn's $P>0.05$ in all inter-time comparisons). No prescribed drug emerged as being statistically related to this reduced risk of suicide ideation at the 1-year follow-up. As for the FEP patients who remained symptomatic ($n = 19$), suicide ideation decreased from assessment to 6 months, then increased thereafter at 12 months, but still at lower levels than at assessment (Friedman test = 6.22, $df = 2$, $P = 0.045$, but post-hoc Dunn's $P>0.05$ in all inter-time comparisons).

3.2. Clinical variables associated with suicidal behavior in HRP

In the HRP group women (12.5%) were more likely to have attempted suicide than men (7.0%), but not significantly (Fisher's exact test, $P = 0.417$) (Table 2).

Among first-degree relatives of HRP patients, we recorded 3 cases of completed suicide (a sister, a maternal aunt and a maternal uncle), and 2 cases of attempted suicide (the mother).

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Table 2
Socio-demographic and clinical characteristics of the first-episode psychosis sample at enrollment.

Data are: *n* (%), or mean (standard deviation) median, according to the measure	First-episode psychosis *N* = 87	Without a past attempted suicide *N* = 81 (93.1%)	With a past attempted suicide *N* = 6 (6.9%)	Statistics
Gender				
Males	70 (80.5%)	67 (80.9%)	3 (50.0%)	Fisher's exact test, *P* = 0.086
Females	17 (19.5%)	14 (19.1%)	3 (50.0%)	
Age at entry	22.6 (3.8) 22.0	22.7 (3.7) 23	21.6 (5.7) 19.5	
Age ≤ 24	60 (69,0%)	56 (69.1%)	4 (66.7%)	Fisher's exact test, *P* = 1.000
Age ≥ 25	27 (31.0%)	25 (30.9%)	2 (33.3%)	
Educational qualification				
High school diploma or higher	43 (49.4%)	40 (49.4%)	3 (50.0%)	Fisher's exact test, *P* = 1.000
Lower than high school diploma	44 (50.6%)	41 (50.6%)	3 (50.0%)	
Marital status				
Single	86 (98.9%)	80 (98.8%)	6 (100.%)	Fisher's exact test, *P* = 1.000
Married	1 (1.1%)	1 (1.2%)	0 (0.0%)	
Family psychiatric history				
Yes	58 (66.7%)	53 (65.4%)	5 (83.3%)	Fisher's exact test, *P* = 0.659
First/second degree relative with psychosis	16 (27.5%)	15 (28.3%)	1 (20.0%)	
First/second degree relative with affective dis.	27 (46.5%)	24 (45.3%)	3 (60.0%)	
First/second degree relative with substance abuse	6 (10.3%)	5 (9.4%)	1 (20.0%)	
First/second degree relative with personality dis.	4 (6.9%)	4 (7.6%)	0 (0.0%)	
Unspecified/unclassified	5 (8.6%)	5 (9.4%)	0 (0.0%)	
None	29 (33.3%)	28 (34.5%)	1 (16.7%)	
Already in treatment for psychological symptoms	46 (52.9%)	43 (53.1%)	3 (50.0%)	Fisher's exact test, *P* = 1.000
Exposure to traumatic events	11 (12.6%)	11 (13.6%)	0 (0.0%)	Fisher's exact test, *P* = 1.000
Substance use (any)	21 (24.1%)	21 (25.9%)	0 (0.0%)	Fisher's exact test, *P* = 0.329
Substance abuse (any)	8 (9.2%)	8 (9.9%)	0 (0.0%)	Fisher's exact test, *P* = 1.000
Duration of untreated psychosis (days)	172.7 (220.2) 90.0	183.7 (224.7) 95.0	40.3 (83.3) 8.5	Spearman's rho = −0.25, *P* = 0.025
Duration of untreated illness (months)	28.7 (20.4) 24.0	29.6 (20.3) 24.0	18.0 (20.1) 8.0	Spearman's rho = −0.16, *P* = 0.16

There were 2 cases (2.7%) of suicidality among relatives in those without a history of suicide attempt, and 3 cases (42.9%) in those with a history of suicide attempt at presentation (Fisher's exact test, *P* = 0.004; AUC = 0.701, but 95% CI = 0.455–0.947). Overall, a psychiatric family history was associated with an enhanced risk of attempted suicide before enrollment

Table 3
Socio-demographic and clinical characteristics of the high-risk person sample at enrollment.

Data are: *n* (%), or mean (standard deviation) median, according to the measure	High-risk persons *N* = 81	Without a past attempted suicide *N* = 74 (91.4%)	With a past attempted suicide *N* = 7 (8.6%)	Statistics
Gender				
Males	57 (70.4%)	53 (71.6%)	4 (57.1%)	Fisher's exact test, *P* = 0.417
Females	24 (29.6%)	21 (28.4%)	3 (42.9%)	
Age at entry mean (SD)	22.3 (3.6) 22.0	22.5 (3.4) 22.0	24.1 (5.0) 27.0	
Age ≤ 24	55 (67.9%)	52 (70.3%)	3 (29.7%)	Fisher's exact test, *P* = 0.203
Age ≥ 25	26 (32.1%)	22 (29.7%)	4 (57.1%)	
Educational qualification				
High school diploma or higher	44 (54.3%)	40 (54.1%)	4 (57.1%)	Fisher's exact test, *P* = 1.000
Lower than high school diploma	37 (45.7%)	34 (45.9%)	3 (42.9%)	
Marital status				
Single	80 (98.8%)	73 (98.6%)	7 (100%)	Fisher's exact test, *P* = 1.000
Married	1 (1.2%)	1 (1.4%)	0 (0.0%)	
Family psychiatric history (*n*, %)				
Yes	50 (61.7%)	43 (58.1%)	7 (100%)	Fisher's exact test, *P* = 0.040
First/second degree relative with psychosis	9 (18.0%)	9 (20.9%)	0 (0.0%)	
First/second degree relative with affective dis.	24 (48.0%)	21 (48.9%)	3 (42.9%)	
First/second degree relative with substance abuse	8 (16.0%)	6 (13.9%)	2 (28.6%)	
First/second degree relative with personality dis.	6 (12.0%)	4 (9.4%)	2 (28.6%)	
Unspecified/unclassified	3 (6.0%)	3 (6.9%)	0 (0.0%)	
None	31 (38.3%)	31 (41.9%)	0 (0.0%)	
Already in treatment for psychological symptoms	31 (38.2%)	27 (37.0%)	4 (57.1%)	Fisher's exact test, *P* = 0.421
Exposure to traumatic events (*n*, %)	7 (8.6%)	6 (8.1%)	1 (14.3%)	Fisher's exact test, *P* = 0.482
Substance use (any)	21 (25.9%)	17 (23.0%)	4 (57.1%)	Fisher's exact test, *P* = 0.070
Substance abuse (any)	5 (6.2%)	1 (1.4%)	4 (57.1%)	Fisher's exact test, *P* = 0.0001
Duration of untreated illness (months)	29.9 (21.9) 24.0	28.5 (21.9) 24.0	43.5 (17.8) 47.0	Spearman's rho = 0.203, *P* = 0.08

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(AUC = 0.570, but 95% CI = 0.445–0.695), with most of the risk depending on a history of one first/second degree relative with affective disorders (Table 3).

An enhanced risk of attempted suicide before enrollment was observed among those who met the criteria for substance abuse (AUC = 0.779, 95% CI = 0.546–1.00).

At assessment, suicide ideation on BPRS was positively related to scores on the HoNOS ($n = 81$, Spearman's rho = 0.283, $P = 0.010$) and on ERIraos-CL (Spearman's rho = 0.250, $P = 0.027$), but not on the core symptoms of psychosis on BPRS (Spearman's rho = 0.210, $P = 0.060$).

As of March 2009, information on the effectiveness at the 1-year follow-up is available for 57 patients in the HRP group (no dropouts). There were 3 new suicide attempts (5.3%) among the 57 HRP patients. A new suicide attempt during treatment was more likely among those who had attempted suicide in the past: $n = 2$ (out of 4 [50.0%]), opposed to $n = 1$ (out of 53 [1.9%]); there was no relationship with the measures of psychopathology at entry.

At the 12-month follow-up, 7 HRP patients (12.3%) manifested core symptoms of schizophrenia, as measured on the BPRS (only 2 of them received a formal diagnosis of schizophrenia), and their suicide ideation did not change over time (Friedman test = 3.84, $df = 2$, $P < 0.146$), while those HRP patients who improved ($n = 50$) also showed a statistically significant decrease of suicide ideation levels (Friedman test = 20.98, $df = 2$, $P < 0.0001$; post-hoc Dunn's $P < 0.05$ from assessment until 1 year later, but not at the 6-month follow-up). No prescribed drug emerged as being statistically related to suicide ideation at the 1-year follow-up.

4. Discussion

The main findings of this study show a similar ratio of previous suicide attempt in early psychosis and individuals at high risk for psychosis, and a significant reduction of suicidal ideation 1 year after enrollment into the program (except in the seven HRP patients who converted to psychosis). In our sample, the prevalence of suicide attempt before enrollment was lower than elsewhere: 6.9% in FEP and 8.6% in HRP patients, opposed to 15 to 26%, according to the studies (Addington et al., 2004; Verdoux et al., 2001). This is consistent with the lower prevalence of suicide attempts in Italy than elsewhere. In the World Mental Health Survey initiative, lifetime prevalence of suicide attempt in community samples was reported to be 1.3% in Europe (Bernal et al., 2007), and 2.7% worldwide (Nock et al., 2008), while in Italy it was 0.5% in the total sample, and 0.4% in northern Italy (Scocco et al., 2008), the same location where *Programma 2000* was carried out.

In our FEP group, DUP was negatively correlated to the occurrence of suicide attempt before enrollment: in all likelihood, a suicide attempt is perceived by the patient and/or by the immediately surrounding social environment as a negative sign and an indicator of symptom severity, thus facilitating access to treatment. Accelerating detection and enrollment in treatment could reduce the risk of transition from suicide ideation to planning and completion in these patients.

In our samples, no socio-demographic variable was related to suicide attempt before enrollment, although a family history of mental disorders known to be associated with suicidal behavior predicted suicide attempt before enrollment in the HRP sample and, marginally, in the FEP group, with a greater effect for affective disorders. Among HRP patients, substance abuse was remarkably related to an enhanced risk of pre-enrollment suicide attempts in these patients. Detailed ascertainment and assertive treatment of substance use/abuse are therefore advisable for these patients, with the aim of preventing suicide.

Globally, suicide attempts were a rather rare occurrence in the sample after enrollment: only three patients attempted suicide within the first year of treatment; none in the FEP group. Suicidal ideation also decreased over time from enrollment: in FEP patients the decrease in suicide ideation levels was smoother than in HRP patients. No prescribed drug emerged as being statistically related to a reduced risk of suicide ideation at the 1-year follow-up: the intensive specialized protocol of care that includes individual psychotherapy, skills training and family support, certainly contributed to reducing suicide ideation in the sample.

We lacked self-report measures on suicide ideation. Since suicidal ideation is more openly disclosed in self-administered than in interview queries (Turner et al., 1998) we might have missed some information on suicidal behavior. In addition, we relied on retrospective self-reports for some clinical data, such as substance use and abuse or the occurrence of mental disorders in the family, which might have conditioned some sort of biased recall. However, it is unlikely that we missed essential information over the course of the disorder as patients were evaluated with a weekly–biweekly frequency of appointments, and no dropout occurred in the sample; most data were crosschecked with a closely related informant, and follow-up data were prospectively recorded as part of the patient's usual assessment.

The main conclusion of this study is that, at enrollment, patients at high risk of psychosis show the same prevalence of past suicide attempts than first-episode patients. Since suicide attempt is the most important predictor of future suicidal attempt and completion (Suominen et al., 2004; Gibb et al., 2005), we think that the assessment of suicide risk should be given a privileged role in patients at high risk of psychosis, too.

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Contributors

Preti, Meneghelli and Cocchi, all co-jointly had the idea and organized the study.

Study concept and design: Preti, Meneghelli and Cocchi.

Acquisition of data: Pisano, Meneghelli, Cocchi, the Programma 2000 team.

Analysis and interpretation of data: Preti, Meneghelli, Cocchi.

Drafting the manuscript: Preti, Meneghelli, Cocchi, Pisano.

Critical revision of the manuscript for important intellectual content: Cocchi, Meneghelli, Preti.

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Study supervision: Cocchi, Meneghelli, Pisano, Preti.

Conflict of interest statement

To the best of our knowledge, no conflict of interest is foreseeable concerning the data and results described in this article.

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