

Early Intervention in the Real World

Early intervention in psychosis: a feasibility study financed by the Italian Center on Control of Maladies

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Abstract

Aim: In November 2005 the Italian Center on Control of Maladies, a department operating under the Ministry of Health, financed a project aimed at evaluating the feasibility of a protocol of intervention based on the early intervention in psychosis (EIP) model within the Italian public mental health-care network.

Methods: The study was carried out between March 2007 and December 2009. It involved five centres operating under the Departments of Mental Health of Milan (Programma 2000), Rome (area D), Grosseto, Salerno (Nocera) and Catanzaro (Soverato).

Results: Enrolment lasted 12 months, at the end of which 43 patients were enrolled as first-episode psychosis (FEP), and 24 subjects as ultra high-risk (UHR) patients. Both FEP and

UHR samples included a preponderance of male patients. A family history of psychosis was rarely reported in both samples. The FEP incidence rate was lower than expected on the basis of international estimates of the incidence of schizophrenia but within the expected figure for the estimated Italian rates in three centres out of five.

Conclusions: Overall, the study proved that an EIP centre can be established within the public Department of Mental Health to reach a good fraction of the cases in need of treatment. Since then, several studies have been set up to assess the feasibility of EIP in the Italian public mental health sector in Lombardy and Tuscany, and in 2012 the Emilia-Romagna Regional Authority started an educational plan aimed at implementing the EIP model in all the Mental Health Departments in the region.

Key words: at-risk mental states, early intervention in psychosis, first-episode psychosis, psychiatric services.

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INTRODUCTION

The new paradigm of early intervention in psychosis (EIP) has gained increased attention in the scientific community.^{1–3} This interest is raised by its rational foundation – the early detection and treatment of cases in need of care being expected to reduce morbidity and its related disability, and to improve the long-term outcome.^{4,5} The demonstration that EIP protocols can sensibly reduce both direct and indirect costs of care contributed to spreading interest in the EIP model as well.^{6–8} On the one hand, evidence on the medium-term

effectiveness of these programmes is unconvincing,^{9–11} and their cost-effectiveness has been questioned;^{12–14} and on the other hand, some promising data indicate that the interventions aimed at treating people at a higher risk of psychosis are able to decrease transition to full-blown psychosis in the short term (up to 24 months).^{15,16}

Over the past 30 years a deep-reaching reorganization of the mental health-care system has occurred in Italy. The complete closing down of the obsolete mental health hospitals (with the exception of forensic mental health hospitals) was accompanied by the development of a dedicated system of

mental health departments.^{17,18} These departments are intertwined with general hospitals (and their operating psychiatric wards for acute treatment), and with a network of community services covering all the requirements of child, adolescent and adult populations.^{19,20} All psychiatric services are free of charge for the patients and their families, as the costs of assessment and treatment are covered by general taxation, although some fees are paid for psychotherapy. The threshold for access to these services is very low, so patients can book a visit even without a formal indication by their general practitioner. This community mental health-care network is the ideal framework for the implementation of the early intervention paradigm within the public psychiatric services.

In November 2005, the Italian Center on Control of Maladies (CCM), a department under the Ministry of Health aimed at studying the best practices to prevent the onset of severe illnesses and their worst outcomes, financed a project aimed at evaluating the feasibility of a protocol of intervention based on the early intervention in psychosis model within the Italian public mental health-care network. The project was allocated to the chairperson of the Programma 2000, the first-ever established early intervention in psychosis programme in Italy, and involved four more Departments of Mental Health, mostly located in central Italy.

The main objectives of the project financed by the Ministry of Health CCM were

- to train the professional staff of each participating centre on the theoretical and operational cores of the EIP model, and
- to establish a specialized EIP programme within the participating Departments of Mental Health, aimed at the assessment, diagnosis and treatment of people with first-episode psychosis or at a high risk of it according to well-defined, state-of-the-art guidelines on the topic.

The study had some research goals, too:

- to collect and evaluate process and outcome data related to the activities expected to be carried out under the programme.

This paper is aimed at describing the organization of this study, the first of its kind in Italy and at reporting its main findings and its most critical limitations.

METHODS

The study – named ‘L’Individuazione e l’intervento precoce nelle psicosi. Un approccio preventivo alla

schizofrenia’ (Early detection and intervention in psychosis. A preventive approach to schizophrenia) – was financed by the CCM following advice of the mental health chair of the CCM and the chair of the Programma 2000. The main goal of the study was to raise greater awareness about the early intervention models by focusing on the most severe conditions: schizophrenia and its related psychoses. The study was carried out between the end of March 2007 and December 2009. It involved five centres operating under the Departments of Mental Health of Milan (Programma 2000), Rome (area D), Grosseto, Salerno (area 1, Nocera) and Catanzaro (Operative Unit of Soverato).

The Programma 2000, operating in Milan since 1999 under the Health Authority of the Niguarda Ca’ Granda Hospital, was the first centre established in Italy with the aim of providing early detection and intervention to people with psychosis at its onset,^{21,22} and served as the coordinating centre for the development of the other centres. The centre on early intervention in psychosis of the Department of Mental Health of Rome (area D) was established in 2004. The other participating centres were activated in connection with the start of the study, in 2007. Details on the organization of the mental health system operating in Italy are reported elsewhere.^{23–25}

Training of the staff

Staff recruitment was based on voluntary participation; the main goal was to have no less than three professionals involved in the study, with at least one psychiatrist and one psychologist among them. During the first 3 months of the study, several seminars were organized illustrating the rationale of the study and the EIP model. Additional training was provided on assessment at enrolment and at follow-up. Finally, guidelines on the treatment of first-episode psychosis and on people at ultra high risk (UHR) of psychosis were illustrated during periodical meetings with verification of the learning process.^{26,27}

At the same time with staff training, periodical meetings with the potential sources of referrals were activated, including general practitioners, emergency service staff, paediatricians and child and adolescent neuropsychiatry unit staff (one meeting per month on average).

One of the goals of the study was to train the participating staff on the assessment of patients by means of standardized tools. All assessors were psychologists or psychiatrists and had a 5-year experience minimum in dealing with patients diagnosed with psychosis or in the prodromal phase.

Inter-rater agreement among the clinical staff was regularly checked to assure good to acceptable concordance on the scales; intra-class correlation coefficients were 0.70 or above in all scales when performed on a small sample of patients ($n = 12$) during training; k-agreement for Global Assessment of Functioning was 0.80 during training.

Assessment and criteria for enrolment

The patients were assessed using the following standardized assessment instruments: (i) a sociodemographic form; (ii) the Early Recognition Inventory Retrospective Assessment of Symptoms checklist (ERiraos-CL), a 17-item screening checklist intended to select persons needing a more in-depth assessment;^{28,29} (iii) the Health of the Nation Outcome Scale (HoNOS), to assess psychopathology and disability: it includes 12 5-point items to evaluate clinical and social functioning in the prior 2 weeks;^{30,31} (iv) the 24-item Brief Psychiatric Rating Scale (BPRS), to assess general psychopathology;^{32,33} (v) the 12-item World Health Organization Disability Assessment Schedule (WHO-DAS) version II.³⁴

The ERiraos-CL has 17 items designed to assist the exploration of individual proneness to schizophrenia. Scores are: 0 – 1 – 2 (absent, doubtfully present, certainly present) for the first 13 items; 0 – 2 – 4 (same assignment) for two items about changes in perception and thought interference; and 0 – 3 – 6 for two items about paranoid ideation and hallucinations, which assign greater weight to those symptoms that are more clearly indicative of psychosis.²⁹

The BPRS is a 24-item measure of general psychopathology in a Likert format, with scores ranging from 1 (absent) to 7 (extremely severe).³³ The range of possible BPRS total scores is 24 to 168, with higher scores indicating higher levels of psychopathology.

The HoNOS comprises 12 items that rate various aspects of mental and social health with a severity score varying from 0 (no problem) to 4 (severe to very severe problem), where higher scores indicate greater occurrence of problems.^{30,31}

In the WHO-DAS, the scores assigned to each item – ‘none’ (1), ‘mild’ (2) ‘moderate’ (3), ‘severe’ (4) and ‘extreme’ (5) – are summed up, with higher scores indicating greater disability.^{34,35}

Patients were included in the study if they were between 17 and 30 years of age, and had been referred to any of the five participating centres after a first contact with any public mental health service of the catchment area for a first episode of psychosis. A first episode of psychosis (FEP) was

defined as any case fulfilling a diagnosis of schizophrenia or related syndromes (F20–29 in International Classification of Diseases, Tenth Revision (ICD-10)) according to the ICD-10 (WHO, 1992) and duration of untreated psychosis (DUP) lower than 24 months. This threshold was selected on the basis of evidence indicating that early deterioration in patients with psychosis stabilizes within the first 2 years since the onset.³⁶ Of course, patients with longer DUP are still worthy of treatment,^{37,38} but they need different protocols of care to take into account the impact of the consequences of a long period of untreated psychosis. It was therefore decided to concentrate the scarce resources of the early intervention centres on those cases that were in the early phases of a first episode, whereas those who had a DUP longer than 24 months were read-dressed back to the service that had asked for the evaluation.

Referral sources were mental health professionals and associated surgeries, family physicians or direct family referrals in response to awareness campaigns; self-referral was also allowed.³⁹

Since its conception, Programma 2000 has focused on the education and training of health-care professionals working within the public health-care network and, in particular, of mental health clinicians and clinic and agency staff serving adolescents and young adults. The aim was to raise awareness on the importance of early detection and referral of patients with or at risk of psychosis, and to disseminate knowledge of the multidimensional protocol of care applied by Programma 2000.^{21,22} Over time, more attention was paid to schools and the public in general through awareness campaigns that were organized primarily by a single dedicated organization: TULIP, *Tutti Uniti Lavoriamo per Intervenire Precocemente* (Working all Together for Early Intervention; <http://www.iniziativatulip.org>). The aim was to reduce help-seeking delays by increasing awareness of the risk of psychosis and its consequences and providing information about the resources available for treatment. The same pattern was applied in the early intervention centre of the Department of Mental Health of Rome. The other three centres mainly focused on the education and training of health-care professionals and further developed the awareness campaigns dedicated to schools and the public in general already in place in their areas.

Besides patients with an ongoing FEP, people diagnosed as being at UHR of psychosis were enrolled in the study, too. Referred UHR patients were initially screened on the ERiraos-CL, and were enrolled in treatment when they scored ≥ 12 , the

threshold that best defined the patients at risk of transition in the German Schizophrenia Network study.^{29,40} The patients screened positive on the ERlraos-CL were further evaluated and enrolled when they met one of these Personal Assessment and Crisis Evaluation operational criteria for UHR: (i) attenuated positive prodromal syndrome; or (ii) brief, limited, and intermittent psychotic syndrome; or (iii) familial genetic risk or schizotypal personality disorder and evidence of deterioration in functioning in the last year.^{41,42} In both FEP and UHR patients, affective psychosis (bipolar disorder, or unipolar disorder with psychotic features) was an exclusion criterion, as was mental retardation or a comorbid persistent substance-use-dependent disorder, whereas substance use/abuse without dependence was not. A past or present diagnosis of psychosis in the spectrum of schizophrenia was a mandatory exclusion criterion for UHR diagnosis.

Additional information was collected during the interview of the patient and of at least one key informant (a close relative, preferably a parent). Duration of untreated illness (DUI) and DUP were both measured as the time elapsed from the onset of key symptoms (anxiety, depression or social withdrawal for DUI; hallucinations, delusions or bizarre behaviour for DUP) to the beginning of treatment (pharmacotherapy or psychotherapy) prescribed by a psychiatrist; DUP was measured in days, DUI in months. To measure DUP/DUI, we considered the symptoms as they were elicited by the ERlraos-CL, and considered the patient's estimated time of onset of key symptoms as listed in the tool. Further information on key symptoms onset was collected during the direct interview of a key informant. A therapist (usually a psychiatrist) and a researcher (usually a psychologist or an educator) of the team made the DUI/DUP assessment jointly. In problematic cases, consensus with a senior clinician was sought.

The enrolled patients received a comprehensive, tailored and flexible intervention package. Proposed tailored interventions included individual psycho-educational and motivational sessions, cognitive-behavioural psychotherapy, family support, therapeutic group activities (e.g. anxiety management, substance abuse prevention), various social group activities (e.g. music, multimedia, computer training sessions) and supportive interventions on employment, school, compliance with medication and planning of recreational activities.^{21,22}

Community-based case management was included in the intervention package, and it is standard within the Italian community-based model of mental health care.

Treatment duration provided by the early intervention centres was set at 3 years.

The institutional review board of the participating centres approved the protocol of the study, which conforms to the provisions of the 1995 Declaration of Helsinki (as revised in Tokyo, 2004). All patients gave their informed consent.

Statistical analyses

All analyses were carried out with the Statistical Package for Social Sciences (SPSS) software version 17 (SPSS Inc, Chicago, IL, USA). All analyses were two tailed, and the statistical threshold was set at $P < 0.05$. Scale reliability was assessed with the intraclass correlation coefficient (ICC), with 95% confidence of interval (CI).⁴³ Categorical data were analysed in inter-group comparisons with χ^2 , with Yates' correction when appropriate, or the Fisher exact test (when $n < 5$ in any cell). The Student's *t*-test was used to analyse continuous variables (age); the Mann-Whitney (M-W) *U*-test was used to compare the ordinal variables.

The main goal of the study was to evaluate the feasibility of establishing an EIP centre under the Italian public Department of Mental Health. The ability of the enrolling centres to capture the emerging incidence of FEP cases was calculated by taking into account the available data on the incidence of schizophrenia and its related psychoses.

McGrath *et al.*⁴⁴ in a large review of international studies on the epidemiology of schizophrenia and related psychoses, estimated an annual incidence rate of 15.2 per 100 000, with a 90% CI varying from 7.7 to 43.0. In Italy, the hospital incidence of psychosis within the spectrum of schizophrenia is lower than the estimated rates in international studies. On the basis of the data from the Italian mental health epidemiological surveillance system gathered by the Centre for Disease Prevention and Control of the Italian Ministry of Health, and by the Mental Health Unit of the Italian National Institute of Health, the annual incidence rate of schizophrenia and related psychoses was estimated at 7.4 (95% CI = 6.2–8.7) per 100 000.²⁵

Outcome at 1 year was evaluated with a random effect model by comparing scores at enrolment and at 1 year follow-up in each site. Results were summarized as a mean with 95% CI, whereas the effect size of the mean difference was expressed by Hedges' *g* (a bias-corrected version of Cohen's *d*) with 95% CI. The random effect model was implemented with Comprehensive Meta-Analysis (version 2.2) software (<http://www.meta-analysis.com/>). Heterogeneity by site was assessed with

Cochran's Q. Significant Q statistics (i.e. $P < 0.05$) was interpreted as suggestive of heterogeneity. Intention-to-treat (ITT) was applied in calculating treatment effect. The excluded subjects were those patients who had been enrolled but researchers had no information about their follow-up. ITT analysis is thought to maintain the prognostic balance generated from the original treatment allocation and to give an unbiased estimate of treatment effect.⁴⁵

RESULTS

The study had duration of 24 months, preceded by a 9-month preparatory phase.

Training of the staff

In each centre, at least three professionals were involved in the establishment of the EIP centre; when necessary, additional staff was hired on contract. All involved professionals regularly participated in the training. In each EIP centre, regular meetings were held with the sources of the potential referrals, but the organization methods and the level of participation in these meetings were not adequately documented and cannot be detailed.

Enrolment of the patients

The enrolment period lasted 12 months, at the end of which 43 FEP patients were enrolled plus 24 UHR patients. With the exception of the Programma 2000, the participating centres did not record how many patients were addressed for evaluation, so no flow chart of referrals could be drawn. Within the Programma 2000, on average one patient out of six was readressed back to the service that had asked for the evaluation because s/he had a DUP longer than 24 months.

Reliability of the scales used in the study

In the FEP group, ICC was 0.63 (95%CI: 0.42–0.78) for the ERiraos-CL; 0.79 (0.69–0.87) for the BPRS; 0.61 (0.35–0.80) for the HoNOS; 0.86 (0.76–0.93) for the WHO-DAS. In the UHR group ICC was 0.63 (0.30–0.85) for the ERiraos-CL; 0.80 (0.67–0.89) for the BPRS; 0.70 (0.46–0.86) for the HoNOS; 0.86 (0.71–0.95) for the WHO-DAS.

General characteristics of the sample

Both FEP and UHR samples included a preponderance of male patients, with a slight excess of male patients in the UHR group (Table 1).

A family history of psychopathology was reported in 57% of FEP and 52% of UHR patients, whereas a family history of psychosis was rarely reported in both samples (Table 1).

As expected on the basis of classification, FEP patients were more severe than UHR patients, and scored higher on the ERiraos and the BPRS, but not on the HoNOS or the WHO-DAS.

DUI was two years, on average, in both groups, but median value was 12 months; the DUP in the FEP sample was on average above 6 months (Table 1).

Expected incidence of schizophrenia and related disorders and incidence of enrolled cases

In the CCM study, the number of cases with a diagnosis of first-episode psychosis within the spectrum of schizophrenia was within the expected figure for the estimated Italian rates in three centres out of five, whereas two centres enrolled a lower number of cases with first-episode psychosis than expected on the basis of the estimated Italian rates for schizophrenia and its related psychoses (Table 2).

Outcome at 1 year

Only two centres out of five adequately recorded the data on the follow-up. Overall, information on follow-up was available for 15 UHR patients and 27 FEP patients and concerned the scores on the BPRS as recorded in four centres. All the other UHR and FEP enrolled patients completed the first year of treatment, with no dropouts; the information on their clinical status was recorded on their chart but the standardized assessment was not carried out.

In FEP patients mean scores on the BPRS changed from 56.5 (95% CI: 51.5 to 61.5) at enrolment to 43.8 (38.7 to 48.8) at 1-year follow-up. In UHR patients, the change was from 47.8 (42.4 to 53.3) to 17.5 (10.3 to 24.7). Mean decrement on the BPRS for FEP patients was –15.3 points, with a mean Hedges' $g = -0.88$ (95% CI: –1.24 to –0.52, $z = -4.82$, $P < 0.0001$). There was no heterogeneity by site: Cochran's $Q = 1.70$, d.f. = 3, $P > 0.05$. Mean decrement on the BPRS for UHR patients was –20.8 points, with a mean Hedges' $g = -2.10$ (95% CI: –2.74 to –1.45, $z = -6.38$, $P < 0.0001$). There was no heterogeneity by site: Cochran's $Q = 4.31$, d.f. = 3, $P > 0.05$. Overall, mean decrement on the BPRS was greater for UHR patients than for FEP patients, but both groups improved from enrolment to follow-up.

TABLE 1. Baseline characteristics of patients enrolled in the CCM study (March 2007 to December 2009)

All data: no. (%) or mean (SD)	First-episode psychosis N = 43	Ultra high risk N = 24	Statistics
Age at entry	22.2 (3.5)	21.2 (4.7)	$t = -0.99$, d.f. = 63, $P = 0.32$
Gender (no., % of males)	29 (67%)	19 (79%)	$\chi^2 = 1.04$ d.f. = 1, $P = 0.30$
Education			
College graduate or higher	4 (10%)	3 (13%)	$\chi^2 = 1.73$, d.f. = 2, $P = 0.42$
High school diploma	16 (39%)	5 (23%)	
Lower than high school diploma	21 (51%)	14 (63%)	
Marital status			
Unmarried	42 (98%)	23 (100%)	$\chi^2 = 0.55$, d.f. = 2, $P = 0.45$
Married	1 (2%)	0 (0%)	
Nationality			
Italian	37 (88%)	21 (91%)	$\chi^2 = 0.21$, d.f. = 2, $P = 0.96$
European non-Italian	2 (5%)	1 (4%)	
Non-European	3 (7%)	1 (4%)	
Family psychiatric history			
First/second-degree relative with psychosis	4 (9%)	1 (4%)	$\chi^2 = 0.58$, d.f. = 1, $P = 0.44$
Duration of untreated psychosis (days)†	207 (244)		
Median	120		
Duration of untreated illness (months)	20.1 (22.1)	24.9 (23.7)	M-W: $z = -0.47$, $P = 0.63$
Median	12	12	
Clinical and functional characteristics at enrolment			
ERlraos-CL	25.0 (5.6)	17.1 (7.2)	M-W: $z = -3.64$, $P = 0.0001$
HoNOS, total score	13.3 (5.8)	14.9 (6.8)	M-W: $z = -0.65$, $P = 0.514$
BPRS, total score	56.5 (16.8)	47.8 (13.4)	M-W: $z = -2.39$, $P = 0.017$
WHO-DAS	14.7 (9.7)	14.2 (9.7)	M-W: $z = -0.19$, $P = 0.843$

†Patients with DUP longer than 24 months were not enrolled and referred back to the service that had asked for the evaluation.
M-W = Mann-Whitney U-test.

TABLE 2. Expected, as reported in McGrath *et al.*⁴⁴, and observed incidence of first-episode psychosis, by enrolment centre – absolute numbers for the 1-year enrolment phase

	Catchment area	Yearly incidence estimates per 100 000 from international studies, rates with 10% and 90% quintiles	Expected number of enrolled cases on the basis of the estimated incidence in international studies	Observed number of enrolled cases in the CCM study	
Milan	200 000	15.2 (7.7–43.0)	30 (15–86)	19	Within the expected rates
Rome (area D, a section only)	250 000	15.2 (7.7–43.0)	38 (19–107)	12	Lower than the expected rates
Grosseto	65 000	15.2 (7.7–43.0)	10 (5–28)	7	Within the expected rates
Salerno (Nocera)	100 000	15.2 (7.7–43.0)	15 (7–43)	3	Lower than the expected rates
Catanzaro (Soverato)	35 000	15.2 (7.7–43.0)	5 (2–15)	2	Within the expected rates

DISCUSSION

This is the first study aimed at evaluating the feasibility of an EIP centre within the public mental health network in Italy. The five participating centres showed the ability of reaching and enrolling patients with an FEP diagnosis in a percentage that was lower than expected on the basis of interna-

tional estimates of the incidence of schizophrenia,⁴⁴ albeit within the limits of the expected incidence of schizophrenia and its related psychoses in Italy.²⁵ Patients at a higher risk of psychosis were enrolled, too, in a number that was about a half of those with an FEP diagnosis. Since there is no established data on the incidence of UHR in the general population, it cannot be said whether the enrolling capacity of

the EIP centres participating in the CCM study was good or not.

Comparison with previous literature on incidence rates

Overall, the rates of three centres out of five were at the lower end of the expected incidence of schizophrenia, and the remaining two centres enrolled a lower prevalence of FEP cases than expected. One of these centres was established at the start of the study and possibly the team was not able to reach all the potential referrals in such a short time of activity. The establishment of collaboration with general practitioners and child and adolescent neuropsychiatry units requires time.^{22,39}

The gap in the treatment needs – the difference between the expected and the treated incidence of a disorder – is common in Italy,²⁴ and partially depends upon the mixed nature of the mental health network of care in Italy, where public and private facilities compete to provide treatment to the people in need. This impacts on the relatively long delay in accessing specialized public services in Italy, where patients are often in their late thirties at their first admission to a psychiatric service.⁴⁶

Since the project had specific age and DUP limits, this might have reduced further the number of patients who could have enrolled in the study.

The characteristics of the patients enrolled in the study were similar to those of the patients enrolled in the Programma 2000, which was the first EIP centre ever established in Italy, in 1999.^{21,22} However, some differences must be noted. Patients had a slightly lower education level than those enrolled under the Programma 2000, and the rate of those with a first- or second-degree relative with psychosis was lower than in past Italian studies.^{22,39}

Regarding the lower prevalence of a family history of psychosis, this may depend upon the staff's being less used to check this information. Also, cultural differences on stigma against disclosing information on family history of psychosis might have played a role in these findings, with less people reporting the information in the EIP centres in the centre of Italy than in the north, although no study specifically investigated the issue.

Limitations of the study

Some limitations of the study should be considered. The collection and the evaluation of the process and outcome data about the activities expected be carried out within the programme were poor.

Effective EIP centres need different professionals and the Department of Mental Health involved in the study sometimes lacked some of these professionals – such as psychotherapists with training in cognitive-behavioural therapy or educators with experience on patients with psychosis. This required the ad hoc stipulation of contracts to hire the professionals required to start the team. Unfortunately, the training of the professional staff into the conceptual and operational cores of the early intervention in psychosis model was not adequately recorded and cannot be detailed.

This study revealed a wide variation in the staff's ability to assess patients in a reliable way, as evidenced by the large CI of the ICC for the BPRS, despite all personnel reached the pre-specified threshold (0.70) in the training with index cases. Since standardized assessment is important in EIP centres, the training of assessors should be especially cared for.

Data on the enrolment phase were regularly collected and recorded, but the follow-up was not adequately documented, and no definite statement can be made on the outcome at 1 year for the enrolled patients. The main reason for the poor recording of outcome data is that staff professionals in Italian public psychiatric services habitually do not perform the standardized assessment of their patients. Brief notes in the patient's chart are used to document the clinical status of the patients, but detailed evaluation is not made.

Challenges in establishing an early intervention centre

The study has highlighted some challenges that are to be expected when establishing an early intervention centre. Lack of continuative collaboration between the psychiatric services and the potential referrals was a critical point that emerged during the formation of the team, and might have affected the quality and the continuity of care within the Italian public mental health-care network.

Resources allocated to the study were scarce and incentives were not provided besides the initial training. Whether monetary or other incentives can favour the implementation of a culture of evaluation in Italian public services is still to be demonstrated.

Since effectiveness of the early intervention protocols is still a matter of debate, documentation of outcome data should be mandatory in EIP centres.^{9–14}

Unfortunately, this part of the study was weak.

CONCLUSION

Overall, the study proved that an EIP centre can be established under the public Department of Mental Health and can reach a good fraction of the cases in need of treatment. Much more needs to be done to reduce the treatment gap, to decrease help-seeking delays by both patients and carers and to improve the detection and referral of the cases in need of treatment by health-care professionals.

This was the first study carried out in Italy to evaluate the feasibility of a protocol of intervention based on the EIP model within the Italian public mental health-care network. Since then, several initiatives have been dedicated to the EIP model in Italy,⁴⁷ including a multi-collaborative study aimed at evaluating a multi-element psychosocial intervention for early psychosis conducted in a catchment area of 10 million inhabitants – the GET-UP study, financed by the Ministry of Health.⁴⁸ Several studies were set up to assess the feasibility of EIP in the Italian public mental health sector in Lombardy and Tuscany.⁴⁹ In 2012, the Emilia-Romagna Regional Authority started an educational plan aimed at implementing the EIP model within all the Departments of Mental Health in the region. In mid-2013, 44 EIP centres are operating within the public mental health-care network of Italy (Lucio Ghio, pers. comm., 2013).

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