

# One-year changes in capacity and participation in patients with schizophrenia or bipolar I disorder treated in community-based mental health services in Italy

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## Summary

### Objective

To investigate the capacity and participation restrictions over one-year in patients treated in community mental health services.

### Materials and Methods

We recruited 100 consecutive patients with schizophrenia or bipolar I disorder. The assessment instruments included the Mini-ICF-APP, the BPRS and the Clinical Global Impression Scale (CGI).

### Results

Capacity/participation restrictions and psychopathology levels improved significantly at one year in each diagnostic group. Moreover, changes in Mini-ICF-APP factors (proficiency, relational capacity, autonomy) were significantly higher in patients

who were improved or much improved (CGI-Improvement = 1, 2) compared with those observed in patients who were not improved. A higher baseline functional impairment and a higher decrease in psychopathology predicted a higher improvement in total Mini-ICF-APP. After controlling for the effect of these predictors, no difference between diagnostic groups was found.

### Conclusions

When a community-based treatment is effective in reducing symptom severity, a concurrent improvement is obtained in capacity and participation functioning. The Mini-ICF-APP was sensitive to change in psychopathology and therefore can be used in routine clinical assessments.

### Key words

Bipolar Disorder • ICF • Mini-ICF • Schizophrenia • Social Functioning

## Introduction

The bio-psycho-social model of the International Classification of Functioning, Disability and Health (ICF)<sup>1</sup> predicates that the definition of illness should include 3 key elements: “impairment of functions” (for instance poor concentration), “limitations in activities or capacities” (e.g. inability to perform daily tasks) and “restrictions in participation” (e.g. reduced work productivity).

This broader view of illness has deeply influenced the scientific community and as a result, in the last decade, research on social and occupational consequences of illness has increased<sup>2-5</sup>. In the field of mental health the relationship between functioning, capacities, and restrictions in participation is a challenge for clinicians<sup>6,7</sup>. The capacity domains, which may be impaired especially in people with mental illness, include adherence to regulations, planning and structuring of tasks, flexibility, endurance, assertiveness, self-maintenance, mobility, or competence in making judgements or decisions.

To our knowledge, only one study to date has examined the extent to which mental disorders are characterized by functional impairment and also by limitations in capacities<sup>8</sup>, so further research on this topic is still needed.

Answering this question would allow to determine which capacities are impaired in specific mental disorders. This could support the choice of specific compensatory treatments, or social interventions tailored to the affected people.

Limitations in capacities can be assessed using the Mini-ICF-APP (“Mini instrument for describing capacity and participation in mental disorders” according to the ICF-model of impairment), a rating scale that has been initially developed in German<sup>9</sup>. Subsequently, the Mini-ICF-APP has been translated to English in a validated version<sup>10</sup>, and its usefulness has been confirmed in a pilot study conducted in a UK community mental health team<sup>11</sup>. This study investigates the capacity and participation restrictions, as measured with the Mini-ICF, over the course

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of one-year community-based treatment in patients with schizophrenia or bipolar disorder.

## Materials and Methods

We recruited 100 consecutive patients (50 with schizophrenia and 50 with bipolar I disorder) attending the Community Mental Health Center (CMHC) of North-Udine (Italy). The diagnosis was determined using DSM-V clinical criteria by the psychiatrists working in the CHMC.

The patients were those recruited for a validation study of Mini-ICF-APP, Italian version<sup>12</sup>. All participants were followed up for one year. All patients were on psychotropic drugs, in monotherapy or polypharmacy as appropriate for the diagnostic indications and the severity of illness (data not provided). One half of patients were involved in rehabilitation programs, that were implemented according to Spivak's model of social competence<sup>13</sup>.

### Instruments

Patients' baseline assessment consisted of a socio-demographic form, including information on gender, age, marital status, working status, duration of illness and duration of untreated illness, previous hospitalizations, alcohol and/or substance abuse, pharmacological treatment, rehabilitation interventions, social network and life events. The Mini-ICF-APP, the Brief Psychiatric Rating Scale (BPRS) and the Clinical Global Impression Scale (CGI) were administered at baseline and one year. All patients were interviewed by 2 psychiatrists with experience in RCTs and mental health research programs, who attended a national training course on the use of the ICF classification system and participated in a specific training on the administration of Mini-ICF-APP. The BPRS is part of the routine clinical assessment of patients and study raters were trained by one psychiatrist (EM).

The Mini-ICF-APP is a clinician-rated instrument designed to assess limitations of capacities in patients with mental disorders<sup>6,7,9,14</sup>. This instrument has been developed by preserving the structure and dimensions of ICF<sup>1</sup> and taking also into account the definitions of the Groningen Social Disabilities Schedule II (GSDS II)<sup>15</sup>. Capacity limitations are rated in terms of activity competence limitations. The 13 items of the instrument explore: (1) adherence to regulations, (2) planning and structuring of tasks, (3) flexibility, (4) competency, (5) judgment, (6) endurance, (7) assertiveness, (8) contact with others, (9) integration, (10) intimate relationships, (11) spontaneous activities, (12) self-care, (13) mobility. For each capacity item, the impairment degree was rated 0 = no impairment, 1 = mild impairment, i.e., there are some difficulties for the person to fulfill the demands, but there are

no negative consequences, 2 = relevant impairment, i.e., there are visible problems in fulfilling the demands, 3 = severe impairment, i.e., help from others is needed regularly in order to fulfill the demands and activities, 4 = extreme impairment, i.e., no activity is possible, and complete dispensation is necessary. The total score ranges from 0 to 52, with higher scores denoting higher disability and vice versa.

The Mini-ICF-APP rater collects information on the patient's capacity, i.e. what the patient can do, in a "uniform or standard environment" or in a social reference group, whichever applies. Information about the patient and his/her living situation is obtained from different sources including self-reports, information from the family, colleagues, friends, caregivers and mental health professionals involved in treatment, from clinical observations or standardized tests. The Mini-ICF-APP assessment requires at least a sufficient acquaintance with the patient and can be filled out in about 20 minutes, and often quite less. A rating manual is currently available in Italian, German and English<sup>9,10,12</sup>. The reliability of Mini-ICF was assessed in the context of mental health services by Balestrieri et al.<sup>12</sup> In particular, this instrument showed excellent inter-rater (ICC = 0.987, 95% CI 0.981-0.990) and test-retest (ICC = 0.993, 95% CI 0.984-0.997) reliability. Moreover, Mini-ICF proved to have a good convergent validity with two well-known instruments designed to assess social functioning (PSP and SOFAS).

In a previous paper<sup>16</sup>, we found that Mini-ICF-APP has a three-factor structure of. The first factor, named "proficiency", represents the cognitive and performance-related skills necessary to begin and maintain a task such as a work or a commitment in general (items 1-7). The second factor was interpreted as "relational capacity" since included the items "contacts with others", "integration", and "intimate relationships" (items 8-10). Lastly, the third factor included the items related with the physical "autonomy" of the individual (items 11-13).

The Brief Psychiatric Rating Scale (BPRS) is a well-known clinician-rated instrument designed to measure the severity of psychopathology in patients with psychosis and mood disorders<sup>17</sup>. For the purpose of the present paper, we used the expanded version of the instrument including 24 items and the 4-factors solution derived by Velligan et al.<sup>18,19</sup>:

- Depression/Anxiety (items 1-6, 13);
- Activation (items 7, 15, 19, 21-24);
- Retardation (items 14, 16-18, 20);
- Psychosis (items 8-12).

Our choice was related to the large sample investigated by Velligan et al.<sup>19</sup>, that included 1331 patients with schizophrenia, depression or bipolar disorder, thereby providing a stable factor solution. The Clinical Global Impressions

Scale (CGI) is an overall clinician-rated instrument that takes into account patient's history, psychosocial problems, symptoms, behaviors, and patient's functioning<sup>20</sup>. The CGI consists of two one-item measures. The first item (CGI-S) measures the severity of psychopathology on a 1 to 7 scale: 1 = normal, not at all ill; 2 = borderline mentally ill; 3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill; 7 = among the most extremely ill patients. The CGI-I measures change from the beginning of treatment on a 7-point scale (1 = very much improved; 2 = much improved; 3 = minimally improved; 4 = no change; 5 = minimally worse; 6 = much worse; 7 = very much worse). In this paper, we dichotomized the CGI-I score into two categories: improved vs not improved.

### Statistical analysis

Quantitative data were summarized as mean  $\pm$  standard deviation or median and range, and qualitative data were summarized as percentages. Wilcoxon sum rank test was used to analyze differences in scores between T0 and T1 in the overall sample.

In order to explore the predictors of changes in capacity/participation, the change in Mini-ICF-APP total score from baseline (computed as baseline total score minus one-year score) was regressed on the diagnostic group and on socio-demographic and clinical predictors, including baseline Mini-ICF-APP total score, gender, age, duration of untreated illness (DUI), presence of specific rehabilitation programs, alcohol or substance abuse, presence of a family network, presence of life events and change in BPRS from baseline. In these models, higher changes in Mini-ICF-APP scores denote higher functional improvement. The diagnostic group was included first into the model, and the other predictors were entered using a forward stepwise procedure that selects only those variables which are significant at 5% and substantially improve the fit of the model. This was done to avoid over-parameterization of the models and improve estimator efficiency<sup>21</sup>.

$\chi^2$  test was used to compare categorical variables between the study groups; when at least one cell frequency in the contingency table was  $< 5$ , Fisher's exact test was used.

The association between changes in three Mini-ICF factors (proficiency, relational capacity, autonomy)<sup>16</sup> and changes in four BPRS factors (depression/anxiety, activation, retardation, psychosis)<sup>19</sup> was analyzed using Spearman's correlation coefficient. For these correlation analyses we set the significance level at  $p < 0.01$ . Lastly, we compared the mean one-year Mini-ICF factor scores between patients improved/much improved and patients with minimal or no improvement, as defined by the CGI improvement score (CGI-I score = 1, 2 vs other). All statistical analyses were carried out using the IBM SPSS Statistics, version 23.

### Ethics statement

The authors assert that this study has been approved by the Local Ethics Committee, and that all procedures contributing to this work comply with the ethical standards of the local institutional committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All patients signed a written consent to participate prior to their inclusion in the study. Data were anonymized before statistical analyses.

### Results

The study sample consists of 100 patients consecutively recruited from those presenting to the CMHC of North-Udine (Italy). The demographic and clinical characteristics of the sample, overall and by diagnostic group, are described in Table I.

Compared with schizophrenia patients, patients with bipolar I disorder were significantly older, more likely to be female, married or separated/divorced, and employed. Moreover, they had a longer duration of illness, a lower severity of illness and a better functioning at baseline. In fact, as shown in Figure 1, patients with bipolar I disorder exhibited lower baseline impairment in each of the 13 Mini-ICF-APP items.

In the overall sample, a general improvement from baseline was found in all psychopathology and capacity/participation (C/P) measures: Mini-ICF total score (from  $23.1 \pm 12.3$  to  $15.6 \pm 11.8$ ;  $Z = -6.6$ ,  $p < 0.001$ ), BPRS (from  $59.0 \pm 22.3$  to  $38.8 \pm 15.0$ ,  $Z = -7.4$ ,  $p < 0.001$ ) and CGI-S (from  $5.1 \pm 1.2$  to  $5.0 \pm 1.2$ ,  $Z = -2.1$ ,  $p = 0.03$ ). All Mini-ICF-APP and BPRS factor scores improved significantly as well ( $p < 0.001$ ).

Changes in Mini-ICF-APP total score were examined in a stepwise linear regression model as a function of diagnosis, baseline Mini-ICF-APP total score, gender, age, DUI, rehabilitation programs (yes/no), alcohol or substance abuse (yes/no), family network (yes/no), life events (yes/no) and change in BPRS from baseline. Table II shows that, when the diagnostic group was first included in the model, patients with schizophrenia exhibited a higher improvement in C/P at one year compared with patients with bipolar disorder. After completing the stepwise procedure, the only predictors of C/P improvement entered and retained in the final model were change in psychopathology and baseline C/P. In particular, patients with a higher decrease in psychopathology levels and higher C/P limitations at baseline exhibited a higher C/P improvement at one year. After controlling for the effect of these two variables, C/P improvement did not differ significantly among diagnostic groups. This model proved to have a good fit to the data and accounted for 58.0% of variance of change in C/P.

**TABLE I.**Characteristics of the sample (n = 100). Data are reported as percentages, or as mean  $\pm$  standard deviation (SD).

Characteristics	Schizophrenia	Bipolar I disorder	Total	Test, p
Gender				7.1, p = 0.008
Males	74	48	61	
Females	26	52	39	
Age (mean $\pm$ SD)	41.1 $\pm$ 10.5	58.3 $\pm$ 13.1	49.7 $\pm$ 14.7	7.2, p < 0.001
Marital status				25.3, p < 0.001
Single	80	30	55	
Married	12	38	25	
Separated/divorced	8	32	20	
Education				11.5, p < 0.05
Less than primary school	0	4.3	2.1	
Primary school	8	13.1	10.4	
Secondary school	40	5.2	28.1	
High school diploma	46	47.8	46.9	
University degree	6	19.6	12.5	
Living situation				1.1, p = 0.29
Self-sufficient/with relatives	88	94	91	
Clinic/Residential facility	12	6	9	
Occupation				8.0, p < 0.05
Employed	22	32	27	
Unemployed	44	18	31	
Housewife/student	10	12	11	
Retired	24	38	31	
Alcohol/substance abuse				0.23, p = 0.63
No	76	80	78	
Yes	24	20	22	
Rehabilitation program at T0				31.3, p < 0.001
No	36	91.3	62.5	
Yes	64	8.7	37.5	
Rehabilitation program between T0 and T1				26.0, p < 0.001
No	26	79.1	50.5	
Yes	74	20.9	49.5	
Duration of illness (mean $\pm$ SD)	17.4 $\pm$ 10.0	22.0 $\pm$ 11.8	19.7 $\pm$ 11.1	-2.1, p < 0.05
Duration of untreated illness (mean $\pm$ SD)	4.3 $\pm$ 6.7	6.9 $\pm$ 9.1	5.6 $\pm$ 8.0	-1.66, p = 0.101
Mini-ICF-APP total score (mean $\pm$ SD)	28.9 $\pm$ 9.9	17.3 $\pm$ 11.7	23.1 $\pm$ 12.3	5.3, p < 0.001
F1: proficiency	17.2 $\pm$ 6.0	10.4 $\pm$ 7.6	13.8 $\pm$ 7.6	4.9, p < 0.001
F2: relational capacity	7.7 $\pm$ 2.9	4.5 $\pm$ 3.3	6.1 $\pm$ 3.5	5.3, p < 0.001
F3: autonomy	3.8 $\pm$ 2.2	2.5 $\pm$ 2.5	3.1 $\pm$ 2.5	2.8, p < 0.01
CGI severity score (mean $\pm$ SD)	5.6 $\pm$ 1.0	4.6 $\pm$ 1.2	5.1 $\pm$ 1.2	4.4, p < 0.01
BPRS total score (mean $\pm$ SD)	68.9 $\pm$ 20.4	50.0 $\pm$ 19.6	59.0 $\pm$ 22.3	5.0, p < 0.001

Mini-ICF-APP: Mini instrument for the observer rating according to ICF of Activities and Participation in Psychological disorders; CGI: Clinical Global Impression Scale; BPRS: Brief Psychiatric Rating Scale.

**TABLE II**

Predictors of change in Mini-ICF-APP total score in patients with schizophrenia and bipolar disorder. Results from stepwise linear regression.

Model	Variables	Unstandardized coefficients (b)	Standardized coefficients (β)	95% Confidence Interval for b	P
1	(Constant)	7.427	7.427	5.605, 9.249	< 0.001
	Schizophrenia vs bipolar disorder	3.985	0.219	0.341, 7.629	0.032
2	(Constant)	7.682	7.682	6.426, 8.937	< 0.001
	Schizophrenia vs bipolar disorder	0.869	0.048	-1.711, 3.449	0.505
	ΔBPRS	6.672	0.731	5.381, 7.962	< 0.001
3	(Constant)	7.654	7.654	6.429, 8.879	< 0.001
	Schizophrenia vs bipolar disorder	-0.565	-0.031	-3.350, 2.220	0.688
	ΔBPRS	6.256	0.686	4.950, 7.561	< 0.001
	Baseline Mini-ICF	1.759	0.190	0.298, 3.220	0.019

Standardization of the regression coefficients was done to allow comparison of variables which are measured on different scales, thus answering the question of which of these independent variables have a greater effect on the dependent variable (i.e., change in Mini-ICF-APP). ΔBPRS: change in BPRS from baseline to one year.

**TABLE III**

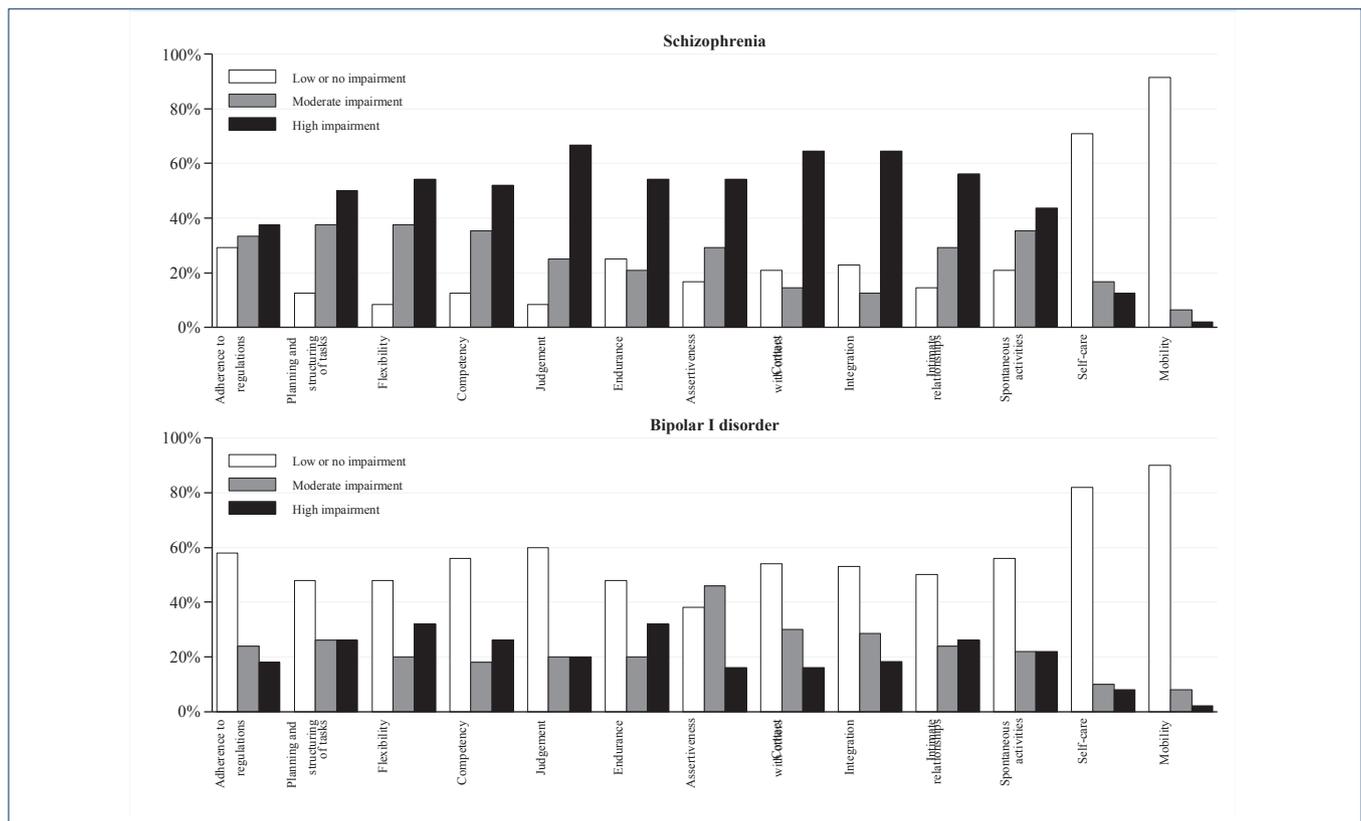
Correlations between % changes from baseline in Mini-ICF-APP factors and BPRS factors, as measured by Spearman's ρ.

Schizophrenia				
Mini-ICF-APP factors	BPRS factors			
	Depression/Anxiety	Activation	Retardation	Psychosis
Proficiency	0.702**	0.778**	0.685**	0.527**
Relational capacity	0.728**	0.715**	0.618**	0.596**
Autonomy	0.569**	0.615**	0.579**	0.523**
Bipolar disorder				
Mini-ICF-APP factors	BPRS factors			
	Depression/Anxiety	Activation	Retardation	Psychosis
Proficiency	0.586**	0.515**	0.474**	0.460**
Relational capacity	0.462**	0.316*	0.310*	0.211
Autonomy	0.472**	0.528**	0.494**	0.388**

\* Correlation is significant at the 0.05 level (2-tailed). \*\* Correlation is significant at the 0.01 level (2-tailed).

We then examined in deeper detail, separately for schizophrenia and bipolar I disorder, the relationship between % changes in Mini-ICF factors and % changes in BPRS factors (Table III). In each patient group, correlations between psychopathology and C/P limitations were all substantive and significant, except for the ICF factor relational capacity and the BPRS factor psychosis in patients with bipolar disorder. In general, correlations were stronger for patients with schizophrenia than for patients with bipolar disorder.

In order to examine the sensitivity to change of Mini-ICF-APP factors, we compared the mean factor scores at one year between patients who were improved or much improved (N = 59) and those who exhibited minimal or no improvement (N = 37). Patients whose severity of illness was improved or much improved had on average lower factors scores than the rest of the sample (proficiency: 1.2 ± 1.9 vs 3.9 ± 2.6, Z = 5.9; p < 0.001; relational capacity: 2.5 ± 2.2 vs 6.6 ± 2.9, Z = 7.7; p < 0.001; autonomy: 6.2 ± 5.1 vs 14.6 ± 6.7, Z = 7.0; p < 0.001).



**FIGURE 1.**

Capacity impairment at baseline in patients with schizophrenia and with bipolar I disorder.

Notes: Low or no impairment (Mini-ICF-Ratings 0, 1), moderate impairment (Mini-ICF-Ratings 2), high impairment (Mini-ICF-Ratings 3, 4).

## Discussion

To our knowledge, this is the first study to evaluate one-year changes in psychosocial C/P in a sample of patients treated within a community-based service, using an instrument built up according to ICF classification.

In this classification, participation is defined as involvement in a life situation, and participation restrictions are impaired capacities that do not allow context or role requirements to be fulfilled<sup>7</sup>.

The emphasis on social functioning has been stressed also by the GBD 2015 study, which underlined that many populations are spending more time with functional health loss, an absolute expansion of morbidity<sup>22</sup>. The relevance of assessing participation as one of the treatment outcomes derives from the shift from the traditional focus of mental health services on deficit amelioration to the promotion of a recovery, defined as “a growing sense of agency and autonomy, as well as greater participation in normative activities, such as employment, education, and community life”<sup>23,24</sup>. It is also worth of mention the original definition of recovery by Anthony<sup>25</sup>, that is “the developing of new meaning and purpose in

life as one grows beyond the catastrophic effects of psychiatric disability”. The World Health Organization underscored the importance of enhancing recovery in the management of psychiatric disorders<sup>26</sup> and this concept has become a core feature of mental health reforms in western Countries, including community psychiatry in Italy<sup>27</sup>. Our community psychiatric centre is strongly committed towards promoting psychosocial recovery, so that the search for a handy instrument to measure the improvements in the C/P has been pursued for a long time. The choice of Mini-ICF-APP was driven by its usefulness in everyday clinical practice to monitor in an operationalized way patients’ variations over time in the C/P domains. Other instruments measuring psychosocial dimensions are available. The WHO has published the WHODAS 2.0<sup>28</sup>, which consists of six domains: cognition, mobility, self-care, getting along, life activities and participation. However, the WHODAS 2.0 does not discriminate well between capacities and participation: most items refer to participation, while only few and very specific capacities are mentioned, which are not very relevant for mental disorders. For a more detailed discussion on the pros and

cons of WHODAS and other instruments, as compared with Mini-ICF-APP, refer to Balestrieri et al.<sup>12</sup>

A major advantage of Mini-ICF-APP is that it can be administered after an in-deep assessment of the patients or after a reasonable time lapse (for example few months) from the first examination, when a sufficient number of mental-health operators remember the characteristics of the patients at a specific point in time. Thus, it is suitable for sharing information among the multidisciplinary team of carers, such as those working in mental health community-based services, who know the degree of restrictions of the subject in different capacities or participation. Another advantage of Mini-ICF-APP over other existing instruments such as the Personal and Social Performance (PSP) or the Global Assessment of Functioning (GAF) is the possibility to detail the restrictions that can hinder the full accomplishment of daily life duties. Thus, the Mini-ICF-APP fulfils the need of an accurate description of the specific restrictions of the person, which is a consolidated principle of rehabilitation programs. Moreover, in this study the Mini-ICF-APP proved to be sensitive to changes in psychopathology.

Our results indicate a general improvement in psychopathology and C/P limitations in both bipolar and schizophrenic patients. This is particularly remarkable, given that the health care staff of the North-Udine CMHC is 0.61 per 1,500 inhabitants, well below the standard of 1 per 1,500 inhabitants recommended by the Italian Ministry of Health. Since the instruments and the diagnostic distribution of other Italian studies focusing on mental health outcomes in the community are different from those of the present study<sup>29,30</sup>, only limited comparisons are possible. However, our results are similar to those obtained by a better staffed (0.7 and over per 1,500 inhabitants) CMHC in Sardinia<sup>30</sup>, and our 100% retention rate is consistent with the 97% rate reported in the large Italian sample of patients treated in CMHCs<sup>29</sup>. Among the number of socio-demographic and clinical baseline characteristics we considered as potential predictors of changes in C/P at one year, only the existing limitations in C/P at baseline proved to be relevant. Patients with most severe limitations were in fact those who benefited most from community treatment.

The implementation of rehabilitation programs was unrelated with the outcome. A possible reason for this result is that, after adjusting for changes in psychopathology over one year and baseline functioning, the presence of rehabilitation programs did not further contribute significantly to the outcome prediction. Moreover, improvement in Mini-ICF-APP factors was highly correlated with the four areas of BPRS psychopathology, except for relational capacities in bipolar I disorder. It seems that the decrease of psychotic symptoms in bipolar disorder did not affect

the relational capacities, which on the other hand were influenced by variation in BPRS factor of mood/anxiety symptoms. This confirms the higher relevance of mood dysregulation as compared with the cognitive domain in bipolar disorder in the process of building and maintaining interpersonal relationships.

The results of the present study should be interpreted keeping in mind some limitations. First, the diagnoses were not made with a standardized clinical interview and, given that non-prototypical cases of schizophrenia and affective psychosis can show similar clinical features, some degree of disease misclassification may have occurred. Second, the lack of a control group did not allow to evaluate the clinical effectiveness of one-year community-based treatment on psychosocial capacities, and the fact that higher Mini-ICF-APP scores at baseline were associated with greater improvement suggests the presence of a "regression toward the mean" effect. Third, we evaluated only the relationship between C/P and impairment due to psychopathology, but we are aware that C/P levels can be influenced also (and sometimes exclusively) by context changes in the patient's life; this issue needs to be addressed in further studies.

## Conclusions

Our results corroborate the observation that in community-based mental health treatment, when treatment is effective in reducing symptom severity, a concurrent improvement is obtained in capacity and participation functioning, and this association is present not only in patients with schizophrenia but also in those with bipolar I disorder. Of note, even (and particularly) patients with the most severe limitations proved to benefit from treatments. The Mini-ICF-APP proved to be sensitive to changes in psychopathology and therefore it is a useful tool to be used in routine clinical assessments.

### Conflict of interest

Prof. M. Balestrieri and Drs. J. Lenzi, A. Lestani, F. Taboga, R. Bonn, P. Rucci, E. Maso declare that they have no conflict of interest in relation to the present work and that they did not receive any grant.

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