Author's response to reviews

Title: A follow-up on patients with severe mental disorders in Sardinia after two changes in regional policies: poor resources still correlate with poor outcomes

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Author's response to reviews: see over
Dear Editor,
We thank you very much for the rapid response to our paper, which we had submitted for publication in your journal.
We are very grateful for the reviewers’ comments that helped us improve the manuscript. In the following lines, you will find our responses to the points they had raised.

Reviewer: Antonio Preti

Reviewer’s report:

Authors investigated a very important topic in the field of Community Mental Health.
I think the paper should be focused on the main aims and findings of the study. Here some suggestion to improve the manuscript.

1. Major Compulsory Revisions

Introduction
“…some regions of southern Italy have implemented complex networks of care”. Please, explain what do you mean: Italian southern regions had better quality care than northern regions? This seems unlikely to me.

“Not surprisingly, the greatest difficulties occurred in the initial phase especially in the southern regions, subsequently some regions of southern Italy have implemented complex networks of care (Bollini et al, 1988)”
The sentence should read entirely! In the first part, which has not been reported, we said "Not surprisingly, greatest difficulties occurred in the initial phase especially in the southern regions, subsequently ...” and continues as reported by the reviewer.
Thus, Bollini et al. wanted to say that first of all local services have been developed in the North of Italy and only later in some areas of the South.
However, we have added “only” to reinforce the meaning of the phrase (“only subsequently…”)

“...an excess of suicides and compulsory admissions to psychiatric units”: I do not think there is one single study investigating the impact on the risk of suicide – or the frequency of compulsory admissions – of the reorganization of psychiatric services in Italy. A very old study found a negative correlation between suicide and the provision of general hospital psychiatric beds: as greater the available resources as lower the suicide rates.


You should also consider that in the period from 1980 to 2000, suicide rates rose all over the worlds, principally as an effect of better recording of suicide deaths and decrease in
underreporting. This should be taken into account.

The excess of suicides among patients discharged from psychiatric hospitals in Sardinia, which was found in Rudas et al.’s study conducted in 1985, cannot be explained by the fact that suicide rates rose all over the world, since it was calculated as SMR, using as reference the suicide rates of the population of the catchment areas of the hospitals, standardized by sex and age. In the same years a similar study carried out by Augusto Debernardi in Trieste did not find a similar excess of suicide, suggesting that the cause may be related to the absence of a comprehensive community care system (V. PASTORE, A. DEBERNARDI, R. PICCIONE: «Psichiatria nella riforma, analisi di un servizio “forte” di salute mentale», Il pensiero Scientifico, Roma – 1983).


We have modified the text to make our point clearer:

“……; a very high average length of hospitalization; an excess of suicides among patients discharged from psychiatric hospitals, showing a higher risk for suicide than the general population living in the same region, as well as a higher standardized mortality ratio for suicide in comparison to patients discharged from hospital in other areas of Italy where a comprehensive community mental health care system had been implemented; and finally a very high rate of compulsory admissions to psychiatric units (Rudas et al, 1988, Pastore et al. 1983) [5].

“Assertive treatment of the severely ill”: do you mean assertive community treatment or assertive outreach?

Assertive treatment has a wider meaning than Assertive Outreach. The term was used by Thornicroft and Tansella synonymously with AO (BJP, 2004, 185:283-290) but it has also been used by the Trieste and Trento teams to describe a constant attitude of attention to patients’ needs and to respond promptly to their needs, with centers open 24 hours a day and 7 days a week. It was used by Falloon to indicate a component of the Optimal Treatment, namely the attitude of promptly responding to the patient’s needs. Thus we need assertive treatment. Adding “community” we could better explain the concept

Is there any published evidence that the official Italian Society of Psychiatry was an opponent of the Italian psychiatric reform? If there is this evidence, please, refer to it. If not, avoid unsupported statement (which could be considered calumnious). Moreover, you should indicate at least one article summarizing the alluded “debate”.

“…the reform of the mental health care should cease”. What do you mean? The Sardinian Regional authority abolished the Law 180?

At that time, representatives of the Italian Society of Psychiatry had repeatedly and officially
criticized the Sardinian regional policies (and obviously not the Italian reform). We therefore would be surprised if they regarded such a statement as slanderous. For instance, during the 10th Meeting of the Italian Society of Forensic Psychiatry in Alghero, the president of the Italian Society of Psychiatry and the regional coordinator of the society expressed their concerns about the reforms in Sardinia in an interview given to a Sardinian newspaper. In contrast, the president of ASARP, the Italian association of families with a member with mental health problems, had supported the reforms in Sardinia. In the text, we have now added references to sources documenting both views:

Inevitably, this change of pace in policy led to a fierce debate between those who were opposed to the regional reform (among others the Italian Society of Psychiatry through the voice of its president and its regional coordinator, as expressed in press interviews during a national congress held in Sardinia at the time (La Nuova Sardegna 2007), and those who were in favor of the reform such as associations of families with mentally ill people (Comitato Salute Mentale 2008).

La salute mentale in Sardegna: le aspettative tradite. Gisella Trincas manifesta il suo scontento sulle valutazioni dei senatori, 23 dicembre 2010

“The study was carried out during 2010-2011, just at the end of the reform period”. Please, specify what kind of “reform” you are taking into account: the Law 180 (which I think is still in place in Italy), or the reorganization of the mental health departments planned by the unknown psychiatrists from Trieste? Do you have any evidence that this project was implemented all over the Sardinia region? Is there any published evidence on this?

In Italy the management of the public health system is the responsibility of the Regions according to the national laws. In January 2007, the Region of Sardinia approved the "Regional Plan for Health Services" (Regione Autonoma della Sardegna 2007), which is in the part related to mental health. The regional law refers openly to the "Trieste model" (planning of beds for patients in post-crisis within outpatient facilities (p. 50), strong emphasis on social inclusion and opening of local services 7 days a week, 24 hours a day (p. 50)).

To prevent any misunderstandings we have added the adjective “regional” to “reform”.

An indication of the changes that had taken place in the Region was the creation of autonomous departments of mental health within the local health areas (ASL), which until then did not exist in Sardinia, a strong emphasis on local services and an increase in spending for mental health (but probably more for social inclusion projects for severely ill patients rather than for augmenting the mental health staff). However, it is clear that it was an official reform of the regional policies and not a reorganization planned by some unknown psychiatrists from Trieste. It is true that at the time the director of the Department of Mental Health and of the WHO Collaborating Center of Trieste (thus the direct heir of Franco Basaglia) was working as a supervisor of the Sardinian Region “Assessorato della Sanità” (Local Health Ministry), as one of the heads of the mental health facilities in Trieste had become head of the Department of Mental Health of Cagliari, the largest department in the Region, attending one third of the Sardinian population.

However, we do not think that it is in the interest of this paper to go into these details. We rather think that it may be more of interest to inform about the general politics and the changes of resources available for mental health care.
Aims

“We aimed to investigate whether the amount of resources available for patient care may be a determinant of the social and clinical outcomes in this patient cohort”.

The aim should be better linked to the introduction. You should explain how the “psychiatrists from Trieste”’s plan was related to the amount of resources available for patient care. Did they provide additional funds for patient care?

The fact that we expected a lot of resources, or at least a sufficient amount of resources, is not only related to the "psychiatrists from Trieste" but to a debate that put mental health at the center of public attention, with two opposing viewpoints being taken by the government of the Region.

We changed the sentence to respond to these recommendations, and to those of the other referee, as follows:

The main objective of this study was to carry out a follow-up study on patients with psychosis who were being cared for by the public community mental health system in Sardinia, using measures of outcome allowing comparison with other similar international and national studies, and to identify key factors which may play a role in their outcome.

The study was carried out during 2010-2011, just at the end of the reform period. A secondary objective was to investigate whether the amount of resources available for patient care, expected to be sufficient given the extent of the political debate on mental health care, was a determinant of the social and clinical outcomes in this patient cohort.

Methods

Please, specify how many people were covered up in the participant CSM.

Unfortunately, such data are not available. The study was conducted in centers which provide routine care and which do not have a case register. A regional survey conducted in 2009 found that the patient load of all the centers (CSM) of Sardinia was 180 x 10,000 (Regione Sardegna 2009). This proportion is also higher than that recorded in the national centers and are known to the international literature (Trieste 151; Arezzo 149; Verona 70 per 10,000 inhabitants, ISTISAN 2006), This excess load in patients is probably due to the fact that in Sardinia there are few alternatives to public services.

But another source of variability may be the non-reproducibility of the observations collected without a standardized method. Therefore, we decided not to bring these data into the text.

“Psychiatric diagnosis was made by clinicians, using ANTAS which is a semi structured interview”. You should specify for doing what this structured interview is aimed to: diagnoses according APA DSM criteria?

It was stated that the diagnoses were made “according to DSM-IV (APA 1990)”

Please, report at least a reference to validation studies on the GAF.

We have added a reference to the first validation study (Endicott et al. 1976). However, in the DSM-IV, which we had already mentioned, the psychometric characteristics of the scales are
reported.

It is not clear whether the assessment was made by the clinicians under evaluation (those working in the participant CSM) or by independent raters. Some information on how the raters were instructed to use these tools should be provided.

We have clarified this point by saying:
“The assessment was made by independent raters who did not belong to the staff of the centers. They used all the sources needed for completing the different instruments (patients, professionals and clinical records)”

Results
Table 1 has incongruent data. For example, total number of participants is 259, available data on parenthood is: yes = 6, no = 19, not reported = 38. And the others? Your total percentage by variable should always be 100%.

We are very grateful for pointing out these incongruences. The figures have been corrected

“In all areas studied human resources were below the standard suggested by the Italian Ministry of Health”. What is this standard? The information should be in the methods. You refer to 1 staff in 1500 person: is it indifferent that the staff personnel are a psychiatrist, a psychologist or a nurse?

In the Methods section has been added:

Data on human resources were collected from administrative records of the centers and compared with the standards recommended by the Italian Ministry of Health, according to which staff should include at least 1.5 professionals (including doctors, psychologists, social workers, nurses and administrative professionals) for a target population of 1,000 inhabitants (Progetto Obiettivo Salute Mentale, Gazzetta Ufficiale n. 274 del 22.11.1999)

Before comparing the DSM with the MANOVA you should introduce some statement about what DSM has better resources than the others. This is essential to your aims.

We have changed the order of presentation starting with the resources available in the various DSMs.

Moreover, you reported data on staff, but no information on accessibility (hours open per week) and beds were reported in the manuscript. Accessibility (keeping community care facilities open 24 hours a day) and additional beds for care.

It would certainly have been more interesting to take into account these variables. However, the resources are so poor and sub-standard that even a coarse measure such as the mere amount of available human resources is of interest. This point is now being addressed in the newly added section on limitations of the study.
(providing beds for patients within the community care structure) was the core of the plan advanced by the unknown (and unnamed) psychiatrists from Trieste, as you described it in the introduction. You did not have really tested the impact of such a plan to be fair with these psychiatrists from Trieste. Resource staff depends on hiring people, opening hours is more a matter of organization. Of course, you need money to have staff personnel working more hours per week, and you need money to have more available beds. Was this money provided by the plan developed by the psychiatrists from Trieste?

We agree with the reviewer that the organization of services is an important point. However, before discussing whether more or fewer beds are needed in a community center, or whether it should be kept open more or fewer hours, one has to have at least the minimum of personnel. If you do not have the minimum staff all the rest is mere talk. In the newly added limitation section we have now addressed this issue.

Discussion

“The study shows that, despite a heated ideological debate about how to organize mental health services in Sardinia, public services remain very resource-poor, at least in terms of human resources”. You did not report any reference about this debate. There is no comparison with data from other Italian regions. Did they have done better than the Sardinia region?

So far, we contrasted our results with the minimum standard suggested by the ministry, which seemed to us to be of relevance. In the Discussion, we are now comparing our data also with those from the centers of excellence in Trieste, Arezzo and South Verona.

“Both the health managers inspired by the model of Trieste who have governed the public health services up to 2009 and the opponents of the Trieste model have failed to provide citizens with a minimum of resources required for an acceptable level of quality of care”.

This is a too hard statement. To evaluate the impact of both models you should have investigated a much larger time interval. Moreover, you should provide evidence on staff hiring, since all your study is on this (how many people did work in each participant DSM). Was staff hiring expected by the plan developed by the psychiatrists from Trieste? Was expected by the plan developed by the opponent of the Trieste model? Do you have any hard evidence on this?

Our point is that today in Sardinia the various public mental health centers operate with 40%-70% of the resources required by the Ministry of Health as a minimum, while in centers of excellence these resources are from 180% in Trieste to 120% in Arezzo or 160% in South Verona. Therefore, this statement appears us not at all too strong. As requested by the reviewer, we have added comparisons with these mental health centers to strengthen our argument.
Since you did not specify whether the assessment was done by the clinicians or by independent raters, it remains unclear what is the reason for the links between better staff resources and better outcome on the HoNOS. In the case the treating clinicians made the assessment, it could be merely an effect of them having more time to fill in the tools in a center with more personnel, so they were more precise in differentiating the patients.

The assessment was made by independent raters. This has now been better explained (see above).

You found no link between staff resources and GAF or CGI scores. So, the finding concerning the HoNOS might be a chance finding. This should be discussed

We now discuss these differences (as requested also by the other reviewer) on page

2. Discretionary Revisions

There is no information on the inter-rater reliability. This is essential to assure that the compared scores are reliable. Poor rating may lead to unreliable comparisons.

As already described (see page ), all raters underwent one week of intensive training in the use of the instruments with crossed assessment to improve the reliability of their assessments.

It is not clear what is the point of the authors. They found some links between staff resources and health problems on the HoNOS. What is the consequence? What kind of recommendation they can advance?

It is obvious: to have more resources available There is no discussion on the limits of the study.

A limitation section has been added.

3. Minor Essential Revisions

English should be improved in both the style and the grammar.

For example “it installed a more traditional system of mental health care have introduced in 2009.” This means nothing (it seems to me that two different versions of the phrase were collapsed into one sentence).

Other example: “eight like sector areas”.

There are many typos, which should be corrected: e.g., “… I standards of epidemiological research…” What is “I”?

Other typo: “Thus t, the debate”.

**Level of interest:** An article of importance in its field
Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests

Reviewer's report

Title: A follow-up on patients with severe mental disorders in Sardinia after two changes in the regional policies: poor resources still correlate with poor outcomes

Version: 1 Date: 2 August 2013

Reviewer: Anita Holzinger

Reviewer’s report:

The paper represents an innovative contribution to mental healthcare research, studying the relationship between the provision of resources for the care of people with severe mental illness and outcome. It addresses an issue of growing importance in view of actual tendencies, as consequence of the current fiscal and economic crisis, to cut funds for healthcare in general and mental healthcare in particular.

Before the paper can be published it needs some reworking. Here a few suggestions:
- In the Introduction, after having described the development of mental health policy in Sardinia in recent years, the authors state that “it makes sense to evaluate the impact of these changes on the patients on whom all the services should focus”. However, is this really the research question addressed by the study? It seems rather questionable that the study design chosen would allow providing an answer to this question. The authors should try to find a better transition between the first part and the aim of the study as described in the last phrase of the Introduction.

This has been changed (see page )

- The authors take the association between the increase in staff available for patient care and better outcome on the HoNOS as indication of the importance of the provision of sufficient resources for successful treatment. Could this finding also be interpreted in a different way? And what about the CGI and GAF? Have the authors some ideas why no significant association was found with these two measures?

As we have pointed out this may be due to a stronger relationship with the social outcome and staff resources (according to previous research) and it is being argued that staff shortages are mainly to be found among the non-medical personnel.
- Although some limitations of the study are acknowledged it seems appropriate to discuss them at some greater length.

A limitation section has been added (see page )

In the manuscript there are numerous typing errors which should be corrected as follows:

**Introduction:**
1st page, 1st paragraph, 4th line: “care although the community services…”
1st page, 1st paragraph, 6th line: “..in southern regions. Not surprisingly..”
1st page, 2nd paragraph, 2nd line: “…using standards of..”
1st page, 2nd paragraph, 3rd line: ”Thus, the debate…”

1st page, 3rd paragraph, 1st line: “..implemented late (Rudas et al, 1988)”
2nd page, 2nd paragraph, 5th line: “..there was a change in the government of the region. The new administration..”
2nd page, 3rd paragraph, 8th line: “In consequence, a more traditional system of mental health care has been installed in 2009.”

**Methods:**
Instruments, 1st line: “..ANTAS which is a semi-structured interview that has previously been successfully used and validated in this population [7,8].”
Statistical analysis, last line: “...DSMs was examined by means of...”

**Results:**
Socio-demographic and clinical characteristics of patients, 1st line: “..recruited, 259 (83.8%) completed..”
Socio-demographic and clinical characteristics of patients, 3rd line: “...regarding gender, age(??) or..”
Socio-demographic and clinical characteristics of patients, 8th line: “..sample are reported in Table 1.”
Staff resources in the DSMs studied, 4th line: “..were below the standard suggested by the Italian Ministry of Health (1 staff person per 1,500 inhabitants) (Gazetta ufficiale 274, 1999).”
Outcome indicators during follow-up (without time!), 5th line: “Even though the severity of illness…”
Outcome indicators during follow-up, 7th line: “…significantly less in DSM6 (F (14.540), p=0.000 and F (18.674), p=0.000, respectively).”
Table 2: “Increase in total staff during follow-up (%)
Correlation between improvement in outcome (without s!) and increase of resources, 3rd line: “..correlated with an improvement in the total score of the HoNOS.”
Table 4, last line (Spearman correlation): “SRRC=0.975”

**Discussion:**
1st page, 2nd paragraph, 5th line: “..the resources are insufficient..”
1st page, 2nd paragraph, 8th line: “…the paucity of resources…”
1st page, 2nd paragraph, 10th line: “..by the HoNOS)..”
1st page, 2nd paragraph, 17th line: “…years. About 80%...”
1st page, 2nd paragraph, 18th line: “…personality disorder. This group showed a mean HoNOS score of 11.36 (SD 6.21) with..”

2nd page, 3rd paragraph, 1st line: “...implemented late (Rudas et al, 1988)”
2nd page, 2nd paragraph, 5th line: “..there was a change in the government of the region. The new administration..”
2nd page, 3rd paragraph, 8th line: “In consequence, a more traditional system of mental health care has been installed in 2009.”
1st page, 2nd paragraph, 19th line: “...end of the follow-up, which is similar...”
2nd page, 4th paragraph, 3rd line: “...in future studies. This conclusion is supported...”

3rd page, 1st paragraph, 1st line: “...important but are also the most expensive part...”
3rd page, 1st paragraph, 2nd line: “...thus need being convinced to invest...”

In addition, there are a number of formal points which should be addressed when revising the paper:
- Pagination is missing
- Reference Rudas et al: In the text (1st page of Introduction, 3rd paragraph, 2nd and 7th line) the year is 1988 whereas in the reference list it is 1989. Please clarify.
- Table 2: In the legend, please omit the phrase referring to the Italian standard. It should be included in the text.
- Table 2: Please check the percentages referring to the increase in staff, since they do not correspond to the difference between the figures given for total staff at the beginning and at the end of the study.
- The subtitle “Correlation between improvement in outcome measures and increase of resources” should be underlined rather than in bold characters.
- In Table 3 and 4 as well as in Figures 1 to 3 commas should be replaced by dots.
- Since the information provided in Table 3 and in Figures 1 -3 is redundant, one might consider dropping the figures since they do not contain additional information. If one decides to keep them the order of DSMs should be the same as in Table 3.
- The reference list must be revised according to the guidelines of the journal.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare no competing interest

As an Associate Editor of BMC Psychiatry, I would claim a 20% discount off the Article Processing Charge (APC)

Sincerely,

Mauro Carta