Author's response to reviews

Title: First Episode Psychosis and Migration in Italy (PEP-Ita Migration): a study in the Italian Mental Health Services

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Author's response to reviews: see over
Reviewer: Gerard A Hutchinson

Reviewer's report:

MINOR ESSENTIAL REVISIONS

Background- 1. Some more detail on the patterns of migration to Bologna in particular would be useful to contextualise this study- where are they coming from; how recently has this increased migration been acknowledged and reasons for migration in the various groups.

Authors: Thanks for suggesting this important perspective of contextualization. Actually, we noticed that a sentence in the Background section (“The study will be carried out at the Bologna Transcultural Psychiatric Team”) could be misleading: in so far, other 10 study centers across Italy have joined our research and will be recruiting immigrant patients with first-episode psychosis. Thus, we corrected the misleading sentence (“The study will be carried out by 11 study centres across Italy and will be coordinated by the Bologna Transcultural Psychiatric Team (BoTPT)”) and following the referee’s suggestion, we now give details about the general patterns of migration to Italy.

“Migration to Italy is a relatively recent phenomenon, mainly developed in the last 20 years and still increasing (+8.2% in 2013) [30]. At the beginning of 2013, migrants represented 7.4% of the resident population. Migrants come to Italy from any continent, more frequently from European countries (both EU, 27.4% and non-EU, 23.4%); 22.1% from Africa, followed by Asian (18.8%) and American (8.3%) migrants. The most represented countries of origin are Romania (21.2%), Albania (10.6%), Morocco (9.9%), China (4.6%), Ukraine (4.4%), Philippines (2.9%), Moldova (2.9%), India (2.6%), Poland (2.4%) and Tunisia (2.3%) [31]. Most migrants in Italy live in the Northern regions (61.8%) and emigrated to find a job, though the reason for migration has suddenly changed in the recent years: in 2012, family reasons (81,322 migrants) became more frequent than work reasons (52,328 migrants), probably because of the progressive decrease of job offer in Italy and the stagnation in labour market [30]. Also, migrants who come to Italy are frequently asylum-seekers: in 2012 about 60,000 people have reached our coasts from Tunisia and Lybia.”

2. The mental health services in Italy are described as having a 'peculiar organization' p6- what does this mean for the study?

A: Thanks for highlighting this point. Now we further explain the organization of Mental Health Services in Italy and how their organization may facilitate access to care (thus allowing us to recruit and study accurately first-episode psychoses in migrants).

“[In Italy] health care is provided to the population by the Italian National Health Service, which is built like the British National Health Service. All the population has unlimited health care coverage, which is provided by “Local Health Units”, each responsible for a geographically defined catchment area. Access to health services is generally free of charge. Accordingly with the 1978 reform, psychiatric care is delivered by general hospital psychiatric wards for acute admissions, and community mental health centres (CMHC) providing psychiatric care to geographically defined areas. Non-resident people such as temporary migrants can access to care as much as resident population for urgent and/or necessary cases. CMHCs (an average of 1.81 services per 150,000 population) deliver individual consultations and domiciliary care activities, keep contacts with other health and social agencies and provide emergency interventions. They have a multidisciplinary staff, including psychiatrists, psychologists, social workers, nurses, and educators. Migrants are
cared by the same CMHCs of the general population, and cultural-competent activities are provided on demand (e.g. interpreters, cultural mediators, social/legal support, etc.) [28, 29]. So structured, such an organization would facilitate access to care for migrants presenting first-episode psychosis in Italy; yet, previous studies demonstrated that migrants with mental disorders might follow different and more complex pathways to care [26].”

3. What methods will be used for the migrant group to ensure that they are first episode and have not sought help in their countries of origin.

A: An accurate medical history will be recorded together with patients and, where necessary, with their families. Of course, also the past use of medications or other therapeutic strategies will be object of a strict survey. We now explain this in the text.

“In order to ensure that patients have not yet presented and been treated for a psychotic episode, an accurate medical history will be recorded together with patients and, where necessary, with their families. Previous use of medications or other therapeutic strategies will be the object of a strict survey.”

4. is it a case control study and if so this should be made clearer with regard to the recruitment of control cases?

A: In the method section we show the three optional levels of research of the study: the second optional level consists of a case-control study with native patients presenting a first-episode psychosis in the same catchment area and study period of migrant patients. Following the referee’s suggestion, we have made clearer what the control group consists of and how it is recruited.

“2) a case-control study, the control group consisting in FEP native patients consecutively attending psychiatric services in the same catchment areas and in the same study period as FEP migrant patients”

5. p8 1st paragraph is confusing, also using the authors’ statistics, i get 280 migrant patents, does their figure of 250 mean that they expect a 10% refusal rate?

A: Thank you for your attention, that was typo! However, since we had to recalculate the denominator after restricting the participation to this study to 11 study centers instead of the 30 previously included, data have changed:

“…we will expect to recruit 111 migrants cases by year 2”

6. how important will translation issues be for the migrants and indeed for the tests/questionnaires themselves and how will these difficulties be managed in the study?

A: Indeed translation issues will be very important in the assessment. As already specified in the text, “in case of relevant linguistic barriers, a cultural mediator will join the clinical researcher”. However, all instruments have been translated into several languages (English, French, German, Dutch, Spanish, Portuguese, Turkish, Serbian), through a back-translation process (within the mentioned EU-GEI research): this will help the direct assessment of the patient, confining the presence of cultural mediators only to those cases
where migrants have significant linguistic barriers and instruments in their own language are not available.

Thanks for highlighting this point, we have expanded the relative section in the text.

“In case of relevant linguistic barriers, a cultural mediator will join the clinical researcher: however, research questionnaires have been translated into several languages (English, French, German, Dutch, Spanish, Portuguese, Turkish, Serbian) through a back-translation process. This will help the direct assessment of the patient, confining the presence of cultural mediators only to those cases where migrants have significant linguistic barriers and instruments in their own language are not available.”

7. in the abstract conclusion, the statement about psychosis causation is misleading, a better word might be understanding.

A: We agree with the referee, the word is quite misleading: we changed it with “risk factors for psychosis”.

“The results of the PEP-Ita study will allow a better understanding of risk factors for psychosis in first-generation migrants in Italy.”

8. there are grammatical errors that need to be corrected
A: The text has been widely reviewed by a PhD in English studies: thank you for suggesting a more accurate revision.

Reviewer: Kevin D Morgan

Reviewer’s report:

The study proposed is one of importance and should contribute to the understanding of the elevated risk factors for psychosis in migrant and ethnic minority groups. The proposal described in the manuscript provides a good outline of the study as a whole including its rationale, aims and methodology.

There are some details regarding the methodology however that may have been omitted or if not omitted, are aspects of the study methodology that should be addressed or at least referred to, in the report.

Major Compulsory Revisions

1) As one of the principal aims of the study is to assess the incidence of psychosis in migrants in Italy it would be helpful if the report could clarify how the population at risk (i.e. migrants living in Italy) has been calculated or estimated. (The figure of 10% of the total population in the catchment area is mentioned but without specifying how this percentage has been reached).
Authors: Thank you for suggesting this specification. In order to calculate the population at risk (migrants living in the catchment areas of research centers involved in the study) we have relied on data from the National Institute of Statistics (ISTAT). We now specify this in the text. Moreover, since we have narrowed the participation to the study to only 11 centers (instead of the 30 previously included), we had to recalculate the denominator and the percentage of migrants.

“Basing on data from the National Institute of Statistics, with a whole catchments area of 2,135,145 inhabitants and 6.5% of migrants, and considering a conservative estimate of yearly incidence cases of 20/100,000 among Italians and 40/100,000 among migrants year as already reported by previous estimates, we will expect to recruit 111 migrants cases by year 2”.

2) The report states that a case-control study on FEP patients in the same catchment area during the same data collection period will be conducted. It would be helpful if the criteria upon which the native FEP patients will be selected is described e.g. will it be based on consecutive admission to designated hospitals or outpatient clinics etc? Will they be matched to the migrant FEP patients and if so, on what basis? The projected number of native FEP patients is also not referred to. This would be useful to know.

A: Thank you for highlighting this point: actually, inclusion criteria for native FEP patients are needed. As the referee correctly suggests, their inclusion will be based on consecutive admission to the designated psychiatric services for each center of study in the same recruitment period (January 2012 – December 2013). We added this point in the text.

“The inclusion criteria for control native patients are the same as migrants; their inclusion will be based on consecutive admission to the designated psychiatric services for each study centre in the same recruitment period.”

We did not give an expected number of natives patients included in the study because only centers taking part to the case-control optional level of study will recruit natives (thus we are not able yet, in this stage of the study, to predict how many natives we will include).

3) In relation to the above, for a study that is investigating risk factors for psychosis in migrants, a case-control study of migrants who do not develop psychosis would be beneficial if they were recruited in the same catchment areas at the same period of data collection. While this is not essential to implement, the report would be enhanced by consideration of such a strategy.

A: Thanks for suggesting such a stimulating perspective: this could be an interesting evolution of our research project. We are happy to add this to the text.

“As a future perspective, it would be an interesting additional research field a case-control study with migrants who, having been recruited in the same catchment areas at the same period of data collection, have not developed psychosis”.

4) For the FEP migrant patients the inclusion criteria should specify what constitutes migrant status e.g. is there a minimum period of residency?
A: Thank you for this comment. We added a clear definition of “migrant”. As for WHO (2003), we define “migrants” people who move from one area to another for varying periods of time and for any reason. So, there is no minimum period of residency required: however, as already specified among inclusion criteria, migrants from our sample have to be resident in the study area of the involved mental health centers. We have expanded this point as suggested.

“We define “migrants” people who move from one area to another for varying periods of time and for any reason.”


5) In similar incidence studies a strategy is usually put in place to estimate the accuracy of the incidence rate reported. Typically, a ‘leakage’ study is conducted after 12 or 24 months of the primary data collection to assess how many FEP may have been ‘missed’ by the researchers during the critical data collection period. It would be helpful to know if such a leakage study or alternative approach has been planned.

A: Thank you for this comment: actually a leakage study at 24 months has been planned. We have now added this point to the text.

“Twenty-four months after the survey period, we will conduct a leakage study to identify any subject that may have been missed during the critical data collection period. In order to do so, we will review all new mental health service registration forms and will interrogate the computerized information systems”.

Minor Essential Revisions

There are several typographical and grammatical errors in the manuscript. I have not listed them here but would be happy to provided the details if required.

A: The text has been widely reviewed by a PhD in English studies: thank you for suggesting a more accurate revision.