Author's response to reviews

Title: Preventing compulsory admission to psychiatric inpatient care through psycho-education and crisis focused monitoring

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Version: 3 Date: 5 June 2012

Author's response to reviews: see over
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**Title:** Study protocol
Preventing compulsory admission to psychiatric inpatient care through psycho-education and crisis focused monitoring

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**Version 2 / Date:** 5 June 2012
Review 1:

On page 5, the authors should also mention the study of Papageorgiou et al. (BJP 2002), describing the negative effects of advanced directives on the number of compulsory admissions.

We inserted on page 6:
Negative effects in terms of subsequent readmissions and self-efficacy at follow-up, however, have been reported by Papageorgiou et al., who studied the effects of advance directives in a sample of 156 in-patients receiving compulsory psychiatric treatment (Papageorgiou et al. 2002). Furthermore, ...

Page 6. The authors state that "the effectiveness of such tools has been studied only with regard to more or less subjective ...". The authors should include one or more references here.

We deleted the whole phrase and rephrased the paragraph (page 7) in order to connect up to the following references:
Effects in terms of more robust effectiveness criteria (e.g. significant reduction of admission rates, cost-effectiveness) have been investigated in larger study samples only lately: ...

Page 6 Last paragraph. The authors should also mention the study of Ruchlewska et al. (BMC Psychiatry 2009), of which the results also are to be expected soon.

We added a paragraph referring to this study on page 7:
A further ongoing randomised controlled trial in the Netherlands aims to study the differential effect of two types of crisis plans (a crisis plan facilitated through the patient's advocate, or through the clinician), compared to a control condition. This study investigates effects on the number of psychiatric emergency visits and (involuntary) admissions and on social and psychological functioning in adult outpatients with psychotic or bipolar disorder. Moreover, it addresses the mediating mechanisms responsible for possible effects, such as the quality of the therapeutic alliance, therapy adherence, self-efficacy and insight into illness (Ruchlewska et al. 2009).

Page 8 and 9 (Intervention): it would be important to know how the personal mental health care worker, who maintains contact with the patient during follow-up, communicates with the regular mental health care workers. This will be crucial when for example the patient reports suicidal or violent thoughts, and may constitute a danger to himself or others. What happens when the patient asks the personal mental health care worker not to report this to the regular mental health care worker? In addition, the following information should be included (1) are regular treatment teams informed about the outcome of the randomization?, if so, (2) is there any structured collaboration between the personal mental health care worker and the regular mental health care worker, (3) do the regular mental health care workers also receive a copy of the individualized crisis card? (4) what happens when the patient repeatedly does not answer the phone when the personal mental health care worker tries to call the patient? Is the patient visited at home and/or are the regular treatment teams informed? Potentially, not answering the phone could be a sign of a crisis.
To make our approach more clear, we added a couple of annotations:

1. On page 9, we inserted:
The intervention programme shall not replace the patients' regular therapy. Rather, it is considered as a supplementary measure to give chronically mentally ill patients individual support to become more actively involved in their care. Because the programme targets an increase in the patient's empowerment, no structured collaboration between the personal mental health care worker and the regular treatment team is intended. The regular (inpatient) treatment team is informed that a patient is participating in the study. Members of the regular treatment team, however, are not aware of the outcome of randomisation.

2. On page 11 we added:
It is only in emergency situations in which a patient may constitute a danger to himself or others, (e.g., if a study participant reports suicidal thoughts, but refuses to see any mental health care professional or other persons) that the personal mental health care worker will adopt measures to protect the study participant. Patients are informed that in such a situation the confidentiality agreement will be ignored.
It is not intended, however, that the personal mental health care worker who maintains contact to the patient during follow-up communicates with a patient’s regular therapists or other mental health care professionals. Only if a patient explicitly desires this, may the personal mental health care worker impart information.

Accordingly, it is left to the patient to provide his/her regular therapist with a copy of the crisis card.

4. Visits at home are neither intended, nor could such be accomplished within the given time frame.
We added on page 11, paragr (c):
Patients, however, are not visited at home. If the study participant does not answer the phone, the personal mental health care worker will follow-up until he/she gets through to the study patient.

Participants
The inclusion criteria tell us that the patients can be included after they have been discharged. On page 8 (last paragraph) it is stated that patients are included during admission. Could this be clarified?

Page 8 was/is correct. The first point of the inclusion criteria, however, was misleading and has been rephrased (now page 13):
- receive inpatient treatment in one of the four psychiatric hospitals participating in the study during the recruitment period (24 months).

The risk of self harm or threat to others is assessed using the patient's files, as well as using the HCR-20 in case harm to others is suspected. This is problematic. The results will depend on the level of accuracy of the clinicians reporting on their patients’ behavior. I would strongly advise to use structured assessment scales to assess danger to others, suicidal thoughts/attempts as well assessing self neglect/social breakdown.
Obviously our approach to assessing the "Risk of self-harm or threat to others" was unclear, too. Indeed, we do not exclusively rely on the clinicians reporting on their patients' behaviour. Rather, the patients' files are checked in preparation for the baseline interview. If there is any indication of such behaviours, the staff member has to do a comprehensive interview, applying the instruments specified in the text. It is to be considered, however, that the majority of study participants are admitted compulsorily and that the situation leading to the inpatient admission (index episode) is therefore documented sufficiently (even if only for legal reasons). Only in the small group of cases (currently 14%) who have been admitted to psychiatry voluntarily (current index episode; compulsory admissions in the past) might there be a risk that such behaviours are overlooked when checking only the patient files. Because the study has been running for quite some time now (and more than 200 subjects have already been recruited), it does not seem viable to exchange these scales at this stage. We tried to clarify this point on page 16, last paragr:

For a first screening of violent or self-harming behaviours in the past, information within the patient's file prior to baseline consultation is checked. If the patient's history is suggestive of such behaviours or the baseline interview brings out such behaviours, risk of self-harm or threat to others is rated by the staff members and if so, is assessed throughout the follow-up. Ratings are based ..... 

Statistical analyses
There is no description of the specific statistical analyses that will be used for answering the 3 research questions, e.g. to test the effects of the interventions as well as the effect modifiers.

On page 19/20 we added the following passage:
To address the major research questions, the quantitative outcome data will be analysed for the whole trial across the four centres, using General Linear Models. T-tests for independent samples are applied primarily to test the comparability of the intervention and the control group. Analyses of covariance are performed to compare the intervention and the control group with respect to the primary outcome (time in hospital accumulated over all involuntary inpatient stays) and secondary outcomes (reduction in levels of subjectively experienced coercion; increase in quality of life, treatment satisfaction and level of empowerment). Age, gender, centre and other variables which show significant between-group differences are included in the GLM models as covariates. To examine which characteristics on the patient level (treatment history, diagnosis, social network, treatment adherence in the two-year follow-up) modify the outcome, we examine the effects of these variables on the outcomes of interest within the intervention group, applying regression analyses. The level of significance is set at 0.05, two-tailed.

On this account, minor modifications were made in the preceding paragraphs (page 19) in order to avoid redundancies. We rephrased:
All major endpoints of the study will be compared between the intervention and the control group. Primary outcome of the study is the time in hospital accumulated over all involuntary inpatient stays during the 24 month period. ... Hypothesised benefits of the intervention are ...
Minor essential revisions
Why did the researchers not include illness insight as a measure. It is likely that this will moderate the effects.

In fact, illness insight would be a very important aspect, but, regretfully, it is not assessed in this study. (There are only a few items within the HCR-20, but these are ratings of the staff members).
All we can say about that is the time limitation of the assessments: Due to the restricted time available for baseline and follow-up interviews, which should not exceed more than two hours per meeting, we had to dispense with some interesting issues and to restrict the number of questionnaire modules. We agree that illness insight should have been included, but at this point we are not able to amend that.

The power analyses is based on the length of compulsory inpatient episodes. Why did the authors chose not to base the power analyses on the number of compulsory admissions per se, which seems the primary primary outcome variable?

The primary outcome criterion is the "time in hospital" accumulated over all involuntary inpatient stays during the 24-month period (page 19). The accumulated time in hospital, rather than the number of compulsory admissions, is, after all, the decisive factor involved in health care costs.
We rephrased what was meant by primary outcome criterion, trying to make it more clear (page 19):
Primary outcome of the study is the time in hospital accumulated over all involuntary inpatient stays during the 24-month period
and rephrased the respective phrase on page 8 and on page 21.

In the discussion, the authors may want to address the negative findings of the study of Papageorgiou. Interestingly, the advanced directives developed in this study were also made during the admission period, before release to outpatient treatment. One reason for the lack of effect of the advance directives in the Papageorgiou study may have been that the outpatient clinicians were not involved in the making of the advanced directive, and therefore the advanced directives may not have been used in outpatient practice. The authors should discuss why they are yes or no afraid this is going to happen in their study.

Of course, the effectiveness of this trial is unsettled at this point. In contrast to the study by Papageorgiou et al., however, our study does not just rely on advance directives. Rather, the outcome of this study will depend mainly on the feasibility of the 24-month crisis-focused preventive monitoring after discharge. We attached this aspect on page 21/22:
Long-term engagement (24-month preventive monitoring), on the other hand, might be a strength of this study. Advance directives alone do not necessarily impact the outcome of care, as the study by Papageorgiou et al. (2002) suggests. There are several reasons attributable to peculiarities on the part of the mental health care system, as well as on the part of patient behaviours, as to why directives might be ignored. It is considered a meaningful and integral part of this trial, therefore, to follow patients after hospital discharge, all the more so as a considerable number of this patient group holds reservations towards visiting an outpatient mental health professional. In this situation, a preventive monitoring may have beneficial effects, bringing to mind betimes the patient's individual action plan in case of a crisis and motivating them to continue treatment.
Review 2:

1. The term “compulsory admission” is context-dependent. Therefore, it needs a detailed explanation and a reference demonstrating the relevant national mental health legislation.

A detailed explanation referring to the respective national regulations has been included on page 4/5. We added:

The legal basis for compulsory admission in Switzerland is regulated by the Swiss Civil Code Art. ZGB 397a, but implementary regulations are on a Federal State (“cantonal”) level. Unlike in other countries, there is no involuntary outpatient commitment in Switzerland. According to Art. 397a ZGB "an adult or a ward of court may be committed to or detained in a suitable institution on account of mental illness, learning disabilities, alcoholism, addiction to other substances or serious self-neglect, provided there is no other way to ensure his personal welfare. Account must be taken of any strain the person places on those around him or her. The person in question must be released as soon as his condition allows" (Ref). Decisions on committal are taken by the guardianship authority at the domicile of the person concerned or, where there is risk in delay, by the guardianship authority of the place where he is staying. In cases where there is risk in delay or the person is psychologically ill, the cantons may authorise other suitable bodies to take such decisions. In the Canton of Zurich, all physicians are authorised to mandate compulsory admission to psychiatric care.

2. It is not fully clear, why the authors did vote in their design for a block random allocation instead of a randomisation patient by patient. The last option would make the study stronger, particularly because a “individualised psycho-educational instruction etc.” is performed and assessed.

The reasons why we used this method to implement the random allocation sequence were (1) to keep the sizes of treatment groups similar and (2) to ensure as well as possible against accidental bias.

If the sample size is not very large, simple randomisation can get imbalanced in treatment assignment. In this situation, simple randomisation does not guarantee a balance in numbers and carries the risk that basic characteristics will be unequally distributed in the (two) blocks. Moreover, imbalanced randomisation reduces statistical power. In smaller trials like ours, block randomisation therefore is often used to fix these issues. – These methodological considerations, to the best of our knowledge, are not bound to the type of treatment at issue for evaluation (individualised or group counselling).

To give reasons for the method used, we rephrased the paragraph on page 12:

To generate comparable groups and to prevent accidental bias as well as possible, block randomisation is used. A block size of 10 is chosen in order to ensure a balance in the numbers of subjects. Random allocation is made until the planned centre-specific sample sizes have been met.

3. I cannot fully understand the basis of the power calculation. The authors emphasize that reduction of the mean length of compulsory inpatient time will be the main outcome parameter. In my understanding, only a proportion of the study sample (as defined by the outlined inclusion and exclusion criteria) will be at risk for future compulsory admissions, and the power calculation should be based on this proportion.

Power calculation, indeed, was based only on the patients compulsorily admitted to psychiatry (as stated on page 20).
Thus the planned sample size would be only the sub-population bearing this specific risk, and the number of participants to be included would be higher depending on the risk estimation the authors would propose for future compulsory admissions.

Statistical theory, of course, cannot tell us what will happen with any particular trial. Through the concept of a sampling distribution, however, it can tell us what will tend to happen in the long run, over many trials of a particular size. Of course, there is no guarantee that present inpatients will be readmitted to psychiatry at the same rate as patients in previous years or that their inpatient stays will be just as long. To perform power calculation, however, we have to make an assumption of the specific distribution of the variable of interest. In this situation, a comparable patient group (involuntary admission; same diagnoses; same age range) appears to be the best starting point to formulate our hypothesis on "inpatient time" for the analytic situation power calculation handles.

4. why don’t the authors use the “ladder of coercion” for assessing perceived coercion? This would increase comparability with other projects.

In fact, the "ladder of coercion" would have been another interesting option to assess perceived coercion. Our arguments for not having included it are the same as those for the additional instruments the other reviewer proposed: Due to the restricted time available for the assessments, we had to restrict the number of instruments. Another argument is the comparability (of the assessment instruments used) to the PRAVENT study currently being conducted in Mannheim. At this point of the study, with more than 200 patients already included, we, unfortunately, see no way of including further scales.