Author's response to reviews

Title: Evaluation of behavioral changes and subjective distress after exposure to coercive inpatient interventions

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Author's response to reviews: see over
Dear Editorial Board,

Thank you for your letter and for giving us the opportunity to submit a revision of our manuscript entitled ‘Evaluation of behavioral changes and subjective distress after exposure to coercive inpatient interventions’. We very much appreciate the reviewers’ thorough and useful feedback. In this letter, we will address their comments and indicate how and where the manuscript has been altered and expanded as a result. While doing so, we have done our best to keep the manuscript concise and to the point.

We do hope that you will consider the revised paper for publication in the Journal and we are looking forward to your reply.

Best wishes,
I. Georgieva, M.Sc.
Comments Reviewer 1
The research question is an important one and adds to the body of knowledge about the use of coercive interventions. To my knowledge, it is the first study comparing the use of different interventions in terms of their impact on the patient. This paper would be of interest to an international audience. Although the data were collected in one country, the use of various interventions varies from country to country and the findings from this study would help clinicians construct a hierarchy for the use of these interventions with patients. The methods are clearly written and appropriate to the study question. The data are sound. The manuscript adheres to standards for reporting and data deposition. The discussion and conclusions clearly follow from the data. Limitations are accurate and clearly identified. The title conveys the essence of the article.

Minor Revisions:
1. The paper needs some editing, such as typographical errors, ensuring that "data" be followed by a plural verb (e.g. data were instead of data was).

Answer: The recommended changes have been made.

2. Reporting of reliability and validity should be more specific than "high" or "Satisfactory."

Answer: The reliability and validity of two scales were reported in the original paper: the Social Dysfunction and Aggression Scale (SDAS; at page 7) and the Coercion Experience Scale (CES; at page 8). After reporting the reliability and validity of these scales we referred to studies which have examined thoroughly the psychometric aspects of the scales. In response to the reviewer’s comments we have added more detailed information by changing the sentences on page 7 and 8, as follow:

Page 7: “The reliability of this scale is high (interclass coefficient: .97, Cronbach’s α: .79) [1]. The validity of the SDAS is high as well: the sum-scores of the scales MOAS [2], SDAS, and SOAS [3] correlate highly (r between .78 and .91) [4].”

Page 8: “The reliability and validity of its psychometric properties are satisfactory” as follows: Cronbach alpha of the CES scale ranged from .67 to .93, while the convergent and discriminant validity yielded respectively: r=.79 (p<.001), and r=.38 (p<.001) [5].”
Comments Reviewer 2
This is a well-designed study which provides significant contributions to the question which kind of coercive measures is least restrictive. Not all good studies yield “good” or clinically significant results. This one does. An important background is that in many countries the legal thresholds for involuntary medication have increased within the last 10 or 20 years and there is a tendency in many countries of Europe to separate involuntary hospitalisation from involuntary treatment, with the inherent danger that elevating the requirements for involuntary medication may increase the use of mechanical measures, first of all seclusion and restraint. Therefore there is high ethical and political interest in the question which kind of measure is least restrictive. Most answers to this question have been rather opinion-based than evidence-based so far. This to my knowledge is the first study with a sufficient sample and well-designed methods yielding evidence that medication is less distressing for patients than seclusion or restraint. Generally, the methods are appropriate and smart, the sample size is sufficient and the paper is well written. I have only some suggestions for minor revisions:

Minor Revisions:
1. Abstract: I would recommend to mention the sample size (n=125) somewhere.

Answer: We have changed the relevant sentence from the abstract’s background as follows: “Therefore we compared ratings of effectiveness and subjective distress by 125 inpatients across four types of coercive interventions”.

2. Page 3, last par. and page 16, study-limitations: This is not the first study. The RCT published by Bergk et al. in Psychiatric Services 2011 should be mentioned. Further, there is a 2nd RCT, the TREC-SAVE study (Huf et al.), the study-design of which has been published in Trials 2011. The paper has just been accepted in Psychological Medicine and could be mentioned as “in press” or by referencing the study-design paper.

Answer: We agree with the comment of the reviewer. These are relevant and very recent publications, which appeared just after we submitted our manuscript to your journal. Therefore we changed the last paragraph on page 3 and highlighted the changes we made as follow: “To make such a judgement, mental health professionals need to have substantial knowledge of the effectiveness and harmfulness of the various coercive interventions. Unfortunately, there is a little evidence on the relative effectiveness and harm of specific
interventions such as seclusion or restraint [6]. Recently two studies have been published, comparing the effectiveness and impact of seclusion and mechanical restraint [7-8]. Although these are methodologically excellently studies as randomized controlled trials, their relevance for clinicians in constructing a hierarchy for the use of coercive interventions is limited in comparison to this study, because their scope is restricted to two interventions (seclusion and mechanical restraint). In addition both studies found no significant differences between the groups in patients’ experienced coercion or satisfaction with care.

In addition we have changed the first sentence of the study limitations on page 16 and highlighted the text that was changed, as follows: “While this is the first study yielding evidence that involuntary medication is less distressing for patients than seclusion or restraint by exploring actual coercive experiences, we must acknowledge a number of limitations.”

3. Page 5, procedure: “Rapid tranquilizer” should be defined more exactly for clinical readers. What is meant, benzodiazepines, antipsychotics, or both?

Answer: We have changed paragraph 2.2.1 Definitions of coercive interventions and highlighted the text that was changed, as follows:

“Involuntary medication was defined as the administration of a rapid tranquilizer without the consent of the patient, and with or without manual restraint. Rapid tranquillization involved the oral or intramuscular administration of a combination of haloperidol and promethazine, or lorazepam to achieve rapid, short-term behavioural control of any extreme agitation, aggression or potentially violent behaviour that placed the individual and those around them at risk. Initially, 10 mg haloperidol and 100 mg promethazine, or lorazepam 2½-5 mg was offered as oral medication to the agitated patients with psychotic or non-psychotic symptoms, respectively. Nevertheless, in some situations patients refused to take the medication orally, so IM medication (5mg haloperidol and 50mg promethazine or 2½-5 mg lorazepam) was used. Due to the coercive nature of the setting, administration of “as required” medication during a period of seclusion was also counted as involuntary medication, regardless of patient consent at the time.”

4. A more precise definition of involuntary medication would be desirable. “Without the consent of the patient” is a rather blunted definition. What about the role of psychological pressure? According to clinical experience, there is a continuum of possible pressure on the
patient, reaching from persuasion to threat of immediate intramuscular application of the medication. The only clear definition of involuntary medication I know is the use of physical force, e. g. holding, which is a very restrictive definition. Perhaps the problem of definition and inclusion should be mentioned as a limitation.

Answer: We agree with the reviewer that coercion or pressure exists on a continuum: it can be explicit, as it is when intramuscular involuntary medication is administrated by force, by holding the patient; or implicit, when it is suggested that other options will have to be explored if the patient will not take medication orally. Therefore we explicitly reported in Table 1 the administration of involuntary medication by dividing it into two groups: oral versus intramuscular medication. Besides that we measured the pressure applied from the staff at the start of the measure and controlled for its effect when comparing different coercive interventions on their effectiveness and subjective distress (see Table 2, 3&4).

5. Table 1: Mean GAF Score: I do not understand why the scores are so high. By definition, danger to self or others results in a GAF Score below 20, presence of any psychotic symptom below 40.

Answer: In a different study we collected data on the same psychiatric ward to investigate the risk factors for seclusion and restraint [9]. We found that violence marginally predicted the risk of seclusion and restraint, while patients who refused to cooperate with the treatment or the rules at the ward were often subjected to coercive measures. Therefore we may presume that some of the patients were not psychotic or violent at the start of the coercive measures, making the mean GAF scores higher.

6. Figure 1: It is striking that the differences in the overall CES Scores are not significant (1,5; 1,4; 1,3 vs. 0,6). At least this needs a comment. Is it because of a low N, because many patients did not fill the CES questionnaire or because of a high standard deviation? By aspect, the difference looks very “significant”. I would recommend using box plots for the total score and for the significant results; the non-significant results could be described in one sentence. The use of lines suggests something like a course which is not very appropriate because the single scores are independent. Also from that point of view I would suggest another kind of illustration.
Answer: We agree with the comment of the reviewer, the sample sizes and thus the statistical power is lower in Groups 2 (n=9) and 4 (n=8) compared to Group 1 (n=44) on the overall CES scores. This may explain the lack of significant differences in the overall CES scores. Besides that, to clarify the differential completion rates, we added the following remark under the table: “* The number of respondents varies in a range between: 44 and 46 (Group 1); 9 and 11 (Group 2); 8 and 9 (Group 4)“.

Further, we agree with the comment of the reviewer that the lines at the graph may incorrectly imply continues variables. Therefore we have changed the graph as follows:

1 Group 2 differs significantly from group 3 & group 4 on Separation
2 The mean values of VAS Global Strain were divided by 30 to stay in proportion with the rest of the scales
* The number of respondents varies in a range between: 44 and 46 (Group 1); 9 and 11 (Group 2); 8 and 9 (Group 4)
** Higher score indicates more psychological and physical burden
References


