Author's response to reviews

Title: Do Routine Outcome Monitoring results translate to clinical practice? A cross-sectional study in patients with a psychotic disorder

Authors:

Magda Tasma (m.tasma@lentis.nl)
Marte Swart (m.swart@lentis.nl)
Gert Wolters (g.wolters@lentis.nl)
Edith J Liemburg (ej.liemburg@lentis.nl)
Richard Bruggeman (r.bruggeman@umcg.nl)
Henderikus Knegtering (h.knegtering@lentis.nl)
Stynke Castelein (s.castelein@lentis.nl)

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Author's response to reviews: see over
To:
The editor of BMC Psychiatry

Date:
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From:
M. Tasma, MSc.
Lentis Research, Lentis Psychiatric Institute
Groningen, The Netherlands
m.tasma@lentis.nl

Subject:
Revised manuscript on the use of routine outcome monitoring results in mental health care (manuscript ID 1822943353175023)

Title:
Do Routine Outcome Monitoring results translate to clinical practice? A cross-sectional study in patients with a psychotic disorder

Authors:
Magda Tasma, Marte Swart, Gert Wolters, Edith Liemburg, Richard Bruggeman, Henderikus Knegtering, Stynke Castelein

Dear Anna Clark,

Thank you very much for your interest in our paper, and allowing us to revise it according to the suggestions of the reviewers. We would like to thank both reviewers for their encouraging feedback. In this cover letter, all changes we have made to the manuscript are described. We repeated all comments of the reviewers in italic, followed by our response.

Also on behalf of my collaborators, I hope to have informed you well. If there are any further questions, please do not hesitate to contact us. We will be pleased to answer any questions you may have.

Kind regards,

Magda Tasma, MSc.
Reply to the reviewers’ comments:

We appreciate the comments as they were helpful to improve the manuscript. Please find below our response to the reviewers’ comments and a description of the changes we have made to the manuscript. The original comments of the reviewers are depicted in italic.

Reviewer #1:

**Major Compulsory Revisions**

The manuscript is generally well written and the statistic methods standard and appropriate. It remains to be established whether this report may be too preliminary. In fact the lack of effect of ROM on treatment plan might depend on the relatively small sample size taken into consideration. This is even worsened by the presence of a not negligible quote of missing data. Furthermore, the random sampling method has not been described in the methods. The authors may want to refer to previously published studies on ROM to detect its effect size and select an adequately powered sample to examine the effect of ROM on treatment decision making in psychotic disorders.

Thank you for your feedback. We will first respond to the comment about the sample size (1), and second, to the comment about the random sampling method (2).

1. Given the time and effort to screen treatment plans manually, we deemed 100 treatment plans the maximum achievable amount. To ensure an adequate sample, a random sample was drawn and in addition, the representativeness of the sample was investigated. The sample turned out to be representative for the sample in the database, with regards to age, gender and duration of illness. We therefore assume our findings may be extrapolated to the whole sample.

With regards to the comment on selecting an adequately powered sample based on previous found effect sizes, we would like to explain that our study did not in fact investigate the effect of ROM on treatment. The study does not use a control group or repeated measures, and therefore, no effect size can be calculated. Moreover, no previous studies have been conducted investigating the effect of ROM on treatment in psychotic disorders. Therefore, we were not able to incorporate this suggestion in the revised manuscript.

2. We added a description of the random sampling method to the manuscript (methods, p. 6). SPSS was used to draw a random sample of 100 patients from the total sample in the database, using the option ‘random sample of cases’ under the tab ‘select cases’. Thank you for this suggestion.

Reviewer #2:

**Major Compulsory Revisions**

1. Methods: "The database covers about 85% of the patients with a psychotic disorder in the catchment area, the Province of Groningen"; how can you state this? Please, add a short sentence to report the epidemiological source where is stated the real data of incidence or the reasoning used to reach this percentage.
Thank you for noticing the missing reference. We decided to remove this sentence from the manuscript (methods, p. 5), as it was incorrect. The 85% we described, was the amount of patients who received a ROM-screening of all patients with a psychotic disorder receiving care at Lentis Psychiatric Institute (not of the whole catchment area). As our sample also included patients of the University Medical Center Groningen, we do not find this percentage relevant to mention.

2. Methods: "battery of instruments, including a physical examination, laboratory tests, interviews and self-report questionnaires"; please, add a brief description, with references and names (e.g. WHOQOL scale, PANSS, etc.).

Brief descriptions and references have been added between brackets (methods, p. 5). For readability, abbreviations of the interview and questionnaires have been used here. Further in the methods section (in the ‘measures’ paragraph) we elaborate in more detail on the instruments we used in our study.

Currently, a manuscript on the ROM-Phamous protocol is in preparation, and will soon be submitted. For those who are interested in the full protocol, we added this reference to the background section (background, p. 4). The full protocol can also be obtained through the authors of this manuscript.

3. Which statistical method have you used to obtain a random sample of 100 patients? Please, describe it.

We added a description of the random sampling method to the manuscript (methods, p. 6). SPSS was used to draw a random sample of 100 patients from the total sample in the database, using the option ‘random sample of cases’ under the tab ‘select cases’.

**Minor Essential Revisions**

1. Abstract: "Average age", sounds too cacophonous; please, replace it with mean age, or an alternative version of the same concept.

We replaced the word ‘average’ with the word ‘mean’ throughout the manuscript (in the abstract, p. 2, and in table 1, p. 17).

2. Background: "DSM-IV Classification system; DSM-IV is from 1994; maybe you intend ‘DSM-IV-TR’ (Year 2000)? Please, check and eventually correct; furthermore, the reference is missing, please, add the citation the first time you use it.

Thank you for this comment. Indeed, we meant to refer to the DSM-IV-TR. We corrected this in the manuscript and added a reference (background, p. 3). Furthermore, all psychotic disorders mentioned in DSM-IV-TR are described in the revised version of our manuscript, to improve the accuracy of the background section.
3. **Background:** "increased tremendously", this sentence is too colloquial; please, replace with "widely" or similar.

‘Tremendously’ was replaced with ‘widely’ (background, p. 4). In the abstract, ‘tremendously’ was also replaced with ‘widely’ (abstract, p. 2).

4. 
"...were found in gender distribution ($X^2 (1) = 0.026; p=0.872$)"; Why have you added a citation on chi-square? It is a basic statistic concept, this quote is therefore superfluous; please, remove.

There is no citation on chi-square in the manuscript, so this might be a misunderstanding. In any case, we agree with the reviewer that there is no need for a citation.

Also, we did realize this sentence would fit better in the results section, and therefore moved “No significant differences were found in gender distribution ($X^2 (1) = 0.026; p = 0.872$), age ($t = 0.979; df = 1137; p = 0.426$) and duration of illness ($t = -0.028; df = 896; p = 0.978$) between the selected sample and the other patients in the database.” from the methods section to the results section (results, p. 8).

5. "A score of 4 or higher..."; please add why have you choosed this value; maybe referring to Andreasen Criteria? Please, specify.

Thank you for this remark. Indeed, we have used the PANSS-R criteria of Andreasen. We have clarified this in the manuscript by adding a reference and explaining the criteria for symptomatic remission (methods, p. 6):

“Symptomatic remission is defined as ratings of mild (score 3) or less on all these items over a 6-month period ([66 Andreasen,N.C. 2005]). Therefore, a score of 4 or higher on one or more of these items was defined as the presence of positive and/or negative symptoms.”

6. "hypertension (blood pressure levels > 140/90 mmHg (without diabetes) or > 130/80 mmHg (with diabetes)); why this values? maybe you refer to American Heart Association Guidelines? Please, specify.

We have chosen these values, based on the criteria of Mark de Hert and others (2009). De Hert has conducted much research on cardiovascular disease and diabetes in people with severe mental illness. He established criteria for cardiovascular risk factors, such as hypertension, dyslipidaemia and diabetes, for this group of patients, in collaboration with the European Psychiatric Association. The reason we chose to use these criteria is twofold:

1) As we investigated ROM results and treatment plans of patients of 2010, we needed to use guidelines that existed in 2010. If we used more recent guidelines, it would not make sense as clinicians at that time (2010) did not have these guidelines.

2) De Hert and others developed guidelines specifically for patients with severe mental illness. As patients with psychotic disorders have a much higher risk to develop cardiovascular disease, it is suggested to use different criteria than for the general population. We therefore did not use, for instance, the American Heart Association Guidelines, as these are for the general population.
We have clarified this in the manuscript, by describing these reasons more explicitly (methods, p. 7): “These criteria were established by De Hert and others, in collaboration with the European Psychiatric Association [6], who have conducted extensive research on cardiovascular risk factors in people with severe mental illness.”

7. "IBM SPSS Statistics 20", reference is missing; please, add.

This reference has been added (methods, p. 7).

8. "months (m = 6.7; sd = 4.9)"; "mean" is more suitable than "m"; please, replace it.

This has been changed (results, p. 8 and p. 9).

9. "A little puzzling"; this sentence is too colloquial; please, rephrase.

‘A little puzzling’ has been replaced with ‘unexpectedly’ (discussion, p. 11). Moreover, a sentence was added to clarify the discrepancy between ROM and the treatment plan for positive symptoms (discussion, p. 11): “Possibly, positive symptoms are still mentioned as treatment goals, even when symptoms do not interfere with daily life functioning anymore and therefore are not detected with ROM.”