Author’s response to reviews

Title: Overcoming recruitment barriers revealed high readiness to participate and low dropout rate among people with schizophrenia in a randomized controlled trial testing the effect of a Guided Self-Determination intervention.

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Version: 3 Date: 23 December 2013

Author’s response to reviews: see over
Response to reviewers’ comments

Thank you very much for your valuable comments on the paper:
Title: Inclusion completed! Recruitment barriers and strategies to overcome them in a randomized controlled trial for people with schizophrenia.

We are very grateful to get the opportunity to rewrite the paper with all comments in consideration and a more clear narrative as pointed out by reviewer 2.

First of all we have changed the title: Overcoming recruitment barriers revealed high readiness to participate and low dropout rate among people with schizophrenia in a randomized controlled trial testing the effect of a Guided Self-Determination intervention.

Response to Reviewer 2:
The paper needs major revisions.
• We have rewritten the paper. All changes are highlighted in yellow in the manuscript.

Abstract:
In the background the authors stated that the aim of the paper is to examine unexpected recruitment challenges experienced in a complex clinical trial, but they do not explain the method in the methods section, rather they present the strategies chosen to overcome these barriers. Methods and results are not clearly separated and it is not so easy to understand the core of the study.
The abstract should be reorganized.
• We have rewritten the abstract in according to the change of narrative/aim of the paper, further we have separated methods and results clearly.

Background
In the background the authors reported a summary of the studies addressing the issue of recruitment barriers, however no one is focused on schizophrenia. (See for example: Ghio L et al. Schizophrenia Trial Participation: Perceived Inclusion barriers and beliefs about Antipsychotics. Pharmacopsychiatry 2011; 44: 123–128)
• We have conducted a new literature search with focus on schizophrenia, and the background is now focused on schizophrenia.

At the end of the section the authors stated that the aim of the study is to examine and discuss the unexpected recruitment challenges experienced in a complex clinical trial. They should at least mention the focus of the clinical trial.
We have changed the aim of the paper to: “This paper reports how recruitment challenges not related to patient issues were overcome and revealed the true readiness to take part in and complete a complex clinical trial testing Guided Self-Determination (GSD) among outpatients with schizophrenia in the northern part of Denmark”.

Methods:
In the methods section the authors describes the method of RCT, but there is no description of the methods with which they investigated the recruitment barriers.
- We have changed the methods section, and we have added the methods of how the aim has been investigated.

Is the RCT protocol published elsewhere? If yes, the part of method describing RCT can be greatly reduced in favour of a more detailed explanation of method of the present study.
- Our RCT protocol has not been published elsewhere, but the methods describing the RCT has been reduced. Further we have deleted the paragraphs with the following headlines: randomization, time, and baseline questionnaires.

The authors should briefly describe what the intervention Guided Self-Determination is.
- We have added a brief description of the intervention in the methods section

Results
- We have decided to change the focus and structure, and most of the headlines in the results section.

Organizational challenges and barriers
Of course the political reorganization accounted for a considerable change in the number of expected eligible participants for the trial. However this reason is more a problem of the design (including service that are not still operating) than a recruitment barrier.
- We still consider organizational changes as a factor that affects recruitment. Which researches must be aware of, when using a rigid design as a clinical trial is. However, we have not emphasized the organizational challenges as much in this second version as we did in the first version.

More important is “the fact that the teams´ main focus was the establishment of the AOT and not research”. However this sentence seems an opinion a not a result based on a specific investigation.
- You are right, we have no evidence to support this claim. Therefore we have decided to delete it.

Recruiting professionals - challenges and barriers
Also in this section the results seems to be based on authors opinion (…even though it appeared that they had not spoken to the eligible participant..
communicated a kind of “silent resistance”) rather than on structural investigation.

Eligible participants - challenges and barriers

- **We did have a logbook containing information about: participation in information meetings, reasons for declining or participating in the trial, and comments regarding the trial from either the eligible participant or his/her mental health care professional. This logbook was not mentioned as data-source in the first version, but is mentioned in the second version. But you are right the first version reflects “authors opinion” several places, but we hope the this second version reflects a more objective stand and that our claims are a product of the data sources used.**

Discussion

The main finding is that the provision of encouragement to the MHCPs had a great impact on the recruitment. However visits and email are commonly used strategies used in trials.

- **In the second version the main finding is; when overcoming recruitment challenges not related to patients one might discover readiness among patients with schizophrenia to take part in and complete a trial. That is a more important message than the main finding in the first version.**

In conclusion, despite the issue investigated is of great interest the main limit of this paper is the lack of a clear methods that supports the results, which seems to be based on authors opinion rather than on evidence.

- **We hope this second version still is of great interest. We have focused on a clearer narrative and taken a more objective stand in looking through the data again. We are grateful for all your valuable comments, which have been very supportive in this new second version.**

Response to Reviewer 2:

- Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

  - **We have rewritten the paper – all changes are highlighted in yellow in the manuscript.**

1. The article begins with a thoughtful review of the barriers to recruitment, with specific references to studies in mental health. However, from this point on the article seems to lack a clear identity.

  - **We have taken this point into consideration; therefore we have changed the aim of the paper and also the background to support the new focus. The overall theme is still recruitment barriers in clinical trials with participants diagnosed with schizophrenia.**

It promises to examine recruitment challenges and how these were overcome. It therefore seems unnecessary to have included so much detail on the RCT study itself (e.g. the
rating scales used on the study, randomisation technique) and the method section should be substantially trimmed to only reflect the information relevant.

- **The methods section has been trimmed for irrelevant information. The following paragraphs have been deleted; randomization, time and baseline questionnaire.**

2. In the Background, the authors write that “even though strategies to overcome recruitment barriers have been described [5,9] they have not very often been evaluated [2]”. However, this article does evaluate the strategies it employed as it implies that it will, as no attempt is made to determine the impact of each of the strategies or compare their success other than by personal interpretation on the part of the authors in the discussion. This fact is acknowledged in the conclusion (“The limitations of this study are that the challenges and the strategies are descriptive, based on our experiences and not based on structured data collection. Neither can we directly confirm that the strategies caused the completion of the trial; we can only assume that the strategies had an impact.”). This comes at the end though, after I had spent the entire reading of the article expecting more than was delivered.

- **As we have changed the focus/aim of the paper, the message is now; when overcoming recruitment challenges not related to patients, one might discover readiness among patients with schizophrenia to take part in and complete a trial.**

In the first version we did not mention that we had a logbook with information about: participation in information meetings, reasons for declining or participating in the trial, and comments regarding the trial from either the eligible participant or his/her mental health care professional. The data from the logbook is now mentioned in the methods section, and we have looked more objectively on the data. We also think that this second version is more clear about what can be expected.

3. In “organizational challenges and barriers” (page10) the article states that changes to the AOTs accounted for a considerable change in the number of expected eligible patients. However, it is not clear where this has come from on examination of the table. Aside from the fact that the word “expected” seems to be incorrectly included in this comment, there is a more fundamental issue concerning how this was determined. I can see that fewer eligible participants were identified than expected, although no statistics are presented even for this. How does this show that changes to AOTs were responsible? The authors suggest that the late inception of AOT 2 and AOT3 had an impact but this is not evident in the table as fewer eligible participants were counted in AOT3 but not AOT2 when compared to AOT1. Analyses should be included here if the authors wish to make these points. Nearly a page is dedicated to the various figures for delay to opening, understaffing and actual participant recruitment in the AOTs which is very personal to the study and seems unnecessary to include if these figures are not used to support the conclusions using analyses. A few percentages in table 1 could replace all of this.
Regarding the comments made in this paragraph, we have added several changes. First of all, we have changed table 1 to a flowchart for recruitment, as table 1 from version 1 was too unclear. We still use the word “expected” to express the difference between the patients expected (or planned) to be in the Assertive Outreach Teams compared to the patients that actually were treated/present after the changes in the implementation plan. We have not come up with a better word, but we are open to suggestions! Second we have tried to explain the changes, but now in percentages to make it clearer. We have also looked at our phrasing so the paragraph supports the conclusion.

Any number of factors could be responsible for under-recruitment in the study and/or at one site and the authors’ conclusions about what was to blame seems to be based entirely on their own perception.

- We have tried to be more objectively and looked at the patterns and the process of the recruitment challenges and barriers encountered in this trial, and how they were overcome. This has resulted in a less opinionated conclusion.

Other factors are listed that “had an impact on the slow recruitment in the project” and, again, in some cases the confident attribution of responsibility seems to be overreaching without any supporting evidence such as clinical staff interviews or analyses to compare sites or identify relationships between factors. For example, a “change of departmental management” is blamed without any further explanation. I am sympathetic to the authors’ conclusions but the lack of presented supporting evidence yet available data make for a confusing presentation. If the authors intend to simply discuss issues that they felt were relevant, this wording of these claims should be substantially toned down to reflect the speculative nature of the statements. The sections on recruiting professionals and eligible participants are more obviously based on the authors’ perception of the difficulties encountered and are easier to read as a result.

- We have taken these points into consideration and changed the phrasing especially in the results section so the claims now are toned down. The change of aim and providing this second version with a more clear narrative has also toned down most of the claims mentioned above. Furthermore we have added a new figure – Figure 2 to support the results section and clarify our main finding.

- Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

4. The authors report that 103 sealed envelopes were produced with 50 participants in each of the study groups – need to account for the other 3.

- This has been deleted, as the paragraph “randomization” has been deleted.

In conclusion, this article did not have a clear narrative and needs to be re-written to be the reporting and obviously personal interpretation of the barriers
experienced by the trial, and the methods employed in order to achieve successful recruitment. Alternatively, the authors may wish to make more of the data that they have reported and analyse it in order to support their hypotheses about the barriers experienced and success of the strategies employed. At the moment it is not clear which is intended but neither is clearly achieved.

- **We have chosen to rewrite the paper and clarify the narrative. We do not answer the question “how to achieve successful recruitment, but point towards the value of thoroughly distinguishing between recruitment challenges. If we do not question the assumption that recruitment challenges are mostly related to the patients, researchers might overlook the importance of and ability to overcome other recruitment challenges.**