Reviewer's report

Title: A multicenter randomized controlled trial of aftercare services for Severe Mental Illness: study protocol

Version: 2 Date: 19 November 2012

Reviewer: Sudipto Chatterjee

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A. Major compulsory revisions:

1. The aftercare intervention group seems to have further subgroups - people who receive a telephone reminder + facility based delivery of aftercare intervention components, those who receive home based after care and people who can move between the groups (see Attachment 1). Though the authors have clubbed these three subgroups, there are problems in considering them as a homogenous group. Firstly, compliance or engagement with treatment is consistently associated with a number of socio demographic, health system related and illness related associations in people with severe mental illnesses. The non random allocation of participants into the 2 groups makes it very likely that systemic differences will confound the interpretation of the results. Similarly, people who potentially cross from one intervention to the other will confound the analysis, especially since there is no a priori plan to deal with this scenario.

2. This is a non pharmacological clinical trial where the intervention is being delivered by more than one care provider in 3 different sites. In such trials, it is necessary that the clustering effect between care providers and sites are accounted for estimating the sample size. This has not been done in the protocol and needs to be incorporated.

3. There is limited information available to make a clear judgement about the methods used to address bias at various stages of the study. For example, people were screened and approached for recruitment in the study 2 days in a week – this introduces the possibility of selection bias and the lack of generalizability to the larger universe of patients. Similarly, the method of random block sequence generation for allocation, allocation concealment and implementation process needs further details to convey the risk of unmasking at this stage. Also, since participants and care providers are unblinded during the study, ascertainment or reporting bias is very likely, especially since care providers are involved in outcome measurements. A completely separate and independent group of researchers are recommended together with further description of how unblinding even when using dedicated researchers is to be dealt with.

4. There is little detail on how the fidelity and quality assurance of the intervention is to be monitored across the sites/practitioners. This is an essential component
of multi site trials of complex, non pharmacological intervention trials and needs to be specified clearly. It might be useful to consider collecting process indicators to describe the key stages of the intervention delivery (number of home based or facility based sessions delivered, number and % who drop out or refuse intervention etc) as this information will be necessary to compare the similarity of the intervention delivery across the 3 sites.

5. The section on statistical analysis is rather bare and needs much greater elaboration. Specifically, the details of the descriptive statistics needs to be detailed, the method of dealing with missing values through imputation needs to be specified, any potential subgroup analysis (by site or gender etc) needs to be spelt out as well as more details of the economic analysis planned.

6. Obtaining informed consent for participation from subjects who are just recovering from an acute episode of schizophrenia, severe enough to warrant admission, poses complex ethical and procedural challenges. The informed consent procedure needs to account for and describe how these challenges (like decisional capacity assessment, methods of information provision to address cognitive deficits, literacy levels etc) need further elaboration. Similarly, specific mention needs to be made of the serious adverse events monitoring (death, suicide attempt, serious medication related side effects) and reporting process as well as details of the trial monitoring committee that will oversee the methodological and ethical standards of the trial, as well as take decisions on any interim analysis and trial termination.

B. Minor essential revisions:

Overall, the authors would need to follow the CONSORT statement for the reporting of non pharmacological trials in further revisions of the protocol. There is a need for further language edits (especially around the terminology used for subjects at various times in the protocol) and to shorten the description of the intervention components.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

'I declare I have no competing interests'.