Reviewer's report

Title: Training in Dual Diagnosis Interventions (The COMO Study): A Randomised Controlled Trial

Version: 2 Date: 11 June 2007

Reviewer: Carl J Lombard

Reviewer's report:

General
In the abstract the trial is described as a cluster randomized trial. Looking at the outcomes used for the sample size calculations (bed-days, drug abuse, compliance score) it is evident that they are outcomes at the patient level. Patients are therefore clustered within mental health workers which were randomized. Looking at the design in more detail one sees that the trial design fits that of a multi centre study with 12 community mental health teams being used. Within each of these teams the mental health workers participating were randomized to the control or intervention group.

For this study the outcomes considered are at the mental health workers level and not at the patient level. The team or centre effect is therefore relevant for the comparison of the outcomes from mental health workers.

The following comments pertain to the discussion above:

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

1. For completeness the distribution of the mental health workers should be given by mental health team, treatment and follow-up.

2. The team effect should be taken into account in the analysis of the attitude and knowledge scores. A mixed effects model will be able to handle the team effect as a random effect and possible imbalances within centers due to loss of follow-up. The book of Helen Brown and Rubin Prescott – Applied Mixed Models in Medicine – 2nd edition, Wiley 2006 provides excellent practical advice and illustration of the analysis requirement for this study.

3. Where the number of mental health workers needed for comparison considered in the sample size calculation? If not it should be stated that the member randomized more a function of the patient level effect sizes considered. Thus sample size calculations for patient level effects can be shortened.

4. What happened to the 6 workers randomized to the intervention arm who do not receive the intervention? Where they followed-up? For intention-to-treat analysis and a pragmatic trial approach it does not matter that they did not receive the intervention. Their outcomes are part of the trial. Although intention to treat analysis is mentioned in the manuscript what really happened is not clear to me.

5. Figure 1. The loss to follow-up reasons resulting in the n=27 (intervention), n=36 (control) should be given.

6. With respect to the trial design the secondary analysis focus of this manuscript is not well introduced.

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

7. p13 , last sentence of paragraph on lost to follow-up. I would suggest adding the words ‘at baseline’ at the end of this section.

8. Table 1. Firstly the number of patients should be given for each column. I do not understand where the percentages come from. For example the 5th row of this table for the control group: 12/36=.33 or 12/39=.31. None of these corresponds with the 15% (.15) from the table for this characteristic.
Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

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

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests