Reviewer's report

Title: Development of mental disorders one year after exposure to psychosocial stressors in primary care patients with a physical complaint; a cohort study

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Reviewer: Matthew Hotopf

Reviewer's report:

The article covers an important topic, namely evaluating an attempt to improve mental capacity in patients with psychosis. There are very few studies which have done so successfully, and despite the weaknesses of the current paper, it presents potentially useful results. The key weaknesses of the paper are (a) the small sample size; (b) the non-randomised nature of the study; (c) ambiguity about the status of the study (it seems to sit in a grey area between research and audit). These cannot be rectified, but I think need to be better explained, and my main objection to the paper as currently crafted is that it is far too definitive – suggesting that the authors have demonstrated a treatment effect, when the evidence is much less clear cut and should be presented with greater diffidence.

Major compulsory revisions.

1. Is this research or audit? Did the authors gain research ethics committee approval? In most respects it reads like a research paper, with a protocol, patients who consent and so forth, but the authors in the discussion propose rather surprisingly that the intervention is known to be effective and therefore it may be unethical to randomise patients (There is also sufficient evidence of efficacy of MCT to make an RCT difficult to justify in such a group) I found this confusing especially as later in the paper the authors say this was the first time such an intervention had been used in this population. The main issue is that if ethics committee approval was not sought or required, the authors should say so, and explain this.

2. In the abstract, results and discussion there are numerous places where the authors seem to attribute differences between the groups at follow up as indicating that the treatment is effective. These are overstated and the paper should be edited carefully to remove the offending phrases. For example:
   • MCT is an effective intervention for patients with psychosis. (abstract – most of the rest of the conclusion of the abstract should be re-written).
   • “Table 3 shows that Mac-CAT-T Understanding was significantly improved after MCT when compared with the waiting list controls, and GAF was also significantly better after MCT.” (results)
   • MCT achieved positive outcomes for patients and this was found to be true in the forensic setting studied. MCT improved knowledge of mental illness, generalised reasoning skills and global functioning of patients with a psychotic
illness. (conclusions)

This list is not exhaustive – the point is that in all these cases the authors seem to be attributing a causal relationship between the intervention and the changes seen, and particularly in the conclusions section the intervention seems to be proposed as a treatment to improve capacity. This is greatly over-selling the study, which is a very small non-randomised comparison. The interpretation throughout should be that the intervention indicates that MCT is associated with some improvements, but the reason for this are not fully understood. It might be that MCT is effective, but confounding, selection bias and information bias have not been ruled out. My interpretation of the paper is that it provides potentially helpful evidence that the intervention might be useful in patients with psychosis, but it by no means proves it is.

3. The limitations section of the discussion is inadequate. Rather than use this section to justify why the study was not randomised (see point 4), the section should explain why the results from the present study cannot be taken to be indicative of a definite effect (hence my criticisms in point 2). So (a) the study is very small. This means that genuine effects (harmful or beneficial) on some scales may be missed; (b) the non-randomised design means that there may be significant confounding – and the fact that there are few statistically significant differences between treatment and control at baseline does not in any way reassure – the sample size is too small to make statistical testing meaningful; (c) the non-randomised design may have led to systematic differences – the patients who were most willing may have been selected first to have the intervention; (d) inferences cannot be drawn about the number of sessions of intervention and efficacy because it is confounded by patient factors likely to be associated with a good outcome (having good insight, being more adherent) these factors are associated with good outcomes across the board in medicine irrespective of the intervention (e) observer bias – it was impossible to blind the rater regarding intervention received and this may have influenced results. All these factors mean that it is not possible to draw strong conclusions about the effectiveness of the intervention.

4. I found the justification of not randomising underwhelming. The authors seem to suggest that (a) randomising is unethical – but this is not explained. There is no reason why patients lacking capacity cannot be randomised, provided there are adequate safeguards, and it is absolutely necessary that randomised interventions happen in patients lacking capacity – otherwise care will not improve. This view is also contradicted by the authors' comment that patients consented to the intervention. The authors seem also to suggest (b) that the intervention is so well proven it is not necessary to randomise. Is this really the case? If so, this implies that there are RCTs of the intervention in people with psychosis aimed at improving mental capacity. If there are such trials, why bother publishing the present paper?

5. Please report p values and avoid “NS” which is meaningless in this context

6. Discussion: I do not think that appreciation can simply be described as a
measure of insight. The relationship is more complex. See Owen et al Psychological Medicine 2009 39 1389-98

7. My interpretation of the paper is that it provides interesting data which would suggest that the intervention may be used in patients with fairly severe psychotic illness, is acceptable to patients and may be associated with benefit. In essence this is a small pilot study. If the paper were to be re-written presenting it as such, and perhaps placing more emphasis on the difficulties inherent in running such research, then I think that it could provide a useful addition to the rather sparse literature.

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests