Reviewer’s report

Title: Effectiveness and Cost-effectiveness of Transmural Collaborative care with Consultation Letter (TCCCL) and Duloxetine for major depressive disorder (MDD) and (sub)chronic pain in collaboration with primary care: a randomized placebo-controlled Multi-Centre trial. TCC:PAINdip.

Version: 4 Date: 11 December 2012

Reviewer: Roland Mergl

Reviewer’s report:

In this article, the authors present the design of an interesting randomized placebo-controlled multi-centre trial to assess effectiveness and cost-effectiveness of transmural collaborative care with a consultation letter and duloxetine for patients suffering from major depressive disorder and concomitant chronic or subchronic pain.

Overall, this trial is innovative since the cost-effectiveness of an integrated treatment of pain in patients with depression is unknown so far and studies addressing treatment of chronic pain in depressed patients are rare. The presentation of the clinical trial is clear and the study design has been carefully devised, but there are some points which could be addressed in a revision.

Major compulsory revisions
1. Abstract – Methods/Design: The primary outcome measures should be specified.
2. Background – Page 5, lines 15-16: “brain areas that are also implicated in depressive disorder and that may diminish the ability of patients to learn, and thus to follow treatment properly.” A reference is missing.
3. Methods/Design – Objectives: PHQ9: The PHQ9 is a highly specific screener for depression; However, it appears to be problematic to use a depression screener for the assessment of antidepressant effects. For this purpose, depression rating scales like the Hamilton Depression Rating Scale or the Inventory of Depressive Symptomatology are better instruments.
4. Exclusion of the study during the intervention phase (page 8): Do the authors use pill counts in order to answer the question whether the patients have taken at least 80% of the prescribed medication?
5. Sample size (page 14, lines 1-2): If the authors anticipate for a possible loss to follow-up being 20%, then 3 x 79 (237) patients have to be included, not 3 x 73 (219). Figure 1 should be accordingly modified.

Minor essential revisions
References 10 and 41: Volume and pages are missing.
References 11 and 12 are identical.
Reference 17: The journal is missing.

Minor issues not for publication:
None.

Recommendation: Accept after minor essential revisions (which the authors can be trusted to make)

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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

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

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