Reviewer’s report

Title: Treatment compliance and effectiveness of a cognitive behavioural intervention for low back pain: A complier average causal effect approach to the BeST data set.

Version: 2 Date: 30 August 2013

Reviewer: Manuela Ferreira

Reviewer’s report:

The low back pain research field has been waiting for this paper! Congratulations to the authors on a well done study! I have only few comments and suggestions.

Minor Essential Revisions

1 – I wonder why full compliance wasn't used to define 'compliers' as a start point, given there is no published guidance in the field of CBT. Wouldn't it be better to use full compliance, and then as a sensitivity analysis, use a different threshold?

2 – As well described by the authors, the CACE analysis relies on the assumption that the proportion of compliers and would-be compliers is well balanced between the two treatment groups, due to the randomisation process. In that sense, we also assume that being a complier is a pre-randomisation, personal characteristic (Yau & Little (2001); Journal of the American Statistical Association; 96:1232-1244 and Imbens & Rubin (1997); Annals of Statistics; 25:305-327). I am not sure therefore, this personal trait can be modified, as suggested in the discussion. Moreover, the associations of being a complier and age and pain level were very small in magnitude and arguably modifiable.

3- Under that same assumption, shouldn't the results be interpreted in regards to 'compliers’, rather than compliance? I believe your results have shown that compliers who receive advice and CBT have better outcomes in terms of pain and disability, compared to (that same group of people) advice alone. I’m afraid referring to ‘compliance’ can be misleading for the reasons given above.

3- The authors suggest that the baseline modified Von Korff score was associated with ‘being a complier’. The univariate results, however, show non-significant associations. Could you please clarify?

4- The paper would benefit from further explanation of the difference between ‘non-compliers and lost to follow-up’, especially given it is one of the first in the back pain field to use this approach.

Discretionary Revision

5- Please clarify how many people were included as compliers and non-compliers in the CACE analysis and the ITT analysis, in the first paragraph of the results.
**Level of interest:** An article of outstanding merit and interest 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.