Author's response to reviews

Title: The effects of using cognitive behavioural therapy to improve sleep for patients with delusions and hallucinations (The BEST study): study protocol for a randomised controlled trial

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Version: 3 Date: 15 May 2013

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We thank the reviewer for the positive comments about the trial. Our team’s response to the helpful suggestions for revisions are as follows:

1. We have now added to the protocol that the inclusion criteria are set to capture individuals who score above sub-threshold insomnia on the ISI (Page 6) i.e. who have insomnia. We will record how many patients do not meet this criterion.

2. We have added to the description of the randomisation process (page 5). We are ensuring that there is balance across the two groups in levels of insomnia and in types of psychotic symptoms (delusions only, hallucinations only, delusions and hallucinations). Further we have added that, as a sensitivity analysis, we will also look at effect of treatment difference by controlling for initial overall symptom severity (assessed by the PANSS) (page 10).

3. We are assessing medication type and dose. We have now added that these effects will be tested in a sensitivity analysis (page 10). We are not measuring medication side effects as we already have an extensive assessment battery.

4. The sample is not by definition treatment resistant. They do have, however, symptoms that have remained for at least three months, typically after use of medication. In our pilot study symptoms needed to have been present for at least six months. The basic point is that we select a group for whom further treatment is indicated. Indeed the selection criteria are precise and therefore easy to compare to other studies if a reader wishes (the sleep in psychosis literature is very mixed in terms of entry criteria).