Reviewer’s report

Title: Relating Therapy for voices (the R2V study): Evaluating a relationally-based therapy for people who hear distressing voices

Version: 1 Date: 18 May 2014

Reviewer: Dave J Dagnan

Reviewer’s report:

Minor essential revisions:

1. The authors describe their study variously as a ‘feasibility/pilot’ study and as ‘feasibility RCT’. It would be good practice to consider whether this is a true feasibility study or a pilot study. The study appears to be a small scale implementation of the full protocol and I would suggest the authors use a consistent language to describe the study, possibly based on a referenced previous discussion of these distinctions. I find the NIHR distinction of internal and external pilot also a useful structure to consider.

2. The authors should identify how many therapists they will be training to offer the treatment.

3. The authors should state a little more about the pathway stage from which participants will be recruited, in particular will the TAU arm systematically include CBT for psychosis, or will participants have already been offered CBT?

Discretionary revisions

1. The authors refer to a previous ‘feasibility’ study that established the acceptability of the intervention; it is not clear whether this study also reported core feasibility parameters such as described in the NIHR feasibility/pilot discussion paper (www.ccf.nihr.ac.uk/.../Feasibility%20and%20pilot%20studies.docx). It would be useful to clarify this.

2. In the participants section the authors assume a 20% attrition rate; they may wish to delete this assumption? Is this assumption taken from the earlier feasibility study and if not does this not pre-suppose one of the core outcomes of the study? In the analysis section the authors identify that the purpose of the feasibility study or external pilot is to establish the actual conversion from first approach to consenting and the actual attrition within treatment and to follow-up. For both true pilot and true feasibility it can be helpful to consider (and state) the levels of conversion and attrition that will suggest that the study is feasible and what levels would suggest it is not, if this is the case is the 20% attrition described a minimum level above which the study will not be considered as feasible for Phase III trial?.

3. The use of pilot studies to establish a simple effect size is open to significant
discussion (e.g. Leon et al, J Psychiatr Res. May 2011; 45: 626–629) as the sample effect size may not be a good estimate of the population effect size. Other important parameters to determine the suitable sample size for the Phase III trail might include clinically significant change. The authors may wish to consider this issue in the analysis section.

4. Fidelity is covered relatively briefly, how significant will the adaptation of the CTC need to be to be able to identify the key differences in the relationally based therapy compared to other forms of CBT and are the authors confident this will not need significant work to establish the reliability of such ratings.

**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 i have no competing interests