Reviewer’s report

Title: Dialectical Behaviour Therapy for treating adults and adolescents with emotional and behavioural dysregulation; study protocol of a coordinated implementation in a publicly funded health service.

Version: 1 Date: 02 Nov 2017

Reviewer: Terry Lewin

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Review for:

BMC Psychiatry (November 2nd, 2017) - Terry Lewin (Newcastle, Australia)

Manuscript: BPSY-D-17-00503R1 - "Dialectical Behaviour Therapy for treating adults and adolescents with emotional and behavioural dysregulation; study protocol of a coordinated implementation in a publicly funded health service" (Flynn et al).

Overall Comments:

The rationale for publishing this study protocol is clear (e.g., co-ordinated national implementation of DBT; limited similar work; opportunity for critical review) and the authors do a reasonable job of outlining their study. I have some 'moderate' issues that probably need to be addressed, and a number of minor corrections/suggestions.

I noticed that this manuscript was tagged "R1" and a quick look at the original submission suggests that the authors were asked to clarify information for the editor about ethical approval, funding approval, previous peer-review, and author contributions. I don't have any specific concerns about these matters; however, it is a little unusual for a protocol paper to be acknowledging author contributions with respect to data acquisition, analysis and interpretation. In this instance, within the Authors' contributions section, the authors might want to make some simple statements about the preparation of this particular paper, together with some more complex statements about each author's key roles with respect to the project as a whole.

Major Issues:

No major issues.

Moderate Issues:
1. Parent/guardian participation and consequences. Within the Participants component of the Methods/Design, the "Parent/guardian of adolescent" subsection does not expressly say whether or not adolescents themselves will be retained in the study if their parent/guardian is unavailable, estranged, in conflict, etc. If adolescents themselves are not excluded, then the statement about '… where family members may be excluded …' needs to be reframed. Likewise, the corresponding statements in the Sample Size section would need to be changed - "As the adolescent … there will also be 96 parent/guardian participants" to something like "… up to 96 parent/guardian participants".

2. Feedback to participating services. While the authors discuss embedding members of the coordinating team within the participating services, no mention is made about specific (ongoing) feedback to teams about how 'recruitment' to the study is going, how well they are doing with respect to adherence to the required clinical/administrative protocols, etc. Likewise, dissemination of the study's findings, opportunities for the teams to explore their own data/outcomes, etc, are not mentioned. To the extent that such elements potentially enhance engagement with the project, they might be worth foreshadowing in this protocol paper.

3. Anticipated uptake and likely recruitment to the non-equivalent comparison groups. While the Sample Size subsection anticipates "… a total of 312 participants across 16 sites", no mention is made of the likely timeframes for recruitment (e.g., over a 4 year period). Likewise, the anticipated uptake rates (or ranges) and retention rates at follow-up are not mentioned (for both the primary groups and the non-equivalent comparison groups).

Minor Issues:

Background:

4. The expression "… in many instances, failed to sustain as a result of systemic issues" could probably be clearer and a little more informative.

5. Are data from the "four sites in the south of Ireland" which provided "early positive research outcomes" being included in the main evaluation - or are new clients/data from these sites being included - and will their previous experiences impact on their involvement and/or subsequent outcomes?

Methods/Design:

6. In view of the preceding paragraph, the second sentence with the Study Design could probably be changed to: "As the setting for this study is the publicly funded health system, staff have a responsibility …".

7. Delete "is" in the sentence "mental health issues/behaviour is at such …".
8. Within the Treatment-As-Usual subsection, "areas where the treatment is not yet available" are to be targeted. However, if the main study takes several years to complete, how likely is it that the status of these areas will change during that time - and that individuals will want to avail themselves of the new treatments on offer?

9. Table 1 (Individual Therapy) - change "strengthens skills" to "skills strengthening".

10. What sessions will actually be "audio recorded" and how will these be sampled for treatment adherence monitoring?

11. Table 2 - consider changing "administered to" to "completed by".

12. The three sub-headings within the "Time point for each outcome" section could possibly have the words "time points" added to them (e.g., "Effectiveness Evaluation Time Points"), to help distinguish them from earlier subsections with the same names.

13. No alpha levels (e.g., 0.05, 0.01) are mentioned within the power calculation paragraph of the Sample Size section, and no mention is made of any intended adjustments for the number of outcome measures. The simplest solution might be to name the primary outcome measure and to describe the power calculations with respect to that measure.

14. Change "will be measures in" to "will be measured in" within the Data Analysis section.

Other:

15. Correct sentence in Declarations to say "of data so that they can make".

I have also included an electronic copy of these comments.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes
Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

**Quality of written English**
Please indicate the quality of language in the manuscript:

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