Reviewer's report

Title: The effectiveness of the Who's Challenging Who support staff training intervention to improve attitudes and empathy towards adults with intellectual disability and challenging behaviours: study protocol for a cluster randomised controlled trial

Version: 0 Date: 06 Aug 2017

Reviewer: Augustine Choko

Reviewer's report:

Well done for designing this important intervention trial. I have some comments, mostly constrained to the design of the trial.

Title

Abstract

Background

Kindly clarify: staff to mean employees of residential settings -- here and in the main methods.

Methods

Here and in the main methods, there is need to be clear about the unit of randomisation. In some parts it appears like the staff (size = 2) and not the residential setting is the unit of randomisation.

Consider including some key assumptions and design characteristics alpha and power for the design. Also consider intra-cluster correlation coefficient.

Clarify briefly how the primary outcome will be measured.

Discussion

Clarify how exactly the would be participants have been involved in the design of the intervention so far (focus group discussions? in-depth interviews? workshops? The main body suggests through a pilot so i suggest you include this piece here.
Main body

Background

Methods

Study design

I suggest that a few statements are inserted here to fully describe the two trial arms followed by detailed approach to participant recruitment and outcome measurement. I think that way more clarity will be achieved.

For example, it is currently not very clear how the control arm of waiting list will measure the outcomes in the trial. I would move the outcome measurement section up here so it is clear how this will work.

Care home and participant selection

"If recruitment is slow..." Are the investigators in doubt of finding enough eligible participants for the trial? This would be unexpected given that a pilot study was conducted? Please clarify.

Randomisation

Is the unit of randomisation the two staff or the residential setting? This needs to be clear because if it is the latter then cluster size (participants) may vary which may affect the current sample size computation.

Summary flow chart figure

The figure needs to have a box for exclusions eg residential settings that are not eligible after screening.

I feel that the introduction and mention of 2 staff per residential setting is a bit confusing. The unit of randomisation is the residential setting so it is better to stick with that and show activities / procedures within that cluster in the control and treatment arm.
I suggest that one box is used to show trial procedures:

1. Baseline data collection

2. Follow-up interviews at 6 weeks

3. Follow-up interviews at 20 weeks

Safety reporting

What are some anticipated AEs?

Outcome measures

How will the questionnaires to measure the outcomes be administered in the control arm?

Main analysis

I suggest that a statement is included to say that baseline characteristics will be presented by trial arm. This will help to judge the success of the randomisation and if there is (reasonable) balance there will be no need to adjust for baseline characteristics as currently stated.

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