Reviewer's report

Title: OPTIMAL, an Occupational Therapy Led Self-management Support Programme for People with Multimorbidity in Primary Care: A Randomized Controlled Trial

Version: 4 Date: 21 November 2014

Reviewer: Suzanne Richards

Reviewer's report:

This is clearly written paper describing an RCT of a complex intervention using an occupational therapy based intervention to improve the management of individuals with multi-morbidity in an Irish primary care setting.

Major revisions
NONE

Minor Essential revisions

Figure 1 - needs to be amended to satisfy consort guidance. The figure should start with information on patients referred to the study, then deemed eligible (or otherwise), and include the % of patients offered study entry who eventually took part. Please check consort guidance on how to present this diagram and amend as appropriate.

Abstract, Line 47. Please describe the number/timing of follow-up assessments and the time point at which the primary outcome measure was assessed,

Abstract, Line 54-57. Would be helpful to present the effect size and 95% CI whenever you report a p-value in the results.

Methods, line 103. Consort guidance for complex interventions - it would be helpful if the authors included a box summarising the 'active ingredients' of their intervention to assist the reader. At present there is not enough description of the intervention. Although line 103 has a cross-reference to a academic paper (reference 11) describing its development/content, there is simply not enough description here to assist the reader. I would put 'see box X' before reference 11 on line 103.

Methods, Line 112. Can you please put a study reference number against the Research Ethics Committee approval by the university? If someone wanted to review the approval they would need it.

Randomisation, Line 136. You report that randomisation was independent of the trial management team. It's a bit picky, but the point is that randomisation is conducted by a statistician who is independent of the people recruiting into the trial. Suggest you put 'trial management team responsible for patient recruitment'
Methods, around line 138. You describe the intervention group reasonably well, but you don't describe the control group. You need a sub-heading with 'control group' and some description on what happened to them.

Outcomes, line 166. FAI - you describe three subcategories of activities, each scoring 0-15, but you don't actually say what these categories are. Please describe here. They are first mentioned in the results section.

Secondary outcomes, lines 168-175. A little more information is required on how each of the measures are scored (e.g. the range of possible scores for the measure/any sub-scores, and how to interpret it). The results tables do not have a foot note explaining the scores - so without any extra information - it is difficult to know whether, for example, a mean HADs anxiety score of 9.77 in the intervention group is a good or bad thing.

Methods, Line 210: you applied the bonferroni correction for multiple comparisons. Please spell out what level of the p-value was deemed significant after this correction was applied, and whether or not this level was applied to the primary analysis, or just the secondary analyses.

Results, lines 214-221: Would appear that all the patients referred to the study were eligible, but not all were recruited. For completeness, you might say that all 63 patients referred to the study met eligibility criteria. It is quite unusual for all patients who are referred to be eligible, so this might need careful description.

Results, lines 225-27. Please put denominators next to the proportions throughout the patient flow section (e.g. XX/X; 12%).

Primary outcome, line 235. You header describes your primary outcome as 'occupational participation' whereas the methods describes it as either the FAI or 'activities participation'. Think you need to be consistent - to me occupational participation means ability to take part in paid work (which is I suspect not what you mean). I would also provide the effect sizes and 95% CIs for the between group differences tested within the text and not just the table. This is your primary outcome, and it would help the reader to see the effects in the text. You probably don't have to do this for your secondary outcomes, mainly as there are a lot of them.

Results, line 256. You refer to a number of EQ-5D domains with a trend to improvement, and cross refer to a table. Might be helpful to put the domains in brackets to assist the reader).

Discussion, throughout. I would avoid the use of abbreviations for the names of outcome measures (e.g. HCU, HeiQ, QoL) in the discussion and write them in full to aid clarity.

Discussion, line 335. You state it is a pragmatic trial. I agree, but you should also use the word 'pragmatic' in your methods section when describing study design.
Box 1, line 531. There is a typo, with 'Priamry'. Also lines 534-535. The sentence starting 'the model of primary care' does not make sense. Please re-write to improve the clarity, possibly splitting into two.

Table 2. The text does not fit onto one page, with the p-value column not visible. Please review.

Table 3. The foot note ‘***’ is potentially misleading. When next to a p-value, most people would erroneously interpret this as highly statistically significant due to convention of using *=0.05. **=0.01 etc. I am not sure on the journal guidance, but it might be better to select a different symbol to aid interpretation.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests