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: 19 December 2014

Reviewer: Malcolm Battersby

Reviewer's report:

Major compulsory revisions:

There are a number of design issues that need to be addressed. The study is described as a randomised controlled trial using the UK MRC design for complex interventions. There is no evidence in the methodology or results and discussion that the trial does match these guidelines. There is for example no description of background theory which matches the intervention and which corresponds with outcome measures designed to measure the theoretical application of the intervention. The intervention could in fact be argued as not being complex. It was a standard 6 week group intervention conducted by occupational therapists. The time frame supports this as a unitary intervention because the measures were taken at baseline then immediately after the group program.

The second issue is related to the title and aim of the study. It is described as an efficacy study with a non specific ie convenience selection of patients, and randomisation which is briefly described. Whilst there are some elements of an efficacy study ie the selection of patients in a real world situation, the intervention is delivered by specially selected and trained occupational therapists identified for the study. Under the Complex intervention guidelines this study is more like a phase I pilot study and should be described like that, although given that it is unlikely to be a complex intervention it could simply be described as a pilot study which would inform the design of a larger RCT. The reference to being a complex intervention should be removed.

Background

A key issue here relates to a lack of theory and reference to previous research. 1. Multi-morbidity: the authors claim this is a first study in multi-morbidity of a group self-management intervention. The problem with putting this study in this framework is that multi-morbidity is a vaguely defined concept. It is confused with co-morbidity and it is unclear whether it includes mental disorders, drug and alcohol as well as physical disorders or disabilities eg post stroke. Any definition which includes nearly 60% of the adult population is probably unhelpful scientifically as a definition and to inform the efficacy of interventions. The authors use the criteria of 2 or more chronic conditions (‘any two chronic conditions’ is probably incorrect) which does not fit with the general use of the term multi-morbidity to refer to those with 5 or more chronic diseases/conditions to imply a more complex severe group of people. I suggest removing reference to
multi-morbidity in the criteria although referring to it in the discussion might have relevance. 2. Self-management; similar to multi-morbidity, self-management is referred to without a definition – there are several international definitions to refer to but again it is a broadly used term but there is a large body of literature which debates concepts like self-management, self-care and self-efficacy and similarly there is a body of literature discussing measurement of self-management based on definitions or where there are no definitions. 3. The intervention; this is a 6 week group intervention delivered by occupational therapists. In the background there is no reference to a large body of research from Kate Lorig and colleagues on the Stanford chronic disease self-management course which is a 6 week course which can be delivered by lay (peers) leaders or health professionals or both. In fact a glaring omission in this paper is the lack of reference to Lorig’s work with only on reference which is to the Stanford outcome measurement tools. The Stanford literature is referred to briefly in the discussion, but it appears that the content and skills being taught to the patients are very similar to the Stanford course. There needs to be a table and description of the similarities and differences between the two programs where the intervention is being described. On the face of it the only significant difference between the two programs is that it is being delivered by occupational therapists. Both are generic not disease specific programs and the literature differentiating the disease specific and generic programs needs to be acknowledged. The claim in the discussion that this is the first to use health professionals in such a program is incorrect – others have tested physiotherapists and other disciplines conducting these Stanford like programs. Indeed Lorig herself has tested a combined model of health professional and peer compared to peers alone. The findings can be summarised that when health professionals conduct these programs the participants know more, when peers conduct the program the participants do more.

Methodology

There needs to be more detail on the randomisation process. Who conducted it, when and how independent was the person conveying the allocated group to the patient. What was the computer allocation method used? What was the procedure in how the patient allocated to the intervention group was then provided with the intervention. How long did it take to fill a group and commence it? Did this impact on the non attendance at the beginning? Sample size – this is based on the FAI difference of 4 points using a 90% power and even including 20% drop out the total is 34 – presumably in each group – this is not clear in the text – and then ultimately each group had 26 and 24, so it is unclear whether this is higher than required or under the desired sample size. This will influence whether there could have been type 1 or 2 errors in the results. Analysis – my understanding is that intention to treat analysis includes all subjects with baseline data whether they have follow up data or not and whether they received the intervention or not.

Results

Whilst 22 in each group were part of the pre and post analysis, the text refers to 23% not attending any session. This breakdown should be included in the
consort flow diagram. Of those who did start, 69% attended three or more sessions – what is this n? it is easy to work out but should be shown. A key issue here is feasibility and this should be a focus of this pilot study. It is a major finding and highly consistent with other group self-management trials that few people attend for significant periods and they are mostly women. Again we do not know the breakdown of those who started and those who attended three or more sessions relating to gender. Whilst the overall outcomes are positive it is critical to know who attends or does not and preferably why. The inference is that other forms of self-management delivery are needed and they may have the advantage of being more accessible and cost effective eg individual one to one interventions or on-line interventions and those targeted specifically at men or disadvantaged groups who do not attend group programs in working hours. The HEI-Q results are not discussed in the results section.

Discussion

Much of the discussion is relevant but would need to be rewritten in the light of the above comments.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

Flinders University is applying for a patent for an electronic (web) based version of the ‘Flinders Program’ of chronic condition self-management. This is an individual health professional to patient delivered program and does not compete with the group program identified in this paper.