Review of: "Effectiveness of a novel multi-modal intervention for family caregivers of persons with age-related macular degeneration: a randomised controlled trial"

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Potential competing interests: No potential competing interests to declare.

The paper is well structured and has several interesting points. I appreciated the idea of providing a new intervention for carers of people with age-related macular degeneration (AMD), especially considering the paucity of proposals in the literature. Furthermore, I also appreciated the idea of a remote intervention so that caregivers are not further burdened.

However, there are some issues that need to be addressed.

INTRODUCTION

The introduction is brief and gets straight to the point. Nevertheless, I would give more details about the psychological and physical consequences of an increased burden: what are the main compromised outcomes and why are they relevant?

"*The novel intervention in this study is the first program globally to provide a tailored support service for family caregivers of individuals with AMD. The intervention comprises of mail-delivered cognitive behavioural therapy (M-CBT), telephone-delivered group counselling and education on available supports. M-CBT involving written materials being posted to caregivers is chosen over standard face-to-face CBT to enable them to review the material as often as needed. There is evidence from randomised controlled trials (RCTs) for the effectiveness of M-CBT in a diverse range of conditions*." You provided evidence for the efficacy of M-CBT, but you did not cite any study regarding the efficacy of telephone-delivered group counselling. Is there any evidence to support this type of intervention? Is this part of M-CBT or is it completely something else? This point is not clear.

METHODS

TRIAL PROCEDURE

I do not understand why you chose to do the post-test assessment after 6 month and not after the end of the intervention. What is the rationale behind this choice? I understand that you were interested in knowing whether the effect of the intervention could last for some time after its conclusion, but it is useful to know if there is a short-term effect too. Perhaps

the intervention might have brought some improvement, in the short term but you did not catch it.

OUTCOMES

I suggest using a random mixed model instead of a paired t-test (GSE, EQ-5D-5L, and EQ-VAS), in order to consider the variability of he cluster “id”, and maybe of the “institution” cluster (since you conducted a multi-centre study, it is advisable to consider the commonality due to belonging to the same institution). Furthermore, you would be able to consider in a single model the covariates you have already assessed but not analyzed: age, sex, employment status, health status, living arrangements, marital status, being or not the sole caregiver, relationship to the care recipient, and years of education.

I also suggest using a generalized mixed model instead of a McNemar’s test (CESD-10, FSS, and CBS) for the same reasons stated above.

RESULTS

Why there were so many dropouts in the intervention group? Could it be due to the nature of the intervention? I suggest that the possible causes that made the intervention not "well-tolerated" should be explored further in the Discussion part and that we should try to analyze possible differences between the 17 participants who dropped out and those who stayed until the end of the experiment (77).

There are some percentages that are not clear. For example, you stated “*77% (n=30) of participants reported that they were satisfied/very satisfied with the intervention*”. If the total of participants you are referring to is 46 (those who started the intervention) or 31 (those who finished the intervention), then I do not understand how 30 participants can account for the 77% of the total. Am I missing something? In addition, it is not clear if all participants in the intervention group received the telephone-based counselling. I thought that all participants in the intervention group received five modules of M-CBT and then five modules of telephone-delivered group counselling. However, you stated “*Of those who participated in the telephone counselling component (n=15), 93% (n=14) were satisfied or very satisfied*”. It is crucial to clarify this part.

DISCUSSION

“*Although the results were not statistically significant, it is not possible to rule out the presence of clinically significant benefits in the multimodal intervention. Statistical significance alone does not necessarily constitute clinically significant improvements or meaningful change when interpreting a study’s outcome for application to patient care. Clinically meaningful changes refer to those that improve an individual’s quality of life, social function, as well as physical and mental wellbeing. The results showed promising non-significant differences in several secondary outcome measures including reduction in depression, fatigue and improved quality of life between the intervention and control group in the expected direction.*” It is important to assume - as you did - a type II error and the presence of a small effect size not

detectable with your small sample size that prevented you from finding a significant result. However, this section provides weak explanations for your non-significant results. If you support the idea of the impossibility of excluding an effect in the presence of a non-significant results, then why did you use a Null hypothesis significance testing approach? It seems contradictory. I understand that you are trying to defend your work, but looking at your data we can only argue that your intervention was not effective. We all know that journals prefer “positive” results, however finding a non-significant result should be considered just as interesting as finding the absence of an effect. This is the biggest limitation of your Discussion. Personally, I suggest rephrasing this section by highlighting the importance of finding a non-significant result and how this evidence could be used to improve your intervention or to choosing something more beneficial for your population.

“*There was also a relatively high withdrawal rate from the intervention group. However, this was comparable to other studies examining the efficacy of CBT for family carers of relatives with dementia, with one such study reporting 17% of participants failing to complete the CBT intervention sessions. Another study involving a CBT-based problem-solving intervention for family carers of stroke victims reported that 30.9% of participants did not complete the intervention, citing similar reasons to those observed in our study*.” As stated above, I suggest providing some hypotheses regarding your high withdrawal rate. Might the intervention have some specific characteristics that discouraged participants from continuing? In addition, were the voluntary dropout concentrated in the first five modules or in the last ones?

“*The intervention was feasible as shown by the relatively high satisfaction and adherence rate, as well as lack of adverse effects*”. This result is in contrast with the high withdrawal rate. Might it possible that participants answered in order to please the experimenter?