

# 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.

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

The provided title indicates a randomized controlled trial evaluating the effectiveness of a novel multi-modal intervention for family caregivers of individuals with age-related macular degeneration (AMD). The authors of the study are Ivan Jin, Richard Kha, Diana Tang, Gerald Liew, Ashley Craig, George Burlutsky, Paul Mitchell, and Bamini Gopinath.

## Comments

1. Provide a clear objective: It would be helpful to clearly state the objective of the study. What specific outcomes or improvements are you aiming to achieve through this intervention?
2. Specify the sample size and recruitment process: Include information about the number of participants involved in the study and how they will be recruited. Will they be recruited from a specific population or through certain healthcare institutions?
3. Define the intervention components: Provide more details about the specific components of the intervention. How will the mail-delivered cognitive behavioral therapy (M-CBT) be structured? What topics will be covered in the telephone-delivered group counseling and education sessions?
4. Explain the control group: Clarify what is meant by "usual care only" in the context of the control group. What specific services or support are they receiving, if any? How will they be comparable to the intervention group in terms of baseline characteristics?
5. Describe the assessment measures: Specify the instruments or scales that will be used to measure perceived caregiver burden, depression, fatigue, health-related quality of life, and self-efficacy. Explain why these measures were chosen and how they will be administered.
6. Outline the study design: Provide information on the study design, such as the randomization process, blinding (if applicable), and the duration of the intervention and follow-up period. This will help readers understand the structure and timeline of the study.
7. Address potential limitations: Acknowledge any potential limitations or challenges that may arise during the study. For example, recruitment difficulties, attrition rates, or possible biases that could affect the results.
8. Ethical considerations: Briefly discuss any ethical considerations related to the study, such as obtaining informed consent from participants, ensuring confidentiality, and obtaining necessary ethical approvals.

9. Funding and conflicts of interest: Mention the source of funding for the study and declare any potential conflicts of interest that could influence the results or interpretation of the study.
  10. Dissemination plan: Share your plans for disseminating the study results, including publication in scientific journals, conference presentations, or any other avenues to reach relevant stakeholders.
- By addressing these points, you can provide a clearer and more comprehensive description of your study, making it easier for readers to understand the goals and methods of your research.

The provided methods section provides a clear overview of the study design, intervention, participants, and outcomes. However, there are a few areas where additional information or clarification could improve the understanding and reproducibility of the study. Here are some suggestions for improvement:

1. Randomization and blinding: It would be helpful to mention the specific method used for randomization (e.g., computer-generated random numbers) and how the randomization sequence was concealed. Additionally, since blinding was not possible, it would be good to explain how potential bias was minimized or controlled for during data collection and analysis.
  2. Trial procedures: Provide more details about the content and structure of each M-CBT module. What specific information and skills were covered in each module? Similarly, elaborate on the content and topics discussed during the Talk-Link group counseling sessions. This information will help readers understand the specific components of the intervention.
  3. Control group: Specify the nature of the reading materials provided to the control group. Were these materials standardized or tailored to the individual caregiver's needs? Also, mention how the opportunity to receive the intervention at the end of the study period was communicated to the control group.
  4. Outcomes: Clarify the timeframe for administering the baseline questionnaire. Was it completed prior to the randomization or before the intervention started? Additionally, provide more information about the scoring and interpretation of the outcome measures, such as the Caregiver Burden Scale (CBS), Centre for Epidemiologic Studies Depression (CESD-10), General Self-Efficacy Scale (GSE), Fatigue Severity Scale (FSS), EQ-5D-5L, and EQ-VAS.
  5. Data analysis: Explain how missing data will be handled, particularly for participants who drop out or do not complete the follow-up assessments. Additionally, consider mentioning the statistical software or methods that will be used for data analysis.
  6. Limitations: Include a dedicated subsection on the potential limitations of the study. Discuss any potential sources of bias, limitations in generalizability, and challenges that may impact the validity or reliability of the results.
  7. Results dissemination: Mention the plan for reporting and sharing the study results. Specify whether the findings will be published in scientific journals, presented at conferences, or made available to relevant stakeholders in any other way.
- By incorporating these suggestions, you can enhance the clarity and transparency of the methods section, allowing readers to better understand the study design and procedures.

The provided results section provides a clear presentation of the findings and includes relevant statistical measures. Here are a few suggestions for improvement:

1. Participant flow: It would be helpful to include the total number of participants screened for eligibility (940) in the

participant flow diagram (Figure 1). This will provide a comprehensive overview of the study's recruitment process.

2. **Baseline characteristics:** Consider including the standard deviations (SD) for the baseline characteristics of family carers and patients presented in Table 1. This will provide a more complete description of the sample and allow readers to assess the variability within each group.

3. **Interpretation of findings:** In the discussion of the results, it would be beneficial to provide a more nuanced interpretation of the findings. For instance, instead of stating that reductions in caregiver burden scores, depressive symptoms, and fatigue were "non-statistically significant," you can mention that there was a trend towards improvement in these outcomes, although the differences did not reach statistical significance. This will provide a clearer understanding of the magnitude and direction of the observed effects.

4. **Treatment acceptability:** In addition to reporting participant satisfaction and adherence, consider providing a more detailed description of the feedback received. Highlight specific aspects of the intervention that were particularly well-received or areas where participants suggested improvements.

5. **Reporting statistical results:** When presenting mean differences and their 95% confidence intervals (CIs), consider rounding the mean differences to two decimal places for consistency. Additionally, ensure that the p-values presented correspond to the appropriate statistical tests used for each outcome measure (e.g., paired t-tests, McNemar's test).

Overall, the results section effectively presents the main findings of the study. By implementing these suggestions, you can enhance the clarity and accuracy of the reported results

The provided discussion provides a comprehensive analysis of the study findings and addresses potential limitations.

Here are a few suggestions for improvement:

1. **Interpretation of non-significant results:** While it is important to acknowledge the non-significant findings, it would be helpful to discuss possible reasons for these outcomes and their implications. Consider exploring factors that may have contributed to the lack of statistical significance, such as the small sample size, high withdrawal rate, or specific characteristics of the caregiver population. Additionally, discuss the potential clinical significance of the observed trends and highlight the importance of further research with larger sample sizes.

2. **Comparison with previous research:** Compare the findings of this study with previous research investigating interventions for caregivers of individuals with chronic conditions. Discuss similarities and differences in the outcomes and implications, highlighting any unique aspects of the current study.

3. **Recommendations for future studies:** Provide specific recommendations for future studies to improve upon the limitations identified in this research. For example, suggest strategies to enhance recruitment and participant retention, increase the number of intervention sessions, or explore alternative outcome measures that may capture the impact of the intervention more comprehensively.

4. **Generalizability of the findings:** Discuss the generalizability of the study results to the broader population of caregivers of AMD patients. Consider any specific characteristics of the study sample or setting that may limit the generalizability and suggest areas for further research to address these limitations.

5. **Clinical implications:** Discuss the potential implications of the findings for clinical practice and policy development. Address how the results contribute to the current understanding of interventions for caregivers of AMD patients and how they may inform future support services and policies.

6. Strengths and limitations: Provide a concise summary of the strengths and limitations of the study. Emphasize the strengths, such as the rigorous study design and multidisciplinary collaboration, while acknowledging the limitations, such as the low sample size and lack of long-term follow-up.

By incorporating these suggestions, you can further enhance the discussion section, providing a comprehensive analysis of the study findings, their implications, and avenues for future research

#### Conclusion

Here are a few critical points to consider for further improvement:

1. The conclusion could further emphasize the limitations of the study, particularly the small sample size and high withdrawal rate. Acknowledge that these factors may have contributed to the non-significant findings and emphasize the need for larger studies to confirm the effectiveness of multimodal interventions for caregivers of AMD patients.
2. Provide a more explicit statement about the implications of the study's findings. Discuss the potential impact on clinical practice, policy development, and the design of future interventions for caregivers of AMD patients. Highlight any areas that require further investigation or refinement.
3. Consider addressing the broader context of caregiver support and interventions. Discuss how the findings of this study contribute to the existing body of literature on interventions for caregivers of individuals with chronic conditions, including the specific challenges and needs of caregivers of AMD patients.

By addressing these critical points, the conclusion can be further strengthened, providing a more comprehensive summary of the study's findings and their implications.