Qeios

Peer Review

Review of: "Mindfulness-Based Intervention Improves Quality of Life and Reduces Burden in Family Caregivers of People with Intellectual Disabilities: A Pragmatic Randomized Trial with an Active Control"

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This is a pragmatic randomized trial with an active control to evaluate selected psychological variables in caregivers, as well as feasibility.

This manuscript presents a pragmatic randomized trial with an active control to evaluate psychological variables and feasibility in caregivers. Overall, this is an interesting article, adapted to the Latin American context. While the research question is relevant and the topic has public health importance, the study requires substantial revisions before it can be considered for publication. Major issues include inconsistencies between the registered protocol and the reported primary outcome, insufficient description and justification of the sample size and recruitment process, unclear handling of randomization and allocation concealment, lack of transparency in the statistical analysis plan (including handling of missing data and multiplicity), and limited reporting of intervention fidelity and adherence. The qualitative component is insufficiently described and does not meet COREQ standards. Additionally, the current presentation suffers from redundancy, unclear phrasing, and suboptimal organization of results. The manuscript would benefit from improved writing clarity, reduction of repetitive content, and prioritization of key findings—particularly highlighting that the primary outcome showed no difference between groups—while moving less relevant results to supplementary material.

The **introduction** is clear and concise; however, there are several issues to address in order to enhance and clarify the research.

It is necessary to better articulate the research gap. The authors state that previous studies “lack methodological rigor” but do not describe the specific limitations. It is also recommended to update the references, as the rationale is based on a systematic review from 2016. Given that 9–10 years have passed, there is likely more evidence available. For example:

https://onlinelibrary.wiley.com/doi/full/10.1111/jar.70081

In Latin America, there are prior pilot studies on brief (4-hour) mindfulness and compassion interventions in this field, such as:

https://www.researchgate.net/publication/350947985_Intervencion_basada_en_mindfulness_y_pintura_para_cuidadores_de_ninos_y_adolescentes_con_necesidades_

It would strengthen the paper to describe the best available evidence to date, identify the gaps, and position the present study accordingly.

It would also be useful to discuss other interventions already supported by evidence for this group, identify their limitations, and explain how mindfulness could address these gaps. A brief review of interventions for caregivers of people with dementia could also provide valuable context.

In addition, **Mindfulness-Based Health Promotion (MBHP)** may not be familiar to all readers. It is necessary to explain what makes it unique, why it might be beneficial for caregivers, and why this program was chosen instead of the standard MBSR.

Given that this is a Brazilian study, it would be desirable to provide background on the caregiving context in Brazil to better contextualize the research.

METHODS

The planned sample size was 128, but only 100 participants were recruited. What happened? Which strategies were used to inform, enroll, and retain participants? How was the sample size calculated—based on which expected effect size and variable? Why does it differ from the preregistered protocol? How many participants were screened and excluded?

What was the content of the informational session? If participants were informed that the study was about mindfulness, this may have biased the results.

Was the analysis conducted on an **intention-to-treat** or **per-protocol** basis?

Randomization: Please specify exactly how random.org was used, how class and block randomization were implemented, and how allocation concealment was maintained.

The **primary outcome** in this article differs from that in the protocol (registered 24 months earlier). This change must be explained.

Figure 1 (participant flow): Please use the standard CONSORT flow diagram and specify dropout reasons.

doi.org/10.32388/E679NK

Clarify whether there were any fidelity or adherence metrics—for example, attendance rates or homework completion.

Was there a study protocol or statistical analysis plan registered before data collection?

For paired, non-normal outcomes, Mann–Whitney U is not optimal; the Wilcoxon signed-rank test would be more appropriate. Multiple tests were conducted—both within and between groups—across five instruments, with only one declared as the primary outcome. How was the issue of multiple comparisons addressed (e.g., Bonferroni correction)?

How was missing data handled? How were dropouts assessed? A mixed model or ANCOVA (adjusting for baseline values and accounting for dropout) might be preferable.

If NNT/NNH is reported, a predefined clinical threshold should be specified.

The rationale for testing associations and performing linear regressions is unclear.

A qualitative component seems to have been included, suggesting a mixed-methods approach. If so, the qualitative methods must be reported according to **COREQ**, including: team characteristics, reflexivity, interview guides, participant involvement in the analysis, illustrative quotes, and coding procedures.

Results

Although a post hoc sample size calculation is presented, it raises the question of how the original sample size for WHOQOL was determined.

The results start with feasibility, but feasibility was not predefined. It may be useful to apply **Bowen's (2009)** feasibility criteria (https://pubmed.ncbi.nlm.nih.gov/19362699/).

Dropout reasons should be included in the CONSORT diagram. Given a 41% dropout rate, it is critical to address how missing data were handled, how dropout may have biased results, and to conduct sensitivity analyses.

The **primary outcome** should be reported first and separately from secondary outcomes, following APA or similar reporting standards. Importantly, both interventions improved WHOQOL, but there were **no differences between interventions** in any domain—this must be stated clearly to avoid confusion.

Main tables and figures should present the most important results, with others moved to supplementary materials.

Given the large number of statistical tests, it is necessary to state how false positives were controlled.

Discussion

The first paragraph should clearly state the primary outcome result: there was no difference between the intervention and control groups in quality of life. Therefore, it is not possible to conclude that the intervention was more effective than the control.

The discussion should address why no difference was found, considering possible explanations (e.g., active control effects, sample characteristics, adherence, measurement issues).

Other results not directly tied to the main research question should be evaluated for relevance before inclusion.

Many of the methodological concerns noted above should be acknowledged in the **limitations**, including the high risk of bias indicated by a RoB 2.0 assessment, discrepancies with the preregistered primary outcome, and changes in the analysis plan.

The conclusion should be based strictly on the study results and avoid overstating effectiveness.

Declarations

Potential competing interests: No potential competing interests to declare.