Reviewer’s report

Title: TALKING TIME: A pilot randomized controlled trial investigating social support for informal caregivers via the telephone

Version: 2 Date: 30 Apr 2020

Reviewer's report:

PEER REVIEWER ASSESSMENTS:

OBJECTIVE - Full research articles: is there a clear objective that addresses a testable research question(s) (brief or other article types: is there a clear objective)?
No - there are minor issues

DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the objective?
No - there are minor issues

EXECUTION - Are the experiments and analyses performed with technical rigor to allow confidence in the results?
No - there are minor issues

STATISTICS - Is the use of statistics in the manuscript appropriate?
Yes - appropriate statistical analyses have been used in the study

INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not overstated?
No - there are minor issues

OVERALL MANUSCRIPT POTENTIAL - Is the current version of this work technically sound? If not, can revisions be made to make the work technically sound?
Probably - with minor revisions

PEER REVIEWER COMMENTS:

GENERAL COMMENTS:
Informal caregivers to persons with dementia are highly vulnerable to both psychological and physical adversity. Although a number of investigative teams have developed telephonic intervention models, each one has its limitations, and scaling these within countries and between countries continues to prove challenging. Innovative approaches are needed to advance the field.

The authors have carefully developed and rigorously tested a novel approach. Their commitment to the field is clearly illustrated from this manuscript.
However, there are a number of remaining areas in need of further attention that are detailed below.

REQUESTED REVISIONS:
Background
Given the number of existing models with similar aims and design, the authors should explicitly state in the Background section what advantage(s) their model offers to the field. Perhaps, it is its less intensive design or alternatively that it has been adapted to German language and culture?

The limitations for patients or families translating traditional educational efforts into action are well known. What do the authors hypothesize the mechanism to be for how this particular intervention may influence caregivers actions which in turn may influence psychological HRQoL? For example, mechanisms might include motivational interviewing, cognitive behavioral therapy, goal setting.

Line 77 - this reviewer is uncertain whether the term "unities" is the correct term.

The authors are asked to re-evaluate Reference [3] in the first paragraph of the Background section as this reviewer did not find content in this reference that supports the statement: "and half of those care recipients are people with dementia [3]."

Methods
The authors are commended for adhering to the principles of CONSORT and the completion of the Randomized Controlled Trial Checklist and Flow Diagram.

Did ICs have direct input (through quantitative or qualitative survey) into the design of the intervention?
Did ICs support and problem-solve with one another?
Did ICs receive any respite from caregiving from other family members or community agencies?
Did any of the persons with dementia attend a day program outside the home?
How were detrimental effects evaluated and by whom?

Results
In the interest of greater clarity for the reader, this sentence from the Discussion section might be instead included in Results section: "Therefore, our analysis is based on the differences in outcome measurements between T1 and T0, and the analysis model was further adjusted to the baseline data T0 data of the aforementioned variables".

Discussion
The first paragraph of the Discussion section on Strengths and Limitations needs editing. In terms of identified strengths, it is reasonable to state the intervention followed a rigorous experimental design. Given that the investigation of adverse outcomes is not presented herein, it is preferable not to reference this as a strength. Further, the statement regarding secondary outcomes as candidates for a primary outcome does not fit well in this section and should either be relocated or not included.
Line 359 - Please change "To the best of our knowledge, there were five previous trials regarding" to "To the best of our knowledge, there have been five previous trials regarding"

Line 431 - It is not clear if the term "planed" was intended to be "planned". Please clarify.

It is quite possible that simply intensifying the prior recruitment efforts may not be adequate to achieve the target recruitment in the next trial. The authors might consider including informal caregivers (including those who consented and those who refused participation in this trial) in the planning team for developing the next recruitment approach and potentially modifications to the intervention protocol to ensure it directly meets their perceived needs.

Based on the learnings from this study, would the authors recommend the same comprehensive approach to data collection be used in a subsequent trial? Given all of the concerns about informal caregivers' lack of time and the challenges with recruitment, perhaps a more streamlined approach is warranted.

Reference 18 - please change Developemt to Development

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

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