Author’s response to reviews

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

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Author’s response to reviews:

Dear Editor,

Please find enclosed our revised paper entitled “TALKING TIME: A pilot randomized controlled trial investigating social support for informal caregivers via the telephone” (Manuscript ID: BHSR-D-19-02036R2) by Martin Nikolaus Dichter, Bernd Albers, Diana Trutschel, Armin Michael Ströbel, Swantje Seismann-Petersen, Katharina Wermke, Margareta Halek, and Martin Berwig.

We thank the editorial team and the reviewers for their helpful comments and hope the article is now suitable for publication.

With kind regards
Yours sincerely,

Martin Nikolaus Dichter on behalf of all co-authors
Reviewer comment 1:
1. Please Add a Declaration header and reorder the declarations so that they are in the following format: Ethics approval and consent to participate, Consent for publication, Availability of data and material, Competing interests, Funding, Authors' contributions and Acknowledgements

Author comment 1:
Changed as proposed.

Reviewer comment 2:
This is a clear and well written manuscript. It is important to publish RCT's which have no significant effects and the possible reasons why no effects could be demonstrated. There is one possible reason which is not described by the authors. Did the intervention fit the needs of the participants? Would it be helpful to conduct a needs assessment before offering the intervention in future studies? May be the authors can reflect on this issue.

Author comment 2:
The results of the process evaluation will show to what extent there is a need to supplement the current intervention components, for example by a needs assessment. However, based on the reviewer’s suggestion we have updated the manuscript section “Conclusion” as follows:

“Finally, the results of the study and the results of our process evaluation (in preparation) will provide insight into the further development of the intervention. The process evaluation will give additional information regarding fidelity, dosage and context. The fidelity results will provide information on the satisfaction of the study participants with the intervention components and thus the extent to which the intervention meets the needs of informal caregivers of people with dementia. In general, our study protocol appears to be feasible, with the exception of the recruitment procedure.”

Reviewer comment 3:
In terms of reporting and discussing the findings, I was uncertain why you included a power calculation as if carrying out a definitive trial and why you have paid a lot of attention to whether there were significant changes in the outcome measures, given that the study was couched as a pilot trial. It does seem that the primary outcome measure you chose was suitable in terms of picking up change and its use has given an indication of the variability in scores that would need to be taken into account in a definitive trial. I wonder if the findings around this and the secondary measures would have been best couched in this way rather than as a test of effectiveness.

Author comment 3:
Our reporting is based on the Consort 2010 statement extension to randomized pilot and feasibility trials (Eldrige et al. 2016). Therefore, we report our power calculation as well as the results for each trial objective. Taking the reviewer’s comment into consideration, we have updated the manuscript sections “Results” and “Discussion”. Using Eldrige’s recommendation (Eldrige et al. 2016) we are now reporting estimates with 95% confidence intervals without P values.
“Results:”

“The overall effect of the primary outcome, i.e. the difference in the self-rated psychological HRQoL scores between T0 and T1 as measured with the MCS of the SF-12, demonstrated a standardized effect size of 1.65, CI-95%: -0.44 – 3.75 (covariate adjusted model in Table 2). The model without the covariate adjustment yielded similar results (Table 2: standardized effect size 0.57, CI-95%: -1.47 – 2.60). Figure 2 illustrates the differences between the intervention and control groups. The MCS score demonstrates a positive difference between T0 and T1 of 3.3 in the intervention group (estimated least square mean; CI-95%: -0.9 – 7.6) compared to the control group (-2.4, CI-95%: -7.3 – 2.4).

For the secondary outcomes (table 3), the adjusted differences between the intervention and control groups were 0.12 (standardized effect size), CI-95%: CI: -1.98 – 2.21 for self-rated physical HRQoL, 0.43, CI-95% -1.67 – 2.52 for perceived social support, -0.31, CI-95%: -2.41 – 1.79 for caregiver self-esteem, -2.56, CI-95%: -4.65 – -0.46 for caregiver lack of family support, -0.46, CI-95%: -2.55 – 1.63 for caregiver impact on finances, -0.42, CI-95%: -2.51 – 1.68 for caregiver impact on daily schedule, 0.52, CI-95%: -1.58 – 2.61 for caregiver impact on health and 1.22, CI-95%: -0.87 – 3.31 for irritability of the relative with dementia.”

“Discussion:”

“The results of the Talking Time trial regarding the change in self-rated psychological HRQoL showed a promising non-significant difference between the intervention and control group in the expected direction (standardized effect size: 1.65 [-0.44 – 3.75]).”


Reviewer comment 4:

The outcomes of the recruitment process, which show that 38 potential participants took part, 33 did not meet inclusion criteria and 30 declined, are of interest. It would have enhanced the paper to see more information about which aspects of the inclusion criteria were not met and what implications this has for targetting of relevant population during a definitive trial. The conclusion you draw, about needing to recruit from more centres and have more resources to enable recruitment would be helpful but maybe other strategies are also implied by your pilot experience, e.g. the need to reach the appropriate people to avoid having such a significant number who do not meet the criteria. The most common reason for declining (i.e. different content had been assumed) also has lessons for a future trial but this is not mentioned in the discussion. Given that this is a group intervention with 4 participants per group, some consideration of the influence of group might be important to address.

Author comment 4:

Based on the reviewer comment we have updated the manuscript section “participant recruitment and retention”.

Participant recruitment and retention:
“Reasons for the refusal were an assumed high burden due to study participation (N = 4), lack of time resources for study participation (N = 6), different intervention content assumed (N = 10), declined participation by care recipient with dementia (N = 4) and no contact after the first call (N = 4). The reasons for the exclusion of potential study participants were: lack of information regarding the medical dementia diagnosis of the care recipient (N = 8), care recipient with a frontotemporal dementia (N = 6), care recipient was admitted to a nursing home (N = 7), the weekly time spent on care by an informal caregiver was too short (N = 7), potential study participants were not the relatives of the person with dementia (N = 2), the care recipient died during the recruitment phase (N = 2) and an psychiatric diagnosis (N = 1).”

Moreover, we have updated our reporting in the manuscript sections “Discussion” and “Conclusion”.

Discussion:
“We recommend the inclusion of more recruitment centers and financial funding for public relations strategies targeting informal caregivers and their relatives with dementia who are living at home. Moreover, the participation of informal caregivers as part of the planning team for a future trial and especially for the planning of the recruitment approach is recommended. In addition, recruitment materials or media for a future trial, such as a trial website or a folder, should include a detailed description of the intervention and the inclusion and exclusion criteria in plain language. The fact that the intervention was group-based seems to have had no effect on recruitment.”

Conclusion:
“For example, it may be sufficient for inclusion if a person who cares for a person with dementia is the primary caregiver and responsible for the stability of care. In addition, recruitment materials that include a detailed description of the intervention and the inclusion and exclusion criteria in plain language will be helpful to make participant recruitment successful. In addition, informal caregivers themselves should be part of the planning team of a future trial and especially with regard to the recruitment strategy.”

Reviewer comment 5:
Additionally, you do mention the value of follow-up but this was precluded by your design which offered the intervention to the control group. I don't understand why this is said to be 'for fidelity reasons', though can see it could be for ethical reasons. A strategy to follow up for a longer period would seem to be important in a definitive trial.

Author comment 5:
In our opinion, an additional follow-up after six months will increase the value of a future trial. After the six months, the control group should also receive the intervention. To increase the willingness to participate in the control group we delivered the Talking Time intervention for the control group after completing the collection of the follow-up data.

Reviewer comment 6:
Some very small presentational points which need to be addressed:

Do carers need to be referred to as ICs? 'Carers' would not add significantly to length of the script and would feel more respectful and be more understandable.

Are the abbreviations necessary in the abstract (PwD, HRQoL, SF-12 etc.)?
Penultimate sentence of the abstract contains a stray 'the'.

p.4, line 13: 'informal caregivers remain the cornerstone of care needs living at home' needs to be rephrased.

p.4, line 71-72, 'The care responsibility increases over the course of dementia, especially as challenging behaviors occur and cognitive abilities decline.' requires a reference.

p.8, line 46: 'the principles of the theme-centered interaction' - no 'the' needed

p.11, line 46: 'The assessment was based on a proxy rating (a particular informal caregiver)' - not sure what the bracket is referring to. Please rephrase.

p.12, line 49 onwards: 'The whole data collection process.....' does not make sense to me. Please rephrase.

p.13, line 39: 'Based on some instances of missing data' - which instances?

p.18, line 49: 'caregiver's' needs to have its apostrophe moved.

p.19, line 7: 'planned'

p.19, line 34: 'was further adjusted to the baseline data T0 data' - doesn't required both baseline data and T0 data.

Author comment 6:
Based on the reviewer’s comment, we have significantly reduced the number of abbreviations used in the abstract and main body text. We are now using the term “informal caregiver” (written out in full) throughout the whole manuscript. This seems to be adequate, since this term is also used in the cited literature, e.g. Dam et al. (2016).

With regard to the further reviewer comments, we have also made appropriate corrections.

Reviewer comment 7:
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.

Author comment 7:
Based on the reviewer’s comment, we have updated the background section as follows:
“Therefore, the purpose of the Talking Time study was to conduct the first evaluation of the feasibility and effectiveness (including possible detrimental effects) of a new intervention focusing on telephone-based support groups [13]. Contrary to traditional psycho-educative approaches, the Talking Time intervention basically follows the principles of theme-centered interaction (TCI) according to Ruth Cohn [14]. In the foreground is the reciprocal exchange of experience between informal caregivers and also joint learning. In doing so, especially the therapeutic group effect factors “universality of suffering” and “interpersonal learning” by Yalom [15] may influence their HRQoL. This is the main advantage of the TALKING TIME intervention compared to classical approaches in lecture format. Since TALKING TIME is also based on the principles of behavioral therapy [16] (problem solving), and the perspective of systemic therapy [16] (role change), the HRQoL of informal caregivers may also be influenced by these factors.

In this paper, we present the results of the recruitment, retention and effectiveness evaluation.”

Reviewer comment 8:
Line 77 - this reviewer is uncertain whether the term "unities" is the correct term.

Author comment 8:
Based on the reviewer’s comment, we have updated the sentence as follows:
“This principle suggests that larger social or state units should have a subsidiary function and perform only those tasks that cannot be performed by a smaller unit.”

Reviewer comment 9:
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]."

Author comment 9:

Reviewer comment 10:
Methods: The authors are commended for adhering to the principles of CONSORT and the completion of the Randomized Controlled Trial Checklist and Flow Diagram.

Author comment 10:
Thank you.

Reviewer comment 11:
Did ICs have direct input (through quantitative or qualitative survey) into the design of the intervention?

Author comment 11:
Informal caregivers were not directly involved in the intervention development.
In process evaluation, the perspective of the study participants is taken into account. The results of the process evaluation (e.g. intervention fidelity) will be an important basis for the future development of the intervention.

Reviewer comment 12:
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?

Author comment 12:
The informal caregivers interacted with each other in the reported small groups. They also exchanged experiences and problem solving strategies as part of the social support intervention. As far as we know, there was no direct exchange between the study participants outside the moderated social support group meetings.
The extent to which the study participants used other forms of support to participate in the social support groups is one subject of the process evaluation of the Talking Time project. The Talking Time Intervention itself has not provided any supporting components apart from those described. Regarding the reviewer’s comment, we refer to this fact in the section “Strength and limitations”: “Fourth, information regarding individual actions of each informal caregiver to participate in the telephone-based social support groups and the consequences of the Talking Time intervention for the respective care arrangement can only be answered after the analysis of the process evaluation data.”

Reviewer comment 13:
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”.

Author comment 13:
We have already described our methodical procedure for data adjustment in the chapters: “Statistical analysis”, “Results” as well as in Table 2. Therefore, we have deleted the corresponding sentence in the manuscript section “Discussion”.

Reviewer comment 14:
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.

Author comment 14:
Based on the reviewer’s comment, we have updated the mentioned sentence in the section “Discussion”: 
“The main strengths of our trial are that it is the first evaluation of the Talking Time intervention based on a rigorous experimental design and a process evaluation as part of the trial (in preparation).”

Reviewer comment 15:
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"

Author comment 15:
Changed as proposed.