PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Seeking the balance between caregiving in dementia, family, and employment: Study protocol for a mixed methods study in Northern Germany
AUTHORS	Neubert, Lydia; König, Hans-Helmut; Brettschneider, Christian

VERSION 1 – REVIEW

REVIEWER	Andrew P Allen Department of Psychology Maynooth University Kildare Republic of Ireland
REVIEW RETURNED	26-Sep-2017

GENERAL COMMENTS	Although generally readable, the protocol as a whole would benefit from a review from a Native English speaker. It's not entirely clear what you mean in the abstract by "We seek for five caregiving networks comprised of at least three dementia caregivers each living in Northern Germany." Could you be more specific about what you mean by "networks" here? Strengths and limitations: By "recreations", do you mean "replications"? Introduction: The description of societal changes such as labour force participation "inevitable" is sweeping and should be avoided. Aims and research questions: It is a bit unclear as to why the qualitative aspect is prioritised? Can the authors provide a rationale for this? If probing open-ended questions about which tasks caregivers are responsible for, it should noted that more structured questionnaires on activities of daily living might also help caregivers to think of aspects of daily life for which they provide help to PwD's. Methods and analysis: The authors state: "Additionally, we will collect quantitative (quan) data by using validated questionnaires, which will be filled out by the caregivers themselves, to objectify both caregivers' evaluation of their current life situation and their sociodemographic and psychographic characteristics (i.e., personality traits, coping skills).

	Although quantitative in nature, are measures such as self-reported personality really objective? It seems a bit much to use the word “objectify” here. In terms of the quantitative data, for looking at how caregivers balance work with caring, is there more information on employment that could be gathered? Hours of work, perceived work stress, etc.? Will relatively in-depth information on other family responsibilities be collected (e.g. caring for young children?) It seems unfortunate that the level of functional impairment of PwD be not be assessed-this would be relevant for contextualising the findings. Data analysis: Given the small sample size, the present research may be rather underpowered to employ correlational analysis. It may, however, be possible to use a test such as a t-test/ANOVA to compare primary caregivers to secondary/tertiary caregivers.

REVIEWER	Dia Soilemezi, Qualitative researcher University of Portsmouth, UK
REVIEW RETURNED	28-Oct-2017

GENERAL COMMENTS	The protocol states many important aspects of the study, but I believe that some are missing or not adequate described, to enable other researchers to replicate this study. Also, I am not convinced that collecting quantitative data (of such a small sample) would be meaningful. See more specific comments below: Abstract: it lacks important information on methods. eg. type of interviews, sampling, type of analysis Introduction: it needs more background information and rationale for the study. Information on previous studies that looked at other aspects (e.g. relationship/bond between caregiver and PwD before diagnosis, geographical distance between the residence of PwD and the caregiver(s) , type of dementia, family responsibilities, etc) would give a complete background picture to the reader. Research questions: Which one out the four qualitative questions is the primary question? In what way you mean the qualitative strand is prioritized? The quant question ‘How do the members of informal caregiving networks evaluate their life situation in consideration of reconciliation between caregiving in dementia, family, and employment?’ could be answered with qualitative data, which makes me wonder whether you need the quantitative strand at all? Participants: The study population needs to be defined further with clear inclusion/exclusion criteria as it is not clear what type of caregivers are eligible for this study. State if you are interested only in adult children of working age with (some) family commitments and (some) experience in caregiving and whether the eligible participants live or not together with the PwD. Would you exclude spouses of people with dementia, who are retired but are the main caregiver? In the inclusion criteria it is stated that ‘at least one member of each participating caregiving network is employed at the time of investigation’.

	If they are not employed, how can they be able to answer 'Which consequences do they experience in their personal, family, and work life?' Recruitment: it is important to mention the sampling strategy (purposive? convenient?). How can you ensure your sample is not biased? What happens if the interviewee's nominated participants withdraw or refuse to participate? Would you still keep the data from the index-interviewee? Why not interviewing participants from the same family unit (husband, wife, child caring for the grandparent) as couples? How long will the recruitment period last? You could collect more data than 15 interviews in a study that has a 3year duration. Explain how the sample size is restricted by the study's feasibility? Data collection: Please explain how the interview guide was pre-tested (piloted?), with who and what was the outcome. Also, please provide some information about the interviewer's experience and training (experience with qualitative methods, work experience relevant to this study). Will you also document if people refuse to participate and reasons for that? Also, justify why all eight questionnaires are needed, especially if this part may add more time to already burdened participants. Are there any dementia-related ones to use instead? Perhaps, a more pragmatic approach would be to offer telephone or skype interviews to minimise burden for those caregivers who wish to participate but live far away, do not have time to travel or do not want to have visitors at home. Analysis: Documentary analysis: The references by Nohl are in German, so I was unable to access. How many researchers will analyse and code the data? Will the data be analysed at the end of data collection period or after each interview? How can you ensure rigour in your analysis? Regarding quant: How can you make any meaningful statements about associations with such a small size? General comments: I would strongly suggest to add 'qualitative methods' as keywords. Please do not use phrases such as 'demented individual'. The preferred term is 'person with dementia'. I would also suggest to ask a fluent English writer to check the small points of the writing and review the manuscript. The 'Conclusions' sections needs to be removed, as this is a protocol. If authors address the above-mentioned points, and justify and describe the design and methods sufficiently, this protocol will become rigorous to allow the study to be repeated.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 (citations from the revised manuscript are marked as quotations, i.e. "…", omissions are in brackets, i.e. (…))

Comment 1-1: Although generally readable, the protocol as a whole would benefit from a review from a Native English speaker.

Answer to 1-1: Thank you for this comment. The revised manuscript was reviewed by a professional proofreader.

Comment 1-2: It’s not entirely clear what you mean in the abstract by “We seek for five caregiving networks comprised of at least three dementia caregivers each living in Northern Germany.” Could you be more specific about what you mean by “networks” here?

Answer to 1-2: Thank you for this comment. According to the comment no. 2 of Reviewer 2, we rewrote the “Methods and analysis”-section in the abstract. At this, we clarified what networks mean. We hope that the reviewer agrees with this adaption.

“By purposive sampling we include at least 5 caregiving networks of home-dwelling PwD, each of them consisting of at least 3 informal caregivers living in Northern Germany. Narrative interviews of participants will be recorded, transcribed verbatim, and interpreted according to the Documentary Method (QUAL). By completing standardized questionnaires, participants will provide sociodemo- and psychographic data concerning theirselves and the networks, from whom they arise (quan). This supplemental, descriptive information will give further background to the themes and types emerging from the interviews. Hence, the quan-data enrich the QUAL-data by exploring the narratives of participants in the light of their personal and network-related characteristics.”

Comment 1-3: Strengths and limitations: By “recreations”, do you mean “replications”?

Answer to 1-3: Thank you for your careful reading. We agree and replaced “recreations” by “replications”.

Comment 1-4: Introduction: The description of societal changes such as labour force participation “inevitable” is sweeping and should be avoided.

Answer to 1-4: Thank you for this comment. We replaced “inevitable changes” by “structural mega-trends” according to the original wording in the reference no. 13. Therefore, we also denoted the replacement as a quotation. We hope that the reviewer agrees with this adaption.

“Society is subject to two “structural mega-trends”, namely women’s increasing labor force participation and an expected increase of people needing care in due to populations’ aging.13”

Comment 1-5: Aims and research questions: It is a bit unclear as to why the qualitative aspect is prioritised? Can the authors provide a rationale for this?

Answer to 1-5: Thank you for this comment. We presented the rationale in the “Measuring instruments”-section of the submitted manuscript (p. 9 of 19). We acknowledge that this aspect occurred too late. Therefore, we deleted it there and added the rationale to the ”Overview of the study design”-section of the revised manuscript. We hope that the reviewer agrees with this adaption.

“Qualitative inquiry refers to the investigation of underlying knowledge and the understanding of social phenomena. Thus, it aims to understand the meaning of human action.25 To gain the personal perspectives of human actors in this study, informal caregivers are invited to tell their subjective experiences. Their descriptions regarding the perceived reconciliation between caregiving in dementia, family tasks, and employment is our leading research interest. It also covers the perceived consequences on the wider family or other related persons, on the subjective health status and quality of life, since they have multiple roles as a caregiver, relative, neighbor or friend, and/or an employee. Therefore, we prioritize the qualitative research strand in this mixed methods study; yet we also appreciate the complementary quantitative approach. In this, we will additionally…"

Comment 1-6: If probing open-ended questions about which tasks caregivers are responsible for, it should noted that more structured questionnaires on activities of daily living might also help caregivers to think of aspects of daily life for which they provide help to PwD's.

Answer to 1-6: Thank you for this comment. We agree with you and would like to provide some clarification. To obtain narratives about caregivers' tasks the interview guide included the question "Please tell me about your last week, day after day. I'm interested in every detail that you did for [the PwD]. Let's start with last [Monday]". In our research, we are rather interested in the caregivers' attitudes towards the provided help than in each activity per se or the quantity of all activities. Furthermore, we added the last question of each interview. With this study participants will be asked to draw their personal network. These network graphs have an intermediate position between the qualitative and quantitative data. We are glad about the opportunity (the revision gave us) to add this aspect now, because we applied it just after the submission of this study protocol (please also consider our adaption in the "Quantitative data analysis"-section: "Network graphs present the number of network members and their degree of importance from the personal perspective of the respective network member. Additionally, combined with the narratives of those, caregiving tasks of each network member are described."). To give a better understanding of the procedure of the interviews, we added the exemplary question named above to the "Qualitative data collection"-section of the revised manuscript. We hope that the reviewer agrees with this adaption.

"An exemplary, narratively formulated request is "Please tell me about your last week, day after day. I'm interested in every detail that you did for [the person with dementia]. Let's start with last [Monday]". … (comment 1-8)... Each interview will close with the invitation to complete a network graph consisting of concentric circles to draw all network members who are important to the interviewee. Used network graphs have an intermediate position between the qualitative and quantitative data (concerning the interpretation of those we refer to the section of quantitative data analysis)."

Comment 1-7: Methods and analysis: The authors state: "Additionally, we will collect quantitative (quan) data by using validated questionnaires, which will be filled out by the caregivers themselves, to objectify both caregivers' evaluation of their current life situation and their sociodemographic and psychographic characteristics (i.e., personality traits, coping skills). Although quantitative in nature, are measures such as self-reported personality really objective? It seems a bit much to use the word "objectify" here.

Answer to 1-7: Thank you for this comment. We decided to replace "objectify" by "measure" – not only at this place but also at another place, where "objectify" was used, in the revised manuscript.

Comment 1-8: In terms of the quantitative data, for looking at how caregivers balance work with caring, is there more information on employment that could be gathered? Hours of work, perceived work stress, etc.? Will relatively in-depth information on other family responsibilities be collected (e.g. caring for young children?)
Answer to 1-8: Thank you for this comment. We agree that detailed employment- and family-related requirements of the caregivers have to be collected in this study. The first interviews demonstrated us that the informants disclosed this information automatically within the narrative interview. If not, the interviewer will ask them at the end of the interview. We also added an example to the "Qualitative data collection"-section of the revised manuscript. We hope that the reviewer agrees with this adaption.

"(…) Non-narratively formulated requests at the end of the interview can refer to information that still did not occur in the narratives of the interviewees, e.g., "How many hours are you currently working? (...)"

Comment 1-9: It seems unfortunate that the level of functional impairment of PwD be not be assessed-this would be relevant for contextualising the findings.

Answer to 1-9: Thank you for this comment. We agree with you. In regards to obtaining the ethical approval, we decided not to collect any data concerning the PwD (otherwise, written informed consent of each PwD would be required). But now, the first interviews demonstrated us that the informants also disclosed this information automatically, i.e., by labeling both the functional impairments according to the German Social Security Code ("Pflegegrad", ³ 14 Sozialgesetzbuch XI) of the PwD and a comprehensive description of his/her physical and mental constitution in their own words. However, we are aware that this information is not standardized, but the narratives illustrate the caregiving situation and the self-perceived burden convincingly. We also added this clarification to the "Sample size and eligibility criteria of study participants"-section of the revised manuscript. We hope that the reviewer agrees with this adaption.

"By ethical reasons we decided to not collect declarations of consent of PwD. Therefore, we cannot directly request any data concerning the care-recipient with dementia while interviewing his/her caregivers. However, it will be essential that the interviewees disclose more or less comprehensive descriptions of the physical and mental constitution of the cared-for person in their own words to illustrate their caregiving situation at home including, for example, their self-perceived burden due to the specific needs of an individual with dementia. Caregivers' perceptions and meanings meet our primary research interest, and additional data like the described functional impairments of the PwD will likely help us to contextualize the findings."

Comment 1-10: Data analysis: Given the small sample size, the present research may be rather underpowered to employ correlational analysis. It may, however, be possible to use a test such as a t-test/ANOVA to compare primary caregivers to secondary/tertiary caregivers.

Answer to 1-10: Thank you for this comment. We agree with you, and we would like to take the opportunity to clarify the role of the quantitative research strand in our study. The quantitative data provide rather additional descriptive information on the sample of included caregivers than meaningful examinations of associations. Therefore, if we employ correlational analysis, we will interpret the results with great caution. We amended this aspect in the "Quantitative data analysis"-section of the revised manuscript. We hope that the reviewer agrees with this adaption. We are also grateful for your suggestion to employ a t-test/ANOVA to compare different types of caregivers.

"With descriptive statistical methods including frequency and contingency analysis we will describe the sample of informal caregivers included in this study. The results of analytic statistical methods like correlational analysis, which examines the association of perceived strain and personality traits or coping skills, will be interpreted with great caution due to the small sample size. These analyses will be supported by the feature "Stats" of MAXQDA (version 12) and IBM SPSS Statistics (version 23). Because of prioritization of the QUAL-approach in this mixed methods study, the quan-data are supplemental to enrich the QUAL-data by exploring the narratives of study participants in the light of their personal characteristics named above and the network to whom they relate. … (comment 1-6)… So, the quan-data may enhance the profiles of included caregivers in this study and can serve –due to the small sample size– at least as a starting point for further research in this field. This study considers personal and network-related characteristics of informal caregivers of PwD for the first time;

in this way, we hope to meet the relevance of these factors in caregivers' experience of the reconciliation between caregiving in dementia, family, and employment."

Thank you for your time!

Reviewer 2 (citations from the revised manuscript are marked as quotations, i.e. "…", omissions are in brackets, i.e. (…))

Comment 2-1: The protocol states many important aspects of the study, but I believe that some are missing or not adequate described, to enable other researchers to replicate this study. Also, I am not convinced that collecting quantitative data (of such a small sample) would be meaningful. See more specific comments below:

Answer to 2-1: We appreciate the reviewer's comments and will answer to each specific comment in the next sections.

Comment 2-2: Abstract: it lacks important information on methods, eg. type of interviews, sampling, type of analysis.

Answer to 2-2: Thank you for this comment. We rewrote the "Methods and analysis"-section of the abstract. We hope that the reviewer agrees with this adaption.

"By purposive sampling we include at least 5 caregiving networks of home-dwelling PwD, each of them consisting of at least 3 informal caregivers living in Northern Germany. Narrative interviews of participants will be recorded, transcribed verbatim, and interpreted according to the Documentary Method (QUAL). By completing standardized questionnaires, participants will provide sociodemo- and psychographic data concerning theirselves and the networks, from whom they arise (quan). This supplemental, descriptive information will give further background to the themes and types emerging from the interviews. Hence, the quan-data enrich the QUAL-data by exploring the narratives of participants in the light of their personal and network-related characteristics."

Comment 2-3: Introduction: it needs more background information and rationale for the study. Information on previous studies that looked at other aspects (e.g. relationship/bond between caregiver and PwD before diagnosis, geographical distance between the residence of PwD and the caregiver(s), type of dementia, family responsibilities, etc) would give a complete background picture to the reader.

Answer to 2-3: Thank you for this comment. We agree that more details concerning the background information/rationale for the study are helpful. Therefore, we first added the hint to figure 1 at the beginning of the fifth paragraph and revised this paragraph. Second, due to the focus of our study by using a network perspective and considering caregivers' personal characteristics we elaborated the fact that caregiving research –in general and in dementia– is about a complex and dynamic phenomenon because of the emotional relationship between both caregiving dyads and different caregivers (if caregiving responsibilities are shared). Based on this phenomenon, experiences depend on, inter alia, the kind and quality of the relationship, and on personal or socially expected norms. Since it is more important to know something about the quality of a caregiving relationship –than which kind this relationship is, e.g., spousal–, we will delve deep into this phenomenon by applying narrative interviews of more than one caregiver of each caregiving network included in this study. We added this elaboration to the fifth paragraph of the introduction. We hope that the reviewer agrees with this adaption.

“How informal caregivers of PwD experience balancing care-, family- and employment-related requirements depends on different factors (figure1). First, country-specific legal regulations (…). Second, personality traits (…) and coping skills (…). In caregiving research, so far, little is understood about how caregivers perform their roles better and why.18 Third, professional (paid) services which form the formal caregiving network contribute to the caregiving situation at home by providing information, respite and support; for example, offered by day care centers.19 Fourth, other (usually unpaid) persons who represent the informal caregiving network contribute to caregivers’ perception and can reduce caregivers’ burden. However, although the value of a cooperative structure within the family or circle of acquaintances seems to affect caregivers’ well-being and quality of life20 21, their possible relevance to mediate work-caregiving conflicts has rarely been examined. It should be noted that other persons in the social network cannot only be mediating but also demanding, which we should also consider in the reconciliation debate. Therefore, further research on reconciliation between caregiving in dementia and other roles might include the perspective of more than one person within the family or circle of acquaintances to gain a more comprehensive picture of the caregiving networks’ impact. Moreover, a short look at the caregiving network might be not sufficient, because caregiving research delves into a very complex and dynamic phenomenon concerning the emotional relationship between a caregiving and cared-for person as well as between different caregivers if caregiving responsibilities are shared.18 For instance, by comparing caregiving spouses, adult children, and children-in-law, data on outcomes like resources, stressors, and psychological distress differ between the groups; so, each of them has different needs based on her or his subjective burden and personal circumstances (e.g., co-residence with the cared-for person, income, other family responsibilities).22 Additionally, caregiver relationships are built on a common descent or by marriage, but they are also influenced by social expectations of family and caregiving varying by culture.23 Furthermore, caregiving research should not ignore personal motives of caregivers if we want to better understand caregiving processes, also, in the light of balancing care-, family- and employment-related requirements.”

Comment 2-4: Research questions: a) Which one out the four qualitative questions is the primary question? b) In what way you mean the qualitative strand is prioritized? c) The quant question ‘How do the members of informal caregiving networks evaluate their life situation in consideration of reconciliation between caregiving in dementia, family, and employment?’ could be answered with qualitative data, which makes me wonder whether you need the quantitative strand at all?

Answer to 2-4: Thank you for these comments.

a) Our leading research interest is to explore the reconciliation between caregiving in dementia, family tasks, and employment of informal caregivers of home-dwelling PwD. The named research questions of both the QUAL- and quan-strand are steps on the way achieving this goal. Each answer to these questions will build the bigger picture; insofar our leading research interest is our primary question (“How do informal caregivers of PwD experience the reconciliation between caregiving in dementia, family tasks, and employment?”) in this mixed methods-study. We added this aspect to the “Aim and research questions of the study”-section. We hope that the reviewer agrees with this adaption.

“The study focuses on the subjective reconciliation described by the study participants in the qualitative research strand. Thus, the primary question of this study is: how do informal caregivers of PwD experience the reconciliation between caregiving in dementia, family tasks, and employment? By merging qualitative and quantitative data, narratives of study participants will be further explored by combining those with their sociodemo- and psychographic characteristics, and the caregiving network to whom they relate.“

To improve consistency, we also reformulate the QUAL-questions by emphasizing our focus on the experience of the caregivers. We hope that the reviewer agrees with these adaptions.

“To gain a broad picture of the experiences of informal caregivers regarding the reconciliation between caregiving in dementia, family, and employment, we formulated the following subordinated research questions. Within the qualitative research strand (comment 2-4b: we deleted the word “prioritized”), narrative interviews with informal caregivers of PwD living in Northern Germany with written informed consent will provide answers to the following research questions: How do members of informal caregiving networks experience assuming caregiving responsibilities for an individual with dementia? How do they experience the division of caregiving tasks, i.e., who feels responsible for which task and how does she/he experience it? How do they experience possible consequences regarding other commitments and areas of life (e.g., child care, work, leisure time) due to caregiving? How do they experience circumstances which may influence the perceived consequences positively or negatively?”

b) We deleted the word “prioritized” at this place to avoid readers’ irritation (please consider the notation in the above citation) and added the rationale for the emphasis of the QUAL-strand (see also comment no. 5 of Reviewer 1) to the next paragraph of the revised manuscript. Here, we would like to take the opportunity to explain the emphasis of the QUAL-strand, too. The QUAL-strand allows us to meet our leading research interest: the exploration of the reconciliation between caregiving in dementia, family, and employment. The quan-strand is an add-on to the QUAL-strand. Herewith, we will illustrate and measure caregivers’ evaluation of their current life, their personal and network-related characteristics by using standardized questionnaires and network graphs. For this, narratives of study participants will be explored in the light of their personal characteristics, and the caregiving network to whom they relate. The exploration of possible associations between caregivers’ narratives and their personal characteristics is subordinated (because of the small sample size), and associations will be interpreted cautiously. We added the rationale for the emphasis of the QUAL-strand (see also comment no. 5 of Reviewer 1) to the first section “Overview of the study design” of the paragraph “Methods and analysis”. We hope that the reviewer agrees with this adaption.

“Qualitative inquiry refers to the investigation of underlying knowledge and the understanding of social phenomena. Thus, it aims to understand the meaning of human action.25 To gain the personal perspectives of human actors in this study, informal caregivers are invited to tell of their subjective experiences. Their descriptions regarding the perceived reconciliation between caregiving in dementia, family tasks, and employment is our leading research interest. It also covers the perceived consequences on the wider family or other related persons, on the subjective health status and quality of life, since they have multiple roles as a caregiver, relative, neighbor or friend, and/or an employee. Therefore, we prioritize the qualitative research strand in this mixed methods study; yet we also appreciate the complementary quantitative approach. … (comment 2-4c)… For this, narratives of study participants will be explored considering their personal characteristics, and the caregiving network to whom they relate.”

c) We agree with you and have to clarify our motivation behind this aspect. The quant-question in this formulation can also be answerable on the basis of the QUAL-data. To avoid readers’ confusion, we deleted this formulation and rewrote this paragraph. We hope that the reviewer agrees with this adaption.

“The quantitative research strand will explore the evaluation of the life situation of network members according to a standardized approach by measuring caregivers' care-related strain via CarerQol-7D, CarerQol-VAS, and ZBI (14th+18th item), and life satisfaction via EQ-5D and EQ-VAS.”

In this way, besides the narrated perceptions of the study participants we decided to measure their evaluation of their life situation according to a standardized approach via the questionnaires named above. In the next steps we will use these data to describe the sample of informal caregivers included in this study. But we will also combine these values with the findings of the QUAL-data, and we might explore possible interrelations between both i) the perceptions (QUAL) and personal characteristics and ii) the standardized evaluation (quan) and personal characteristics. Again, we have to note that these examinations are explorative, they will not provide meaningful results. We also elaborated this aspect more distinctly at two places, in the ”Overview of the study design”-section and in the “Quantitative data analysis”-section of the revised manuscript. We hope that the reviewer agrees with these adaptions.

“Therefore, we prioritize the qualitative research strand in this mixed methods study; yet we also appreciate the complementary quantitative approach. In this, we will additionally collect quantitative (quan) data by using validated questionnaires, which will be filled out by the caregivers themselves, to measure both caregivers’ evaluation of their current life situation and their sociodemographic and psychographic characteristics (i.e., personality traits, coping skills). For this, narratives of study participants will be explored considering their personal characteristics, and the caregiving network to whom they relate.”

“With descriptive statistical methods including frequency and contingency analysis we will describe the sample of informal caregivers included in this study. The results of analytic statistical methods like correlational analysis, which examines the association of perceived strain and personality traits or coping skills, will be interpreted with great caution due to the small sample size. These analyses will be supported by the feature “Stats” of MAXQDA (version 12) and IBM SPSS Statistics (version 23). Because of prioritization of the QUAL-approach in this mixed methods study, the quan-data are supplemental to enrich the QUAL-data by exploring the narratives of study participants in the light of their personal characteristics named above and the network to whom they relate. … (comment 1-6)… So, the quan-data may enhance the profiles of included caregivers in this study and can serve –due to the small sample size– at least as a starting point for further research in this field. This study considers personal and network-related characteristics of informal caregivers of PwD for the first time; in this way, we hope to meet the relevance of these factors in caregivers’ experience of the reconciliation between caregiving in dementia, family, and employment.”

Comment 2-5: Participants: The study population needs to be defined further with clear inclusion/exclusion criteria as it is not clear what type of caregivers are eligible for this study. State if you are interested only in adult children of working age with (some) family commitments and (some) experience in caregiving and whether the eligible participants live or not together with the PwD. Would you exclude spouses of people with dementia, who are retired but are the main caregiver? In the inclusion criteria it is stated that ‘at least one member of each participating caregiving network is employed at the time of investigation’. If they are not employed, how can they be able to answer ‘Which consequences do they experience in their personal, family, and work life?’

Answer to 2-5: Thank you for this comment. We agree that more clarification regarding the inclusion criteria is necessary. Therefore, we added the following explanations to the “Sample size and eligibility criteria of study participants”-section. We hope that the reviewer agrees with these adaptions.

“Members of the informal caregiving network are individuals who are important for care delivery to the affected person with dementia or the first informal caregiver (index-interviewee), (...) The degree of involvement in caregiving and both the relationship to the individual with dementia and the living situation (living together with the cared-for person or not) are not relevant for study inclusion. For instance, an eligible caregiving network can comprise a retired wife caring for her husband with dementia, a daughter of employment age –not living with her parents, with her own family commitments, and supporting her mother in decision-making and visits to medical professionals or authorities–, and a volunteer who supervise the cared-for person once a week for a few hours. (…), and iv) at least one member of each participating caregiving network is employed at the time of investigation. Since many caregivers are old themselves and already retired22, only employed (younger) caregivers will be asked how they experience the reconciliation between their caregiving and work responsibilities (whether their contributions in caregiving are small or large, i.e., these network members do not need to be the primary caregivers).“

Comment 2-6: Recruitment: a) it is important to mention the sampling strategy (purposive? convenient?). b) How can you ensure your sample is not biased? c & d) What happens if the interviewee's nominated participants withdraw or refuse to participate? Would you still keep the data from the index-interviewee? e) Why not interviewing participants from the same family unit (husband, wife, child caring for the grandparent) as couples? f & g) How long will the recruitment period last? You could collect more data than 15 interviews in a study that has a 3 year duration. Explain how the sample size is restricted by the study's feasibility?

Answer to 2-6: Thank you for these comments.

a) We also agree that more clarification regarding the sampling strategy is necessary. We use a purposive sampling strategy to reach maximum variation between characteristics of the study participants. These characteristics primarily include gender, age, relationship to the cared-for person, and living situation (with or not with the cared-for person). Because of the comparative analysis within the Documentary Method further characteristics, i.e. themes, will be probably used as varying factors during the interpretation and may provoke re-sampling. We added these aspects to the "Sample size and eligibility criteria of study participants"-section and "Qualitative data analysis"-section of the revised manuscript. We hope that the reviewer agrees with these adaptions.

"In total, (at least) 5 networks consisting of (at least) 15 informal caregivers of PwD will be included in this study through purposive sampling to reach maximum variation between characteristics of the study participants (e.g., gender, age, relationship to the cared-for person, and living situation)."

"Because of the comparative analysis within the Documentary Method, further characteristics, i.e. themes, will be used as varying factors during the interpretation and may provoke re-sampling to recruit further study participants who may provide heterologous themes."

b) Due to the used purposive sampling (aimed to reach maximum variation), we are able to reduce this risk. Furthermore, we initially contacted different gatekeepers in different regions of Northern Germany to broaden the possibilities to come in contact with eligible study participants. Then, during recruiting we take care through whom study participants will be recruited to balance study entries out. However, gatekeepers may pre-select clients, yet, the main investigator (LN) inform them comprehensively about the in- and exclusion criteria. And, experience has taught us that only gatekeepers with relationships of trust to the informal caregivers can allow us to convert this vulnerable population group to participate in scientific projects. We added this aspect to the "Recruitment of study participants"-section. We hope that the reviewer agrees with these adaptions.

"By addressing different gatekeepers in different regions of Northern Germany, we were able to broaden the possibilities to come in contact with eligible study participants and to reduce sampling bias. (...) Furthermore, she visited these service points to inform both gatekeepers and potential study participants face-to-face. Within these visits, the main investigator (LN) informed the gatekeepers comprehensively about the in- and exclusion criteria to avoid unsuitable pre-selection of clients, (…)."

c & d) If participants withdraw or refuse to participate (after they were nominated by the index-interviewee) and cannot be replaced, the index-interviewee's data are be considered as individual data. This means, their interpreted narrations and analyzed data are relevant for the aggregated results but cannot contribute to the specific results from the network-perspective. We also added this aspect to the “Sample size and eligibility criteria of study participants”-section. We hope that the reviewer agrees with this adaption.

“If participants withdraw or refuse to participate –after they were nominated by the index-interviewee– and cannot be replaced, the index-interviewee’s data are be considered as individual data. This means, their interpreted narrations and analyzed data are relevant for the aggregated results but cannot contribute to the interpretations from the network-perspective.”

e) We decided not to interview participants from the same family unit as couples or a group because every study participant should have the equal opportunity to respond freely. If study participants wished to be interviewed as a couple or a group, we would agree; and, the Documentary Method would also be suitable to interpret this kind of interviewing. We also added this aspect to the end of the “Measuring instruments”-section. We hope that the reviewer agrees with this adaption.

“If study participants wished to be interviewed as a couple or a group, we would accept this; however, our intention is that each study participant should have the equal opportunity to respond freely.”

f & g) Recruitment period will likely last when we will reach our target sample size of (at least) n=15. However, we would initiate re-sampling if we need further contrasting cases during the interpretation process. Therefore, a purposive sampling is used, and qualitative data-analysis is/will be conducted after each interview (please also consider our answer to comment 2-8). The target sample size is explained by the explorative character of this study that is conducted by the main investigator (LN) during her PhD-studies. In this, she has to do three projects in total. Furthermore, this mixed methods-study is preparatory and embedded in a larger project that has a 3-year-duration; therefore, the funder also expects results of this study only in 2020. But the main investigator is planning to finish this study in 2018 to get on with her PhD-studies. We also added this clarification to the end of the “Sample size and eligibility criteria of study participants”-section. We hope that the reviewer agrees with these adaptions.

“The sample size is restricted by the feasibility of this study; i.e., the target sample size is explained by the explorative character of this study that is a preparatory part of a larger study. (…) Recruitment of study participants started in October 2017, and first results are expected in 2018. The study is a preparatory part of a larger project (funded by the German Federal Ministry of Education and Research; grant: 01EH1601A) that ends in August 2020; then, results of this study will be published.”

Comment 2-7: Data collection: a) Please explain how the interview guide was pre-tested (piloted?), with who and what was the outcome. b) Also, please provide some information about the interviewer’s experience and training (experience with qualitative methods, work experience relevant to this study). c) Will you also document if people refuse to participate and reasons for that? d) Also, justify why all eight questionnaires are needed, especially if this part may add more time to already burdened participants.
Are there any dementia-related ones to use instead? e) Perhaps, a more pragmatic approach would be to offer telephone or skype interviews to minimise burden for those caregivers who wish to participate but live far away, do not have time to travel or do not want to have visitors at home.

Answer to 2-7: Thank you for these comments.

a) We agree that more information regarding the pretest of the interview guide is necessary. We developed it together with professor Nohl who proposed the interpretation of narrative interviews of individual persons according to the Documentary Method (please see also Reference no. 29 and 32). Afterwards, the interview guide was submitted to a workgroup of qualitative methods located at the

University Medical Center Hamburg-Eppendorf. Participants were asked to provide feedback regarding the comprehensibility of questions, but no amendments were proposed. We added this information to the “Qualitative data collection”-section. We hope that the reviewer agrees with this adaption.

“For this, each question was first discussed between the main investigator (LN) and professor Nohl from the Helmut Schmidt University in Hamburg, who considerably developed the interpretation of narrative interviews by means of the Documentary Method29; then we tested the interview guide in a workgroup of qualitative methods located at the University Medical Center Hamburg-Eppendorf. Participants were asked to provide feedback regarding the comprehensibility of questions; no amendments were necessary after this pretest.”

We also added further information to the “Quantitative data collection”-section regarding the pretest of the standardized questionnaire focused on needed time.

“After its development, the questionnaire was also pretested; previously, we have asked different colleagues to complete the questionnaire while the time needed was measured.”

b) We would like to take the opportunity to provide further information about the interviewer’s experience and training. We added these skills of the main investigator (LN) to the end of the “Qualitative data collection”-section. We hope that the reviewer agrees with this adaption.

“The main investigator (LN) will conduct all interviews. She is trained in applying qualitative research methods in general and, in particular, in interviewing informal caregivers because of another qualitative study31. She is also aware of the specific life situation of caregivers, due to her previous experience as a registered nurse, and she interacts with them empathetically.”

c) Both aspects will be documented in the study diary. We added this clarification to the end of the “Recruitment of study participants”-section. We hope that the reviewer agrees with this adaption.

“The number of persons who refuse to participate and their reasons for opting out will be documented in the study diary.”

d) To the best of our knowledge, we are not aware of dementia-related questionnaires to measure caregiver strain, life satisfaction, personality traits, and coping skills. After a literature search, the chosen questionnaires are the most frequently used and are characterized by their brevity (i.e., if a short version exists like the NEO-FFI-30, we used it). And even if the questionnaires taken together seems to be elaborate, each questionnaire aims to one specific aspect of interest (please also consider the first sentence of the “Quantitative data analysis”-section); there are no redundancies between them, and we cannot reject one without losing important information about participants’ characteristics.
To minimize possible burden due to study participation caregivers get the opportunity to fill them out after the interview. We already presented this aspect at the end of the “Measuring instruments”-section. Our pretests and the first interviewed study participants revealed that completion of these questionnaires takes about 20 minutes, which is much less than we had expected and announced in the study information (45 minutes). If the reviewer has some references to access dementia-related questionnaires regarding the aspects named above, we would be happy to hear them.

e) We also discussed to use telephone or skype interviews, but our qualitative approach requires narrative, face-to-face interviews to elicit stories of experiences. If a study participant wished a telephone interview, we would not decline (but, previous experiences and the first interviews show us that informed and motivated study participants welcome the interviewer warmly). We added this aspect to the end of the “Measuring instruments”-section. We hope that the reviewer agrees with this adaption.

“If study participants did not wish to visit the research department or to be interviewed at home, we would also arrange interviews via telephone or skype.“

Comment 2-8: Analysis: Documentary analysis: a) The references by Nohl are in German, so I was unable to access. b, c & d) How many researchers will analyse and code the data? Will the data be analysed at the end of data collection period or after each interview? How can you ensure rigour in your analysis? e) Regarding quant: How can you make any meaningful statements about associations with such a small size?

Answer to 2-8: Thank you for these comments.

a) Reference no. 29 (in the firstly submitted manuscript it was no. 27) is a translation in English of Nohl’s work, you will have access via this link: http://www.ssoar.info/ssoar/bitstream/handle/document/31725/ssoar-2010-bohnsack_et_al-Wualitative_analysis_and_documentary_method.pdf?sequence=1, starting on p. 196. This reference was already placed in the middle of the paragraph, yet, we also added this reference to the first sentence of this paragraph to address international researchers directly.

b, c & d) Data analysis starts at the beginning of interviews and continues during all following interviews. At the moment, the main investigator (LN) is interpreting the first interview, and a research assistant on the bachelor level will support her very soon. Thought processes and decision trails during data analysis and subsequent interpretations will be documented, and interpretations will be discussed with the project leader (CB) and two other members of the workgroup. Furthermore, LN participates in an interpretation group working with the Documentary Method located at the University of Hamburg. These meetings will also be used for validating the interpretation. Lastly, the Documentary Method includes the comparative analysis which ensures methodical control and rigor during interpretation. We added these explanations to the “Qualitative data analysis”-section of the revised manuscript. We hope that the reviewer agrees with these adaptions.

“Data analysis will be conducted after each interview from the beginning of the data collection process by the main investigator (LN) and a research assistant on the bachelor level. ... (comment 2-6a)… Thought processes and decision trails during data analysis and subsequent interpretations will be documented, and interpretations will be discussed with the project leader (CB) and other members of the workgroup. Furthermore, attendance of an interpretation group working with the Documentary Method located at the University of Hamburg will also be used to validate the interpretation.”

e) We would like to refer to our answer to the comment no. 10 of Reviewer 1 and comment 2-4c of Reviewer 2. The quantitative data provide rather additional descriptive information on the sample of included caregivers than meaningful examinations of associations. Therefore, if we employ correlational analysis, we will interpret the results with great caution. We amended this aspect in the “Quantitative data analysis”-section of the revised manuscript. We hope that the reviewer agrees with this adaption.

“With descriptive statistical methods including frequency and contingency analysis we will describe the sample of informal caregivers included in this study. The results of analytic statistical methods like correlational analysis, which examines the association of perceived strain and personality traits or coping skills, will be interpreted with great caution due to the small sample size. These analyses will be supported by the feature “Stats” of MAXQDA (version 12) and IBM SPSS Statistics (version 23).

Because of prioritization of the QUAL-approach in this mixed methods study, the quan-data are supplemental to enrich the QUAL-data by exploring the narratives of study participants in the light of their personal characteristics named above and the network to whom they relate. … (comment 1-6)… So, the quan-data may enhance the profiles of included caregivers in this study and can serve –due to the small sample size– at least as a starting point for further research in this field. This study considers personal and network-related characteristics of informal caregivers of PwD for the first time; in this way, we hope to meet the relevance of these factors in caregivers' experience of the reconciliation between caregiving in dementia, family, and employment."

Comment 2-9: General comments: a) I would strongly suggest to add 'qualitative methods' as keywords. b) Please do not use phrases such as 'demented individual'. The preferred term is 'person with dementia'. c) I would also suggest to ask a fluent English writer to check the small points of the writing and review the manuscript. d) The 'Conclusions' sections needs to be removed, as this is a protocol. If authors address the above-mentioned points, and justify and describe the design and methods sufficiently, this protocol will become rigorous to allow the study to be repeated.

Answer to 2-9: Thank you for these comments.

a) We added 'qualitative research' as a keyword in the revised manuscript.

b) We are very sorry for this imprecision and replaced it (please look at page 10 of the revised manuscript). We also replaced "people with dementia" (that we used in the submitted manuscript before) by the more common "persons with dementia" in the revised manuscript.

c) The revised manuscript was reviewed by a professional proofreader.

d) We agree with you that 'Conclusions' is not the right term, as this is a study protocol, but we would prefer to maintain this section under the term 'Expected impact of the study'. We hope that the reviewer agrees with this adaption.

Thank you for your time!

VERSION 2 – REVIEW

REVIEWER	Andrew P Allen Dept of Psychology Maynooth University Ireland
REVIEW RETURNED	30-Nov-2017

GENERAL COMMENTS	The authors have addressed my previous comments for the most part. A final spell/grammar-check should be conducted (there is an obvious mistake/typo in "Strenghts (sic) and limitations of this study") The reference in the data analysis to "The results of analytic statistical methods like correlational analysis, which examines the association of perceived strain and personality traits or coping skills" is rather vague. The specific tests should be outlined (as far as is practical at this stage).

VERSION 2 – AUTHOR RESPONSE

Reviewer 1 (citations from the revised manuscript are marked as quotations, i.e. "…", omissions are in brackets, i.e. (…))

Comment 1-1: A final spell/grammar-check should be conducted (there is an obvious mistake/typo in "Strenghts (sic) and limitations of this study")

Answer to 1-1: Thank you for your careful reading. We corrected "Strenghts" with "Strengths". The revised manuscript was checked once again for spell/grammar mistakes. Please consider the uploaded document with track changes.

Comment 1-2: The reference in the data analysis to "The results of analytic statistical methods like correlational analysis, which examines the association of perceived strain and personality traits or coping skills" is rather vague. The specific tests should be outlined (as far as is practical at this stage).

Answer to 1-2: Thank you for this comment. We added some more elaboration to the paragraph of "Quantitative data analysis":
"Using analytic statistical methods (i.e., correlational analysis by calculating Pearson's correlation coefficient r or Spearman's rank correlation coefficient ρ), we will explore possible associations of care-related strain and personality traits or coping skills variables. We will also examine if topics or types emanating from the qualitative data analysis could be used as variables that may also be associated with the personality traits variables, for example. Furthermore, using a regression model by applying care-related strain (measured by the CarerQol-7D) as outcome variable, we will generate an equation to describe the statistical relationship between this outcome and predictor variables based on the quan-data. These results will be interpreted with great caution due to the small sample size."

We hope that the reviewer agrees with this adaption.
Thank you for your time!