PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluation of DementiaNet, a network-based primary care innovation for community-dwelling dementia patients: protocol for a longitudinal mixed methods multiple case study
AUTHORS	Richters, Anke; Nieuwboer, Minke; Perry, Marieke; Olde Rikkert, Marcel; Melis, Rene; van der Marck, Marjolein

VERSION 1 - REVIEW

REVIEWER	LOUISE ROBINSON Newcastle University UK
REVIEW RETURNED	28-Feb-2017

GENERAL COMMENTS	This was an interesting paper to review and I look forward to seeing the outcomes of such an innovative project. However there are some areas that require further clarification and detail publication. Introduction: The authors rightly point out the future need to explore primary care based models of dementia care with a rapidly increasing demand and a need for more efficient integrated care. The intervention Dementia Net is introduced with a brief description but there is no reference to other primary care based approaches to dementia care and how effective these have been - this is an important omission and if not included in the introduction, should be incorporated into the discussion. In terms of the intervention under evaluation, there is a detailed description for the reader but no mention of how this differs to 'usual care' in the study setting and also how specialist secondary care are involved. There is reference to a paper as to how DementiaNet was developed but as it seems to be quite a complex intervention with many components, it would be useful for the reader of this paper to have a brief summary of its development, perhaps in a BOX, and how evidence based this process was, rather than having to find another paper. This is especially important as the paper referenced re the development is a Dutch journal and may not be widely available to non-Dutch speaking readers. Methods; a mixed methods study is entirely appropriate for this and the rationale behind the chosen approach, as opposed to the transitional pilot trial and RCT, is welcome and innovative. However there is no detail provided around one of the crucial aspects of a mixed methods study.. how qualitative and quantitative data will be integrated and what theoretical approach will be used. The proposed data collection worries me , not from the perspectives of this paper, but for the future study. Assessment of network domains - this looks as though it will comprise a quantitative assessment using a known model with 8

	items in 3 domains ; however the authors state the assessment of network maturity will be based on qualitative data from interviews. Is this in addition to the use of the measurement scale? Quality indicators - the study is using locally developed QIs which have not been tested - that is fine but in view of the lack of validated scales being used generally (see below) , I wonder if they should consider introducing some standard previously validated measures somewhere in the evaluation, while testing new ones. Carer outcomes - there are many validated outcomes, would it not be useful to add in some eg carer health/wellbeing/quality of life/burden Discussion - this would benefit from more critical discussion especially the need to future more efficient models of dementia care and other previously test primary care approaches. Where possible the paper should be written in the correct 'tense' consistently ie future tense for what work is being proposed and past tense for work previously completed.

REVIEWER	Michael Pentzek Institute of General Practice, Medical Faculty, Heinrich-Heine University, Düsseldorf, Germany
REVIEW RETURNED	14-Mar-2017

GENERAL COMMENTS	DementiaNet as an intervention is very interesting and well described. This protocol depicts a very innovative way of evaluating a complex intervention. As a whole, such a design is of high quality and adequate for complex interventions. Looking into the single methodological parts and their combination, I have some suggestions: Although the design is rather new, please consult the reporting guideline SPIRIT for interventional study protocols for important items to be reported: http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/ You refer to a “mixed methods design”: Please consider the GRAMMS guidelines for reporting. Then you will see, that a key element of real mixed methods is methods integration. In the manuscript I cannot find details on how quantitative and qualitative data are integrated. Parallel reporting of quantitative and qualitative data is not mixed methods. Qualitative methods are insufficiently explained. Please consult the SRQR guideline for important items to be reported. (Not in such detail as in the SRQR, but central aspects should be reported). For instance, the type of data processing and analysis is not reported. The term “in-depth semi-structured interviews“ is contradictory. Normally, “In-depth” is narrative or episodic, rather than “semi-structured”. “Semi-structured” implies asking closed questions which excludes “in-depth” interviewing. Why the interviews are only conducted at one time-point? It would

	be interesting to see a development in narratives. You mention “dyads of patients and informal caregivers”. Do you exclude patients living alone as an important and vulnerable group that would strongly benefit from such an intervention. Regarding quantitative data, you gather data on two levels: primary care networks und dyads patient/informant. Such data structure should be analysed with multi-level models or structural equation modelling. The statistical approach to the quantitative data is not explained. Dissemination: In case of promising results, it would be interesting for stakeholders, how such a DementiaNet can be established in other regions. Is it possible to disseminate a guideline for network building?

VERSION 1 – AUTHOR RESPONSE

Reviewer Name: LOUISE ROBINSON
Institution and Country: Newcastle University, UK Competing Interests: NONE

This was an interesting paper to review and I look forward to seeing the outcomes of such an innovative project. However there are some areas that require further clarification and detail publication.

1. Introduction: The authors rightly point out the future need to explore primary care based models of dementia care with a rapidly increasing demand and a need for more efficient integrated care. The intervention Dementia Net is introduced with a brief description but there is no reference to other primary care based approaches to dementia care and how effective these have been - this is an important omission and if not included in the not included in the introduction, should be incorporated into the discussion.
Thank you for pointing this out. There are indeed multiple earlier initiatives to improve dementia primary care via integrated interventions. Although elements are overlapping, we feel that none of these previous innovations is similar to ours. Most of them target specific aspects of care and not the overall management of dementia patients as a whole. We have added a paragraph to the introduction to provide a broader context to the DementiaNet innovation.

2. In terms of the intervention under evaluation, there is a detailed description for the reader but no mention of how this differs to 'usual care' in the study setting and also how specialist secondary care are involved. There is reference to a paper as to how DementiaNet was developed but as it seems to be quite a complex intervention with many components, it would be useful for the reader of this paper to have a brief summary of its development, perhaps in a BOX, and how evidence based this process was, rather than having to find another paper. This is especially important as the paper referenced re the development is a Dutch journal and may not be widely available to non-Dutch speaking readers.
Thank you for this remark. Indeed, we did not specifically address ‘usual care’ in the manuscript. This is partly due to the fact that it is difficult to describe, as major practice variation exists; care is differently organized in every region and even in sub regions and district level (NB this is also the reason that we individualize our DementiaNet approach to each, individual network/district). In order to have a good overview of the innovation under study, there was a comprehensive description about the key components of the innovation and the processes regarding for instance the recruitment of networks.
In order to adequately understand the difference and what DementiaNet is adding, we agree that it would be useful to give more information on usual care in the Netherlands, and how secondary care is

involved. For this purpose, we have added a box with the most relevant points on usual care and DementiaNet to the manuscript.
Lastly, we would like to point out that the paper we are referring to is in English (although published in a German journal) and we have specifically published it open access to ensure free access and to ensure transparency.

3. Methods; a mixed methods study is entirely appropriate for this and the rationale behind the chosen approach, as opposed to the transitional pilot trial and RCT, is welcome and innovative. However there is no detail provided around one of the crucial aspects of a mixed methods study.. how qualitative and quantitative data will be integrated and what theoretical approach will be used.
We have added more details to the qualitative data collection and analyses. Also, we have described how the quantitative and qualitative data will be integrated. For this, we have made an addition to the analysis paragraph in the methods section in order to be more specific regarding the qualitative data processing and analysis.

4. The proposed data collection worries me , not from the perspectives of this paper, but for the future study. Assessment of network domains - this looks as though it will comprise a quantitative assessment using a known model with 8 items in 3 domains ; however the authors state the assessment of network maturity will be based on qualitative data from interviews. Is this in addition to the use of the measurement scale?
We can understand that the classification might be confusing. The data on which the rating is performed is derived from structured interviews with network's leader(s). These interviews are designed in such a way that very specific information is obtained to score each of the 8 items. We believe that structured interviews are the best option, because they leave some flexibility to the differences between networks but still target the specific topics to be scored. Hence, we will be able to derive maturity scores as assessed by the Primary Care Maturity Model. We have rephrased this paragraph in the methods section in order to be clearer on the approach.

5. Quality indicators - the study is using locally developed QIs which have not been tested - that is fine but in view of the lack of validated scales being used generally (see below) , I wonder if they should consider introducing some standard previously validated measures somewhere in the evaluation, while testing new ones.
We agree with the reviewer that it would receive strong preference to use already validated quality indicators. However, in our opinion, there are two drawbacks to that approach.
Firstly, there is a strong discrepancy between the coverage of the existing quality indicator sets and the context to which we aim to apply them. For instance, the Dutch set of quality indicators that was previously developed (Perry et al. J Am Geriatr Soc, 2010) focussed greatly on the aspects that precede the dementia diagnosis, which is not the target population of our intervention. Another set (Vasse et al. Int Psychogeriatr, 2012) only focuses on psychosocial care. As primary care, and more specifically dementia care, is set up differently across countries, sets from other countries were not appropriate (e.g. the Third Canadian Consensus Conference on Diagnosis and Treatment of Dementia indicators are not fully supported by Dutch guidelines for dementia care).
Secondly, validation usually includes only one aspect of validation, i.e. testing of face validity. We have validated our set on face validity as well. This has been added to the bullet point in the revised manuscript about the quality indicators.
Because of these reasons, we felt that there were no indicator sets available that were both appropriate to the aim of the measurement and deemed more established than our newly developed set, resulting in the choice to use a new set of quality indicators. We would like to point out that these are based on established guidelines and multidisciplinary agreements for dementia management and have been constructed in a rigorous approach with input from all relevant disciplines.
Lastly, data collection of indicators requires a significant amount of time from the health care professionals involved in the networks. To maintain their support in the study, we believe it is a strong

argument to keep data collection as parsimonious as possible.

6. Carer outcomes - there are many validated outcomes, would it not be useful to add in some eg carer health/wellbeing/quality of life/burden
We agree with the reviewer that these are important outcomes and therefore we have included these in the study (e.g. quality of life of the patient and informal caregiver, informal care-related quality of life, subjective and objective burden of informal care, perseverance time of informal caregiver). This is mentioned in the paragraph “informal caregiver-reported outcomes” in the method section, but the actual instruments used are summed in the figure that shows the data collection. We have now added a reference in the text to this figure to make this clearer.

7. Discussion - this would benefit from more critical discussion especially the need to future more efficient models of dementia care and other previously test primary care approaches.
We agree that a critical discussion of efficient care models of dementia care would be a very valuable addition to literature. We feel that our addition to the introduction to provide a broader context to DementiaNet including other integrated care initiatives has covered this point.
Furthermore, we believe the lessons to be learned from the evaluation study at hand will provide essential information regarding this issue. Because of that, it will definitely be a major part of the discussion of the paper that will describe the results of this evaluation study.

8. Where possible the paper should be written in the correct 'tense' consistently ie future tense for what work is being proposed and past tense for work previously completed.
Thank you for pointing out the inconsistency. We have addressed this issue with changes throughout the manuscript.

Reviewer Name: Michael Pentzek
Institution and Country: Institute of General Practice, Medical Faculty, Heinrich-Heine University, Düsseldorf, Germany Competing Interests: None declared

DementiaNet as an intervention is very interesting and well described. This protocol depicts a very innovative way of evaluating a complex intervention. As a whole, such a design is of high quality and adequate for complex interventions. Looking into the single methodological parts and their combination, I have some suggestions:

We would like to thank the reviewer for expressing compliments on the study, pointing towards the different reporting guidelines and addressing several opportunities for improving the manuscript.

1. Although the design is rather new, please consult the reporting guideline SPIRIT for interventional study protocols for important items to be reported: http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/
Thank you for pointing out this helpful tool. We have reviewed the SPIRIT guidelines and checklist to identify any important omissions and have adapted the manuscript accordingly.

2. You refer to a “mixed methods design”: Please consider the GRAMMS guidelines for reporting. Then you will see, that a key element of real mixed methods is methods integration. In the manuscript I cannot find details on how quantitative and qualitative data are integrated. Parallel reporting of quantitative and qualitative data is not mixed methods.
We agree that in an attempt at conciseness, we have omitted important information. We have therefore added the following to the analysis paragraph in the methods section, after reviewing the

GRAMMS guidelines:
“The findings from these qualitative data are conjointly used with the quantitative findings in the interpretation phase of the study in multiple manners: a) through triangulation, to corroborate findings and provide a stronger basis for conclusions, b) the qualitative findings are used to augment quantitative findings, c) the qualitative findings are used to identify unexpected and/or unintended effects that are not covered by the quantitative data.”

3. Qualitative methods are insufficiently explained. Please consult the SRQR guideline for important items to be reported. (Not in such detail as in the SRQR, but central aspects should be reported). For instance, the type of data processing and analysis is not reported.
We have added the following to the analysis paragraph in the methods section in order to be more specific regarding the qualitative data processing and analysis:
“A thematic analysis was used to analyze the verbatim transcripts of the semi-structured interviews. The analysis was partly guided by a predetermined framework of potential experiences and perceived benefits based on the development of the innovation. We remained open to discovering unanticipated nuances and topics in the data. Firstly, transcripts were independently coded by two trained researchers. Subsequently, both coding schemes were jointly reviewed to reach consensus about most appropriate coding. After that, codes were categorized and major themes were identified by the same two researchers. Lastly, both researchers independently drew overall findings from the codes in each category, after which a consensus round was applied to these findings. Qualitative data analysis was performed in Atlas.ti software.”

4. The term “in-depth semi-structured interviews“ is contradictory. Normally, “In-depth” is narrative or episodic, rather than “semi-structured”. “Semi-structured” implies asking closed questions which excludes “in-depth” interviewing.
We understand the ambiguity that has arisen from our phrasing. We would like to point out that by ‘semi-structured’, we mean that the interview was not totally open. This means that it consists of several key questions to define areas to be explored, but allows the interviewer or interviewee to diverge in order to pursue an idea or response in more detail (Britten N. Qualitative interviews in healthcare. BMJ Books, 1999). To our knowledge, this is a commonly used definition of semi-structured interviews and implies space to explore some topics in-depth. To avoid any ambiguity, we have removed the in-depth part from the phrasing.

5. Why the interviews are only conducted at one time-point? It would be interesting to see a development in narratives.
From our perspective, there were several arguments to decide for interviews to be conducted at one time-point. Firstly, we agree with the suggestion that development in narratives is interesting. This is indeed covered in another part of the study, namely through the ongoing logs. These contain relevant information on a network level (e.g. changes in composition of the network and possible reasons behind some actions or lack of actions) and are kept for every network.
Specifically, the interviews are aimed at answering the question regarding the effects of and experiences with the DementiaNet approach. This implies that this is impossible to ask at start, because effects first have to occur/be experienced by the interviewee. Also, given the cyclic process of quality improvement, we had no reasons to assume that effects would be essentially different after the second cycle than after the first.
Moreover, practical issues were at play. This evaluation study takes place in the setting of an innovation being implemented in daily care practice. This already puts a large burden on care professionals and we have looked for opportunities to address the evaluation through methods that do not put too much burden in order to maintain sufficient support from the field. Finally, conducting multiple interviews over time in multiple participants in multiple networks requires a huge effort of the research staff; we currently do not have funding opportunities to assure this. We are working on obtaining funding to extend the evaluation period, and as such, possibility to conduct interviews at

several time-points.

6. You mention “dyads of patients and informal caregivers”. Do you exclude patients living alone as an important and vulnerable group that would strongly benefit from such an intervention.
We fully agree with the statement that patients living alone are an equally important group, and might even benefit most from this approach. We would like to clarify that we have not excluded persons with dementia who live alone.
Firstly, we would like to point out the distinction between the intervention program and the evaluation study. The intervention is aimed at network-based care for community-dwelling dementia patients, and applies to all patients cared for by each network.
Regarding the evaluation study, we would like to clarify the phrasing of “dyads of patients and informal caregivers”. By informal caregivers, we do not necessarily restrict to partners of people with dementia nor informal caregivers who live with the patient. In many cases, the informal caregivers are children or other relatives/acquaintances that do not reside with the person with dementia.
For the questionnaire part of the study, we decided to focus on informal caregiver-reported outcomes, as many people with dementia are unable to complete the questionnaire, which would hinder comparability. This decision was also based on the experience that the vast majority of all persons with dementia have at least one eligible person that could participate and complete the questionnaires. Therefore, persons with dementia who live alone were not excluded from this part of the study. In addition, for the interviews we will select a number of patients, regardless of whether they live alone or not. This phrasing of ‘dyads’ was only used in the abstract, and we have now removed “dyads” to avoid this confusion.

7. Regarding quantitative data, you gather data on two levels: primary care networks und dyads patient/informant. Such data structure should be analysed with multi-level models or structural equation modelling. The statistical approach to the quantitative data is not explained.
We fully agree on the statement regarding the data structure. We have a data analysis plan that incorporates this. Before, we had not specified this particular part in the manuscript because it may very well be the case that data points on the level of the networks (i.e. 16 networks, of which 10 will have one baseline and one follow-up measurement and 6 will have one baseline and two follow-up measurements is expected) are insufficient to reliably built a multi-level model. If insufficient, we will be restricted to descriptive analyses.
Regarding the informal caregiver-reported outcomes, we will take the clustering of data (multiple measurements from the same informal caregiver over time; clustering of informal caregivers in networks) into account by using mixed effects models. We have made an addition to the analysis paragraph of the methods section to clarify.

8. Dissemination: In case of promising results, it would be interesting for stakeholders, how such a DementiaNet can be established in other regions. Is it possible to disseminate a guideline for network building?
We are currently working on ways to facilitate dissemination and implementation elsewhere. Currently, we have 20 ongoing networks in multiple regions across the Netherlands. Also, we have obtained additional funding to expand with 10 new networks and in the process of getting more networks funded. Also, we are in contact with healthcare insurance companies, and we have a broad network of collaborating practice organisations and universities to ensure consolidation.
The knowledge that will be derived from the current evaluation study will have an important role in the justification of future funding, both for healthcare and research. We surely plan to use the results of the evaluation study in further substantiating and improving future possibilities for implementation. A guideline is among the options.

VERSION 2 – REVIEW

REVIEWER	LOUISE ROBINSON Newcastle University UK
REVIEW RETURNED	19-Apr-2017

GENERAL COMMENTS	I am happy with the reviewers responses to my queries.

REVIEWER	Michael Pentzek Institute of General Practice (ifam) Heinrich-Heine University Düsseldorf Germany
REVIEW RETURNED	04-May-2017

GENERAL COMMENTS	Many thanks for this reasoned revision. The authors addressed all but one of the points in adequate detail. I would only like to suggest a completed SPIRIT checklist as a supplement: http://www.spirit-statement.org/wp-content/uploads/2013/08/SPIRIT_Fillable-checklist-15-Aug-2013.doc Such a checklist would be very helpful for readers and can serve as a specification of the authors' response to my first point.