

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Quality of relationships as predictors of outcomes in people with dementia: a systematic review protocol
AUTHORS	Edwards, Hannah; Savovic, Jelena; Whiting, Penny; Leach, Verity; Richards, Alison; Cullum, Sarah; Cheston, Richard

VERSION 1 - REVIEW

REVIEWER	Ryan Li NICE International, National Institute for Health and Care Excellence, UK
REVIEW RETURNED	04-Jan-2016

GENERAL COMMENTS	<p>This is a robust and on the whole clearly written protocol for a review of family relationship quality factors as a predictor of outcomes for people with dementia. To my knowledge, previous reviews have considered the various potential factors in isolation, and the proposed review and meta-analysis should provide a timely and more holistic update of the current state of the evidence .</p> <p>The main challenge that I can foresee for the authors is in being able to identify the right studies (both in terms of sensitivity and specificity), as 'relationship quality' encompasses so many different some of which you have already identified - I have not attempted the evidence search but imagine it will probably be a big job! Then there is also the issue of categorising and synthesising studies and exposures/outcomes of interest in a meaningful way, of which there will be many. All of this will be complicated by the very nature that relationship "quality" is qualitative, where factors such as attachment or coping (of which there are different kinds) will not give you a clear cut answer of 'more or less is better', and this is even before we start thinking about mediators and moderators.</p> <p>In my opinion, you have done an admirable job in anticipating some of these challenges upfront in the protocol, and laid out a relatively flexible approach which gives equal emphasis to quantitative and qualitative synthesis. My recommendation for when you come to conducting the review would be mindful of retaining both this methodological robustness and flexibility; and carefully document and justify any decisions you make.</p> <p>Specific comments on the protocol:</p> <p>- Title: "Individual and family relationships and predictors of outcomes in people affected by dementia.."</p> <p>a) I am not aware that there exists such a term as "individual relationship". Why not simply "family relationships", or "relationship</p>
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	<p>quality" (as this is the exposure of interest as stated in your Abstract and throughout), or "Quality of family relationships"?</p> <p>b) "People affected by dementia" is ambiguous, as carers for example are arguably affected by the dementia, but your review will only consider outcomes for the patients themselves. Suggest you reword as "people with dementia".</p> <p>- p6, lines 55-56 "Cross-sectional studies will only be included if there are too few cohort and case-control studies". How many studies are 'too few', and how would you make that decision?</p> <p>- Exposures / Risk factors studied:</p> <p>a) p7, Line 58: The term "intra-psychic factors" jars me as it is used here. Intrapsychic has a very specific meaning in psychoanalysis and reads a bit quaint for a general BMJ audience; and in any case I am not even sure that depression, anxiety and stress can be considered intrapsychic, given that the environment and interpersonal interactions play key roles in all three.</p> <p>I think I know what you mean, but to avoid confusion I suggest you use a less loaded (if equally generic) term, e.g. "**Psychological factors* such as depression, anxiety, and stress..."</p> <p>b) From what I can see, carer burden has not been explicitly addressed throughout the protocol. Carer burden is a very well researched concept in dementia, and I have no doubt that a large number of studies in your search will include it as an exposure or outcome, so you cannot ignore it. Please mention carer burden and how you will deal with it in the review (e.g. include it under carer stress? or as a separate exposure/risk factor?)</p> <p>As a psychological construct, carer burden is not problem-free; e.g. commonly used measures of carer burden such as the Zarit Burden Interview seem to include elements of subjective stressors, relationship quality and carer depression. It may be worth unpacking some of this in the current protocol, and almost certainly in the review itself.</p> <p>c) Carer abuse is known to strongly predict your primary outcome of interest (institutionalisation) and almost certainly related to relationship quality (and indeed could be considered an adverse outcome for the patients themselves). As above, please mention carer abuse explicitly as an exposure/risk factor, and how you plan to include it in the review.</p> <p>- p10 Data synthesis: This section seems quite generic, but perhaps necessarily so as it is difficult to foresee what kind of studies and exposure/outcome measures you will find. Nonetheless more explicit detail would be appreciated:</p> <p>a) How would you synthesise studies of different designs (i.e. cohort, case control, cross-sectional)? For cohort studies, how would you synthesise follow-up data?</p> <p>b) Throughout para 1: "Studies will be grouped by outcome..", and other occurrences of "outcome" where it is not clear whether you mean exposure, or outcome, or both. The various potential relationship factors you listed (e.g. amount of contact and coping</p>
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	<p>style) are qualitatively quite different, and it is difficult to imagine studies exploring these different kinds of exposures in the same meta-analysis; as such it would be useful to have further clarification on how you would group and synthesise studies.</p> <p>c) You may wish to comment on whether meta-regression is appropriate for synthesising studies with categorical factors for relationship quality, and how you would do this.</p> <p>d) p10 line 27-28 "type of relationship": Do you mean 'type' as in e.g. spouse vs parent-child vs neighbour/friend vs other relative? If so, please clarify with examples.</p> <p>-p10 line 52-56: The list of potential confounders seem sensible on the whole, but please include reference to existing literature (if available) to justify your choices. From my impression, I would have thought patient BPSD to be a potentially important confounder given that it is known to be strongly linked to carer burden and carer depression/anxiety.</p>
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REVIEWER	Elizabeth Fauth Utah State University, USA
REVIEW RETURNED	04-Feb-2016

GENERAL COMMENTS	<p>The research questions addressed in this review (care dyad closeness and outcomes for persons with dementia) are important, timely, and of interest to readers of this journal (and to the scientific community).</p> <p>While I see that review protocols have been published before in BMJ Open, I, personally, feel the article would be of much higher readership and citations (higher contribution to the field of science) if it actually included the results of the review. As a scientist who studied this content area, I am unsure what a review protocol adds to the literature in an of itself, without the results. However this is an editorial decision, not one of an individual reviewer, and if the journal editorial team finds these kinds of submissions useful, I would not object to this particular one being published.</p> <p>In addition to asking relevant questions in the review, I feel as though the authors have done a good job defining the search indicators, and defining the processes for organizing and summarizing the results. The only outcomes I thought might be useful to consider, are those related to dementia progression in the person with dementia. That is, outcomes such as cognitive performance or functional ability over time. There is some research related to how closeness in the informal caregiver predicts slower rates of progression (cognitive and functional) over time, and I might suggest adding these as outcomes in the review. I am familiar with Norton et al., 2009.</p> <p>I also advise that while the research team has indicated that the next viable step after such review is to inform intervention, that it may be best to take a step back before doing so. Let's say that the review suggests that closer emotional relationships serve as a protective factor for person's with dementia across many outcomes (as wold be hypothesized). The implications for intervention might be to try and promote closer emotional relationships among caregivers and their</p>
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	<p>family members with dementia. However, research on caregiver outcomes and emotional closeness is mixed - some studies find that caregivers fare better when they have closer emotional bonds with the person with dementia (e.g. Spaid & Barush, 1994), but others find that caregivers fare worse (Tower, et al., 1997; Fauth et al., 2012) - the closer emotional relationship may benefit the person with dementia, but possibly at the cost of the mental and physical health of their caregiver.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1 (Ryan Li)

• This is a robust and on the whole clearly written protocol for a review of family relationship quality factors as a predictor of outcomes for people with dementia. To my knowledge, previous reviews have considered the various potential factors in isolation, and the proposed review and meta-analysis should provide a timely and more holistic update of the current state of the evidence.

Response: Thank you.

• The main challenge that I can foresee for the authors is in being able to identify the right studies (both in terms of sensitivity and specificity), as 'relationship quality' encompasses so many different some of which you have already identified - I have not attempted the evidence search but imagine it will probably be a big job!

Response: Dr Li correctly identifies the broad, diverse nature of our exposure of interest as one of the key challenges in developing this review. To address this we decided to concentrate this review on five specific measures of relationship quality (amount of contact, closeness, attachment style, expressed emotion, coping style).

We originally planned to also look at three 'indirect' measures of relationship quality (depression, anxiety and stress in either the person with dementia or their carer). However, in light of the reviewers' comments, and pilot work undertaken while the protocol was under review, we are now amending this plan. These indirect measures of relationship quality will now be excluded. The reason is that pilot work revealed that the current inclusion criteria are too sensitive and would lead to inclusion of a large number of studies that are not really addressing the question of interest. For example, a study looking at the association between stress and depression in dementia would currently be included. This is not the focus of this review but would be technically includable under the original criteria, so we felt this needed to be tightened up.

Consequently we have updated the text in the protocol (p8) as follows:

Original text:

"Exposures / Risk factors studied: Studies will be included if they measure an element of the quality of relationship between the person with dementia and their carer. For example the amount of contact, closeness, attachment, expressed emotion, and coping style could all be assessed as elements of relationship quality..... Intra-psycho factors such as depression, anxiety, and stress in either the person with dementia or their carer are expected to reflect and impact on the caring relationship and are also included as exposures of interest."

Updated text:

"Exposures / Risk factors studied: Studies will be included if they measure an element of the quality of relationship between the person with dementia and their carer. Amount of contact, closeness,

attachment, expressed emotion, and coping style are primary exposures of interest.”

- Then there is also the issue of categorising and synthesising studies and exposures/outcomes of interest in a meaningful way, of which there will be many. All of this will be complicated by the very nature that relationship "quality" is qualitative, where factors such as attachment or coping (of which there are different kinds) will not give you a clear cut answer of 'more or less is better', and this is even before we start thinking about mediators and moderators.

Response:

Dr Li is correct that this is not a straightforward quantitative review, and the sort of conclusions we will be able to draw from the findings will not always be simple quantitative answers. For example in terms of attachment, the sort of conclusion we would hope to be able to draw is along the lines of 'insecure attachment styles are associated with higher risk of institutionalisation'. However, the elements of relationship quality that we chose to focus on are those that can be measured, even if categorically rather than ordinal/numerically. The review is restricted to studies that use quantitative tools and methods, and qualitative studies are excluded.

For synthesis, we anticipate that a narrative synthesis of results is most likely. (We have described the synthesis plan in more detail below, in response to a comment specifically requesting this.)

- In my opinion, you have done an admirable job in anticipating some of these challenges upfront in the protocol, and laid out a relatively flexible approach which gives equal emphasis to quantitative and qualitative synthesis. My recommendation for when you come to conducting the review would be mindful of retaining both this methodological robustness and flexibility; and carefully document and justify any decisions you make.

Response:

Thank you. As Dr Li recommends, we are striving to keep a flexible approach, and will document and justify all decisions. We have added a statement to this effect at the start of the methodology section of the protocol (p6):

New text: "A somewhat flexible approach will be necessary for this review, as it is difficult to know in advance the nature of the studies and data that may be available. We will clearly document and justify any decisions made regarding amendments to the inclusion/exclusion criteria and synthesis plan proposed in this protocol, should they become necessary. The details below reflect the planned methods at the outset of the review."

- Specific comments on the protocol:

(a) Title: "Individual and family relationships and predictors of outcomes in people affected by dementia.." I am not aware that there exists such a term as "individual relationship". Why not simply "family relationships", or "relationship quality" (as this is the exposure of interest as stated in your Abstract and throughout), or "Quality of family relationships"?

Response:

We originally included the term 'individual relationships' to capture relationships with carers who were not family members. However we accept that this may be confusing terminology, and have therefore amended the title (p1):

Original title: "Individual and family relationships as predictors of outcomes in people affected by

dementia”

Updated title: “Quality of relationships as predictors of outcomes in people with dementia”

- “People affected by dementia” is ambiguous, as carers for example are arguably affected by the dementia, but your review will only consider outcomes for the patients themselves. Suggest you reword as “people with dementia”.

Response:

We have reworded this as suggested, both in the title and throughout the protocol (p1, p5, p6, p7):

Original text: “People affected by dementia”

Updated text: “People with dementia”

- p6, lines 55-56 “Cross-sectional studies will only be included if there are too few cohort and case-control studies”. How many studies are ‘too few’, and how would you make that decision?

Response:

We do not feel that at this point it would be particularly helpful to set an arbitrary threshold for minimum numbers of studies. Our main criteria for considering inclusion of methodologically less robust evidence will be based on whether meaningful conclusions can be drawn from focusing on the most methodologically robust studies.

Some pilot work undertaken while the protocol was under review has indicated that volume of higher quality evidence may be higher than initially expected. In light of this, we will now limit the review to just cohort studies, in the first instance. The reason for doing so is that both case-control and cross-sectional studies are vulnerable to recall bias.

If cohort studies alone do not provide meaningful results, then we will cautiously consider including case-control and cross-sectional studies too. This decision (as all important decisions) would be made by the full study team, which includes both topic and methodological experts, and would be fully documented in the final study report.

We have amended the relevant text in the protocol (p7):

Original text:

“Study type: Cohort studies and case-control studies will be included. Intervention studies, including RCTs, where the interventions target the relationship between the person with dementia and their carers will be excluded. However, intervention studies could be included if they specifically report data on the associations of exposures and outcomes for the control group (e.g. a cohort study nested within an RCT). Cross-sectional studies will only be included if there are too few cohort and case-control studies. Conference proceedings will be included if they contain sufficient data to assess inclusion and extract results. Relevant systematic reviews will be obtained and used as a means of identifying additional primary studies. Case reports, qualitative studies, cost-effectiveness studies, group-level / ecological studies, and editorials will be excluded.”

Updated text:

“We plan to include cohort studies as the most robust methodology for the research question.

However, at the screening stage of the review, we will also record case-control and cross-sectional studies. If the synthesis of cohort studies alone does not yield a sufficient body of evidence to draw any useful conclusions, we will at that stage cautiously consider including case-control and cross-

sectional studies.

Intervention studies would be included if they specifically report data on the associations of exposures and outcomes for the control group (e.g. a cohort study nested within an RCT).

Relevant systematic reviews will be obtained and used as a means of identifying additional primary studies. Case reports, qualitative studies, cost-effectiveness studies, group-level / ecological studies, and editorials will be excluded. Conference proceedings will be included if they contain sufficient data to assess inclusion and extract results."

• Exposures / Risk factors studied: p7, Line 58: The term "intra-psychic factors" jars me as it is used here. Intrapsychic has a very specific meaning in psychoanalysis and reads a bit quaint for a general BMJ audience; and in any case I am not even sure that depression, anxiety and stress can be considered intrapsychic, given that the environment and interpersonal interactions play key roles in all three. I think I know what you mean, but to avoid confusion I suggest you use a less loaded (if equally generic) term, e.g. "Psychological factors* such as depression, anxiety, and stress..."

Response:

As noted above, we are now excluding these factors so they are no longer exposures of interest. We have deleted this section of the text (p8).

• From what I can see, carer burden has not been explicitly addressed throughout the protocol. Carer burden is a very well researched concept in dementia, and I have no doubt that a large number of studies in your search will include it as an exposure or outcome, so you cannot ignore it. Please mention carer burden and how you will deal with it in the review (e.g. include it under carer stress? or as a separate exposure/risk factor?)

As a psychological construct, carer burden is not problem-free; e.g. commonly used measures of carer burden such as the Zarit Burden Interview seem to include elements of subjective stressors, relationship quality and carer depression. It may be worth unpacking some of this in the current protocol, and almost certainly in the review itself.

Response:

Also as Dr Li notes, 'carer burden' is a very well-researched topic in dementia, and there are a very large number of studies looking at this as either an exposure or an outcome. For this reason we felt carer burden would warrant a separate, stand-alone review, and have decided not to incorporate it into this review. Although we acknowledge there will be some overlaps between elements of carer burden, and the aspects of relationship quality that we are focusing on here, due to limited resources we have had to make some exclusions.

• Carer abuse is known to strongly predict your primary outcome of interest (institutionalisation) and almost certainly related to relationship quality (and indeed could be considered an adverse outcome for the patients themselves). As above, please mention carer abuse explicitly as an exposure/risk factor, and how you plan to include it in the review.

Response:

Although we agree that carer abuse is related to, and arguably an element of relationship quality, we are not including carer abuse as a specific exposure of interest in this review. There are several reasons behind this decision. 1. This topic belongs to a different area of research – it tends to be known as elder abuse, and although the victim of this abuse often has dementia, the research literature often does not focus specifically on dementia, but rather tends to situate the abuse both

within the context of long-term abusive relationships, and also the broader context of ageing. 2. There are a range of behaviours that might be defined as “abusive”, not just physical abuse, but emotional, sexual, financial and verbal abuse, as well as neglect. If we attempt to incorporate this work (which is extensive, and has been dealt with elsewhere), then we risk making the review much more general and losing our focus. 3. Finally, there are the service implications of this work. We are interested in identifying risk factors within relationships that might lead to a therapeutic, or psychosocial intervention that can be delivered in a memory clinic setting. The intervention for elder abuse is very different – e.g. Safeguarding and (potentially) criminal proceedings.

The context in which we would include studies involving carer abuse are studies in which participants in abusive relationships are included alongside participants in non-abusive relationships, that are also exploring our specified eligible exposures (and outcomes) of interest. We have added an explanation in the protocol to clarify this (p8):

New text:

“Studies specifically focused on carer abuse, such as those that only include participants who are in abusive relationships (as defined by study authors), will be excluded. The rationale is that abuse is an ‘extreme’ dimension of relationship quality belonging to a different area of research (‘elder abuse’, which tends to focus on long-term abusive relationships and in the broader context of aging, and does not focus specifically on dementia). It has also been dealt with elsewhere.[35 36] Studies in which participants in abusive relationships are included alongside participants in non-abusive relationships, that are also exploring our specified eligible exposures (and outcomes) of interest will be included”

• p10 Data synthesis: This section seems quite generic, but perhaps necessarily so as it is difficult to foresee what kind of studies and exposure/outcome measures you will find. Nonetheless more explicit detail would be appreciated:

How would you synthesise studies of different designs (i.e. cohort, case control, cross-sectional)? For cohort studies, how would you synthesise follow-up data?

Throughout para 1: “Studies will be grouped by outcome..”, and other occurrences of “outcome” where it is not clear whether you mean exposure, or outcome, or both. The various potential relationship factors you listed (e.g. amount of contact and coping style) are qualitatively quite different, and it is difficult to imagine studies exploring these different kinds of exposures in the same meta-analysis; as such it would be useful to have further clarification on how you would group and synthesise studies.

Response:

As Dr Li notes, it is difficult at this stage to be specific about the plan for data synthesis before we know more about what sorts of studies and data we will find. We will however deal with cohort studies separately from studies that assess the exposure retrospectively (if retrospective studies end up being included).

Dr Li is right to feel that a meta-analysis is not likely to be possible given the different exposures of interest, and we would like to clarify that we not anticipate that meta-analysis will be possible for this review.

The narrative synthesis we envision will present results organised by outcome. Within each outcome heading, where possible relationship factors would be grouped together. For each outcome category relationship factors would be grouped together. For example, for the outcome ‘institutionalisation’ we would present all results on the association of attachment style with the risk of institutionalisation, followed by the association of expressed emotion with the risk of institutionalisation, etc. We would not combine the effect of different exposures in a meta-analysis. We have amended the text for this in the protocol (p11), and hope that the synthesis intention is now clearer:

Original text:

“Characteristics of included studies will be presented as a narrative summary or table, including study design, aims, population, setting, assessments and outcomes. If the data are too heterogeneous to pool, then narrative synthesis will be used to present results. Studies will be grouped by outcome, with descriptive text and tables used to summarise the range of results. Commentary will detail how differences in methodologies used and potential biases could be affecting each study’s results.”

Updated text:

“Characteristics of included studies will be presented as a narrative summary or table, including study design, aims, population, setting, assessments and outcomes. If the data are too heterogeneous to pool, then narrative synthesis will be used to present results. Studies will be grouped by outcome, with descriptive text and tables used to summarise the range of results. For each outcome category relationship factors would be grouped together. For example, for the outcome ‘institutionalisation’ we would present all results on the association of attachment style with the risk of institutionalisation, followed by the association of expressed emotion with the risk of institutionalisation, etc. (The effect of these different exposures would not be combined in meta-analysis.) Commentary will detail how differences in methodologies used and potential biases could be affecting each study’s results.”

- You may wish to comment on whether meta-regression is appropriate for synthesising studies with categorical factors for relationship quality, and how you would do this.

Response:

We do not plan to do a meta-regression, but we will endeavour to formulate main conclusions based on results from studies at low risk of bias. We have amended the sentence referring to sensitivity analysis as the original wording implies that we would attempt a meta-regression by risk of bias (p11).

Original text:

“Depending on the number and nature of the results, sensitivity analysis may be performed to see if conclusions are robust to the inclusion/exclusion of studies at high risk of bias.”

Updated text:

“We will investigate whether the conclusions are robust to the exclusion of studies at high risk of bias. We plan to formulate main conclusions based on results from studies at low risk of bias.”

- p10 line 27-28 “type of relationship”: Do you mean ‘type’ as in e.g. spouse vs parent-child vs neighbour/friend vs other relative? If so, please clarify with examples.

Response:

Yes that is the meaning intended, and we have now clarified this in the protocol (p11):

Original text:

The effect of relationship factors may plausibly vary by subgroups, for example type of relationship, type/severity of dementia...”

Updated text:

The effect of relationship factors may plausibly vary by subgroups, for example type of relationship (spouse vs parent-child vs other relative vs neighbour/friend), type/severity of dementia...”

- p10 line 52-56: The list of potential confounders seem sensible on the whole, but please include reference to existing literature (if available) to justify your choices. From my impression, I would have thought patient BPSD to be a potentially important confounder given that it is known to be strongly linked to carer burden and carer depression/anxiety.

Response:

Thank you for this helpful suggestion. We have now added BPSD to the list of potential confounders in the protocol, and added references. In the presentation of results we will be commenting on whether studies adjust for baseline BPSD and other potential confounding factors. We have updated the text to clarify this (p12):

Original text:

“Factors considered a priori potential confounders are: age, gender, socio-economic status, ethnicity, dementia type, dementia severity, carer co-morbidity, employment status of carer, and alcohol consumption.”

Updated text:

“Factors considered a priori potential confounders are: age,[24] gender,[38] socio-economic status,[39] ethnicity,[40-42] dementia type,[43] dementia severity,[44] BPSD,[45] carer co-morbidity,[46] employment status of carer,[47] and alcohol consumption.[48] ... in reporting we will comment on whether studies adjusted for potential baseline confounding factors.”

Reviewer 2 (Elizabeth Fauth)

- The research questions addressed in this review (care dyad closeness and outcomes for persons with dementia) are important, timely, and of interest to readers of this journal (and to the scientific community).

While I see that review protocols have been published before in BMJ Open, I, personally, feel the article would be of much higher readership and citations (higher contribution to the field of science) if it actually included the results of the review. As a scientist who studied this content area, I am unsure what a review protocol adds to the literature in an of itself, without the results. However this is an editorial decision, not one of an individual reviewer, and if the journal editorial team finds these kinds of submissions useful, I would not object to this particular one being published.

Response:

We agree with Dr Fauth that ‘results’ are in general a more valuable contribution to the literature on any topic than study protocols. However we strongly feel that publication of review protocols is worthwhile, as it provides methodological transparency and accountability. Additional benefits are that it alerts interested parties to current work being undertaken, and enables contact and collaboration from other researchers working in similar areas. There is currently a wider drive in the field for registration of reviews, and publication of protocols, and we are delighted that journals like the BMJ Open are helping to support this agenda. Our funder (NIHR) also encourages registration of systematic reviews and publication of protocols.

- In addition to asking relevant questions in the review, I feel as though the authors have done a good job defining the search indicators, and defining the processes for organizing and summarizing the results.

Response: Thank you.

- The only outcomes I thought might be useful to consider, are those related to dementia progression in the person with dementia. That is, outcomes such as cognitive performance or functional ability over time. There is some research related to how closeness in the informal caregiver predicts slower rates of progression (cognitive and functional) over time, and I might suggest adding these as outcomes in the review. I am familiar with Norton et al., 2009.

Response:

We agree that cognitive and functional outcomes are also an important area of research, and the role of relationship factors on these outcomes is an interesting research question. However as there is very extensive literature on cognitive and functional outcomes of dementia, we felt that these outcomes would warrant a separate review in it's own right. Also some exclusions were necessary for the review to be feasible, given limited resources.

- I also advise that while the research team has indicated that the next viable step after such review is to inform intervention, that it may be best to take a step back before doing so. Let's say that the review suggests that closer emotional relationships serve as a protective factor for person's with dementia across many outcomes (as would be hypothesized). The implications for intervention might be to try and promote closer emotional relationships among caregivers and their family members with dementia.

However, research on caregiver outcomes and emotional closeness is mixed - some studies find that caregivers fare better when they have closer emotional bonds with the person with dementia (e.g. Spaid & Barush, 1994), but others find that caregivers fare worse (Tower, et al., 1997; Fauth et al., 2012) - the closer emotional relationship may benefit the person with dementia, but possibly at the cost of the mental and physical health of their caregiver.

Response:

We take on board Dr Faust's caution about the implications of this work for potential future interventions. We have now attenuated or cut the relevant statements about this in the protocol, and hope the wording no longer implies that the findings from this review could be all that is needed to develop an intervention. The amended text (p3, p4, p13) now reads:

Original text, p3:

"Results will also be disseminated to a patient and public involvement (PPI) group for their views on the findings, and input on the development of a future intervention study."

Updated text, p3:

"Results will also be disseminated to a patient and public involvement (PPI) group and an Expert Panel for their views on the findings and implications for future work."

Original text, p4:

"Results will inform the development of interventions to support families affected by dementia, with the aim of reducing or delaying institutionalisation."

Updated text, p4:

"Results may help to inform future work to support families affected by dementia, with the aim of reducing or delaying institutionalisation."

Original text, p13:

"Results will also be disseminated to a patient and public involvement (PPI) group for their views on

the findings, and input on the development of a future intervention study.”

Updated text, p13:

“Results will also be disseminated to a patient and public involvement (PPI) group and an Expert Panel for their views on the findings and implications for future work.”

VERSION 2 – REVIEW

REVIEWER	Ryan Li NICE International, National Institute for Health and Care Excellence, UK
REVIEW RETURNED	07-Mar-2016

GENERAL COMMENTS	Thank you for your comprehensive and clear responses, and the opportunity to review this much improved manuscript. I am very happy to recommend it for publication.
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