PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Substituting physicians with nurse practitioners, physician assistants or nurses in nursing homes – protocol for a realist evaluation case study
AUTHORS	Lovink, Marleen; Persoon, Anke; van Vught, Anneke; Schoonhoven, Lisette; Koopmans, Raymond; Laurant, Miranda

VERSION 1 - REVIEW

REVIEWER	Ralph Möhler Cochrane Germany, Medical Center - University of Freiburg
REVIEW RETURNED	12-Dec-2016

GENERAL COMMENTS	Thank you for this well written and interesting study protocol. I have only some minor comments. Methods - Observations Please specify the time periods of the planned observation and why exactly these time periods have been chosen. I am not sure whether a non-participating observation will be feasible, therefore it might be of interest to keep this in mind during the data collection and analysis.

REVIEWER	Faith Donald Daphne Cockwell School of Nursing, Ryerson University, Canada
REVIEW RETURNED	18-Dec-2016

GENERAL COMMENTS	This is an interesting protocol about an important topic. Overall, the protocol is quite complete. Suggested edits for grammar and clarification are provided for consideration. Page 8, Line 26, 'provides' should be 'providers'. Page 8, Line 32 '(resulting in the same number of shifts with fewer people)' is unclear, as it is the same number of off-hour shifts with the same number of ECPs; the NPs and PAs are not currently providing off-hours care, so their lack of participation should not affect the number of ECPs taking on this responsibility. Page 9, Line 19 "clear vision on their role" please replace with "clear vision of their role". Page 10, lines 7-8, "treatment protocols that are adjusted to the mid-level provider", such as (please provide examples or a description, such as "based on the scope of practice" or something similar. Page 10, Line 26, an extra period after the citation number. Page 10, lines 52-53, "a neutral or positive effect on hospital admissions, hospital days, emergency department visits, mortality, and number of medications used" would be clearer for international readers if reworded to "a neutral effect on or reduction in the number

	of hospital admissions, hospital days, emergency department visits, mortality, and number of medications used." 'Positive' could be interpreted as an 'increase' by readers who have English as an added language. Page 11, lines 11-13, "In addition, mid-level providers contribute to efficiency as they work in a structured manner and take into account the organisation of care while planning care activities, sometimes even more than ECPs do" requires a reference and I suggest deleting ", sometimes even more than ECPs do". If that is removed, there is no indication that ECPS don't also do this, and it sounds as if the authors want to placate the ECPs. Generally, that ECP addition seems awkward. Page 11, lines 20-21, "if they know and point out their boundaries" is true for any provider and provides some discomfort that these providers do not do this. Could it be replaced by "within their boundaries" The sentence needs a reference. Page 11, line 23, "at the wards" needs to be changed to "on the units" to have consistent terminology in the paper. Page 11, lines 50-51 needs a reference. Page 11, line 56, "Other outcomes include, for example, continuity of care." can be deleted, as the next sentence can easily be the first sentence of the paragraph. Page 12, lines 5-6, needs a reference regarding coaching effects. Page 12, lines 7-8, needs a bit more explanation. Do you anticipate that these 'indirect' outcomes will be discussed during focus groups? Therefore, you will include them in the analysis? Page 12, lines 17-18, the format for 1. and 2. differs from previous numbering. Please follow the format of BMJ Open. Page 13, line 29, Table 1, the (1), (2), and (3) are confusing, perhaps replace with superscript stars. Page 13, Line 11, "patients the mid-level provider takes care for" should be edited to "patients the mid-level provider takes care of or "patients the mid-level provider provides care for" Page 13, line 13-14, excellent to see the two years criteria. Is this 2 years in the current position, or two years total in nursing homes? If total, how long should they have worked in their present position, necessary to know to understand time to build credibility, know patients, know routines, community supports for referral, etc. Page 13, line 29, Is giving injections only a physician responsibility in the Netherlands? Nurses do not give injections? Page 13, lines 35 to 39, what is the total member number in each of these associations? Do they represent all members of their respective professions? If not, what is the total number for each profession? What is your anticipated return rate? What strategies will you use to enhance response rates? What percentage is anticipated to be sufficient to allow you to choose representative cases? Page 13, line 43-44, Might there be more than one NP and/or PA in some of the nursing homes or are you targeting homes with one type of provider to compare the roles? How many nursing homes would have NPs and how many would have PAs? Are geographical variations important? Page 13-14, Participants list, is there a reason that the practice nurse is not included as a participant? Do they not work on units that have NPs or PAs? Page 14, will all participants also provide written consent? Is there criteria for inclusion of patients who are diagnosed with dementia, but would be able to participate? For example, able to describe the purpose of the study, the benefits and risks of participation and how to withdraw from the study? These criteria are consistent with

	informed consent. Page 15, line 6, does (4x4 hours) mean 4 consecutive days x 4 hours, or 4 days x 4 hours within the 2 week period? This question also applies to line 12 (2x2 hours), and are the ECP observations on different days than the NP/PA? Would this observation only occur if you did not observe the collaboration when observing the NP/PA? Unclear as to how this observation would occur to contribute to the data, would the two hours be scheduled when the ECP has scheduled time at the nursing home? Page 15, lines 21-23, will you interview patients separate from their family members, same question for patient and family councils. Page 14, line 14 needs to include documents as a source of data. Page 15, line 23, "Different participants" does not accurately describe the use of documents for data. Perhaps the "Participants" heading for the column could be replaced with Sources of Data" or some other term. Page 15, line 40, is this "informed 'written' consent"? Page 15, Informed Consent section could be more concisely written - e.g., The contact person and/or the mid-level provider will assist in identifying all participants. (then go on to identify the participants.) What are the limitations of having the NP/PA identify participants, such as bias? How will you address this? Page 16, line 40, "will be asked whether they perceive the way physician substitution is modelled as being optimal" appears to be a biased question, might you ask participants to rate their perception of the way physician substitution is modeled? Page 16, lines 54-55, the question is worded differently than in the research questions earlier in the paper. Is there a reason for this? If not, I suggest using the same wording as your originally intended, as it is more complete and likely addresses what you are aiming to address. Page 17, I'm a bit confused, will both researchers be doing the observation? If not, how can the other researcher check the data? Do you mean that they will discuss questions that arise? Page 17, line 33, will "outlining the main message" also be done with participants as a mechanism for member checking during the interview? Page 17 to 18, your description of member checking for the case description is an interesting process. Caution will be needed that the participants in the member check not have the ability to change information that came from others not represented in the member check group. In my country, the ethics review board would have concerns about this group process, as it provides feedback about the NP/PA employee that might risk their employment. There's also a risk to reputation, as there is a group who hear about the results specific to the NP/PA in their organization. Might it be better to member check on the collective data across all sites? Page 19, line 23, will clear descriptions of the organisations potentially reveal the identity of the organizations? Is this "clear description" consistent with the ethics review and informed consent processes? If not, please consider general descriptions that provide sufficient information to implement a similar role and model of care. Pages 19-20, for the Discussion section, consistent with the PEPPA model, if the roles were developed based on a needs assessment and clear goals, objectives and outcomes identified, then the role might be optimal for that facility. The needs of the patients, families, staff, organisation and healthcare system drive what is 'optimal' in any given context. You might consider using the PEPPA model as a secondary consideration for data analysis. Page 19, line 33, "the model might strongly depends on the context,"

	should be "the model might strongly depend on the context," (no s on depend). Page 19, Discussion section, an acknowledgement of power dynamics and how they may influence NP/PA activities and outcomes would be a realistic addition to the protocol. A general discussion of differences in boundaries/scope of practice for NPs and PAs in the Netherlands versus other countries will enhance generalizability of the study. Reference list, please edit to BMJ Open format, e.g., first 3 authors then et al, page numbers truncated, e.g., 2148-2161 would be changed to 2148-61., etc. Thank you for submitting this quality protocol, as it will assist others who are asking similar questions about NPs and PAs in their countries. The use of realist evaluation is an interesting and note-worthy approach. (As you have likely noticed, my preference is to identify the role titles, rather than using the non-specific 'mid-level provider' terminology; however, I defer to terminology used in the Netherlands).

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Ralph Möhler
Institution and Country: Cochrane Germany, Medical Center - University of Freiburg
Competing Interests: None declared

Thank you for this well written and interesting study protocol. I have only some minor comments.

Methods - Observations

Please specify the time periods of the planned observation and why exactly these time periods have been chosen. I am not sure whether a non-participating observation will be feasible, therefore it might be of interest to keep this in mind during the data collection and analysis.

>> Response and action of the authors:
We thank the reviewer for the compliments about the protocol and for the constructive comments. We agree that it is important to argue the time periods of our observations. In short, we have chosen to observe the ECP for 2x2 hours to gain a general impression of the patient related tasks of the ECP and the mid-level provider for 4x4 hours to gain a more detailed impression of these tasks of the mid-level provider. The relatively short observation periods will help to prevent the observers from ‘going native’. However, the observers have to keep in mind during the observations that they are non-participants. We made the following changes to the manuscript under Data collection, Observations, page 16:

>>The mid-level provider will be observed for 4 days x 4 hours within the 2 weeks period and the ECP for 2 days x 2 hours within the 2 weeks period. These time periods have been chosen as it is anticipated that an observation of 2 or 4 hours gives a good impression of the tasks the mid-level provider and the ECP perform. By planning multiple observations the chance of only observing exceptional situations is diminished. The mid-level provider will be observed for a longer period of time as he/she is the subject of the study. In addition, within the observation of the mid-level provider all scheduled contact moments between the mid-level provider and the ECP will be observed. The ECP will be observed to discover differences or similarities in performing the tasks they have in

common with the mid-level provider. Observations will be planned in advance based on indication of the mid-level provider and the ECP which time they perform the most patient related tasks. Both researchers will carry out half of the observations. The role of the researcher during observations will be as a non-participant.36 In non participant observation it is important to find a balance between building trust among the participants and ‘going native’. The relatively short observation periods will prevent the observers ‘going native’.

Reviewer: 2
Reviewer Name: Faith Donald
Institution and Country: Daphne Cockwell School of Nursing, Ryerson University, Canada
Competing Interests: None declared

This is an interesting protocol about an important topic. Overall, the protocol is quite complete.

>> Response of the authors: We thank the reviewer for the compliments about the protocol and for the useful suggestions to improve our protocol.

Suggested edits for grammar and clarification are provided for consideration.
• Page 8, Line 26, 'provides' should be 'providers'.
>> Response and action of the authors: Changed accordingly.

• Page 8, Line 32 '(resulting in the same number of shifts with fewer people)' is unclear, as it is the same number of off-hour shifts with the same number of ECPs; the NPs and PAs are not currently providing off-hours care, so their lack of participation should not affect the number of ECPs taking on this responsibility.

>> Response and action of the authors: This sentence refers to the situation in which an NP of PA is employed instead of an ECP, but does not participate in off-hours care. To clarify this we have added the following:

>> Although physician substitution releases the burden on ECPs during the day, the burden during evening, night and weekend shifts may increase because, in most cases, mid-level providers are employed instead of an ECP but they do not participate in these off-hours shifts (resulting in the same number of shifts with fewer people).

• Page 9, Line 19 "clear vision on their role" please replace with "clear vision of their role".
>> Response and action of the authors: Changed accordingly.

• Page 10, lines 7-8, "treatment protocols that are adjusted to the mid-level provider", such as (please provide examples or a description, such as "based on the scope of practice" or something similar.
>> Response and action of the authors: Changed accordingly.

• Page 10, Line 26, an extra period after the citation number.
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• Page 10, lines 52-53, "a neutral or positive effect on hospital admissions, hospital days, emergency department visits, mortality, and number of medications used" would be clearer for international readers if reworded to "a neutral effect on or reduction in the number of hospital admissions, hospital days, emergency department visits, mortality, and number of medications used." 'Positive' could be interpreted as an 'increase' by readers who have English as an added language.
>> Response and action of the authors: We thank the reviewer for this suggestion and we have

reworded the sentence according to the suggestion.

• Page 11, lines 11-13, "In addition, mid-level providers contribute to efficiency as they work in a structured manner and take into account the organisation of care while planning care activities, sometimes even more than ECPs do" requires a reference and I suggest deleting ", sometimes even more than ECPs do". If that is removed, there is no indication that ECPS don't also do this, and it sounds as if the authors want to placate the ECPs. Generally, that ECP addition seems awkward.

>> Response and action of the authors: We agree with the reviewer that the wording is a bit odd and it is not our intention to placate the ECP, so we decided to remove the ECP addition. The information in this sentence is based on the focus group study we performed as referred to in the paragraph Initial theory substitution on page 5. To enhance the readability of the protocol we decided not to refer to this study all the time. To clarify this we have added the following to Design, Initial theory, page 5:

>> If no reference is provided the information is based on our focus group study [Lovink et. al. in preparation].

• Page 11, lines 20-21, "if they know and point out their boundaries" is true for any provider and provides some discomfort that these providers do not do this. Could it be replaced by "within their boundaries" The sentence needs a reference.
>> Response and action of the authors: We thank the reviewer for this suggestion. With this sentence we did not want to suggest that mid-level provider do not know and point out their boundaries so we have reworded the sentence according to the suggestion. For clarification about references see our response to the comment starting with ‘page 11, lines 11-13 ...’ above.

• Page 11, line 23, "at the wards" needs to be changed to "on the units" to have consistent terminology in the paper.
>> Response and action of the authors: Changed accordingly.

• Page 11, lines 50-51 needs a reference.
>> Response and action of the authors: For clarification about references see our response to the comment starting with ‘page 11, lines 11-13 ...’ above.

• Page 11, line 56, "Other outcomes include, for example, continuity of care." can be deleted, as the next sentence can easily be the first sentence of the paragraph.
>> Response and action of the authors: Changed accordingly.

• Page 12, lines 5-6, needs a reference regarding coaching effects.
>> Response and action of the authors: For clarification about references see our response to the comment starting with ‘page 11, lines 11-13 ...’ above.

• Page 12, lines 7-8, needs a bit more explanation. Do you anticipate that these 'indirect' outcomes will be discussed during focus groups? Therefore, you will include them in the analysis?

>> Response and action of the authors: During the interviews we will first ask the open question: what is the effect of physician substitution. After this question we will ask questions about the effects of physician substitution on effectiveness, efficiency etc. We expect that in reaction to the open question some ‘indirect’ outcomes might be discussed. To clarify this we have added the following:

>> As the goal of this study is to describe physician substitution, we did not focus explicitly on ‘indirect’ outcomes, but they might be discussed in answers to our open interview questions and then will be included in the analysis.

• Page 12, lines 17-18, the format for 1. and 2. differs from previous numbering. Please follow the format of BMJ Open.
>> Response and action of the authors: Changed accordingly.

• Page 13, line 29, Table 1, the (1), (2), and (3) are confusing, perhaps replace with superscript stars.
>> Response and action of the authors: Changed accordingly.

• Page 13, Line 11, "patients the mid-level provider takes care for" should be edited to "patients the mid-level provider takes care of or "patients the mid-level provider provides care for"
>> Response and action of the authors: Changed accordingly.

• Page 13, line 13-14, excellent to see the two years criteria. Is this 2 years in the current position, or two years total in nursing homes? If total, how long should they have worked in their present position, necessary to know to understand time to build credibility, know patients, know routines, community supports for referral, etc.
>> Response of the authors: The two years criterion means that the mid-level provider has to work for minimal two years as a NP, PA or practice nurse in a nursing home (not necessarily the nursing home they are working at the moment). We will not apply a criterion for how long they should have worked in the current nursing home, but we will inventories this in the questionnaire and discuss the effect of it in the interview.

• Page 13, line 29, Is giving injections only a physician responsibility in the Netherlands? Nurses do not give injections?
>> Response of the authors: In the Netherlands giving injections is a so-called 'reserved procedure. These procedures may be performed by nurses but only in order and under supervision of a physician. See the text under the heading: Social, political, and legal factors, on page 10 for more information.

• Page 13, lines 35 to 39, what is the total member number in each of these associations? Do they represent all members of their respective professions? If not, what is the total number for each profession? What is your anticipated return rate? What strategies will you use to enhance response rates? What percentage is anticipated to be sufficient to allow you to choose representative cases?

>> Response and action of the authors: In the Netherlands 303 NPs are working in nursing homes and 224 of them are member of their association. In addition, 38 PAs are working in nursing homes and 30 of them are member of their association. The number of practice nurses working in nursing homes is unknown, however we do know that 180 of them are member of their association. Above mentioned illustrates that we will not reach all mid-level providers by our sampling approach, so we apply a convenience sampling method. In line with this we do not have a minimum response rate, but we will use reminders to enhance the response rate. In addition, we will describe the numbers and our response rate in our final article and draw conclusions about how representative the cases are. We have also added the numbers and the use of reminders to the protocol:

>> The professional associations of NPs, PAs, and practice nurses in nursing homes will be asked to distribute a questionnaire among their members (NPs: 224, PAs: 30, practice nurses: 180). This questionnaire contains questions about the inclusion criteria and the maximum variation criteria. Reminders will be used to enhance the response rate.

• Page 13, line 43-44, Might there be more than one NP and/or PA in some of the nursing homes or are you targeting homes with one type of provider to compare the roles? How many nursing homes would have NPs and how many would have PAs? Are geographical variations important?

>> Response and action of the authors: In this study ‘the case’ is an individual mid-level provider. So the sample will be drawn on the individual-level and not on nursing home level. For (maximum variation) selection criteria we refer to Table 1. It might be that nursing homes with multiple or different mid-level providers are included, but this is not a selection criterion as we think the other selection criteria are more important. If we have the opportunity to chose between two exact same cases we will take in to account the geographical variations. In addition, we have added the number of each type of mid-level provider that will be selected to Table 2:

>> Mid-level provider (3 NPs, 2 PAs and 2 practice nurses)

• Page 13-14, Participants list, is there a reason that the practice nurse is not included as a participant? Do they not work on units that have NPs or PAs?
>> Response and action of the authors: We use the term mid-level provider to refer to NPs, PAs and practice nurse, see our introduction. So practice nurses are included in the participants list as mid-level provider. In addition, if a NP or PA collaborates with a practice nurse we will include this practice nurse for an interview as one of the five nurses/healthcare assistants/nursing team leaders.

• Page 14, will all participants also provide written consent? Is there criteria for inclusion of patients who are diagnosed with dementia, but would be able to participate? For example, able to describe the purpose of the study, the benefits and risks of participation and how to withdraw from the study? These criteria are consistent with informed consent.

>> Response and action of the authors: All participants who will be interviewed will provide written consent. We will not interview patients who are diagnosed with dementia, because we think this might be a burden to them. On dementia special care units we will interview the informal care givers. We have written an information letter to inform all participants. If the reviewer wish we could provide this letter to her. In addition, we have developed several documents such as a flyer and a poster to inform all patients, informal caregivers and care providers of the units where the observations will take place to inform them about the study and the observation. As described under the heading Informed consent on page 15 the method for informing participants about the observation will be determined in collaboration with our contact person and the Board of Directors. To clarify this we made some minor changes to the manuscript on page 15:

>> All participants who will be interviewed will be informed verbally and by letter and will be asked to provide informed consent.
...
Before the start of the study, all patients, informal caregivers and care providers of the units where observations will take place, will be informed about the study and the observations, so they have the chance to object to the observation in advance. The method for informing participants about the observations will be determined in collaboration with our contact person and the Board of Directors.

• Page 15, line 6, does (4x4 hours) mean 4 consecutive days x 4 hours, or 4 days x 4 hours within the 2 week period? This question also applies to line 12 (2x2 hours), and are the ECP observations on different days than the NP/PA? Would this observation only occur if you did not observe the collaboration when observing the NP/PA? Unclear as to how this observation would occur to contribute to the data, would the two hours be scheduled when the ECP has scheduled time at the nursing home?

>> Response and action of the authors: 4x4 hours means 4 days x 4 hours within the 2 weeks period, 2x2 hours means 2 days x 2 hours within the 2 weeks period. The observations will be planned in advance based on indication of the mid-level provider and the ECP which time they perform the most

patient related tasks. The observations of the ECP might be on the same or on different days as/than the observations of the mid-level provider; as explained above this depends on the planning of patient related tasks of both providers. If they are planned on the same day the mid-level provider will be observed by the first observer and the ECP by the second. The scheduled contact moments between the mid-level provider and the ECP will be observed during the observation of the mid-level provider. The ad hoc collaboration between the mid-level provider and the ECP will be observed during the observation of the mid-level provider as well as during the observation of the ECP. In all cases the ECP will be observed for 4 hours. In the Netherlands, ECPs are employed by the nursing home organisation, so they only work in the nursing home. The observation of the ECP in the nursing home will give a general impression of his/her tasks in respect of the tasks of the mid-level provider. We made the following changes to the manuscript under Data collection, Observations, page 16:

>> The mid-level provider will be observed for 4 days x 4 hours within the 2 weeks period and the ECP for 2 days x 2 hours within the 2 weeks period. These time periods have been chosen as it is anticipated that an observation of 2 or 4 hours gives a good impression of the tasks the mid-level provider and the ECP perform. By planning multiple observations the chance of only observing exceptional situations is diminished. The mid-level provider will be observed for a longer period of time as he/she is the subject of the study. In addition, within the observation of the mid-level provider all scheduled contact moments between the mid-level provider and the ECP will be observed. The ECP will be observed to discover differences or similarities in performing the tasks they have in common with the mid-level provider. Observations will be planned in advance based on indication of the mid-level provider and the ECP which time they perform the most patient related tasks. Both researchers will carry out half of the observations. The role of the researcher during observations will be as a non-participant.36 In non participant observation it is important to find a balance between building trust among the participants and ‘going native’. The relatively short observation periods will prevent the observers ‘going native’.

• Page 15, lines 21-23, will you interview patients separate from their family members, same question for patient and family councils.

>> Response and action of the authors: On dementia special care units only the informal care giver will be interviewed. On the other units the patient and the informal care giver will be interviewed together. Whether the patient council and the family council will be interviewed together depends on the way they are organized. In most organisations the patients and the family have a joint council and they will be interviewed together. However, if there is a separate patient and a separate family council they will be interviewed separate. We added the following to Participants, page 14:

>>
• Five patients the mid-level provider takes care of and their informal caregiver
(at dementia special care units; only informal caregivers will participate)
• Patient council, family council or patient-family council

• Page 14, line 14 needs to include documents as a source of data.
>> Response and action of the authors: Changed accordingly.

• Page 15, line 23, "Different participants" does not accurately describe the use of documents for data. Perhaps the "Participants" heading for the column could be replaced with Sources of Data" or some other term.
>> Response and action of the authors: Changed accordingly.

• Page 15, line 40, is this "informed 'written' consent"?
>> Response and action of the authors: Yes it is. Changed accordingly.

• Page 15, Informed Consent section could be more concisely written - e.g., The contact person and/or the mid-level provider will assist in identifying all participants. (then go on to identify the participants.)
>> Response and action of the authors: We thank the reviewer for this suggestion and we have rewritten this section according to the suggestion.

• What are the limitations of having the NP/PA identify participants, such as bias? How will you address this?
>> Response and action of the authors: We think that in some cases the mid-level provider is needed to identify patients for an interview, as the mid-level providers knows best which patients are capable of taking part in an interview and the mid-level provider can identify patients he/she has seen most often. However, this method has indeed some limitations, for example selection bias. It might be that the mid-level provider only identifies patients with which he/she has a good relation. Nevertheless, we think that we will notice it if this is the case due to data triangulation (observations and interviews with other care providers).

• Page 16, line 40, "will be asked whether they perceive the way physician substitution is modelled as being optimal" appears to be a biased question, might you ask participants to rate their perception of the way physician substitution is modeled?

>> Response and action of the authors: We think this question encourages participants to reflect on this topic. In addition to this question we will of course ask why the participants perceives the situation as optimal or not optimal. We are interested in this explanation. Asking participants to rate their perception might be a good alternative, but we think that the question we formulated will provide us with in-depth insight. We added the following to Data collection, Interviews and questionnaires, page 17:

>> In addition, all participants, except for the patients and/or their informal caregiver and the patient/family council, will be asked whether they perceive the way physician substitution is modelled as being optimal and why they think so or not. They will also be asked whether they would recommend it to other organisations and why they would or would not.

• Page 16, lines 54-55, the question is worded differently than in the research questions earlier in the paper. Is there a reason for this? If not, I suggest using the same wording as your originally intended, as it is more complete and likely addresses what you are aiming to address.
>> Response and action of the authors: we agree with the reviewer that the same wording as used earlier is more complete. We added all three research questions, see page 17.

• Page 17, I'm a bit confused, will both researchers be doing the observation? If not, how can the other researcher check the data? Do you mean that they will discuss questions that arise?
>> Response of the authors: Both researchers will carry out half of the observations. They will not check each other's observation data (part one of the observation instrument), bus they will compare their notes in the second part of the observation instrument. In this part, the researcher will write down a general impression on topics such as level of autonomy and care for the client/family after each observation moment. Together the researcher will merge these forms into one form for the mid-level provider and one form for the ECP. If there are differences between the forms and no consensus can be reached, clarification will be asked during the member check.

• Page 17, line 33, will "outlining the main message" also be done with participants as a mechanism for member checking during the interview?
>> Response of the authors: Both researchers are experienced interviewers. They will use different

interview techniques such as paraphrasing, remain silent, encouraging body language, and outlining the main message, to collected in-depth data and to check their understanding of the data.

• Page 17 to 18, your description of member checking for the case description is an interesting process. Caution will be needed that the participants in the member check not have the ability to change information that came from others not represented in the member check group. In my country, the ethics review board would have concerns about this group process, as it provides feedback about the NP/PA employee that might risk their employment. There's also a risk to reputation, as there is a group who hear about the results specific to the NP/PA in their organization. Might it be better to member check on the collective data across all sites?

>> Response and action of the authors: We thank the reviewer for pointing out this important issue. As written on under the heading Member check, we are aware of the drawbacks of a member check but in our study participants of the member check do not have the ability to change information that came from others. However, the member check gives us the opportunity to ask for clarification on factual information and the discussion between the participants will enrich the data as a focus group provides more information than the sum of individual interviews because of the interaction process. To protect the reputation of the mid-level provider and the ECP we will first send the case description to them, so they have the opportunity to react on it. We will ask them for permission before we send the case description to the other participants of the member check. A member check on the collective data may be difficult as participants might not recognise themselves in the abstract synthesis.

• Page 19, line 23, will clear descriptions of the organisations potentially reveal the identity of the organizations? Is this "clear description" consistent with the ethics review and informed consent processes? If not, please consider general descriptions that provide sufficient information to implement a similar role and model of care.

>> Response and action of the authors: It is not our intention to reveal the identity of the organisations, so we agree with the reviewer that a general description that provides sufficient information to implement a similar role and model of care would be better than a clear description. We have changed this in the manuscript, Validity and rigour, page 19:

>>Transferability: a general description of the organisations that provides sufficient information to implement a similar role and model of care will be presented in the paper to be published.

• Pages 19-20, for the Discussion section, consistent with the PEPPA model, if the roles were developed based on a needs assessment and clear goals, objectives and outcomes identified, then the role might be optimal for that facility. The needs of the patients, families, staff, organisation and healthcare system drive what is 'optimal' in any given context. You might consider using the PEPPA model as a secondary consideration for data analysis.

>> We thank the reviewer for this great suggestion. We are aware of the PEPPA framework and this framework has a lot in common with the method used in our protocol. The needs assessment referred to is in line with the context factors of the Tailored Implementation for Chronic Diseases checklist which will be use in our study. It is true that these context factors drive what is perceived as optimal. However, in our study we would like to go beyond the general statement that if roles are developed based on a needs assessment and clear goals, objectives and outcomes identified then the role might be optimal. We would like to find some concrete examples of this general statement and concrete preconditions of implementing a mid-level provider. For example (1) what are examples of goals an organization could pursue by implementing a mid-level provider?, (2) if you want to employ a mid-level on a dementia care unit how should you organize this?, (3) how should the mid-level provider and the ECP collaborate if they both have their own unit, and how if they share a unit? etc.

Nevertheless, the PEPPA model shows why we will not find one single best model and to explain this we have added the following to the Discussion page 20:

>> Bryant and DiCenco developed the PEPPA framework which states that the role of an advanced practice nurses should be developed based on a needs assessment and clear goals, objectives and outcomes identified.44 A model might be optimal if the role of a mid-level provider is developed in this manner. In addition to this framework this case study will provide some concrete examples of this general statement and concrete preconditions of implementing a mid-level provider.

• Page 19, line 33, "the model might strongly depends on the context," should be "the model might strongly depend on the context," (no s on depend).
>> Response and action of the authors: Changed accordingly.

• Page 19, Discussion section, an acknowledgement of power dynamics and how they may influence NP/PA activities and outcomes would be a realistic addition to the protocol.

>> Response and action of the authors: We agree with the reviewer that power dynamics might hinder 'real' physician substitution. In addition, the situation in the Dutch nursing homes is different from the situation on other countries. To discuss this we have added the following to the Discussion, page 20:

>> This study is conducted in the Netherlands and it is important to point out that the nursing home setting might differ from other countries. In the Netherlands multidisciplinary teams are employed by the nursing home organisations, including the ECP, physiotherapist, occupational therapist, speech therapist, dietician and psychologist.8 9 45 This means that all these providers are full time present at the nursing home and not only on call. Worldwide the employment of a broad multidisciplinary team is unique, especially the presence of an ECP as a medical specialist in elderly care.7 45 The cooperation between the Dutch ECPs and the relatively new mid-level providers will be influenced positively as well as negatively, as it is facilitated by the presences of the ECP, but possibly hindered by competition. The interaction between the ECP and the mid-level provider and how this interaction influences physician substitution is part of the current study in observations as well as in interviews; resulting in recommendations on how to strengthen the cooperation.

A general discussion of differences in boundaries/scope of practice for NPs and PAs in the Netherlands versus other countries will enhance generalizability of the study.

>> Response and action of the authors: We thank the reviewer for this suggestion and we have added a short discussion about this topic, page 20:

>> Besides the differences in the nursing home setting, there is also a huge difference in the extent of substitution of physicians by NPs and PAs between countries. As in other countries, PAs in the Netherlands mainly focus on the medical domain, while NPs combine the medical with the nursing domain. In the Netherlands, NPs and PAs are educated at the master's level, they have a protected title and are authorized to indicate and perform some of the so called 'reserved procedures', like prescribing medication and giving injections.32 33 46 Research shows that in some countries (like Australia and the USA) NPs are able to substitute physicians like in the Netherlands, while in other countries (like France and Germany) they are not.47 For PAs applies that like in the Netherlands they are also recognized in Australia, Canada, United Kingdom and the USA, but in these countries they are only allowed to work under a supervising physician.48

Reference list, please edit to BMJ Open format, e.g., first 3 authors then et al, page numbers truncated, e.g., 2148-2161 would be changed to 2148-61., etc
>> Response and action of the authors: Changed accordingly.

Thank you for submitting this quality protocol, as it will assist others who are asking similar questions about NPs and PAs in their countries. The use of realist evaluation is an interesting and note-worthy approach. (As you have likely noticed, my preference is to identify the role titles, rather than using the non-specific 'mid-level provider' terminology; however, I defer to terminology used in the Netherlands).
>> Response of the authors: We thank the reviewer for raising this important topic. We agree with the reviewer that NPs, PAs and nurses are all qualified professionals in their own right and with their own focus on healthcare. We applied the term mid-level provider for more pragmatic reasons as it is also used in other articles about this topic (Maier & Aiken 2016). In the Introduction we explain what we mean by mid-level provider.