PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Expanded nursing competencies to improve person-centred care for nursing home residents with complex health needs (Expand-Care): study protocol for an exploratory cluster-randomised trial
AUTHORS	Silies, Katharina; Vonthein, Reinhard; Pohontsch, Nadine; Huckle, Tilman Alexander; Sill, Janna; Olbrich, Denise; Inkrot, Simone; Frielitz, Fabian-Simon; Lühmann, Dagmar; Scherer, Martin; König, Inke; Balzer, Katrin

VERSION 1 – REVIEW

REVIEWER	Amy-Louise Byrne Central Queensland University School of Nursing and Midwifery
REVIEW RETURNED	02-May-2023

GENERAL COMMENTS	Thank you for the opportunity to review this protocol. My feedback is not so much about this paper, which I believe to be sound, but rather the wider study itself. 1. Has the team reviewed the outcomes from the Australian Nurse Navigator study? While this wasn't specific to aged care, it was inclusive of aged care, and measured many similar outputs. Nurse Navigators are an autonomous nurse led service who work with people with complex multi morbidity. I believe the authors of this paper will get some clarity around similar projects abroad and the systemic issues present for nurses, though I appreciate that the practice context may differ. The timeframes for data collection here seem very narrow. Given that person-centred care is about building rapport and relationships, this will take time to build, and expecting an outcome of reduced hospital usage in 3 months is, in my view, optimistic. Lastly, I would like the authors to take a look at the term person-centred care. What does this mean? If it is an individual thing for people and their families, then why is a marker of this hospital avoidance? Measuring PCC against hospital avoidance has been done in many studies, and my own work has found that this is fundamentally flawed, especially when looking at people with complex care needs. This needs a critical lens, and I implore the authors to think this through. If you want to investigate hospital avoidance, that is fine, but this is not always person-centred care, and where hospital cannot be avoided, this is not a failure on the part of the person or the nurse. There are big implications in matching PCC with hospital avoidance. Without sounding conceited, you can read my thesis on this topic Byrne, A. -L. (2022). Person-centred care as a technology of compliance: A critical investigation of how nurse navigators care for people with complex conditions. (CQUniversity). It is prudent to have a discussion about this now, prior to data collection, as your results may raise these issues.

REVIEWER	Denise Edgar University of Wollongong Illawarra Health and Medical Research Institute
REVIEW RETURNED	16-May-2023

GENERAL COMMENTS	Thank you for your study which will have implications for the homes where older people stay, globally. This study will also have implications for the educational needs of registered nursing staff and the skills required to enhance person-centred safe care. The protocol is very detailed with the additional supplementary files which are helpful for further information. The following details are mainly about the protocol as a stand-alone document reading the supplementary if requiring or wanting more detailed information. Abstract could have its mixed methods study capturing qual and quant data. For publication of the protocol, it would be helpful to see your definition of person-centredness which is in your title. There are so many different definitions globally with some groups considering it more aligned to understanding the personhood of the person/resident. Much of your data is around other metrics with one particular tool measuring person-centredness but omits part of the survey (with no explanation why). How does all these metrics fit together to improve safe person-centred care. There is some information on your program but doesn't elaborate what the person-centred network is in your implementation curriculum or the communication and empowerment modules. This would be helpful to understand the whole program, even in small detail since the study is about the training and implementation of the training back in the workplace. The strengths and the limitations should be split, and I wonder even though they are clusters if there are other limitation such as the short timeframe to implement and collect data as it make take time to implment depending on the context. The agreement with the Nursing Homes is a definite strength of the study and engagement technique. The statistical methods are written in a complex manner in the protocol considering you have a full supplementary document while the process evaluation on the protocol is simplified and possibly need a bit more detail, who will do it and what analysis will you follow (these are in the supplementary document but could transfer a bit more information). Thank you for your contribution to person-centred safe care for people living in aged care facilities, otherwise known as their homes. I hope this feedback assist you.

REVIEWER	Sharon Anderson University of Alberta, Department of Human Ecology, University of Alberta
REVIEW RETURNED	17-May-2023

GENERAL COMMENTS	This is such a readable protocol. Really enjoyable to to read. COVID-19 has really demonstrated the need for research such as

	this in nursing homes. I have attached my PDF with comments. There are not many comments. This is a very comprehensive, thoroughly described protocol. In Canada, anecdotally patients, staff and family caregivers are more satisfied in the nursing homes which have nurse practitioners. They know the patients and families so there is more trust, fewer unnecessary transfers to hospitals. Looking forward to seeing the final research report in print. The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

VERSION 1 – AUTHOR RESPONSE

	Reviewer 1	
1.	Thank you for the opportunity to review this protocol. My feedback is not so much about this paper, which I believe to be sound, but rather the wider study itself.	Thank you!
2.	Has the team reviewed the outcomes from the Australian Nurse Navigator study? While this wasn't specific to aged care, it was inclusive of aged care, and measured many similar outputs. Nurse Navigators are an autonomous nurse led service who work with people with complex multi morbidity. I believe the authors of this paper will get some clarity around similar projects abroad and the systemic issues present for nurses, though I appreciate that the practice context may differ.	Thank you for this suggestion. We have discussed your suggestion and find the work highly informative for a follow-up trial we are currently developing.
3.	The timeframes for data collection here seem very narrow. Given that person-centred care is about building rapport and relationships, this will take time to build, and expecting an outcome of reduced hospital usage in 3 months is, in my view, optimistic.	True. The short follow-up is due to the pilot character of the current study. Also, one focus of this study was the development phase, in which we aimed to meticulously follow established frameworks for the development and evaluation of complex interventions and to incorporate stakeholder involvement. Therefore, the first 12 months of the study period were dedicated to this aspect. However, we are currently developing a follow-up trial and this will provide longer periods of follow-up. We added your comment to the limitations section, though. Revision: • *The pilot study will be exploratory in nature as we will rely on a small sample size and a short follow-up of three months after completed implementation.*
4.	Lastly, I would like the authors to take a look at the term person-centred care. What does this mean? If it is an individual thing	Thank you for raising this important point. We appreciate your comprehensive work on this topic. From our point of view, the definition of the distal outcome is a constant challenge in complex interventions. There is a need for

	for people and their families, then why is a marker of this hospital avoidance? Measuring PCC against hospital avoidance has been done in many studies, and my own work has found that this is fundamentally flawed, especially when looking at people with complex care needs. This needs a critical lens, and I implore the authors to think this through. If you want to investigate hospital avoidance, that is fine, but this is not always person-centred care, and where hospital cannot be avoided, this is not a failure on the part of the person or the nurse. There are big implications in matching PCC with hospital avoidance. Without sounding conceited, you can read my thesis on this topic Byrne, A. -L. (2022). Person-centred care as a technology of compliance: A critical investigation of how nurse navigators care for people with complex conditions. (CQUniversity). It is prudent to have a discussion about this now, prior to data collection, as your results may raise these issues.	validated measures which, at the same time, due to their distal character, are often influenced by other factors apart from the intervention. We try to meet this dilemma by collecting a range of intermediate outcomes, aiming to depict change mechanisms in addition to distal outcomes. A recent review of reviews displays a range of outcomes of centredness of care, among these also measures of organizational effects such as healthcare utilisation, length of stay, costs, readmission rates (Feldthusen C, Forsgren E, Wallström S, Andersson V, Löfqvist N, Sawatzky R, et al. Centredness in health care: A systematic overview of reviews. Health Expect. 2022;25(3):885-901.). The specific outcome of hospitalisation has been successfully addressed with nurse-led interventions focusing on person-centred care (Zúñiga F, Guerbaai RA, de Geest S, Popejoy LL, Bartakova J, Denhaerynck K, et al. Positive effect of the INTERCARE nurse-led model on reducing nursing home transfers: A nonrandomized stepped-wedge design. J Am Geriatr Soc. 2022;70(5):1546-57.). Therefore, in summary, we strongly agree that person-centredness should be evaluated from the perspectives of patients and families in terms of their lived experience, but also believe that it is important to understand how person-centred care models can affect healthcare utilisation.
	Reviewer 2	
5.	Thank you for your study which will have implications for the homes where older people stay, globally. This study will also have implications for the educational needs of registered nursing staff and the skills required to enhance person-centred safe care. The protocol is very detailed with the additional supplementary files which are helpful for further information.	Thank you!
6.	Abstract could have its mixed methods study capturing qual and quant data.	Thank you for this suggestion. We have added the information. Revision: *… tasks as part of the process evaluation (mixed methods).*
7.	For publication of the protocol, it would be helpful to see your definition of person-centredness which is in your title. There are so many different definitions globally with some groups considering it more aligned to	Thank you, we have incorporated a definition now. Revision: *Academic training enables nurses to combine their clinical expertise with scientific evidence to provide care according to patient's or resident's preferences (evidence-based nursing, Scott and McSherry, 2009). Care that is guided by individuals' values and preferences*

	understanding the personhood of the person/resident.	*is referred to as person-centred care and can improve patient experiences and outcomes, and enhance the efficiency of health care delivery (The American Geriatrics Society, 2016, Santana et al., 2018).*
8.	Much of your data is around other metrics with one particular tool measuring person-centredness but omits part of the survey (with no explanation why). How does all these metrics fit together to improve safe person-centred care.	Thank you for raising this point. The reason behind choosing two out of three subscales for person-centred care was that the third subscale is not directly addressed by our intervention and we aimed to ensure that residents are not overly burdened through the data collection. Revision: *…and a climate of everydayness, as the climate of community is not addressed by the intervention.* The chosen range of metrics is based on the theoretical assumptions of how the complex intervention will work, and what kind of factors will influence the implementation. The fitting of the metrics with the implementation and intervention processes is sketched out in the logic model, which is also the basis for the comprehensive process evaluation. More detailed information on the "why", i.e. the assumptions we make on change mechanisms and reasons for single intervention components are outlined in the TIDieR template in supplement 2. In accordance with your comment on process evaluation below, we have elaborated on this further in the relevant section (see comment #20).
9.	There is some information on your program but doesn't elaborate what the person-centred network is in your implementation curriculum or the communication and empowerment modules. This would be helpful to understand the whole program, even in small detail since the study is about the training and implementation of the training back in the workplace.	Thank you for raising this point. We have added some information outlining the main learning topics of the curriculum. Revision: Text: ~~*This is outlined in a detailed curriculum containing two modules*~~ *This education will be delivered based on a detailed curriculum containing two modules: 1) enhanced roles and competencies for nurses* ~~*management of chronic and geriatric illnesses*~~*, and 2) person-centred nursing and care for people with chronic diseases* ~~*empowerment and communication with patients and person-centred care*~~*. Module 1) targets topics such as interprofessional communication, coaching and consulting, evidence-based practice, role development, and legal aspects. Example topics of modul 2) are pathology of chronic diseases, geriatric and nursing assessments, exacerbation of symptoms, pharmacological therapy, models of self-care, person-centred care, and advanced care planning.*
10.	The strengths and the limitations should be split, and I wonder even though they are clusters if there are other limitations such as the short timeframe to implement and collect data as it may take time to implement depending on the context. The agreement with the Nursing Homes is a definite strength of	Thank you for your suggestions. We have added the aspects you mention and split the section, which we find helpful. Yet, the original combined order is based on the journal's guidelines. We would therefore like to ask the editor to decide on this aspect. Revision: • *The pilot study will be exploratory in nature as we will rely on a small sample size and a short follow-up of three months after completed*

	the study and engagement technique.	*implementation.*
11.	The statistical methods are written in a complex manner in the protocol considering you have a full supplementary document, while the process evaluation on the protocol is simplified and possibly needs a bit more detail, who will do it and what analysis will you follow (these are in the supplementary document but could transfer a bit more information).	Thank you. We were not quite sure, whether the description of statistics was meant to be simplified. For that eventuality, we propose the following minor changes in phrasing: *All participants will be ~~are~~ analysed by intention to treat ~~allocated intervention disregarding all intercurrent events following the treatment policy strategy~~. Absorbing endpoints like death are considered as competing risk or worst possible assessment ~~by the composite strategy~~, so that other missing observations may be considered missing at random. The hospitalisation ~~primary estimand of the marginal~~ rates in treatment groups are ~~is~~ estimated by mixed logistic regression from the occurrence of hospitalisation within 6 months on treatment and occurrence of hospitalisation within 3 months prior to the trial (both fixed factors with two levels) and institution (random effects). The primary treatment effect estimator ~~estimand~~ is the marginal odds ratio in that model fit. ~~It has two sensitifity estimands: t~~ The hazard ratio from Cox regression and the marginal rate ratio from Poisson regression serve as sensitivity analyses. Proof of mechanism is tested at multiple significance level 0.05 in a Bonferroni-Holm procedure for sixteen endpoints of the nine variables of formal process evaluation (proximal endpoints describing changes in care).* For the process evaluation, we have added information on the points you raise. Revision: *Qualitative methods of data collection are guideline-based semi-structured interviews, focus groups and observation or recording of practice supervision, conducted by trained members of the research team at the NH or via telephone (relatives). We will evaluate these data by qualitative content analysis (Kuckartz, 2012). Quantitative methods of data collection are questionnaires, which we will analyse using descriptive statistics. We will triangulate data at the analysis stage on the level of results using joint displays. They will then be evaluated in terms of recruitment, implementation, intervention and maintenance, and context factors (Grant et al., 2013). The process evaluation study design and procedures are outlined in Supplement 1.*
12.	Thank you for your contribution to person-centred safe care for people living in aged care facilities, otherwise known as their homes. I hope this feedback assists you.	Thank you, it definitely does!
	Reviewer 3	
13.	This is such a readable protocol. Really enjoyable to read. COVID-19 has really demonstrated the need for research such as this in nursing homes. I have attached my PDF with comments. There	Thank you!

	are not many comments. This is a very comprehensive, thoroughly described protocol. In Canada, anecdotally patients, staff and family caregivers are more satisfied in the nursing homes which have nurse practitioners. They know the patients and families so there is more trust, fewer unnecessary transfers to hospitals. Looking forward to seeing the final research report in print.	
14.	Strengths and Limitations section, "tensed staff capacities" - Is this staff shortages generally? Can you use more common language?	Thank you for this suggestion, we have amended this point. Revision: • *A potential limitation is the risk of early drop out of whole clusters (nursing homes) due to ~~tensed staff capacities~~ nursing staff shortages in the German elderly long-term care sector.*
15.	Strengths and limitations section: More readable perhaps: This pilot study will be exploratory in nature as we will rely on a small sample size.	Thank you, we are happy to use alternative phrasing. Revision: • *The pilot study will ~~have an exploratory character based~~ be exploratory in nature as we will rely on a small sample size.*
16.	Background and rationale: "These decisions are influenced…" Wow, In Canada it is often the family caregiver who asks for transfer to hospital because they don't feel that nursing home staff can manage the condition, pain etc.	The literature cited here describes pressure that can be exerted on nurses by relatives as a subfactor that challenges nurses' ability to advocate on behalf of the resident. Revision: *Inadequate access to multidisciplinary outpatient care, as well as poor communication with other decision-makers or families exerting pressure on nurses may also contribute to hospital admissions although in principle they might be avoidable. [3]*
17.	Background and rationale: "In the Expand-Care process… with a focus on residents' needs." Nicely explained. Very readable.	Thank you!
18.	Trial objectives: "With an economic analysis … resource utilisation" Comment: Yes!	Thank you!
19.	Interventions "…we will offer a 1,5 h workshop…" Style for BMJ journals should this be a period rather than a comma.	Thank you for spotting this. Revision: We corrected the number to *1.5 h workshop*.

VERSION 2 – REVIEW

REVIEWER	Amy-Louise Byrne Central Queensland University School of Nursing and Midwifery

REVIEW RETURNED	21-Jun-2023

GENERAL COMMENTS	Thank you for your very thoughtful responses. I wish you the best of luck with this study and will be interested to see your outcomes.