PEER REVIEW HISTORY

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

ARTICLE DETAILS

TITLE (PROVISIONAL)	Improving Quality and Safety in Nursing Homes and Home Care:
	The study protocol of a mixed methods research design to
	implement a leadership intervention
AUTHORS	Wiig, Siri; Ree, Eline; Johannessen, Terese; Strømme, Torunn; Storm, Marianne; Aase, Ingunn; Ullebust, Berit; Holen-Rabbersvik, Elisabeth; Hurup Thomsen, Line; Sandvik Pedersen, Anne; van de Bovenkamp, Hester; Bal, Roland; Aase, Karina

VERSION 1 – REVIEW

REVIEWER	Professor Gunnar Tschudi Bondevik, MD, PhD Department of global public health and primary care University of Bergen Bergen Norway & National centre for emergency primary health care Uni Research
	Bergen Norway
REVIEW RETURNED	22-Dec-2017

GENERAL COMMENTS	Manuscript BMJ Open-2017-020933
	Improving Quality and Safety in Nursing Homes and Home care: The study protocol of a mixed methods research design to implement a leadership intervention.
	This study protocol describes the SAFE-LEAD Primary Care project, which aims to develop and evaluate a research-based leadership guide for managers to increase quality and safety competence. The implications of this guide on knowledge, attitudes and practices will be investigated in an intervention study in four nursing homes and four home care services in Norway. Surveys, interviews, observations and document analyses will be done to evaluate the leadership intervention. A comparative study with nursing homes and home care services in the Netherlands will investigate the role of contextual factors.
	Abstract.
	The abstract gives a clear summary of the main study aim and planned methods.
	Strengths and limitations.

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	The authors describe the strengths, but should also have included some limitations.
	Introduction. This part is overall well written with relevant references. It gives useful information regarding today's knowledge about the research topic – and gaps that need to be investigated further. The reader is introduced to the quality and safety challenges, the role of management and context, and organizational issues.
	It might be somewhat confusing that the authors repeatedly refer to the term "primary care" in the protocol, while much of the description – for obvious reasons – is about nursing homes and home care services. However, primary care also includes several other services not being part of this study - like general practice, emergency out-of- hours service, child health clinics, school health services, and municipal psychiatric services.
	The authors could consider whether they – at least some places in the manuscript – should be more specific, using the terms "nursing homes" and "home care services" – rather than the broader "primary care". One example: On page 7, it is stated that all specific objectives – and several of the research questions - are related to the primary care setting, while the methodology part of the protocol clearly states that the aims and research questions refer to nursing homes and home care services only.
	Methodology. The study sample and the five work packages are presented clearly. The protocol gives a thorough description of the development of the guide, mapping tool, intervention, evaluation, tracer project, cross- country comparison and theory development. Some of the information is, however, very detailed - and the authors may consider whether the seven pages description of the phases/work packages could be somewhat shortened, without loosing essential information for the reader.
	The procedures for translation, adaptation and implementation of the QUASER Hospital Guide for use in the home care and nursing home settings are well described. However, the authors could use some more space describing possible challenges with adapting a tool that is originally developed for secondary care into these two primary care settings. It is also unclear whether the project will develop one adapted version, or whether two versions are needed – as the nursing home and home care settings are quite different.
	The guide will be tested in one nursing home and one home care service – are these two of the total eight services included in the main study? Will the guide be tested in the Netherlands? The web- based version will be "available for all Norwegian primary care institutionsafter completion of the project in 2021", does this include primary care institutions beyond nursing homes and home care services?
	The plans for dissemination are good with relevant and interesting tentative titles of the planned papers. However, the research group should consider rephrasing the titles including the term "primary care" to be more specific on nursing homes and home care services.
	Conclusion.

This is an important project of high scientific quality aiming to
improve quality and safety among groups of patients that are
particularly vulnerable. Participation of patients and next-of-kin
representatives throughout the project is a strength. It is appreciated
that the authors have submitted this study protocol, increasing
transparency – and thereby improving the quality of the study.

REVIEWER	Christine W. Hartmann
	Bedford VA Medical Center, Bedford, Massachusetts, USA
REVIEW RETURNED	03-Jan-2018

GENERAL COMMENTS	This is a well-written article about a protocol investigating an
	important topic. The only recommendation I have is to define all
	acronyms the first time they are used, e.g., SAFE-LEAD, QUASER,
	EU FP7, etc.

VERSION 1 – AUTHOR RESPONSE

Response letter Manuscript ID bmjopen-2017-020933

Title:

"Improving Quality and Safety in Nursing Homes and Home Care: The study protocol of a mixed methods research design to implement a leadership intervention"

Authors responses to the editor' and reviewers' comments:

The authors would like to thank the reviewers for their valuable comments. We have corrected the manuscript and believe that the comments have contributed to an improved version of the SAFE - LEAD study protocol.

Below we summarize the reviewer comments that needed a response from authors. The authors' responses shows after the comments below, and in track changes in the revised manuscript.

Editor comment: Comment: The Strengths and Limitations section should include at least one limitation of the study/study design.

AUTHORS: Thanks for spotting this. We agree and have included two study limitations.

REVIEWER 1 Gunnar Tschudi Bondevik

Comment:

It might be somewhat confusing that the authors repeatedly refer to the term "primary care" in the protocol, while much of the description – for obvious reasons – is about nursing homes and home care services. However, primary care also includes several other services not being part of this study - like general practice, emergency out-of-hours service, child health clinics, school health services, and municipal psychiatric services.

The authors could consider whether they – at least some places in the manuscript – should be more specific, using the terms "nursing homes" and "home care services" – rather than the broader "primary care". One example: On page 7, it is stated that all specific objectives – and several of the research questions - are related to the primary care setting, while the methodology part of the protocol clearly states that the aims and research questions refer to nursing homes and home care services only.

AUTHORS: We agree and have changed "primary care" to "nursing homes and home care" throughout almost the entire document.

Comment:

The study sample and the five work packages are presented clearly. The protocol gives a thorough description of the development of the guide, mapping tool, intervention, evaluation, tracer project, cross-country comparison and theory development. Some of the information is, however, very detailed - and the authors may consider whether the seven pages description of the phases/work packages could be somewhat shortened, without loosing essential information for the reader.

AUTHORS: We have considered this carefully, but chose to keep the details. This is a large research project and the only place where we can give so much detailed information about the methods, is in a study protocol. This enables transparency throughout the project, and later others can replicate our process and/or assess the changes we potentially have to do at later stages of the project. Therefor we would like to keep the length. We believe we will lose essential information if we reduce this description in the manuscript.

Comment:

The procedures for translation, adaptation and implementation of the QUASER Hospital Guide for use in the home care and nursing home settings are well described. However, the authors could use some more space describing possible challenges with adapting a tool that is originally developed for secondary care into these two primary care settings. It is also unclear whether the project will develop one adapted version, or whether two versions are needed – as the nursing home and home care settings are quite different.

AUTHORS: Thanks for this comment. We have included reflections on possible challenges and stated that it is only one guide, similar for both settings.

Comment:

The guide will be tested in one nursing home and one home care service – are these two of the total eight services included in the main study? Will the guide be tested in the Netherlands? The web-based version will be "available for all Norwegian primary care institutions...after completion of the project in 2021", does this include primary care institutions beyond nursing homes and home care services?

AUTHORS: Thanks for these questions. We have included information about these issues in the manuscript. The two pilot institutions are not part of the sample of eight in the full intervention. The guide is not tested in a similar version in the Netherlands. The guide (paper and web-version) will be publicly available after the project (for all who may find it relevant).

Comment:

The plans for dissemination are good with relevant and interesting tentative titles of the planned papers. However, the research group should consider rephrasing the titles including the term "primary care" to be more specific on nursing homes and home care services.

AUTHORS: We agree and have changed this in the dissemination plan.

REVIEWER 2 Christine W. Hartmann Comment:

This is a well-written article about a protocol investigating an important topic. The only recommendation I have is to define all acronyms the first time they are used, e.g., SAFE-LEAD, QUASER, EU FP7, etc.

AUTHORS: We agree and have defined all acronyms the first time they are used.

VERSION 2 – REVIEW

REVIEWER	Professor Gunnar Tschudi Bondevik Department of global public health and primary care, University of Bergen, Bergen, Norway & National centre for emergency primary health care, Uni Research, Bergen, Norway
REVIEW RETURNED	10-Feb-2018
GENERAL COMMENTS	The authors have addressed the concerns in the first review - and have made relevant changes in the revised manuscript. A (very) minor comment: On page 3, last parapragh, the authors may consider whether it is sufficient to refer only once to (4) in the last sentence.