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) | Last Year of Life Study-Cologne (LYOL-C) (Part II): Study protocol of a prospective interventional mixed-methods study in acute hospitals to analyse the implementation of a trigger question and patient question prompt sheets to optimise patient-centred care |
|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| AUTHORS             | Strupp, Julia; Kasdorf, Alina; Dust, Gloria; Hower, Kira; Seibert, Melissa; Werner, Belinda; Kuntz, Ludwig; Schulz-Nieswandt, Frank; Meyer, Ingo; Pfaff, Holger; Hellmich, Martin; Voltz, Raymond |

VERSION 1 – REVIEW

| REVIEWER            | Donkor, Andrew  
University of Technology Sydney Faculty of Health, IMPACCT (Improving Palliative, Aged and Chronic Care through Clinical Research and Translation) |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------|
| REVIEW RETURNED     | 15-Mar-2021 |

GENERAL COMMENTS

The article is a protocol to: develop patient QPS and tailor the SQ and SPICT-DETM (Phase I); and test the perceived benefits of, and possible barriers to, integrating our two-sided intervention in hospitals in Germany (Phase II). The study is a great addition to the literature on palliative care. However, the authors should consider the following major and minor suggestions:

Major
• Title: The title of the manuscript is cumbersome and difficult to digest. Please consider a brief enough title (at least 25 words maximum)

Abstract: Please remove all references in the abstract section (see line number 8). Clearly state the aim of the study. The aim in the abstract should align (same) with the aim in the main article.

Interview
• What sampling technique will be used to select participants for the interview
• How will you approach participants?
• How many participants will be interviewed? What are the exclusion criteria?
• Please provide details about the data collection, including: interview guides; recording; field notes; duration; and transcripts return
• Qualitative data analysis: Please describe how you will analyse the qualitative data (step-by-step details). It is not enough stating ‘Miles and Huberman’. Provide details about codes, software and participant checking

Pre- and Post-intervention
• It is unclear the type of intervention that will be provided to healthcare professionals, patients and relatives. Please describe
the intervention – Description of intervention (separate section).
Provide the components of the intervention. Indicate the duration of the workshop as well as number of workshop(s) organised
• What recruitment technique (random or purposive) will you use to select patients and their relatives?
Minor
• Provide reference (line numbers 39 – 43)
• Why the section ‘Rationale’? Please merge the ‘Introduction’ and ‘Rationale’, unless it is the journal’s style.
• Change ‘Objective’ to ‘Aim’ (line number 41). Please maintain consistency throughout the article.
• Please change ‘Trial Design’ to ‘Study Design’. It gives a wrong expectation (throughout the article). You keep interchanging trial, study and project.
• Please limit the use of non-standard abbreviations
• The level of English is good. But the manuscript will benefit from using professional proofreading and editing

REVIEWER
Bayly, Joanne
King’s College London, Cicely Saunders Institute for Palliative Care, Policy and Rehabilitation

REVIEW RETURNED
06-Apr-2021

GENERAL COMMENTS
I look forward to seeing how this study progresses.
The protocol is thorough and the PPI involvement is to be commended. The involvement of the consortium will support trial conduct and dissemination of the findings. You have well-developed pathways to impact.

I recommend the following minor amendments to the protocol paper:
1. You provide much fuller detail on your quantitative analysis than the qualitative analysis. I would prefer to see more detail on how you expect to use Miles and Huberman to analyse the qualitative data.
2. It would help the readers not familiar with the SPICT criteria if you provide more details on how the criteria are met to ensure eligibility.
3. Has the trial been registered?

VERSION 1 – AUTHOR RESPONSE

Response to reviewer

We appreciate the reviewer’s constructive and valuable comments. We have addressed each of the reviewer’s concerns and questions in the following response letter and have revised the manuscript carefully and think that the manuscript has benefitted greatly from the subsequent changes. More detailed responses to each comment are given below.

Reviewer: 1
Mr. Andrew Donkor, University of Technology Sydney Faculty of Health, Korle Bu Teaching Hospital

Comments to the Author:
The article is a protocol to: develop patient QPS and tailor the SQ and SPICT-DETM (Phase I); and test the perceived benefits of, and possible barriers to, integrating our two-sided intervention in hospitals in Germany (Phase II).
The study is a great addition to the literature on palliative care. However, the authors should consider the following major and minor suggestions:

Major
- Title: The title of the manuscript is cumbersome and difficult to digest. Please consider a brief enough title (at least 25 words maximum)

Thank you for your comment. We have changed the title of the manuscript as follows: "Last Year of Life Study Cologne (LYOL-C) (Part II): Study protocol of a prospective interventional mixed-methods study in acute hospitals to analyse the implementation of a trigger question and patient question prompt sheets to optimise patient-centred care". Please see the title page with highlighted changes.

- Abstract: Please remove all references in the abstract section (see line number 8). Clearly state the aim of the study. The aim in the abstract should align (same) with the aim in the main article.

We have removed all references in the abstract section and aligned the aim of the study in the abstract with the aim in the main article. Please see changes highlighted in the manuscript.

Interview
- What sampling technique will be used to select participants for the interview
- How will you approach participants?

The sample will include HCP and patient representatives involved in caring for people in their last year of life. They will be recruited via networks of practice partners and cold calling. Based on purposeful sampling, semi-structured face-to-face narrative interviews will be conducted.

- How many participants will be interviewed? What are the exclusion criteria?
In total, 10 interviews will be conducted. The exclusion of individuals from the interviews occurs when the inclusion criteria are not met and when there is no experience in caring for people in the last year of life.
- Please provide details about the data collection, including: interview guides; recording; field notes; duration; and transcripts return

The semi-structured qualitative interview guide revolves around three theme blocks:
- Block I: Experiences, attitudes and requirements concerning the identification and standardised care of people in the last year of life
- Block II: Presentation/discussion of the planned intervention
- Block III: Tailoring (for the development of the barrier-driven implementation strategy)

Each topic will be operationalised by core questions facilitating story-telling and narrative-generating subquestions. The interview guide will be flexibly adapted to the type of expert, the position or background, or the course of the conversation. The interviews will be conducted via video conference and will last about 60 minutes. In addition to the interviewee, two interviewers will be present. Interviews will be audiotaped, transcribed verbatim and anonymised by an external professional typist. Interviewees will provide written informed consent before the interviews.

Qualitative data analysis: Please describe how you will analyse the qualitative data (step-by-step details). It is not enough stating ‘Miles and Huberman’. Provide details about codes, software and participant checking

We are pleased to go into the details of the qualitative data material. All transcripts will be entered into MAXQDA software (VERBI GmbH, Berlin, Germany). Qualitative content analysis will be chosen to explore the participants’ unique perspectives in order to extract on the descriptive level of content. The analysis of the interview content will be conducted independently by two researchers to ensure the validity of the data interpretation by minimising the subjectivity of data interpretation. A coding
frame will be developed by combining deductive and inductive approaches. Content-related codes will be constructed by descriptive coding/subcoding and provisional coding/subcoding. Codes for the intervention-related information will be constructed with an inductive approach. In order to identify and structure determinants for the implementation of the intervention, codes will be constructed based on a conceptional model for the implementation of patient-centred care interventions combined with dimensions of the Consolidated Framework for Implementation Research (CFIR). Transcripts of interview data were not returned to the participants.

Pre- and Post-intervention

- It is unclear the type of intervention that will be provided to healthcare professionals, patients and relatives. Please describe the intervention – Description of intervention (separate section).
- Provide the components of the intervention. Indicate the duration of the workshop as well as number of workshop(s) organised
- What recruitment technique (random or purposive) will you use to select patients and their relatives?

The project aims to test an intervention for general acute hospital units by using a two-sided (healthcare professionals (HCPs) and patients) intervention to “shake” the system in a minimally invasive manner. The intervention planned for use by HCPs consists of the Surprse Question (SQ) and the German version of the SPICT. The use of the SPICT is intended to be used whenever the HCP is unsure of the answer to the SQ.

During the modelling phase of the project, the formal (e.g., duration and number of workshops needed) and contextual aspects of the workshop will be discussed. Thus, in collaboration with experts, a flexible implementation concept will be designed to effectively accommodate the use of the intervention.

The intervention planned for use by patients and relatives consists of question prompt sheets (QPSs) to encourage patients to initiate discussions with their HCPs. As part of the intervention, patients identified using the SQ + SPICT will receive the QPSs from the HCP who participated in the workshop (see p. 6).

Minor

- Provide reference (line numbers 39 – 43)

Thank you for your comment. We are unsure exactly where we should provide the reference. Would you be so kind to tell us where exactly the reference is missing?

- Why the section ‘Rationale’? Please merge the ‘Introduction’ and ‘Rationale’, unless it is the journal’s style.

Thank you for your comment. We have merged both sections into one.

- Change ‘Objective’ to ‘Aim’ (line number 41). Please maintain consistency throughout the article.

We have deleted ‘Objective’.

- Please change ‘Trial Design’ to ‘Study Design’. It gives a wrong expectation (throughout the article). You keep interchanging trial, study and project.

We have changed the wording accordingly.

- Please limit the use of non-standard abbreviations
Thank you for your comment. We have limited some non-standard abbreviations. Please see changes to the manuscript.

• The level of English is good. But the manuscript will benefit from using professional proofreading and editing

Thank you for your comment. We engaged a professional proofreading agency and hope that the manuscript has been improved.

Reviewer: 2
Dr. Joanne Bayly, King's College London

Comments to the Author:
I look forward to seeing how this study progresses.
The protocol is thorough and the PPI involvement is to be commended. The involvement of the consortium will support trial conduct and dissemination of the findings. You have well-developed pathways to impact.

We appreciate the reviewer’s constructive and valuable comments. We have addressed each of the reviewer’s concerns and questions in the following response letter and have revised the manuscript carefully and think that the manuscript has benefitted greatly from the subsequent changes. More detailed responses to each comment are given below.

I recommend the following minor amendments to the protocol paper:
1. You provide much fuller detail on your quantitative analysis than the qualitative analysis. I would prefer to see more detail on how you expect to use Miles and Huberman to analyse the qualitative data.

Thank you for pointing this out. In the revised version of the manuscript, we have provided further details on the qualitative interviews.

2. It would help the readers not familiar with the SPICT criteria if you provide more details on how the criteria are met to ensure eligibility.

SPICT-DETM is a helpful and practical tool to support the identification of patients who might benefit from palliative care. Patients will be defined as SPICT-positive if they meet two or more clinical indicators (see p. 5).

3. Has the trial been registered?

The study is registered in the German Clinical Study Register (DRKS00022378, Date of Registration: 14 December 2020).

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VERSION 2 – REVIEW

| REVIEWER                  | Donkor, Andrew                      |
|---------------------------|-------------------------------------|
|                           | University of Technology Sydney Faculty of Health, IMPACCT (Improving Palliative, Aged and Chronic Care through Clinical Research and Translation) |
| REVIEW RETURNED           | 14-Jun-2021                         |
On page 11, lines 3 and 8 you state that the outcome measures will be 'similar' to the control group. If they are not identical, how do they differ? Is it just that the intervention group get asked about the QPS, but otherwise identical?

Thank you for your question. Yes, measures will be completely identical to the control group plus including items about the QPS. Participants of the intervention group will be asked about their experiences when using the QPS. We have adapted the main text accordingly. Please see highlighted changes to the manuscript.