PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Improvement of transitional care from hospital to home for older patients - The TIGER-study: protocol of a randomized controlled trial
AUTHORS	Rimmele, Martina; Wirth, Jenny; Britting, Sabine; Gehr, Thomas; Hermann, Margit; van den Heuvel, Dirk; Kestler, Andreas; Koch, Thomas; Schoeffski, Oliver; Volkert, Dorothee; Wingenfeld, Klaus; Wurm, Susanne; Freiberger, Ellen; Sieber, Cornel

VERSION 1 – REVIEW

REVIEWER	Supreeda Monkong Ramathibodi School of Nursing, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand
REVIEW RETURNED	06-Apr-2020

GENERAL COMMENTS	1. The outcomes were needed to clarify related to comprehensive geriatric assessments since in the hospitals and at home. 2. There are 66 references. Please review and choose the significant references related to the study.

REVIEWER	Jacqui Allen School of Nursing and Midwifery, Monash University, Australia
REVIEW RETURNED	14-Apr-2020

GENERAL COMMENTS	Thank you for the opportunity to review the manuscript bmjopen-2020-037999 'Implementation of a transitional care model in a German hospital setting to improve transition from hospital to home for older patients-the TIGER study: protocol of a randomized controlled trial.' Study protocols are important to improve transparency of research processes, reduce duplication and enhance collaboration. Improving transitional care of older adults from inpatient to home settings is important for quality health care and efficient health services. Transitional care has been a long-standing research and practice improvement focus in English speaking countries for over 30 years. Based in this research, in particular the work of Mary Naylor and her team, and also Eric Coleman and his colleagues, we know what works in improving transitional care: advanced practice nurse roles across transitions, self-management focus, multi-disciplinary teams, and the emergent service navigator roles. From a practice perspective, difficulty persists in implementation of quality safe care transitions due to the high fragmentation of services in health and aged care across the care continuum. The authors note limited research in Germany as the rationale for their study. I would encourage consideration of other reasons for this

	research in order to be of interest to an international audience and contribute new knowledge in this field. Considering my comments above, clearer and more detailed presentation of health and aged care service contexts in Germany would be of interest to an international readership. This requires attention within the protocol manuscript in both the introduction/background and also in the description of the study methods. I appreciate that the authors do not speak English as a first language, and I congratulate their efforts in presenting this manuscript. The paper would benefit from consultation with an academic experienced in writing at publication standard in English with attention to a more succinct manuscript, no colloquial English, avoidance of 'etc', and consistent use of terminology. At this point the manuscript reads like a study protocol written in a list like manner as opposed to a clear and succinctly written journal article. The title of the manuscript is long and confusing. This is not a study investigating implementation issues and I am unclear why 'implementation' is in the title? Abstract: Should be written more succinctly. What is meant by 'monocentric'? This is also noted in other areas in the manuscript. The phrase 'so-called pathfinders' is noted and also in other areas in the manuscript? This is awkward English and requires revision. What is the study intervention? How is it being investigated? Clear reporting is required. The phrase 'uninterrupted' care is used (and in other parts of the manuscript). Do the authors mean continuous care? The ethics and dissemination section is not required in the abstract. Strengths and limitations of the study: Dot points 2, 3, 4 state what we already know about transitional care. These are not strengths of the study. How are the challenges to recruitment (which are not at all explained in the manuscript) a study limitation? This is common in research. This section requires clarification. Introduction: This section is long and not well presented. It contains what is already well known in transitional care research. There is material presented about health services in Germany and then about the United States with no linking statements. A clearly structured narrative is required to establish the rationale for the study and for this manuscript re the study protocol. Is there something particular to the German health services context that might add important information re the rationale for this study? Outpatient setting seems to be used as meaning home setting? The phrase 'stop at the front door' is used and does not make sense. Please avoid colloquial English in a manuscript. 'Children' are included but I understood that the paper was about care of older adults? What is meant by a 'structured program of activities'? This is unclear. Naylor's Transitional Care Model is a model of advanced practice nursing care for an older adult with complex chronic disease across the inpatient to home continuum. This is much more detailed and skilled than 'a program of activities' suggests because it includes complex nursing clinical decision making. How does Naylor's model influence the proposed intervention in this study? The term 'pathfinders' is introduced but not clearly explained. In the introduction, the pathfinder is presented as a registered nurse yet later in the manuscript the

	reader is informed that pathfinders are also occupational therapists. Please take care to clearly explain the the intervention and please be consistent in reporting. Where is the justification for the outcome measures? There are difficulties in solely focussing on readmission rates in a population of older adults living with chronic disease. We would expect them to continue to be high users of inpatient services and many studies find no difference on this outcome measure following transitional care interventions (see Cochrane reviews). This requires some consideration by the authors here and also in later sections of the manuscript. Objectives: This section is unclear and is not written in a scientific manner. What is the link between the study outcomes and implementation into the health system? This claim is not supported in the manuscript at this point – or have I misunderstood? The term 'stabilise' the patient at home is used. This is unclear. Methods: This section should be written more clearly using expected headings and sub headings. The dates of data collection should be written in the body of the manuscript. What is the study setting – detail should be presented here. What is 'usual care'? This is noted but not explained. Recruitment processes are not presented in enough detail. How is the randomisation fidelity optimised in busy ward environments? A clear description of the intervention is required. What happens when pathfinders are not available on the weekends? What is meant by 'the pathfinders do not provide active care services themselves'? This does not make sense as they are a part of the care service. More detail is required re the pathfinder role and the educational preparation of the practitioners – nurses and occupational therapists? Why are both disciplines included In the pathfinder role. Tables and figures are referred to in text. These are not always clearly labelled in the attachments at the end of the manuscript. All tables and figures should be written more succinctly as appropriate for a journal article. Material is gender specific in areas as for example in Table 2 where the pronoun 'his' is used on a number of occasions. Are only males a part of the study? This is not clarified. The statistical methods are not reported in some detail as would be expected in a trial testing hypotheses. This requires attention. Ethics and dissemination: Reporting of ethics approval is generally considered adequate. Discussion: This section contains repetition and is not a discussion of the methods to be employed in the study. There is comment re recruitment difficulties, yet this is not presented in the methods. I suggest restructuring the manuscript and presenting some early results from the study such as results of recruitment. If this was challenging, what was done to increase recruitment? This would be of interest to other researchers. A conclusion is required re the significance of the manuscript.

REVIEWER	Marc Saez University of Girona, Spain
REVIEW RETURNED	03-May-2020

GENERAL COMMENTS	The authors attempted to evaluate a trial that sought the improvement of geriatric care at the transition from hospital to home reflected by a reduction of the all-cause readmission rate within a follow-up of up to 12 months after hospital discharge (primary outcome). Although the authors have been quite successful in achieving their objective, I have a few minor comments. Minor comments 1.- In the 'Statistical Methos' section, the authors do not indicate which variables they consider confounding in the logistic regression. Authors should explain in detail the model specification. 2.- The authors also do not explain whether they considered the existence of any interaction in the logistic regression. They should explain it in some detail.

REVIEWER	Martine Puts University of Toronto Toronto, ON, Canada
REVIEW RETURNED	03-May-2020

GENERAL COMMENTS	Review Thank you for giving me the opportunity to review. Next time please do the reviewers a favor and double-space the manuscript, it makes reading so much easier. Why trial only in 1 centre please clarify? How will you prevent contamination between the groups if you expect the same care in hospital providers to do usual care Please clarify why depending on time of enrollment the length of intervention is 12, 9, or 6 months? What is the rationale for that? How will you take that into account in the analyses section? How was this taken into account in the sample size calculation? General physicians= better to use family physicians I think the wording of the primary objective can be better formulated , please reformulate Table 1 is too large, it cuts off; please check that all is readable In table 1 Minimental State Examination should be Mini-Mental In Table 1 social and social law situation, please clarify what social law situation means In Table 1 why CGA at discharge why not at admission? Table 1 what is NBA? Inclusion criteria: why does the MMSE have to be 22 and over? One could argue that probably those with dementia are the ones who experience the most gaps in continuity of care and are at highest risk of readmission? Please clarify what palliative care situation means as it means different things in different countries, is there a way you can say for example estimated life expectancy<6 months or something? All patients admitted between April 2018 and December 2019 are scanned by this tool

	Table 2 typo it should be registered nurses In the outcome section please add your tools there as well how these outcomes will be measured The statistical analyses section is lacking details, please add the detailed analyses plan. Please clarify while the hospital REB approved the study did the participants also provide written informed consent?

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1
Reviewer Name
Supreeda Monkong

Institution and Country
Ramathibodi School of Nursing, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand

Please state any competing interests or state ‘None declared’:
None

Please leave your comments for the authors below
1. The outcomes were needed to clarify related to comprehensive geriatric assessments since in the hospitals and at home.

Response: We have included a sentence in the Outcomes section now pointing to the time points of the geriatric assessments as being depicted in Table 1.
Additionally, we have included in the section “Assessments in both groups” (page 13 in the doublespaced "Main document") now:

"Assessments in both groups
All study participants receive regular standardized assessments at visits T0 to T4 using validated instruments (see Table 1) to assess health and care degree, functionality and mobility, nutritional status, geriatric and cognitive situation, and domestic care situation. Since a comprehensive geriatric assessment is not mandatory at hospital admission of an older patient in all wards, it is administered in the TIGER study directly at recruitment and up to four times after discharge (depending on IG / CG and duration of participation: 6-12 months)."

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2. There are 66 references. Please review and choose the significant references related to the study.
Response: Thank you for drawing our attention to this point. We omitted several references now, but kept most of the references to make sure to cite according to good scientific practice.

Reviewer: 2
Reviewer Name
Jacqui Allen

Institution and Country

School of Nursing and Midwifery, Monash University, Australia

Please state any competing interests or state ‘None declared’:
Nil

Please leave your comments for the authors below
Thank you for the opportunity to review the manuscript bmjopen-2020-037999 ‘Implementation of a transitional care model in a German hospital setting to improve transition from hospital to home for older patients-the TIGER study: protocol of a randomized controlled trial.’ Study protocols are important to improve transparency of research processes, reduce duplication and enhance collaboration.

Improving transitional care of older adults from inpatient to home settings is important for quality health care and efficient health services. Transitional care has been a long-standing research and practice improvement focus in English speaking countries for over 30 years. Based in this research, in particular the work of Mary Naylor and her team, and also Eric Coleman and his colleagues, we know what works in improving transitional care: advanced practice nurse roles across transitions, self-management focus, multi-disciplinary teams, and the emergent service navigator roles. From a practice perspective, difficulty persists in implementation of quality safe care transitions due to the high fragmentation of services in health and aged care across the care continuum. The authors note limited research in Germany as the rationale for their study. I would encourage consideration of other reasons for this research in order to be of interest to an international audience and contribute new knowledge in this field.

Response: Thank you very much for bringing up this issue. In Germany, the health system is also quite fragmented. In addition, the fragments are incorporated in rigid structures with their own legal regulations and reimbursement options.
We have tried to reformulate and add the relevant arguments in this respect (and also in respect to the following comment) in the introduction now and have revised the introduction. We have also added other reasons for the importance of our research. Please see the Introduction section on page 4-5 in the doublespaced "Main document".
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Considering my comments above, clearer and more detailed presentation of health and aged care service contexts in Germany would be of interest to an international readership. This requires attention within the protocol manuscript in both the introduction/background and also in the description of the study methods.
Response: We have added several arguments in the introduction now, addressing this issue. Furthermore, we now explain that academically educated advance-practice nurses have not yet been available in Germany. The registered nurses in Germany have multiple training routes. We explain this differently now in various chapters.
Please see the Introduction section (page 4-5 in the doublespaced "Main document")
We explain this also in Methods sub-section "Study staff and training" (page 9 in the doublespaced "Main document"):
"Study staff and training
Academically educated advanced nurse practitioners are not available yet in Germany. The study is thus performed by geriatric-experienced care professionals, consisting of a registered nurse, a case manager, a head nurse and an occupational therapist, to combine multiple expertises when addressing the broad spectrum of care need aspects, such as care quality, mobility, nutrition. The care professionals of the TIGER project are exclusively responsible for TIGER participants. They are supported by the study physician. The staff is divided into pathfinders supporting the intervention group participants, and study nurses assessing the control group participants (see also Table 1). ”

I appreciate that the authors do not speak English as a first language, and I congratulate their efforts in presenting this manuscript. The paper would benefit from consultation with an academic experienced in writing at publication standard in English with attention to a more succinct manuscript, no colloquial English, avoidance of 'etc', and consistent use of terminology. At this point the manuscript reads like a study protocol written in a list like manner as opposed to a clear and succinctly written journal article.
Response: Thank you very much, we have consulted another academic experienced in writing in English now and hopefully could improve the manuscript also in this respect.

The title of the manuscript is long and confusing. This is not a study investigating implementation issues and I am unclear why 'implementation' is in the title?
Response: Thank you for this advice. We changed the title and agree that it is more precise now. The title reads now:
"Improvement of transitional care from hospital to home for older patients - The TIGER-study: protocol of a randomized controlled trial"

Abstract: Should be written more succinctly. What is meant by 'monocentric'? This is also noted in other areas in the manuscript. The phrase 'so-called pathfinders' is noted and also in other areas in the manuscript? This is awkward English and requires revision. What is the study intervention? How is it being investigated? Clear reporting is required.

Response: Thank you for pointing this out. We have now tried to be more succinct and describe the intervention in the Abstract (Please see Abstract, page 1-2 in the doublespaced "Main document") more clearly. The meaning of the term 'pathfinder' is now introduced and explained in the introduction section (page 5 in the doublespaced "Main document").

The phrase 'uninterrupted' care is used (and in other parts of the manuscript). Do the authors mean continuous care?
Response: Thank you for commenting on this, we corrected this to continuous care at the respective parts throughout the manuscript.

The ethics and dissemination section is not required in the abstract.
Response: With due respect to the reviewer, we are unsure about how to address this comment, as in preparing the manuscript, we conformed to the regulations of BMJopen for protocols:
https://bmjopenrespres.bmj.com/pages/authors/#protocol
In these regulations, you will find for the abstract:
"This should be structured with the following sections. Introduction; Methods and analysis; Ethics and dissemination.
Registration details should be included as a final section, if appropriate."

Strengths and limitations of the study: Dot points 2, 3, 4 state what we already know about transitional care. These are not strengths of the study. How are the challenges to recruitment (which are not at all explained in the manuscript) a study limitation? This is common in research. This section requires clarification.

Response: Thank you for pointing this out to us. We have reformulated the strengths accordingly. Dot 4 is a limitation. We agree with the reviewer that the challenges to recruitment are not a specific limitation of this study and have introduced another limitation (dot 5) instead (page 3 in the doublespaced "Main document").
New dot 5:
"Patients with cognitive deficits might profit from our intervention; however, only individuals with a Mini-Mental Sate Examination Score of at least 22 points are included to ensure that participants are able to benefit from the Self-Management-approach of the TCM."

Introduction: This section is long and not well presented. It contains what is already well known in transitional care research. There is material presented about health services in Germany and then about the United States with no linking statements. A clearly structured narrative is required to establish the rationale for the study and for this manuscript re the study protocol. Is there something particular to the German health services context that might add important information re the rationale for this study?

Response: Thank you for bringing this important Point to our attention. We have introduced the issue of the different German and US health services, since this is improving the understanding of the rationale of the manuscript and study consirderably.
We have revised the introduction intensively to present the rationale transparently.
Please see page 4-5 in the doublespaced "Main document".

Outpatient setting seems to be used as meaning home setting?
Response: Yes, thank you, we changed the wording accordingly.

The phrase ‘stop at the front door’ is used and does not make sense. Please avoid colloquial English in a manuscript.

Response: We removed this phrase and redrafted (page 4 in the doublespaced "Main document"):
“However, hospital discharge planning is not sufficient to guarantee the patients’ re-adaptation and well-being at home after hospital-discharge.”

‘Children’ are included but I understood that the paper was about care of older adults?
Response: We only mentioned children as (another) example in the context of vulnerable groups. As this is obviously misleading, we omitted this phrase and wrote (please see page 5 in the doublespaced "Main document", in the Introduction section):
“Applying transitional care programs aiming at patients with high risk for poor outcomes and readmissions, such as older people with multimorbidities and complex chronic diseases can reduce preventable readmissions by up to 75 %.”

What is meant by a ‘structured program of activities’? This is unclear. Naylor’s Transitional Care Model is a model of advanced practice nursing care for an older adult with complex chronic disease across the inpatient to home continuum. This is much more detailed and skilled than ‘a program of activities’ suggests because it includes complex nursing clinical decision making. How does Naylor’s model influence the proposed intervention in this study?

Response: Thank you for pointing this ambiguous phrasing out to us. We had no intention to diminish the complex advanced practice nursing clinical decision making of TCM interventions when using the

wording structured program of activities. Our study is based on the modules of Naylor's TCM and we apply all of them and as thorough as possible in our German hospital and ambulant care system when introducing the care professionals bridging function in the different care settings.
We explained this differently now in the text, please see the "Intervention group"-section (page 10-11 in the doublespaced "Main document") and Table 2 (page 11-12 in the doublespaced "Main document", in Assessing/Managing Risks and Symptoms).

"Intervention group
For the intervention group (IG), the pathfinders' activities are based on the TCM.24 The authors described nine distinct but interdependent components in their program, which may be combined both pre- and post-discharge to achieve the best results for the participants. The TIGER intervention is based on all nine components of the TCM (see Table 2). For the German hospital and home-setting of this study, however, the modules needed some adaptation due to German health care settings, work law, and local requirements, as described in Table 2.
[…]
" The pathfinders' work is supported by a standardized questionnaire instrument based on the "Neues BegutachtungsAssessment", an assessment to determine eligibility for benefits from the long-term care insurance in Germany, 31 to identify individual care needs out of a broad range of possible care needs as well as to document and evaluate the needed or already initialized measures (for details on the spectrum of specified care needs see Table 2).
An individual care plan is developed for each of the IG participants according to their symptoms, risks, needs, and values. All care activities for the IG participants are initiated by the pathfinder for and within the care team (see Table 2, Collaborating, including the family physician). The pathfinder coordinates, monitors, evaluates, adapts if necessary, and documents the execution of the activities, and the participants' adherence.
In developing the care plan, the pathfinders do not provide active care services themselves (e.g., physiotherapy, drug application), but coordinate their execution by contacting ambulant services for the required service activities. For the project, it was essential to ensure that the pathfinders would not compromise the operational tasks of the usual ambulant services to be able to build a trusting relationship with these services. Participants and their caregivers are actively engaged in the care planning process. Progressively during the course of the intervention, self-management is promoted."

Table 2, Assessing/Managing Risks and Symptoms
"- Assessing, identifying, and managing risks and symptoms according to individual health status and situation is performed intensively, starting in the hospital and integrating the information of the hospital. The pathfinders_ assessment is supported by a standardized questionnaire instrument based on the "Neues BegutachtungsAssessment), an assessment to determine eligibility for benefits from the long-term care insurance in Germany, 31 to identify individual care needs as well as to document and evaluate the needed or already initialized measures. The instrument assesses the participant's care situation, care supply, and quality by examining the participant's living situation, mobility and falls, cognition, psychological situation, nutrition, self-support, medication, daily activities, housekeeping, vision and hearing capacities, continence, pain score, wound management, health and disease knowledgeability of participant and caregiver and caregiver burden. For each topic, the pathfinder evaluates whether or not there is a need for change, which measures would provide a remedy or whether or not already taken measures have helped to solve the problem or which amendments are needed. This instrument is applied at the first home visit and at visits T1, T2, T3, and T4."

The term 'pathfinders' is introduced but not clearly explained. In the introduction, the pathfinder is presented as a registered nurse yet later in the manuscript the reader is informed that pathfinders are

also occupational therapists. Please take care to clearly explain the the intervention and please be consistent in reporting.

Response: Thank you for showing us the need to be more precise here. We now speak of ‘geriatric-experienced care professionals’ and explain which professions this includes in the methods section, in the "Study staff and Training" – section (page 9 in the doublespaced “Main document”):

"Study staff and training
Academically educated advanced nurse practitioners are not available yet in Germany. The study is thus performed by geriatric-experienced care professionals, consisting of a registered nurse, a case manager, a head nurse and an occupational therapist, to combine multiple expertises when addressing the broad spectrum of care need aspects, such as care quality, mobility, nutrition. The care professionals of the TIGER project are exclusively responsible for TIGER participants. They are supported by the study physician. The staff is divided into pathfinders supporting the intervention group participants, and study nurses assessing the control group participants (see also Table 1)."

Where is the justification for the outcome measures? There are difficulties in solely focussing on readmission rates in a population of older adults living with chronic disease. We would expect them to continue to be high users of inpatient services and many studies find no difference on this outcome measure following transitional care interventions (see Cochrane reviews). This requires some consideration by the authors here and also in later sections of the manuscript.

Response: Thank you for bringing up this issue. We added the justification in the Outcomes section and also added a sentence in the discussion (page 10) considering your point:
Outcomes section (page 14 in the doublespaced "Main document"):
“The primary outcome is the readmission rate, since application of TCM in the US has been shown to reduce readmission rate as a major negative outcome for geriatric patients leaving the hospital.27 29 Readmission rate is defined as the proportion of patients who have at least one unplanned readmission into any hospital (not rehabilitation clinic) within a follow-up of up to 12 months after hospital discharge, using anonymized data of the health insurance fund AOK Bavaria.”
Discussion (page 19 in the doublespaced "Main document"):
"The detailed analysis of assessments of mobility and functionality, nutrition, geriatric issues, and wound situation of the TIGER study will shed light on the most needed areas of intervention for this vulnerable patient group, even if the readmission rates of this patient group ≥ 75 years of age with chronic disease might not be reduced as much by the intervention as anticipated.”

Additional information to the reviewer, not integrated in the manuscript: Furthermore, the funding association of this study needs the readmission rate as a hard outcome for later decisions on a possible inclusion of a TCM-concept into Germany’s public health care system. Due to the word count, we did not include this argument in the study protocol.

Objectives: This section is unclear and is not written in a scientific manner. What is the link between the study outcomes and implementation into the health system? This claim is not supported in the manuscript at this point – or have I misunderstood? The term ‘stabilise’ the patient at home is used. This is unclear.

Response: We have rewritten this section (please see page 6 in the doublespaced "Main document", "Objectives") and hope that it is more precise now and that the link between the study evaluation and a possible implementation into the health care system are explained better now.

The term ‘stabilise the patient at home’ has been reformulated.

Methods: This section should be written more clearly using expected headings and sub headings.
Response: We thank the reviewer for this important comment and structured the Methods section now into sub-headings (please see pages 6-16- in the doublespaced "Main document").

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The dates of data collection should be written in the body of the manuscript.

Response: For better understanding, we have added the dates now (page 15 Methods, sub-section ‘Data collection and monitoring methods’, in the doublespaced "Main document":
"The recruitment period started with the First-patient-in on April 25th, 2018 and ended on December 31st, 2019. The pathfinders, study nurses, and partly the study physician and / or participants’ family physicians collect the assessment and questionnaire data on paper forms at visits T0, T1, T2, T3 and T4, respectively for each participant (see Table 1) and before data entry into the eCRF."

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What is the study setting – detail should be presented here. What is ‘usual care’? This is noted but not explained.
Response: We included more details in the methods section now regarding the study setting (page 6 in the doublespaced “Main document”), and regarding usual care as applied in the control group (page 13 in the doublespaced “Main document”):
“Control group
The control group (CG) receives usual hospital discharge planning by hospital staff not related to the TIGER study and usual ambulatory care after discharge. Usual discharge planning involves the first initiation of procurement of therapeutic adjuvants or appliances after hospital discharge, taking the hospital information, and if possible, a conversation with the patient and a caregiver into account. Medication for the first few days after discharge is supplied. No verifications of the arrangements at home are possible; the family physician of the patient is not contacted. No measures are initiated associated with the TIGER study.
The CG is assessed (see section ‘Assessments in both groups’) by the TIGER study nurses at the beginning (T0), after three months (T2) and at the end of the study (T4). It fills out the standardized questionnaires for participants also at T1 (after one month) and T3 (after six months) (see Table 1).“

Recruitment processes are not presented in enough detail. How is the randomisation fidelity optimised in busy ward environments?
Response: We added more detail now in the Recruitment and Randomization section (page 8-9 in the doublespaced "Main document", sub-headings “Recruitment process” and “Randomization”) and hope, this answers the reviewer’s question:
"Recruitment process
A TIGER-specific IT tool supported screening for potential participants according to the eligibility crite-ria age, health insurance, and residence within a 50 km radius electronically in all wards via the pa-tient management system of BBR. All patients admitted between April 2018 and December 2019 were scanned by this tool. Potential participants identified by this tool were visited in person by TIGER staff who assessed all other eligibility criteria and informed about the project. Patients in BBR fulfilling all eligibility criteria and present caregivers were then provided with the participant information bro-chure and informed consent forms. Patients were given at least one day to read the provided infor-mation and informed consent forms and receive further information on the project. After signing and dating the informed consent forms, the MMSE36 was performed as a last inclusion criterion for re-cruitment.

Randomization
Stratified block randomization was performed with the following three strata: (1) gender (male / female), mobility (can walk at least four stair steps – yes / no),54 (3) living condition (lives alone – yes / no). These strata were chosen because of their potential to influence the overall need for care and study outcomes.
The randomization blocks varied between 2, 4, and 6 to guarantee a minimum of predictability for the randomization. When receiving a recruitment number for a newly recruited participant in the electronic data acquisition and case report form (eCRF)-System (secuTrial®), the stratification questions had to be answered, the inclusion criteria affirmed and the exclusion criteria denied in the eCRF file. Then the randomization into intervention or control group was performed automatically by the eCRF-System."

A clear description of the intervention is required. What happens when pathfinders are not available on the weekends? What is meant by 'the pathfinders do not provide active care services themselves'? This does not make sense as they are a part of the care service.
Response: Thank you for this advice! We explained the intervention in more detail now (page 10-11 in the doublespaced "Main document", explained the pathfinder's working-instrument and explained why the pathfinders do not provide active care service themselves, as well as what happens when pathfinders are not available on weekends (explained in Table 2 page 11-12 in the doublespaced "Main document"):

"For the intervention group (IG), the pathfinders' activities are based on the TCM.26 The authors described nine distinct but interdependent components in their program, which may be combined both pre- and post-discharge in order to achieve the best results for the patients. The TIGER intervention is based on all nine components of the TCM (see Table 2). For the German hospital and home-setting of this study, however, the modules needed some adaptation due to German health care settings, work law, and local requirements, as described in Table 2.
IG patients and their caregivers are accompanied by the pathfinders in the process of hospital discharge, during transition from hospital to home and for a minimum of six up to 12 months after discharge (see Figure 1). The family physicians of the IG patients are invited to actively take part in the study by the TIGER consortium partner Regensburger Aerztenetz, a network of family physicians in Regensburg, but this is no inclusion criterion. The IG patients are visited by the pathfinders and contacted by telephone. The individual care plan is regularly evaluated in the home visits (at least 2x/month in the first month after discharge, at least 1x/month in the second and third month after discharge) and telephone calls (at least 2x in the first month after discharge and at least 1x/ month in all following months until the end of study visit.
The pathfinders' work is supported by a standardized questionnaire instrument based on the "Neues BegutachtungsAssessment", an assessment to determine eligibility for benefits from the long-term care insurance in Germany, 31 to identify individual care needs out of a broad range of possible care needs as well as to document and evaluate the needed or already initialized measures (for details on the spectrum of specified care needs see Table 2).
An individual care plan is developed for each IG participant according to their symptoms, risks, needs, and values. All care activities for the IG participants are initiated by the pathfinder for and within the care team (see Table 2, Collaborating, including the family physician). The pathfinder coordinates, monitors, evaluates, adapts if necessary, and documents the execution of the activities and the participants' adherence. In developing the care plan, the pathfinders do not provide active care services themselves (e.g., physiotherapy, drug application), but coordinate their execution by contacting ambulant services for the required service activities. For the project, it was essential to ensure that the pathfinders would not compromise the operational tasks of the usual ambulant services to be able to build a trusting relationship with these services. Participants and their

caregivers are actively engaged in the care planning process. Progressively during the course of the intervention, self-management is promoted."

In Table 2, we introduced in the Assessing/ Managing Risks and Symptoms:
"The instrument assesses the patient's care situation, care supply, and quality, by examining the patients living situation, mobility and falls, cognition, psychological situation, nutrition, self-support, medication, daily activities, housekeeping, vision and hearing capacities, continence, pain score, wound management, health and disease knowledgeability of patient and caregiver and caregiver burden. For each topic, the pathfinder evaluates whether or not there is a need for change, which measures would provide a remedy or whether or not already taken measures have helped to solve the problem or which amendments are needed. This instrument is applied at the first home visit and at visits T1, T2, T3, and T4."

In Table 2 (page 11-12 in the doublespaced "Main document"), we explained in the "Maintaining Relationships" – section, what happens when pathfinders are not available on weekends:

"According to German working hour acts, the pathfinders will be available from Monday to Friday, not seven days a week. The participants and their caregivers receive a telephone number of the pathfinder-office, so that they can call the pathfinders with any occurring questions or problems. On weekends, when the office is closed, participants and their caregivers are instructed in detail how to leave a message on the pathfinder's answering machine and to call the hospital's emergency department if immediate assistance is needed. On early Monday mornings, the pathfinders then contact every person who has left a message on the answering machine to trace back everything that occurred over the weekend."

More detail is required re the pathfinder role and the educational preparation of the practitioners – nurses and occupational therapists? Why are both disciplines included In the pathfinder role.
Response: We have addressed this issue now in the methods section, (oage 9 in the doublespaced "Main document", sub-heading "Study staff and Training") :
"Study staff and training
Academically educated advanced nurse practitioners are not available yet in Germany. The study is thus performed by geriatric-experienced care professionals, consisting of a registered nurse, a case manager, a head nurse, and an occupational therapists, to combine multiple expertises when addressing the broad spectrum of care need aspects, such as care quality, mobility, nutrition. The care professionals of the TIGER project are exclusively responsible for TIGER participants. They are supported by the study physician. The staff is divided into pathfinders supporting the intervention group participants, and study nurses assessing the control group participants (see also Table 1)."

Tables and figures are referred to in text. These are not always clearly labelled in the attachments at the end of the manuscript. All tables and figures should be written more succinctly as appropriate for a journal article.
Response: Thank you for pointing this out to us. We checked the labels of the figures at the end of the manuscript (page 20 in the doublespaced "Main document"). The tables are implemented with their labels in the text flow and we have focused the contents of the tables now to be more succinct (page 7 and pages 11-12 in the doublespaced "Main document").

Material is gender specific in areas as for example in Table 2 where the pronoun 'his' is used on a number of occasions. Are only males a part of the study? This is not clarified.

Response: Thank you for pointing this out. We had addressed this issue only in the randomization section. But we went through the text now, used his/her and have added the clarification also in the eligibility section (page 8 in the doublespaced "Main document"):
“Eligibility criteria
Male and female patients from all wards of BBR, aged 75 years or older, and being insured by the health insurance fund AOK Bavaria are eligible for this study.”

The statistical methods are not reported in some detail as would be expected in a trial testing hypotheses. This requires attention.
Response: We agree and have corrected this chapter accordingly on page 16 in the doublespaced "Main document":
"Statistical methods
The primary outcome hospital readmission rate will be evaluated by Fisher’s exact test. Possible interactions with housing situation, availability of caring relatives, and risk factors like care dependency or limitations in cognition will be analyzed by multiple regression for a better understanding of the intervention’s impact on the hospital readmission rate.
Secondary outcomes (e.g., quality of life, mobility) will be analyzed by t-test, Fisher-test, Mann-Whitney-test, or Chi-square-test, depending on distribution and number of cases.
The analysis of possible financial benefits of implementing a pathfinder will be carried out by t-test.
The main analyses will be performed using SPSS and R."

Ethics and dissemination: Reporting of ethics approval is generally considered adequate.
Response: We are not quite sure what the reviewer is referring to with this comment. If this was not an approval, we tried to address this in the following way (page 16 in the doublespaced "Main document", Ethics and dissemination, sub-section research ethics approval):
“Research ethics approval
The ethical committee of Friedrich-Alexander Universität Erlangen-Nürnberg approved the study on March 5th, 2018 (# 60-18 B) prior to first participant inclusion. The study will be conducted in accordance with the HELSINKI declaration.”

Discussion: This section contains repetition and is not a discussion of the methods to be employed in the study. There is comment re recruitment difficulties, yet this is not presented in the methods. I suggest restructuring the manuscript and presenting some early results from the study such as results of recruitment. If this was challenging, what was done to increase recruitment? This would be of interest to other researchers.
Response: We thank the reviewer for the constructive comment, and we have revised the discussion section (please see pages 17-19 in the doublespaced "Main document"). We omitted the repetitive parts now and have focused on a discussion of the recruitment challenges in this patient population in general as well as on the applied remedies to solve this in our trial.
As we are already preparing other papers for the dissemination of our results, we prefer not to publish results in the study protocol.

A conclusion is required re the significance of the manuscript.
Response: Thank you for this comment. We have included as a conclusion in the discussion now (please see page 19 in the doublespaced "Main document"):
"In general, this study and its wide scope of combined qualitative and quantitative analyses will provide important additional data on the TCM component implementation over different time periods

ranging from 4 weeks to 12 months. On a national level, it will add knowledge concerning if and how a transi-tional care concept can also be applied in Germany with its fragmented established structures. In case of a positive evaluation regarding its scientific and health-economic outcomes, a prospective goal is to define clear implementation possibilities of pathfinder activities in the German health care system."

Reviewer: 3
Reviewer Name
Marc Saez

Institution and Country
University of Girona, Spain

Please state any competing interests or state 'None declared':
None declared

Please leave your comments for the authors below
The authors attempted to evaluate a trial that sought the improvement of geriatric care at the transition from hospital to home reflected by a reduction of the all-cause readmission rate within a follow-up of up to 12 months after hospital discharge (primary outcome). Although the authors have been quite successful in achieving their objective, I have a few minor comments.

Minor comments

1.- In the 'Statistical Methos' section, the authors do not indicate which variables they consider confounding in the logistic regression. Authors should explain in detail the model specification.
Response: Thank you very much for pointing this deficit out to us. We improved the description of the statistical analysis now on page 16 in the doublespaced "Main document":
"Statistical methods
The primary outcome hospital readmission rate will be evaluated by Fisher's exact test. Possible interactions with housing situation, availability of caring relatives, and risk factors like care dependency or limitations in cognition will be analyzed by multiple regression for a better understanding of the intervention's impact on the hospital readmission rate.
Secondary outcomes (e.g., quality of life, mobility) will be analyzed by t-test, Fisher-test, Mann-Whitney-test, or Chi-square-test, depending on distribution and number of cases.
The analysis of possible financial benefits of implementing a pathfinder will be carried out by t-test.
The main analyses will be performed using SPSS and R."

2.- The authors also do not explain whether they considered the existence of any interaction in the logistic regression. They should explain it in some detail.
Response: Thank you very much for pointing also this deficit out to us. We improved the description regarding possible interactions in the statistical analysis section now, please see the chapter in the response to your comment directly above.

Reviewer: 4
Reviewer Name
Martine Puts

Institution and Country
University of Toronto
Toronto, ON, Canada

Please state any competing interests or state ‘None declared’:
none declared

Please leave your comments for the authors below
Review
Thank you for giving me the opportunity to review. Next time please do the reviewers a favor and double-space the manuscript, it makes reading so much easier.
Response: We included double spacing now in the uploaded “Main Document”.

Why trial only in 1 centre please clarify?
Response: Thank you for pointing this out to us. We clarified this now in the Methods section ("Trial design and study Setting") on page 6 in the doublespaced "Main document":
“The Transsectoral Intervention Program for Improvement of Geriatric Care in Regensburg (TIGER) study is a randomized controlled clinical trial with an intervention and a control group (see Figure 1). It takes place at the Hospital St. John of God Regensburg (BBR), Germany, in the city of Regensburg and surroundings. Since the effectiveness and feasibility of the application of a transitional care interven-tion itself will be evaluated in the study, the intervention is focussing on one hospital setting.”

How will you prevent contamination between the groups if you expect the same care in hospital providers to do usual care
Response: Thank you for bringing this important issue to our attention. We have given more detail now on what the intervention is and what the control group receives as usual care by Non-TIGER hospital staff, thereby addressing the issue of contamination prevention (please see page 9 in the doublespaced "Main document"):
"Study staff and training
[…] “The care professionals of the TIGER project are exclusively responsible for TIGER participants. They are supported by the study physician. The staff is divided into pathfinders supporting the intervention group participants, and study nurses assessing the control group participants (see also Table 1). To prevent contamination between the intervention and the control group in the hospital, all patients receive usual care as far as the Non-TIGER hospital staff is concerned. Additional actions in the intervention group are initiated by the pathfinders.”

Please clarify why depending on time of enrollment the length of intervention is 12, 9, or 6 months? What is the rationale for that? How will you take that into account in the analyses section? How was this taken into account in the sample size calculation?
Response: We added further explanation in the Methods section now and changed the section “Participant timeline” accordingly (please see pages 6-7 in the doublespaced “Main document”):
“The study duration per patient is at least six months, and in case of early recruitment up to 12 months (see Figure 1). Since recruitment was lagging, we had to prolong the recruitment phase from originally planned 12 months to 20 months in order to reach the calculated sample size. The follow-up visit plan had to be adapted, since the end of the overall study intervention phase could not be prolonged proportionately due to project funding reasons.”

General physicians= better to use family physicians
Response: We thank the reviewer for this advice and changed the wording accordingly throughout the manuscript.

I think the wording of the primary objective can be better formulated , please reformulate.
Response: We agree with the reviewer. We reformulated the "Objectives" to improve this section (please see page 6 in the doublespaced "Main document":
"Objectives
The main objective is to improve geriatric care at the transition from hospital to home, reflected by a reduction of the all-cause readmission rate within a follow-up of up to 12 months after hospital discharge (primary outcome) in a randomized controlled trial. We hypothesize that the TCM-based intervention performed by geriatric-experienced care professionals will achieve a readmission reduction by improving the care situation of the patients at home, contributing to a stable or improved state of their mobility, functionality, nutrition, wound healing, independence and health-related quality of life while reducing costs.
The effects of the intervention will be analyzed and its efficacy and feasibility evaluated to be able to make recommendations on which parts or activities of this TCM-concept-intervention might be implemented in the German health care system."

Table 1 is too large, it cuts off; please check that all is readable
Response: Thank you for pointing this out. We addressed this and reformatted the table to be readable (please see page 7 in the doublespaced "Main document").

In table 1 Minimental State Examination should be Mini-Mental
Response: Thank you, we corrected this.

In Table 1 social and social law situation, please clarify what social law situation means
Response: With social law situation, we meant care degree leading to certain reimbursement possibilities by health insurances. We improved the wording now in Table 1 (please see page 7 in the doublespaced "Main document"):
"Hospital admission situation, and social, housing, care and medication situation"

In Table 1 why CGA at discharge why not at admission?
Response: Thank you for adressing this. We have included the explanation in the sub-section “Assessments in both groups” of the Methods now, on page 13 in the doublespaced “Main document”:
“Since a comprehensive geriatric assessment is not mandatory in all wards at hospital admission of an older patient, it is administered in the TIGER study directly at recruitment and up to four times after discharge (depending on IG / CG and duration of participation: 6-12 months).”

Table 1 what is NBA?
Response: We have included a more detailed explanation of the NBA now in the notes of Table 1 (please see page 7 in the doublespaced "Main document") and in the respective parts in the body of the text:
** The NBA (Neues BegutachtungsAssessment) is an assessment to determine eligibility for benefits from the long-term care insurance in Germany 31.

Inclusion criteria: why does the MMSE have to be 22 and over? One could argue that probably those with dementia are the ones who experience the most gaps in continuity of care and are at highest risk of readmission?
Response: Thank you for this important comment. We agree with the reviewer that patients with lower MMSE might benefit from the TCM model. Nevertheless, some components as e.g. individualized goal setting and self-empowerment are requiring a certain level of cognitive capacities to be successfully implemented. We added this now as a limitation of the study (dot 5 in the “Strengths and limitations” on page 3 in the doublespaced “Main document”) and added an explanation in this respect now in the “Eligibility criteria”-section of the Methods on page 8 in the doublespaced “Main document”:

Dot 5 in “Strengths and limitations”, page 3 in the doublespaced “Main document” reads now:
"Patients with cognitive deficits might profit from our intervention; however, only individuals with a Mini-Mental Sate Examination Score of at least 22 points are included to ensure that participants are able to benefit from the Self-Management-approach of the TCM.”

on page 8 in the doublespaced “Main document”, we added:
“Eligibility criteria
[…] Although patients with less than 22 points in the MMSE might also benefit from the intervention, we chose this threshold to ensure that participants will be able to benefit from the Promoting Self-Management-approach, and to fill out the questionnaires themselves.”

Please clarify what palliative care situation means as it means different things in different countries, is there a way you can say for example estimated life expectancy<6 months or something?
Response: Thank you very much, we addressed this now according to how it is performed in the trial hospital (please see page 8 in the doublespaced “Main document”, in the section “Eligibility criteria” […]:
“Exclusion criteria are palliative care situation (defined by the statement “therapeutic goal: palliative” (instead of curative) in the medical report) and planned readmission to the hospital within the next four weeks.”

All patients admitted between April 2018 and December 2019 are scanned by this tool
Response: We are insecure about what the reviewer is referring to with this comment. The information is now given in the body of the text in the recruitment section (please see page 8 in the doublespaced “Main document”, “Recruitment process”). We hope this answers the comment:
“A TIGER-specific IT tool supported screening for potential participants according to the eligibility criteria age, health insurance and residence within a 50 km radius electronically in all wards via the patient management system of BBR. All patients admitted between April 2018 and December 2019 were scanned by this tool. Potential participants identified by this tool were visited in person by TIGER staff who assessed all other eligibility criteria and informed about the project."

Table 2 typo it should be registered nurses
Responsew: Thank you, we corrected this.

In the outcome section please add your tools there as well how these outcomes will be measured.

Response: Unfortunately, the word count for the text of the manuscript is very limited. Therefore, we added the validated instruments and tools that belong to every listed secondary outcome in detail in Table 1, but referred to them now also in the body of the text of the outcome section (please see page 14 in the doublespaced “Main document”):
“[…] Secondary outcomes include care situation, care supply and quality at home, functionality, and mobility, nutritional status, geriatric assessment-outcomes (depression and cognitive status, activities of daily living) Questionnaires for participants-outcomes (wound condition, health-related quality of life, psychosocial resources of patients regarding health, burden of informal caregivers), frequency of transfers into nursing homes. A detailed description of all assessment instruments and when they are performed, including their quotes, is depicted in Table 1.
Another important secondary outcome is the evaluation of the efficiency of the pathfinder-intervention. In a cost-cost analysis, costs of both groups (e.g., intervention costs, health care costs) will be compared to assess if the intervention leads to monetary savings. In an additional cost-utility analysis, costs of the intervention will be compared in both groups to non-monetary benefits (e.g., higher quality of life).”

The statistical analyses section is lacking details, please add the detailed analyses plan.
Response: Thank you very much for pointing this deficit out to us. We improved the description of the statistical methods now (please see page 16 in the doublespaced “Main document”):
“The primary outcome hospital readmission rate will be evaluated by Fisher’s exact test. Possible interactions with housing situation, availability of caring relatives, and risk factors like care dependency or limitations in cognition will be analyzed by multiple regression for a better understanding of the intervention’s impact on the hospital readmission rate.
Secondary outcomes (e.g., quality of life, mobility) will be analyzed by t-test, Fisher-test, Mann-Whitney-test, or Chi-square-test, depending on distribution and number of cases.
The analysis of possible financial benefits of implementing a pathfinder will be carried out by t-test.
The main analyses will be performed using SPSS and R.”

Please clarify while the hospital REB approved the study did the participants also provide written informed consent?
Response: Thank you for giving us the opportunity to clarify. Please take another look into our section “Recruitment process”. We had addressed that the informed consents were signed by the patients. But we clarified this point further now (please see page 8 in the doublespaced “Main document”):
" […] Patients in BBR fulfilling all eligibility criteria and present caregivers were then provided with the par-ticipant information brochure and informed consent forms. Patients were given at least one day to read the provided information and informed consent forms and receive further information on the project. After signing and dating the informed consent forms, the MMSE36 was performed as a last inclusion criterion for recruitment."

VERSION 2 – REVIEW

REVIEWER	Assoc Prof Dr. Supreeda Monkong Mahidol University, Thailand
REVIEW RETURNED	30-Jun-2020

GENERAL COMMENTS	Recommendations

	The outcomes (mobility, functionality, nutrition, wound healing, independence, and health-related quality of life reducing costs) were needed to be mentioned in the background and significance. The culture issues might related to patients and their family caregivers and the health care system during transitional process from hospital to home. The word “pathfinder” should be used the common term to communicate with readers. The role of pathfinders should be clear, not only one person but multidisciplinary team approach. A clear description of the intervention is required. Please clarify the details of the program: What is the study duration per participant; 3 months 6 months or 9 months, 12 months? (page 4) Please clarify for the term the end of study visit. Please clarify the term the “BBR” “AOK Bavaria” stand for (page 6, Eligibility criteria) Which part in the study that showed “its wide scope of combined qualitative and quantitative analyses” A conclusion is required to state how the program guide to improve the geriatric care at the transition from hospital to home. However, the results from the study could not generalization to other groups for example “patients with cognitive deficits might profit from this intervention”. The context is different.

REVIEWER	Marc Saez University of Girona, Spain
REVIEW RETURNED	29-Jun-2020

GENERAL COMMENTS	The authors have responded very well to both my comments and those of the rest of the reviewers. In addition, they have incorporated many of them in the new version of the manuscript. I have no further comments.

REVIEWER	Martine Puts University of Toronto Canada
REVIEW RETURNED	26-Jun-2020

GENERAL COMMENTS	thank you for the revised paper, it reads very well. However, the statistical analyses section is very brief, you have participants with different length of follow-up but for the analyses there is no mention how/at what time point you main analyses will be. And for the secondary outcomes you have numerous repeated measures but the analyses plan only describes t-tests etc so you are not capturing the repeated data, please clarify. We can also read in the analyses section you will examine interactions with housing status etc but there is no research question about it? Perhaps you can more clearly describe the subgroup analyses planned? And there is no plan for dealing with the missing data included?

VERSION 2 – AUTHOR RESPONSE

Answers to Reviewer: 4

Martine Puts, University of Toronto, Canada:

Thank you for the revised paper, it reads very well. However, the statistical analyses section is very brief, you have participants with different length of follow-up but for the analyses there is no mention how/at what time point you main analyses will be.

- Answer: Thank you very much and you are right, this section is brief due to the limitation of word counts for manuscripts. We will amend this section according to your notes:

"The main analysis will be performed for the first three months follow-up of patients after discharge. In addition a subanalysis will be performed with data after six, nine and 12 months follow-up."

And for the secondary outcomes you have numerous repeated measures but the analyses plan only describes t-tests etc so you are not capturing the repeated data, please clarify.

- Answer: We have clarified this now in the statistics section:

"Repeated measurements will be analyzed by ANOVA or linear mixed model."

We can also read in the analyses section you will examine interactions with housing status etc but there is no research question about it?

- Answer: Thank you for asking, since it has not been clear enough in our manuscript then, so far. There is a research question about it, as we had tried to point out in the objectives section. The improvement of the care situation - which we hypothesize will lead to a reduction in readmission – will be related to the housing situation, the availabilty of caregivers and also several risk factors, as described in the statistical section. These interactions will be analyzed. We try to make this more clear now in the Objectives section:

"Objectives

The main objective is to improve geriatric care at the transition from hospital to home, reflected by a reduction of the all-cause readmission rate within a follow-up of up to 12 months after hospital discharge (primary outcome) in a randomized controlled trial. We hypothesize that the TCM-based intervention performed by geriatric-experienced care professionals will achieve a readmission reduction by improving the care situation of the patients at home

and according to their housing and caregiving situation,

contributing to a stable or improved state of their mobility, functionality, nutrition, wound healing, independence and health-related quality of life while reducing costs. The effects of the intervention will be analyzed and its efficacy and feasibility evaluated to be able to make recommendations on which parts or activities of this TCM-concept-intervention might be implemented in the German health care system."

Perhaps you can more clearly describe the subgroup analyses planned?

- Answer: Thank you very much we will make this mroe clear in the statistic section:

"Subgroup analysis will be performed for primary and secondary outcomes e.g., for participants with or without caregivers, for participants with risk of malnutrition, for participants with different classifications from long-term care insurance."

And there is no plan for dealing with the missing data included?

- Answer: Thank you for pointing this out to us. We are happy to add this into the statistics section:

"To deal with missing data, for the primary outcomes complete case analysis will be applied. In case of the secondary outcomes either complete case analysis or, if appropriate and applicable, multiple imputation will be considered."

Answer to Reviewer: 3

Marc Saez, University of Girona, Spain

The authors have responded very well to both my comments and those of the rest of the reviewers. In addition, they have incorporated many of them in the new version of the manuscript. I have no further comments.

- Answer: Thank you very much for this positive feed back.

Answers to Reviewer: 1

Assoc Prof Dr. Supreeda Monkong, Mahidol University, Thailand

The outcomes (mobility, functionality, nutrition, wound healing, independence, and health-related quality of life reducing costs) were needed to be mentioned in the background and significance.

- Answer: Thank you for pointing this out to us. We have added in the introduction section now:

"...Moreover, in Germany, approximately 30 % of hospital patients who are ≥70 years old, show a hospital-associated impairment in Activities of Daily Living (ADL) and health related quality of life at hospital discharge.6 Mobility and nutritional status are especially prone to deteriorate during hospital stays in older patients (Admi et al 2015, now citation Nr. 7) and can lead to rehospitalizations. In addition, patients with chronic wounds (e.g. diabetic feet) run the risk of poor wound healing and wound care during transition from hospital to home. Moreover the Diagnosis Related Groups...."

- Independence had already been addressed in the Introduction section, in sentence:

"As reported in 2015, in 20 % of Medicare beneficiaries in the US, readmissions occur within 30 days of discharge and in 34 % within 90 days, leading not only to additional loss of independence of patients, but also to additional costs for the health care system.10 11"

The culture issues might related to patients and their family caregivers and the health care system during transitional process from hospital to home.

- Answer: Thank you for mentioning this. We have introduced a sentence on this behalf in the introductions second last Paragraph now:

"The study investigates geriatric patients in a semi-rural setting in southern Germany, so cultural aspects could influence the transitional process from hospital to home."

--

The word “pathfinder” should be used the common term to communicate with readers. The role of pathfinders should be clear, not only one person but multidisciplinary team approach.

- Answer: To be more clear now, we have introduced more Explanation in the different sections of the manuscript:

- in the Introduction, second last sentence: "Since academically educated advanced nurse practitioners are only starting to be trained in Germany, the intervention is performed by geriatric-experienced care professionals embedded in a team combining complementary expertises."

- in the Study staff section: "Academically educated advanced nurse practitioners are not available yet in Germany. The study is thus performed by geriatric-experienced care professionals called “pathfinders”, consisting of a registered nurse, a case manager, a head nurse, and an occupational therapist, to combine and exchange if needed multiple expertises when addressing the broad spectrum of care need aspects, such as care quality, mobility, nutrition."

- and also in Table 2 at 2- Staffing, we added: "Each IG patient is supported by one designated pathfinder during the intervention period. If complementary skills advice is needed, the pathfinder will find this within his pathfinders team or within the collaborating care team of his patient."

- in the Intervention description: "IG participants and their caregivers are accompanied by the one pathfinder each in the process of hospital discharge, during the transition from hospital to home and for a minimum of six up to 12 months after discharge (see Figure 1)."

A clear description of the intervention is required. Please clarify the details of the program:

- Answer: We described the Intervention more explicitely now in an extra "Intervention" section within the section "Intervention and Intervention Group":

"Intervention

IG participants and their caregivers are accompanied by one pathfinder each in the process of hospital discharge, during the transition from hospital to home and for a minimum of six up to 12 months after discharge (see Figure 1). An individual care plan is developed by the designated pathfinder for each of the IG participants according to their symptoms, risks, needs, and values (e.g., physiotherapy, drug application, nutritional counceling) and in close collaboration with the care team (see Table 2, Collaborating, including the family physician). All care activities for the IG participants are initiated by the pathfinder within the care team. The pathfinder coordinates, monitors, evaluates,

adapts if necessary, and documents the execution of the activities and the participants' adherence. In developing the care plan, the pathfinders do not provide active care services themselves, but coordinate their execution by contacting ambulant services for the required service activities. For the project, it was essential to ensure that the pathfinders would not compromise the operational tasks of the usual ambulant services to be able to build a trusting relationship with these services. Participants and their caregivers are actively engaged in the care planning process. Progressively during the course of the intervention, self-management is promoted."

What is the study duration per participant; 3 months 6 months or 9 months, 12 months? (page 4). Please clarify for the term the end of study visit.

- Answer: We have made this more clear now in the section Participant Timeline (now on page 7 of the manuscript):

"Participant Timeline

The study duration per participant is at least six months, and in the case of early recruitment up to(before end of June 2019) 12 months (see Figure 1). Since recruitment was lagging, as also reported in other clinical trials engaging persons over 65 years,30 we prolonged the recruitment phase from initially planned 12 months to 20 months to reach the calculated sample size. The follow-up visit plan had to be adapted, since the end of the overall study intervention phase could not be prolonged pro-portionately due to project funding reasons. The intervention period is planned to end on June 30th, 2020. In Figure 1, the timeline for each participant according to his recruitment date is illustrated with all visit times T0 to T4. The schedule of intervention and control group assessments is shown in Table 1."

- We also added in the legend of Table1:

" * For participants with study duration of 9 months, the T4 = end of study visit takes place nine months after hospital discharge. For participants with study duration of six months, the T3 measurements taking place after six months is replaced by the T4 = end of study visit measurements, but including all T3 assessments."

Please clarify the term the "BBR" "AOK Bavaria" stand for (page 6, Eligibility criteria)

- Answer: We have introduced in the "Trial design and study setting" section now:

"It takes place at the Hospital St. John of God Regensburg ("Barmherzige Brüder Regensburg", BBR), Germany, in the city of Regensburg and surroundings."

- and in the "Eligibility" section (now on page 8) :

"...statutory health insurance AOK (Allgemeine Ortskrankenkasse) Bavaria ."

Which part in the study that showed "its wide scope of combined qualitative and quantitative analyses". A conclusion is required to state how the program guide to improve the geriatric care at the transition from hospital to home. However, the results from the study could not generalization to other

groups for example “patients with cognitive deficits might profit from this intervention”. The context is different.

- Answer: We have tried to adress these issues now in our improved conclusion paragraph at the end of the Discussion section:

"In general, this study shows a wide scope of combined qualitative and quantitative analyses of the care situation of geriatric patients, of influencing factors and of the impact of pathfinders activities on readmission rate. The study will provide important additional data on the TCM component implementation over different time periods ranging from 4 weeks to 12 months. On a national level, it will add knowledge concerning if and how a transitional care concept or parts of it can also be applied in Germany with its fragmented established structures in order to define necessary steps to improve continuous transitional care for the geriatric patient group analyzed in this study.

For patients with cognitive deficits further transitional care intervention studies need to be conducted.

In case of a positive evaluation regarding its scientific and health-economic outcomes, a prospective goal is to define clear implementation possibilities of pathfinder activities for the analyzed patient group in the German health care system."

VERSION 3 – REVIEW

REVIEWER	Supreeda Monkong Mahidol University
REVIEW RETURNED	30-Aug-2020

GENERAL COMMENTS	Please consult the statistician for analyzing the data. There are 59 references. Please choose the suitable references for the study and follow the guideline for the format of references

REVIEWER	Martine Puts University of Toronto, Toronto, Ontario, Canada
REVIEW RETURNED	21-Aug-2020

GENERAL COMMENTS	Thank you for your revisions, all reviewers' comments have been addressed

VERSION 3 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:
Reviewer: 4
Reviewer Name: Martine Puts
University of Toronto, Toronto, Ontario, Canada

Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below
Thank you for your revisions, all reviewers' comments have been addressed.

Answer: Thank you very much.

Reviewer: 1
Reviewer Name: Supreeda Monkong
Thailand

Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below:
Please consult the statistician for analyzing the data.
There are 59 references. Please choose the suitable references for the study and follow the guideline for the format of references
---
Answer: We certainly will consult our statistician for analyzing all of our data.
We once again went through the references and omitted three. These are:
former Reference 2: Nowossadeck 2012, referenced in the Introduction section, page 4,
former Reference 9: Philibert and Barach 2012, referenced in the Introduction section, page 4,
former Refernce 19: Bixby and Naylor, eds. 2009, referenced in the Introduction section, page 5.

We reformatted the references according to the guidelines that we found (https://paperpile.com/s/bmj-open-citation-style/) and set up a fitting format in our Endnote program, since we could not find a ready-to-use Endnote format style BMJopen to download.
Thank you.
-
In addition, as requested by the Editorial office, the Funding section is removed now from page 3 and placed directly before the Reference list on page 21. The Authors' contributions and the Conflict of Interest section had been placed before the Appendices section before, but are placed now, on Editorial request, behind the Appendices section and directly before the Funding section.
This is correct, I hope?