Author’s response to reviews

Title: Use of robot technology in passive mobilization of acute hospitalized geriatric medicine patients: a pilot test and feasibility study

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Author’s response to reviews:

Dear Editor Carmel Hughes,

Thank you very much for a thorough review and the critical assessment of our paper:” Use of robot technology in passive mobilization of acute hospitalized geriatric patients: a pilot test and feasibility study”.

We hereby submit a revised version. Below, you will find our response to the issues raised by the reviewers. The positive criticism and suggestions has been immensely helpful and allowed us the opportunity to improve the paper.

We hope that our revision has improved our manuscript sufficiently to be acceptable for publication in your journal. In the following we address the reviewers’ comments point by point.

Reviewer #1:
This is a well-written paper that with a few adjustments is suitable for publication. However there is an imbalance between the rather positive conclusions about the intervention and the practical difficulties reported by the physiotherapists using the robot.
Thank you very much for taking time to review our manuscript and for your useful comments.

Abstract:
Background: Surely a pilot and feasibility study is help design a full RCT and not a "future pilot randomized controlled trial".
Methods:
29: "Recruited" rather than "included: patients.
31: Severe rather than server (this error is repeated further on the paper).
33: Pressure ulcers rather than bedsores.
37: The dates are not necessary.
Results:
40: Confident rather than confidential.
44. Difficult or unwieldy rather than unhandy.
Thank you for these suggestions for the abstract. We agree with you and have changed the wording as suggested throughout the paper.

Conclusion:
47. I do not understand the reason why the fact that the robot you used is unsuitable for a RCT. Is there not a role for passive mobilization in some circumstances?
Thank you for this question. In general, active mobilization is more important than passive mobilization in most geriatric patients. Not only due to case mix but also due to the fact that patients in our ward have short in-hospital stay (median of 6 days). In our study we tried to identify patients upfront who might benefit from passive mobilization as part of their recuperation. This was not the case for the majority of our patients. Those who tried the Robot liked it but due to their physical recovery the physiotherapist concluded that they would benefit more from active mobilization.
As you can see in our response to a question from reviewer#3 below, our study and conclusions had impact on the developer of the robot and resulted in further development of the robot so a new version now includes the possibility to perform active mobilization sessions.

Main text:

Background:
59: I would use geriatric medicine patients rather than just geriatric.

We agree with you and have changed the wording throughout the paper.

75: I think up to line 80 could be omitted.

We agree with you and have deleted these lines.

Participants:
98: Were the patients screened systematically? All patients on day 3 for example?
Thank you for this question. We have added the following to line 94 to clarify:
“All patients were screened systematically during the inclusion period.”

Intervention:
113: Who made the robot?
Information on who made the robot is now added in line 114:
”The robot was developed by Life Science Robotics ApS, Aalborg, Denmark”.

118: Is it possible to state how the robot learns? Where was the physiotherapist when the 20 repetitions were carried out?
Unfortunately we don’t hold information on the electronical software from the company and are therefore not able to give any technical information regarding the robot. More information on the presence of the physiotherapist during the repetitions has been added in line 122-124:
“This enables the physiotherapist to perform other tasks and see other patients, while the robot is doing the repetitions by itself”
and 222-224:
“During the interview, the physiotherapist expressed that it would not be safe for the patient to do exercise with the robot without a physiotherapist being next to the patient in order to provide a safe mobilization session”.

Outcomes and Data collection:
125: I would combine these. What patient data did you collect? What were the diagnoses?
Thank you for the suggestion, we have now combined this in one section.
Patients admitted to our department are characterized by acute medical illness on top of multimorbidity and polypharmacy. Most patients are admitted with infections, falls, or electrolyte disturbances. In this
study we focused on the feasibility of introducing a robot to perform passive mobilization. Besides the information collected in the inclusion/exclusion criteria we did not collect details regarding the specific diagnoses.

131: What were the questions?
Thank you for pointing this out. We have added the following tables as supplementary files:
• Supplementary, Table A: Interview guide for structured interviews with patients
• Supplementary, Table B: Interview guide for physiotherapist

144: Could you include the questionnaire?
Yes, same as above.

151: The "training physiotherapist". Who was this? How many physiotherapists were involved and did they also undertake any other treatments with the patients.
Thank you for this question. More information is now added in line 127:
“An experienced physiotherapist, who was trained in the management and use of ROBERT® prior to the study, managed the robot daily. A second physiotherapist was also trained in order to step in in case of absence of the primary physiotherapist. However, this was not needed. The physiotherapists in the department would provide usual care to all patients during the study period”.

Also, a line has been added to the limitation section of the paper:
“Finally, results from the interviews of the robot user should be interpreted with caution since we were only able to include one physiotherapist due to practicalities”.

Pilot Test:
This have now been corrected

176: A study board is mentioned. This should be in the methods or in the declarations.
This information is now added to the methods section in line 109:
“A study board was established prior to study initiation. The board included the head consultant and head nurse of department of Geriatric Medicine and the authors of this article: ASB, master of science in public health; AS, physiotherapist and master of health science; LM, PhD physiotherapist Head of Rehabilitation Research Unit; and JR, PhD consultant Head of Geriatric Research unit”.

187: One could debate below is or below are. I prefer the latter!
191: Were rather than was.
200: Wise rather than wisely.
Thank you for these grammatically suggestions. All have been changed.

206: I have not used the word shine being used in this context.
This has now been changed to “velcro-sheet”
209: How close is close?
Thank you for pointing out this imprecision. We have changed the wording to “next to”

Management:
220: I do not understand what the statement about the physiotherapist and technical functions means.
Sorry for this mistake. It was the robot which did not lack any technical functions. The text has now been corrected:
“In almost all mobilization sessions, the physiotherapist reported the robot was easy to apply to the patients’ legs (88.2%) and that the robot did not lack any technical functions (97.1%).”

225: Did everybody find this?
As specified now in the text according to your prior question, the management was carried out by one physiotherapist. Following every test the physiotherapist experiences the same problem with the physical environment. This information has been added:
“In every questionnaire answered by the physiotherapist, it was reported that the robot did not work satisfactory in the physical environment …”

230: Time consuming rather than time spending.
Agree. Has now been changed.

The perspective:
Could this not be shortened? After all this is only a pilot study and not too much can be made of these findings.
Thank you for this observation. We see this as a comment to the “Perception” section of the paper and not the “perspective” section. Accordingly, the “perception” section has been shortened.
290: geriatric medicine not geriatric. (and elsewhere).
This has now been changed throughout the paper.

316: I think making any conclusions about the effectiveness of this technique is very questionable. You did not test the conclusions reached on line 321.

We agree our wording in the discussion section might confuse our message and have changed the paragraph:
“However, despite our inclusion criteria aiming at including patients in need of passive mobilization the patients in this study improved their clinical condition quickly. Thus, the staff assessed that geriatric medicine patients are more in need of active mobilization and wished that the robot also could perform active mobilization”.

325: Again very questionable results. Tone these down.
Using the word ”effect” is not backed by our results. Therefore, we have changed the sentence:
”However, regardless the dubious need for passive mobilization, our study indicates that passive mobilization by the robot has an positive influence for the motivation and mood of geriatric medicine patients”
326: Feeling nice. Is that how you judge efficacy?

Some of the patients stated in the interview that it felt nice to train with the robot. We agree that this is not a way to judge efficacy and have changed the wording in the strengths and limitation section:
“our study indicates that geriatric medicine patients are positive about the passive mobilization sessions by the robot and they felt it was motivating to do the sessions”.

353: This paragraph could be omitted.
We have shortened the sentence so it now reads:
“Also, older people are often excluded from clinical trials, resulting in uncertainty about risks and benefits of new treatments for older people (1, 2)”.
Bertelsen et al may be congratulated for having performed and described a state of the art pilot and feasibility study in the paper entitled: "Use of robot technology in passive mobilization of acute hospitalized geriatric patients: a pilot test and feasibility study".

They rightly point at the necessity for performing both types of preparatory studies before undertaking a randomized controlled trial. The methods of both studies are clearly described and fulfill the CONSORT criteria for pilot and feasibility studies. The table summarizing the aims, methods and outcomes of the feasibility study is very helpful to insight in the research performed at a glance.

Thank you very much for taking time to review our manuscript and thank you for your positive response.

The major concern I have with the study is the tension between having been able to include only less than 10% of the patients admitted at the geriatric ward, and their firm conclusion that robot application is feasible for geriatric inpatients.

Their exclusion criteria select only the cognitive best patients, exclude all patients who are admitted as orthopedic-geriatric patients, and exclude the most frail. This seriously limits the external validity of their conclusion on feasibility. The paper would be strengthened by clearly elaborating on this.

Thank you for this important comment. We acknowledge your concern and have expanded our limitation section adding a paragraph on the limitations of external validity:

“Third, due to our exclusion criteria we excluded important geriatric patient groups such as cognitive frail patients and those with recent fractures. This may limit the external validity of our results. However, only few patients with dementia or delirium (~10%) were excluded and patients with recent fractures had to be excluded due to safety. In addition, we specifically aimed at identifying patients who potentially would benefit from passive mobilization and the majority of excluded patients were excluded since they were well mobilized already at admission”.

Furthermore, we have also rephrased the first sentence of the conclusion:

“In this pilot test and feasibility study, we show that a passive mobilization robot is feasible to use in a sample of older acutely hospitalized geriatric medicine patients”.

Moreover we also deleted the sentence “confusion due to personality disorder” as we already elaborates this a bit further down in the text:

Furthermore, we excluded patients if the healthcare professional assessed that the patient were not suitable for mobilization sessions with the robot”.

Moreover, not only the feasibility, but also the indication and performance of robot-assisted moving limits application in practice. There is only very limited place for passive movement in the management plan during rehabilitation. This seriously limits the relevance of the study performed.

We agree that active mobilization is more important than passive mobilization in most geriatric patients. As stated in the answer above we therefore tried to identify patients upfront who might benefit from passive mobilization as part of their recuperation. This was not the case for the majority of our patients. Those who tried the Robot liked it but due to their physical recovery the physiotherapist concluded that they would benifit more from active mobilization. Despite this, we believe our study is well worth publishing. It is a state of the art pilot and feasibility study and as you can see in our response to your question below, our study and conclusions had impact on the developer and resulted in further development of the robot so the new version includes the possibility to perform active mobilization sessions.

Moreover, if indicated and correctly applied by the physiotherapist, it costs more time than while doing manually. These relevant conclusions on the reasons to use the robot deserve more room in the
discussion, as the introduction of the robot was motivated by the option of saving time and having a more efficient use of the available work force.

Thank you for this important observation. The physiotherapist could potentially perform other tasks while the robot was working and in this way be more efficient. However, this was not possible in our study due to the lack of an emergency stop bottom. As stated below, these results have led to an upgrade of the robot including such a button. It would be interesting to investigate if a future version of the robot might lead to more efficient use of the available work force. Accordingly, we have changed a part of the discussion section:

“Finally, the physiotherapist only performed the movement with the patient once and then the robot repeated these movements. In this way, the musculoskeletal system of the physiotherapist was spared. While the robot was performing the mobilization sessions, the physiotherapist could potentially use the time to perform other tasks. In this way, the available work force would be used more efficiently. However, the physiotherapist did not feel the patient could be left alone with the robot in our study because the robot lacked an emergency stop bottom for the patients. Besides an emergency stop bottom, our feasibility study also pointed at other recommendations for technical issues to be implemented into the robot like a display where number of repetitions can be seen, as well as a wish for a smaller and handier robot”.

The study ends with uncertainty on the effects of the pilot and feasibility study on their plans for the RCT. It affects these plans, but the readership looks forward to learning how. Will the RCT be conducted still on passive movement support or not? If not, will a new pilot and feasibility study be performed? Now the paper ends without telling how the story ends.

We agree that our discussion section ends with uncertainty regarding the next step. When we submitted the paper we were not sure if a new version of the robot would be developed. The company has now successfully developed an upgraded version due to our feedback and this version includes the possibility of active mobilization. We hope to be able to perform a new study with the upgraded robot; however, the details and arrangements regarding this option are not in place yet.

We have added information to the last part of the discussion section:

“With our results in mind the current robot design needs some modifications and upgrades before launching a RCT. However, due to our results and feedback the developers have modified the robot introducing several upgrades including a stop button for the patients and the ability to perform both passive and active mobilization sessions. Whether the upgraded robot version could successfully be introduced in a geriatric ward initially requires a new pilot and feasibility study”.

-Next, addressing some minor points would also benefit the quality of the paper:

-Several grammar mistakes are made throughout the text. A native speaker should best correct these. Thank you for this observation. Reviewer #1 also commented on this. A native speaking English researcher has now gone through the paper. Subsequently, we have corrected misspellings and made several grammatical changes in the revised submission.

-In the methods section the procedures of qualitative evaluation can be clarified further. It would be good to know whether the interview results were transcribed verbatim and evaluated independently by two researchers. Possibly also software tools were used in this evaluation such as Atlas-T.

More information is added in the section of “Statistics and Analysis”.

-It would also be of added value to know whether the researchers reached data saturation, and how this was judged.

Thank you for these relevant comments. In qualitative research it is often discussed when data saturation is achieved and in our case with only twelve participants this might be relevant. However,
due to the uniqueness of each person, it can be argued that no data can be truly saturated (3). We believe the study reached the right amount of data saturation regarding the structured patient interviews. Referring to Malterud et al., a sample of six to 10 participants with diverse experiences might provide sufficient information power (4). The Information power model indicates that the more information the sample holds, relevant for the actual study, the lower number of participants is needed. The model can be used to reflect systematically on sample size for qualitative studies.

We have rewritten much of the “Statistics and Analysis” part. The whole section now reads: “The data was analyzed using descriptive statistics for all variables in questionnaires and for the questions in the structured interviews. Due to the aim of the present study no power calculation was performed. We aimed at including at least ten patients by convenience sampling. By applying the concept and tool information power, we reflected systematically on sample size and thereby agreed that at small sample size was appropriate for our study (4).

Data from the verbatim transcribed semi-structured interview and observation-notes were analyzed using a deductive (5) thematic analysis approach to reveal issues of importance to the feasibility study (6). All coding and analysis for the semi-structured interview was performed systematically using the software QSR NVIVO Pro 11. The main author did all primary statistics and analysis. Subsequently, the authors discussed these and agreement on results was obtained”.

Furthermore, we recognize the limitation of only using one physiotherapist to manage the robot. This has been added to the limitation section: “Finally, results from the interviews of the robot user should be interpreted with caution since we were only able to include one physiotherapist due to practicalities”.

-In the inclusion criteria it is stated that a positive CAM score would exclude a patients, however it would be informative to know what was considered a positive CAM score. We have added this information in the “Participants” section line 98: “CAM score was used to identify a patient with potential delirium. Using local standard procedures a positive CAM score was given in case of an acute onset or fluctuating course, inattention, and disorganized thinking or altered level of consciousness”.

Yours Sincerely

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