Author’s response to reviews

Title: Unsupervised progressive elastic band exercises for frail geriatric inpatients objectively monitored by new exercise-integrated technology - a feasibility trial with an embedded qualitative study

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Author’s response to reviews:

Reviewer reports:

Reviewer #1:

Thank you for your insightful and constructive comments to our manuscript. We have carefully considered your comments and responded to each of them below.

1:

Abstract:

-The feasibility criteria are 30% of total population performed at least 33% of # of sets. The way results are presented is confusing. Should present total #/% that completed 33% of number of sets (and therefore met both feasibility criteria), and then the average % of sets performed by total sample and by those who trained, for reference.

Response: We have rephrased to hopefully present the feasibility criteria more clearly. We have added the extra numbers for the whole population and for those who did train.

Changes to text:
Four (27%) out of 15 patients completed 33% of the recommended number of sets. For the total sample, the average percent of performed sets was 23% and for those who actually trained (n=12) 26%, respectively.

2:

- It is not clear what "if adjusted" means in conclusion.

Response: We agree that the wording is unclear. We have rephrased the paragraph.

Changes to text:

As even a small training dosage has been shown to improve the physical performance of geriatric inpatients, the proposed intervention might be relevant if the interruptions are decreased in future large-scale trials and if the adherence is increased.

3:

- What was the intensity and reps and sets for the program - was the focus on strength, endurance? It might be important to briefly mention in abstract methods.

Response: Good point we have now added an extra paragraph to address your comment.

Changes to text:

The patients were instructed in performing strength training: 3 sets of 10 repetitions (10–12 repetition maximum (RM)) with a separation of two-minute pauses and a time-under-tension of eight seconds.

4:

- My take on the results is that you need to supervise exercise to ensure they do it, if to be used in a future efficacy trial, where adherence is critical to make accurate inferences.
Response: Interesting point of discussion - and you definitely have a point in relation to increased adherence before an efficacy trial is undertaken. We agree that firstly a large-scale trial or a bigger cohort should look at how adherence could be increased before the efficacy is determined. We have tried to incorporate this point in the conclusion of both the abstract and manuscript.

Changes to text:

In abstract:

As even a small training dosage has been shown to improve the physical performance of geriatric inpatients, the proposed intervention might be relevant if the interruptions are decreased in future large-scale trials and if the adherence is increased.

In manuscript:

As even a small training dosage has been shown to improve the physical performance of geriatric inpatients, the proposed intervention might be relevant if the interruptions are decreased in future large-scale trials. However before any efficacy trials are initiated the adherence need being increased.

5:

Manuscript

The rational for the intervention is that there are studies that show that high intensity training is effective. Most studies implement more of a moderate intensity strength training - high intensity would imply very low repetitions and high load e.g., lifting 85%+ of 1 repetition maximum. This distinction is important because it would be difficult to use elastic band exercises to deliver high intensity exercise. A more comprehensive review of the types of interventions that have been shown to be effective may be needed to inform the proposed future trial.

What is the primary outcome for the future trial? If the focus is strength, then low-moderate intensity elastic band exercises may not be very helpful, for example. If focus is function - multijoint functional exercises may be more relevant than exercises with a theraband. More detail is required on the nature of the proposed larger trial.
Response: You have an important point here. Normally in a Danish hospital setting we do not have spezialised training equipment at the wards. An elastic band seem an alternative but you might be right that it can be difficult to perform straight forward strength training without continuous supervision. In a recent meta-analysis it has been shown that strength training with lower loads until failure seems to induce a similar muscle hypertrophy compared to higher loads (ref#14). Additionally this tendency is also seen in the context of older adults (ref#15).

The proposed larger and future trial would be planned and initiated after the adherence has been increased.

We have tried to further strengthen the argument in the background, discussion and conclusion for the choice and effect of elastic band exercises.

Changes to text:

Background (second last paragraph):
Sarcopenia is considered an important factor of frailty and is defined as “a condition characterized by loss of muscle mass combined with decreased strength and physical performance” [5]. It can be treated with strength training [6], which is why strength training for the older inpatient is a common prescription during hospitalization. Numerous studies have found that strength training is an effective treatment for frail geriatric inpatients [7-11] and can increase strength by 113% when performing high-intensity progressive resistance training for hip and knee extensors three times per week [11]. However, it is not always possible to ensure an adequate amount of supervised training needed for frail geriatric inpatients to minimize their loss of functioning [12]. This is due to a lack of resources amongst staff and lack of motivation on the part of the inpatient at the specific time of the supervised training session [13]. A possible solution to the problem could therefore be to supplement the supervised training sessions with feasible unsupervised exercises. In a recent meta-analysis it has been shown that strength training with lower loads until failure seems to induce a similar muscle hypertrophy compared to higher loads [14]. Additionally this tendency is also seen in the context of older adults [15]. Based on this elastic band exercises might be a useful method.

Clinical implications for a future trial:
A future large-scale randomized controlled trial might not be the obvious next step as achieving higher adherence is essential before designing and powering a future efficacy trial. Instead, the
following step should be based on smaller studies examining whether adherence can be increased by context-specific and implementation-tailored adjustments of the intervention in relation to the registered advantages and challenges. A hybrid design study could involve the inpatients and relatives in developing an intervention that potentially increases the adherence [67].

Conclusion of the abstract:

As even a small training dosage has been shown to improve the physical performance of geriatric inpatients, the proposed intervention might be relevant if the interruptions are decreased in future large-scale trials and if the adherence is increased.

Conclusion of the manuscript:

As even a small training dosage has been shown to improve the physical performance of geriatric inpatients, the proposed intervention might be relevant if the interruptions are decreased in future large-scale trials. However before any efficacy trials are initiated the adherence need being increased.

6:

Provide some rationale for the selection of knee flexion and elbow flexion exercises. Are these the types of exercises you would include in the larger trial, or in clinical practice? Elbow flexion in particular, seems a strange choice. Inpatient rehab typically focuses on functional exercises like sit to stand, stairs etc, so is it possible to relate the choice of exercises to what would be done in the larger trial?

Response: Our purpose of the exercises in general was to target muscle strength especially in the bigger muscle groups and therefore we included a rowing exercise involving muscles in the upper body and upper extremity and an exercise involving muscle groups in the lower extremities. We used exercises on three different levels to increase the number of patients capable of being eligible for the study. The choice for this was that we considered that performing some unsupervised exercises would be superior to performing none in regards to minimizing the disuse-related muscle wasting.
Changes to text:

Methods, The unsupervised strength training intervention measured by the BandCizer:

The follow-up instructions had a duration of a maximum of 15 minutes. The exercises included one exercise for the upper body and upper extremity and one for the lower extremity to target larger muscle groups, and were divided into three levels of progression with different start positions (lying, sitting, standing) (Figure 1) (Table 2) depending on the functional level of the frail geriatric inpatient.

7:

A target of 30% adherence seems low if the target is a future trial. It would be very hard to power an efficacy trial with an expected adherence of 30%. If the target was implementation, it might be more realistic. Although adherence to exercise is low in older adults, if you were planning a trial you would have to put things in place to get higher adherence to be able to make inferences. Or focus on supervised exercise.

Response: We agree that it may be difficult to power a future trial with an expected adherence of 30% and we agree on your point that this might be a pragmatic implementation study to accommodate the frail geriatric inpatients with the capability to perform unsupervised exercises as an add on to the routinely supervised training. This study should be seen as some kind of a proof-of-concept study why the 30% adherence was set low. In addition it was believed that if only a few patients would be able to do the unsupervised training they would likely benefit quite a lot even with a low training dosage (reference to response #5).

Changes to text:

Clinical implications for a future trial

A future large-scale randomized controlled trial might not be the obvious next step as achieving higher adherence is essential before designing and powering a future efficacy trial. Instead, the following step should be based on smaller studies examining whether adherence can be increased by context-specific and implementation-tailored adjustments of the intervention in relation to the registered advantages and challenges. A hybrid design study could involve the inpatients and relatives in developing an intervention that potentially increases the adherence [67].
It is not explicitly stated if the qualitative work involved thematic analysis, content analysis or other type of analysis, if it was informed by theory e.g., behaviour change theory. Some of the questions were yes/no, or a bit confrontational, which is a bit concerning for qualitative analyses. It also seems odd that the qualitative analyses were done by the person instructing the exercises, given the nature of the questions - huge potential for social desirability bias. These are limitations that need to be acknowledged. What are artificial citations?

Response: We agree that there is a potential desirability bias and we have incorporated this in the section about limitations in the discussion. Furthermore, we have clarified the analytic approach used in the qualitative work.

Artificial citations is an expression and part of the methodology from Malterud 2003 (ref# 39) describing the outcome of the process abstracting the contents of each meaningful unit. The artificial citation was constructed based on the qualitative data why the actual content had the essentials from each meaningful unit but was transformed into a general form.

Changes to text:

Strengths and limitations:

A desirability bias may potentially have occurred as the qualitative analysis was done by the person instructing the exercises. Given the nature of the questions it is possible that the patients might have answered more positively than they actually wanted to. On the other hand, a more authentic answer might have been likely as they were familiar with the interviewer. In addition to this, the interviewer had been associated with the geriatric ward and the patients during a long period of time which has been previously highlighted as having a major positive impact on the quality of the interview [61].

Qualitative methods:

A four-step data controlled analytic approach called systematic text condensation was used: 1) Identification of themes from the transcription; 2) Coding of meaningful units under themes; 3) Subdivision of codes and forming of artificial citations; and 4) Description of contents [39].
9:

It is stated that the patients lost the will to live - would it be more appropriate to say they declined further participation?

Response: It was chosen to write that the patients lost their will to live because this was the wording they used when retrieving their consent to further participation. The endpoint was that they declined further participation so it might be a good idea to change the wording to clarify this.

Changes to text:

Fifteen patients were analyzed, however two of these patients declined further participation before being discharged, which is why they were not interviewed.

Figure 3:
Follow-up: Declined further participation before being discharged (n=2)

10:

It seems that feasibility of implementation or of a future trial may be more affected by the presence of dementia than willingness to do unsupervised exercise. This is perhaps an important finding that would inform any future trial of exercise in this population - the need for an intervention that can be used in individuals with cognitive impairment.

Response: We fully agree on your point and acknowledge that dementia is a problem amongst the frail geriatric inpatients, however, in the present study we excluded patients with moderate to severe cognitive impairment. As we write in the methods section, in- and exclusion criteria “…Patients were excluded if they had a low cognitive level defined as a score <5/10 on the Short Portable Mental Status Questionnaire (SPMSQ),…” This is why we do not find that feasibility of implementation or of a future trial may be more affected by the presence of dementia than willingness to do unsupervised exercise in this case.

Changes to text:

No changes to text.
On the one hand the qualitative results are presented as positive, yet the adherence data suggest that it was not an activity people wished to engage in. What do you make of this? Is it possible there is some bias in the reporting of the qualitative data - either that you are focusing on the positive, or that only the positive comments came out (social desirability bias)? There is mention of this in the discussion. Consider discussing this in more detail, and perhaps consider the limitations of the study design.

Response: We hope that we have already addressed and unfolded this based on your previous comment #8 addressing the desirability bias. We also believe that the population can experience the intervention as positive but other factors may influence their actual performances, such as e.g. tiredness, pain, lack of desire to exercise, mind set on other things (see Table 6).

Changes to text:

A desirability bias may potentially have occurred as the qualitative analysis was done by the person instructing the exercises. Given the nature of the questions it is possible that the patients might have answered more positively than they actually wanted to. On the other hand, a more authentic answer might have been likely as they were familiar with the interviewer. In addition to this, the interviewer had been associated with the geriatric ward and the patients during a long period of time which has been previously highlighted as having a major positive impact on the quality of the interview [61].

The section on clinical implications is a bit confusing, and lacks detail. More detail in the discussion about how this relates to the future trial is needed. Provide more detail on what types of adjustments are needed. What would you change? Could you have a hybrid, where the intervention includes teaching others to coach the person to do their exercises, like family, or other hospital staff? Would you have designated times for exercise or prompts in the environment? Could the technology beep or flash to act as a reminder? Would that be realistic?

Response: We have added some of your very relevant perspectives to the manuscript.

Changes to text:

Clinical implications for a future trial
Based on this study, no immediate clinical implications can be made, but indirect implications can be derived from it. In case of a future successful implementation of a modified version of the intervention in the context of hospitalization, it can be expected that the daily disturbances will be a challenge that should be managed. This could possibly be done by introducing designated times to complete the exercises. The type of intervention is considered to have in-built clinical implications because it is evaluated as being resource-light. A future large-scale randomized controlled trial might not be the obvious next step as achieving higher adherence is essential before designing and powering a future efficacy trial. Instead, the following step should be based on smaller studies examining whether adherence can be increased by context-specific and implementation-tailored adjustments of the intervention in relation to the registered advantages and challenges. A hybrid design study could involve the inpatients and relatives in developing an intervention that potentially increases the adherence [67].

13:
The limitations section needs to acknowledge more of the limitations, as mentioned above.

Response: We hope that we have already addressed and unfolded this, based on your previous comment #8 and #11.

Changes to text:

Strengths and limitations:

A desirability bias may potentially have occurred as the qualitative analysis was done by the person instructing the exercises. Given the nature of the questions it is possible that the patients might have answered more positively than they actually wanted to. On the other hand, a more authentic answer might have been likely as they were familiar with the interviewer. In addition to this, the interviewer had been associated with the geriatric ward and the patients during a long period of time which has been previously highlighted as having a major positive impact on the quality of the interview [61].

14:
The conclusions section appears overly positive and focused on the qualitative data rather than the objective results.
Response: We agree and have tried to unfold the quantitative results to a larger degree.

Changes to text:

This is the first feasibility trial objectively monitoring training dosage during unsupervised elastic band exercises for frail geriatric inpatients. Based on the predefined criterion for feasibility, the unsupervised training was not feasible because only 27% of patients performed at least 33% of the prescribed number of sets, although the criterion of 30% was almost met. The patients and staff mainly expressed positive attitudes towards the unsupervised training. The most frequent reasons mentioned for the positivity about the exercises being that they had an in-built possibility to regain an earlier functional level, they were flexible in time and task, and gave the patients an increased responsibility for their own life. In addition, the implementation of exercises was thought of as a resource-light task for the staff and contains no risks. However, despite the positive attitudes the exercises were not performed as much as defined in the feasibility criteria.

As even a small training dosage has been shown to improve the physical performance of geriatric inpatients, the proposed intervention might be relevant if the interruptions are decreased in future large-scale trials. However before any efficacy trials are initiated the adherence need being increased.

Reviewer #2:

This is a well written paper and should be of interest to readers working in this subject area. I have a few comments below for the authors to address.

15:

As this is not a trial the word 'trial' in the title would be better changed to 'study' to avoid confusion with randomised trials.
Response: Thank you for your thoughtful comments. We adhere to the International Committee of Medical Journal Editors (ICMJE) definition of a trial: "The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome". This definition is in line with the one from the World Health Organization (WHO): http://www.who.int/topics/clinical_trials/en/. So, we respectfully decided to keep “trial” in the manuscript. We sincerely hope the reviewer can appreciate the reason for this choice.

Changes to text:

No changes to text.

16:

There was no age based inclusion criteria. Was this deemed unnecessary, please comment.

Response: As the patients were hospitalized patients recruited from a geriatric ward they are at least 65 years of age. In retrospect, this should be mentioned in the text.

Changes to text:

Patients were included if they were at least 65 years of age, frail based on a score of at least 5/15 points on the Tilburg Frailty Indicator (TFI) questionnaire [19,20] and if they were able to read and understand Danish.

17:

At the end of the data analysis section please add a rationale for the sample size initially targetted and what it was.

Response: From the literature we have taken that standard sample size estimations are generally not used in the context of feasibility trials (e.g. Arain et al. BMC Medical Research Methodology 2010, 10:67 http://www.biomedcentral.com/1471-2288/10/67). This is why no formal sample-size estimation was done for this feasibility trial. Instead it was determined pragmatically with the purpose of estimating critical parameters (e.g. recruitment) to a necessary degree of precision as clarified by Arain et al. 2010. To meet the request we have added a paragraph regarding the sample size for further elaboration.
Changes to text:

The sample size for this trial was determined pragmatically. It was possible to include participants for a period of 7 weeks, which we initially estimated to result in a sample of 10 to 20 participants. This was considered sufficient to assess feasibility.

18:

Please also add a brief description of the quantitative methods used in the analysis e.g. Mainly descriptive using mean(sd) to summarise continuous measurements, median (IQR) to summarise skewed data and count (percent) for categorical data.

Response: We have added a description of the quantitative methods used in the analysis as proposed. We have not included anything about the percentages because it might confuse when the percentages have been used in different contexts.

Changes to text:

Descriptive methods were used to present the data. Mean (sd) was used to summarize continuous measurements and median (IQR) to summarize not normally distributed data.

19:

On page 10 which question was added after piloting, please specify.

Response: As written on page 10 (page 11 after resent changes), no questions were added after piloting. In the text it is written: ”The semi-structured interview guide was pilot-tested in a physiotherapist and a nurse and did not result in any subsequent changes (Table 3).“

Changes to text:

No changes made.

20:

On page 13 how was 'lost will to live' determined, the table suggests a decline in general condition, please explain.
Response: The patients expressed that they lost their will to live when withdrawing their consent to further participation in the study. The endpoint was that they declined further participation. The wording was changed to “declined further participation” as proposed by reviewer#1.

Changes to text:

Fifteen patients were analyzed, however two of these patients declined further participation before being discharged, which is why they were not interviewed.

21:

On page 14 line 257 please make clear in the text that figure 4 contains two examples (and not data for all patients).

Response: We have reworded the paragraph accordingly.

Changes to text:

Performance of elastic band exercises:

The patients varied greatly in how they performed the exercises, which is illustrated in Figure 4 with two individual examples of training data.

Figure title: Figure 4: Two examples of individual training data. One exercise set performed close to that prescribed (A) and one very far from that prescribed (B).

22:

Reference 25 is in capital letters, please amend.

Response: We have changed the capital letters as requested. After recent changes the reference is now number 27.

Changes to text:

In Table it would be clearer to write out the text in the exercise level column in full, and not abbreviate.

Response: In Table 2 the abbreviations have been changed into the complete word.

Changes to text:
[min] changed to [minutes]
[s] changed to [seconds]
[h] changed to [hours]

Some evidence eg. Letter is required from the ethics committee to show that permission was not deemed necessary.

Response: We have now provided the journal with the email correspondence (in Danish) with the local Ethical Committee. We will be happy to translate this if further action is required. We have added an extra paragraph to highlight that the journal is provided with the evidence of the permission not to be necessary.

Changes to text:

Methods, Ethics

The Ethics Committee of North Denmark Region assessed the feasibility trial and stated that no approval was required (December 8, 2015, e-mail correspondence, Ethical Committee of North Denmark Region). The journal is provided with the evidence. The Declaration of Helsinki was followed, and all patients gave written informed consent.

Declarations

Ethics approval and consent to participate
The Ethics Committee of North Denmark Region assessed the feasibility trial and stated that no approval was required (December 8, 2015, e-mail correspondence, Ethical Committee of North Denmark Region). The journal is provided with the evidence. The Declaration of Helsinki was followed, and all patients gave written informed consent.