Author’s response to reviews

Title: Validity, reliability and feasibility of commercially available activity trackers in physical therapy for people with a chronic disease: a study protocol of a mixed methods research

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Author’s response to reviews:

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Dear Milica Blagojevic-Bucknall,

I like to thank you for providing us with the opportunity to revise the manuscript. We are grateful to the reviewers for their comments. Herewith I send you the revised manuscript titled ‘Validity, reliability and feasibility of commercially available activity trackers in physical therapy for people with a chronic disease: a study protocol of a mixed methods research’ (PAFS-D-17-00087).

Below you find a list of changes or a rebuttal against each point that was raised by the reviewers.

Reviewer 1’s comments:

- The stage of the study is unclear since all three (past, present and future) tenses are used in the text:
The use of different tenses in the text is a fair point made by the reviewer. This was done on purpose as the study preparations are finished. Some of these study preparations include the examples used by the reviewer: the selection of activity trackers (past tense under the subheading line 128) and the approval of this study protocol by the ethics board (past tense in text and declarations).

Although the preparations and the first data collection are finished, the execution of the study is still going on. Therefore, the statistical software package is still used (line 249, present tense) because we are still collecting and processing data at the moment.

However, we do understand that it might be confusing for readers to see different tenses across the manuscript. Therefore we checked the whole manuscript and changed the tenses to a present tense. With the exception of the sentences related to the ethical approval (as this process was finished with a positive outcome), the selection of activity trackers and the development of the activity protocol.

Moreover, the tense in the following sentence pointed out by the reviewer: "All participants WILL provide written informed consent" (line 147) was indeed chosen wrongly. Here, we changed ‘will provide’ into ‘are asked to provide’ (in the revised manuscript: line 181).

The changes made in the manuscript are highlighted for your convenience with the help of “track changes”.

- Line 83: rewrite five% as 5%: We did so accordingly (in the revised manuscript line 93).

- Line 120: 1. "cost" not "costs": We did so accordingly (in the revised manuscript line 131).

- Line 124-131: can this part please be written more clearly and transparently. e.g. what is the number in the pool from which trackers were selected?:


We adjusted the text between the lines 124-131 (in the revised manuscript lines 135-154) and added the following information:

“After an extensive online search for all commercially available activity trackers that were on the market by May 2015, a total of 72 trackers were found eligible (a data file of the selection can be found on a Dutch website: http://www.meetinstrumentenzorg.nl/Home/Sources, under the purple button). From these trackers a maximum of ten trackers was picked for the study.” And “Hence, nine activity trackers were selected and are investigated in this research project, covering the variety in wearing place, type and activities measured (Table 1).”

We have executed the selection of trackers fully independently, without competing interests and according to a transparent procedure. If it helps to understand the procedure better, we provide you with a link to the data file that was created during the selection of trackers.

If you prefer not to mention a link in the text, we can also refer to the file in your journal as additional online material. For that reason we uploaded the file as a separate file in the editorial manager system.

- Line 152: beta=0.9. This means that power is 0.1 (?) In these settings, Beta denotes type 2 error and power is calculated as 1 minus beta:

Power (1- β) of 0.9 was used. We accidently typed the word ‘beta’ (as the type two error) instead of ‘power’ (as 1 minus beta). We thank the reviewer for noticing this unfortunate mistake. We adjusted the text accordingly (in the revised manuscript line 191).

- Line 153: "...to detect differences between trackers" can you please be more specific what you mean by differences?

The considerations and calculations regarding the sample size are on the basis of the number of steps, our outcome measure. We formulated the whole sentence more specifically (in the revised manuscript line 193):
``...to detect differences in the number of steps between trackers (based on a SEM of 1.9 or to identify a correlation of 0.5 as being statistically significant different from no correlation) (27)].``

- How will participants be identified for therapists to approach them? Through the clinics they attend for their chronic condition? If so details on how this will be done are needed. All detail that is given is in Line 302: "Each therapist will select five-six patients with a chronic disease to participate in the study" However detail needed on how these physical therapists will access these patients in the first place. Further it states that each therapist will select 5-6 patients, how will they select them - randomly?

Physical therapists treat many patients with chronic illnesses, like the six target groups in this study. In the Netherlands a physician`s referral is not necessary for physical therapy treatment. In this way therapists have direct access to the target population for this study. Physical therapists check the official diagnosed diseases as well as comorbidity with the physician; this is standard procedure for physical therapist in the Netherlands. With the start of the study physical therapists check whether their current patients fit the study inclusion criteria. Eligible patients are asked to participate in the order of appearance in the treatment agenda.

We elaborated on the selection procedure in the part of the manuscript that was mentioned by the reviewer (in the revised manuscript lines 406-424): ``Physical therapists have direct access to the target population for this study (in the Netherlands physician referral is not necessary). Physical therapists check the official diagnosed diseases as well as comorbidity with the physician; this is standard procedure for physical therapist in the Netherlands. With the start of the study physical therapists check whether their current patients fit the study inclusion criteria. Eligible patients are approached and asked by their participating therapists in the order of appearance in the consultation agenda. Each therapist selects five-six patients with a chronic disease to participate in the study.``

Accordingly, we wrote more specific information under the subheading `Participants` of study part A (lines 162-163).

- At what exact point will informed consent be given? A flowchart of the study would be very helpful
All participants are asked to provide written informed consent one week after they received written information en before the activity tracker is introduced into the therapy.

The information in the text is adjusted accordingly (in the revised manuscript lines 427-428).

A flow chart of the study, part A as well as part B, was added to the manuscript: lines 181-182, 184-185, 315, 428

- Where will the tests be done?

In Part A of the study, patient and disease characteristics, questionnaires and physical tests are collected by the physical therapist in the practice on the day of testing. This is addressed more specifically in the manuscript, lines 226-227. Also the testing of trackers, the actual validation, with the physical activity protocol was executed in the physical therapy practices (added to line 229).

As Part B is a feasibility research aimed at the physical therapy treatment process, the study itself took place within the physical therapy practices. However, the interviews held with participating patients took place at the patients home or in the physical therapy practice (whatever was more convenient for the patient). The text in the manuscript was extended with regard to this matter (lines 433-434). Also the lines 464-465 are extended with information regarding the handling of questionnaires regarding location.

Reviewer 2’s comments:

- Rationale: Based on rationale please state your testable hypothesis.

In this study we considered the null hypothesis: no correlation (r=0) between the gold standard and the activity trackers regarding step count. The alternative hypothesis is: there is a correlation (r≠0, more specifically a positive correlation r>0) between the gold standard and the activity trackers regarding step count. For a more specific testable hypothesis we considered the accepted boundaries described in the literature following the CONSORT statement. We considered an outcome measurement of an activity tracker to be valid in this study population if r ≥ 0.7 (Terwee et al. 2006). (lines 283-284)
This is a value that can be expected in this field of research seen the body of literature on clinimetric quality of commercially available activity trackers (Evenson et al. 2015; Van Remoortel et al. 2012; Kooiman et al. 2015; Case et al. 2015). These studies however, are all based on healthy participants. The clinimetric quality of commercially available activity trackers for activities in everyday life in people with chronic diseases was never studied before. This stresses the need for our study. (lines 101-106)

- Ethics approval: Please provide more details for ethics committee application procedure.

Our study protocol is reviewed by the independent committee of experts called METC Z (the Dutch term for the MREC of the medical centre Zuyderland-Zuyd). There are 23 accredited MRECs in the Netherlands that review medical/scientific research proposals. The majority are linked to an institution such as an academic medical centre or a hospital. An accredited MREC determines the region it covers with regards to reviewing research. This is known as the working environment. Information on the national Research Ethics Committees (RECs) of all the European member states, including links, is to be found on the website of the European Network of Research Ethics Committees (EUREC).

Our study protocol (part A as well as part B), including all questionnaires, written patient information, information for participating physical therapists and resumes of the researchers (authors), was send to the METC Z. On the approval of the protocol and additional materials we received a number for part A (15-N-109) and a number for part B (15-N-48).

Some clinics in the Netherlands have their own ethical board to review all research that is executed at their location. One of the participating physical therapy practices in our study (MEC Adelante) had such a board and therefore we were obliged to have them reviewed our protocol again. After approval we received a unique study number by this local board (MEC-15-07). This is the reason why we provide the readers of our manuscript with an additional number for approval from the ethics board of one of the participating healthcare facilities (lines 61-62, 125-127, declarations).

- Inclusion criteria: Please provide more details about your inclusion criteria for each chronic disease: i.e. severity or stage of disease, age of participants.
People with one or more of the following chronic diseases are included: cancer, cardiovascular disease, COPD, diabetes mellitus, arthritis or chronic pain.

Important for the inclusion is that all conditions are diagnosed by a physician. The existence of this diagnosis is verified by the physical therapists. For cancer all types of malignity and both curative as well as palliative treatment phases are considered; for cardiovascular disease no type or severity is defines for inclusion; for COPD all Global Initiative for Chronic Obstructive Lung Disease (GOLD) stages are considered; for diabetes type 1 or 2; for arthritis all body locations are considered; and in the case of chronic pain the pain is lasting more than 3 months at the time of inclusion.

We like to stress that all these disease characteristics are registered during the study.

To be included in the study, participants have to have sufficient understanding of the Dutch language and they have to be able to perform light to moderate physical activity.

Although people with one of the mentioned chronic diseases are likely to be over 40-50 years of age, we did not use a restriction regarding the age of patients. This is in line with the World Health Organization recommending increasing physical activity in all ages.

More details are provided in the manuscript (lines 164-170).

- Exclusion criteria: Please provide more details about your exclusion criteria: i.e. no clinical stable patients or no optimal medical treatment.

Our exclusion criteria are: Potential participants that use a walking aid or have an asymmetric walking pattern are excluded from participation (line 178). This is checked by the physical therapists by means of a walk test right before the start of the actual testing in the study (lines 218-220).
All potential participants have to sign informed consent otherwise they cannot participate.

When patients have no clinical stable state or no optimal medical treatment they are referred to the physician by their physical therapist (standard procedure in the Netherlands) and are therefore not available for study participation.

- Power calculation: Please provide effect of size and mean±SD values that you used for your power calculation.

In the case of an effect size study we would have provided the readers with effect size and mean±SD values. The quantitative part A of this study design however, concerns a validation and reliability study. In line with the CONSORT statements we relayed on the overall accepted publications of Terwee et al. 2006.

Terwee at al. state that with respect to reproducibility the absolute measurement error should be smaller than the minimal amount of change in the scale that is considered to be important (minimal important change (MIC)). But a MIC is unknown for the outcome step count measured by activity trackers. Therefore, we followed the advice of the same literature on this topic to consider a sample size of at least 50 patients, adequate for the assessment of the agreement parameter (based on a general guideline by Altman 1991 and based on Terwee et al. 2006.

Terwee et al. give a positive rating for criterium validity if firstly the used standard is “gold”, which is unmistakable in our case because it is the actual video recording of the step count, and secondly if the correlation with the gold standard is at least 0.70. This exact number can be found in the data analysis in our manuscript in line 217.

With respect to validity, there are several ways to calculate the needed sample size. We used a SEM of 1.9 based on an average standard deviation and means for step count in a former study that used a similar gold standard. This calculated sample size of 24, together with a sample size of 23 based on the probability to detect a correlation of 0.5, based on Busse et al. 2009, served us with a conservative sample size of 25.
We adjusted the line in the manuscript to: “…a conservative sample of 25 participants wearing an activity tracker type would be needed to detect differences between trackers (based on a SEM of 1.9 or to identify a correlation of 0.5 as being statistically significant different from no correlation) (27).” (lines 191-194)

- Please replace reference 2 with World Health Organisation details.

We did so accordingly in lines 72-73: `In Western countries there is an increase in incidence and prevalence of chronic diseases, like the most prominent chronic diseases as chronic obstructive pulmonary disease (COPD), cardiovascular diseases, type 2 diabetes and oncological diseases (1, 2).`

The latest information of the WHO also included type 2 diabetes in the list that was mentioned in our background. Therefore we added type 2 diabetes to the sentence (line 73).

- Please use article from Rabinovich et al., 2013 to discuss validation protocol of activity monitors in COPD.

The study by Rabinovich et al. 2013 `Validity of physical activity monitors during daily life in patients with COPD`, performed by one of our colleagues, focused on total energy expenditure as their primary outcome. This explains why Rabinovich and colleagues did an interesting study with total body water as the ultimate gold standard to validate energy expenditure, whereas we have another focus and use step count as our primary outcome. For the latter, the actual steps made by patients and captured by video recordings is the ultimate gold standard for this outcome measure. Two studies with different focus and therefore different validation protocols. However, we did study this publication before and did so again after the request by the reviewer. The study by Rabinovich et al. does stress the need for validation of outcomes like step count. Therefore we included this reference in our discussion (lines 527-531).

- Please try to use more specialized literature.

We added the reference of the World Health Organization and the reference of Rabinovich et al. 2013 to the manuscript. There is a plethora of literature regarding the validation of activity monitors.
trackers that is interesting to discuss. Of them, many have studied validity of (commercially) available activity trackers in healthy participants often in lab settings and often focused on energy expenditure. However, little is known about which (types of) activity trackers provide valid and reliable results regarding step count in everyday life situations in people with chronic diseases (Ainsworth et al. 2015; Berlin et al. 2006). (lines 104-106)

Apart from the above changes based on the received comments, we did not make additional changes except for a typographical error:

- line 347: ‘was’ instead of ‘were’ in the sentence “The selection criteria for the activity trackers was based…”

Reviewer 1 stresses the relevance of the paper, which we embrace. This comment is in line with the extended systematic review we have undertaken to identify our research question with regards to up to date activity trackers in a population with disorders, as reviewer 2 mentioned.

We believe that the above-mentioned revisions based on the reviewers’ comments have improved the manuscript.

We look forward to hearing from you at your earliest convenience.

Kind regards,

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