Author’s response to reviews

Title: Multi-part Quality Evaluation of a Customized Mobile Application for Monitoring Elderly Patients with Functional Loss and Helping Caregivers

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Author’s response to reviews:

Prof. Dr. Dirk Krüger
BMC Medical Informatics and Decision Making

Dr. Deepa Nath
Editorial Office

and

Dear reviewers Prof. Dr. Gaby Anne Wildenbos (Reviewer 1) and Prof. Dr. Mona Choi (Reviewer 2).

Thank you for your valuable comments and suggestions. We have worked in all technical issues pointed in the reviews and included corresponding texts in the uploaded paper. An additional file was also uploaded with the “track changes” containing the structural changes in different color.

Best regards,

Matheus Stutzel, Michel Filippo and, 1Eng. Dr. Alexandre Sztajnberg (corresponding author - alexszt@ime.uerj.br) Rosa Maria E. M. Costa – for the Computing Science team
Response to Reviewers

Technical Comments:

Editor Comments:

1) We request you to provide IRB approval

Dear Editor, we had already included this information in the “Ethics approval and consent to participate” section, before the references. The “Hospital Universitário Pedro Ernesto Ethics Committee” has the IRB role at UERJ.

However, the reviewers recommended us to also mention this information in the Methods section. So, we have included a “Setting” subsection at the beginning of the Methods section introducing our team and mentioning the IRB approval and also completed the “Ethics approval and consent to participate” section with more information.

“This study and the consent to collect and use data information from participants was approved by Hospital Universitário Pedro Ernesto Ethics Committee (UERJ Hospital’s Institutional Review Board), 2014, April 7th, under registration CAAE: 32654014.9.0000.5259, final approval in 2017, July 17th, positive report number 2.013.410, revalidated in 2016, August 4th. The research protocol was registered in “Plataforma Brasil”, a national unified database of research records involving human beings, based on Resolution 466/2012 of the National Health Council (NHC), Brazil, respecting its guidelines and regulatory norms.

Additional information:

Submission to the Ethics Committee of Pedro Ernesto University Hospital: 04/07/2014

- Approval: 7/17/2014
- Modification of Responsible Researcher Validated on 08/04/2016
- CAAE: 32654014.9.0000.5259
- Proposed Institution: Hospital Universitário Pedro Ernesto
Reviewer reports:

Dear reviewers Prof. Dr. Gaby Anne Wildenbos (Reviewer 1) and Prof. Dr. Mona Choi (Reviewer 2),

Before getting into your specific observations we are responding to the comments and observations regarding the contents of the Methods, Results, Discussion and Conclusion section, which guided us in the same direction. In your specific comments regarding this points we have placed a “please see previous response” note.

We have restructured several parts of the text by following and combining all the suggestions of the two reviewers.

a) We organized a “Setting” subsection, in the beginning of the “Methods” section, inspired by other BMC articles. In this section we have concentrated information on the two research groups that co-designed the SMAI project and on the target group of caregivers for which the system was developed. Some of these information was brought from the “Background” section. At the end of this subsection we have included the information about the IRB approval.

b) We have included at the end of the “Methods” section, an “Evaluation Methods” subsection as suggested by Dr. Mona Choi, Reviewer # 2, concentrating all the information regarding the evaluation conception, how the studies were programmed and their respective conceptual bases.

c) The “Results” section was remodeled to effectively concentrate the results obtained in each evaluation and some outcomes obtained by direct observation of the results.

d) The “Discussion” section now presents the discussions derived from elaborated observations on the results, and a text organizing the types of changes in the prototypes of the SMAI Caregiver and SMAI Doctor applications in technical, functional and interface, and also have added two tables summarizing the main changes in Project Stages from 2 to 4, when new versions were produced. We also included a positioning of our work in relation to the related works presented in the “Background” section and other relevant works.

e) The” Conclusion’ section now brings a more assertive and compact closure to the text.

We tried to make these changes highlighted in the track-changes file in different colors.

Gaby Anne Wildenbos (Reviewer 1):

Thank you for the opportunity to review this manuscript. The research presented here is regarding a timely and interesting subject. The authors present the results of the preliminary use/feasibility to implement a mobile health tool aimed at strengthening care giver and health
care professional communication in the care for dementia patients. The strength of the research is a robust foundation in several evaluation moments with multiple target groups of evaluators as well as the reporting on adjustments made in the care processes to align with the tool. The weaknesses include the variety in the structure of the manuscript and (limited reporting on) theoretical background of methods used during the various evaluation moments.

Dear Prof. Dr. Gaby Anne Wildenbos, please find our answers interlaced with your comments.

Major comments

Introduction

2) The argument made in line 59-62 could be made more concrete or stronger in my opinion. Increasingly reviews are performed on mobile health applications’ use. Why is the review from Mosa et al chosen?

Mosa et al have presented a broad review on the use of mobile applications applied to the support of the elderly with functional limitation. In this review there was a discussion on many aspects related to caregivers, which are important in our argumentation. Afterwards, in the text, we have a “Related Work” subsection where we mention other references that cover the many relevant points of our argumentation: applications specifically developed (or not) for the caregiver, benefits of the interaction between caregiver and health team mediated by mobile applications and the adherence to the application.

However, we agree that there are more recent references, with equally broad studies. We have updated this paragraph and made the argumentation more concrete and strong.

3) In literature on this topic it is often mentioned that the interaction between patients (including caregivers) and health professionals is important. What is the specific difference in this interaction when it comes to caregiver communication? Do they require a different communication approach then patients?

We tried to characterize the profile of the caregiver of our study. In Brazil, especially in the group monitored by the NAI service, the caregiver is a member of the family - not a professional caregiver, with low income (many are actually poor), stressed and has almost no training to perform care.

In addition, the patient no longer has independence to use mobile applications and often has compromised physical mobility. Public transportation system in Rio de Janeiro, where the study was carried out, is very deficient. So that the patient's and the caregiver's coming to the clinic is almost always a sacrifice.

Thus, the interaction between caregiver and physician would be used not only to send information about the patient, but also to receive guidance from the medical staff and also to
provide information about the caregiver herself/himself (stress and health level). The information transmitted and the structure with which they are collected and transmitted are those that the health professionals would obtain in an ambulatorial visit, but now more frequently, without waiting for the next visit.

In summary, the health team wanted to study a new way to interact specifically with the caregiver, driven by their clinical experience.

In the original text, these points were highlighted some how:

Page 2, left col, lines 43 to 52 (Background)
Page 2, right col, lines 11 to 14 (Background)
Page 3, left col, lines 28 to 39 (Related Word)
Page 4, left col, lines 10 to 31 (Design Guidelines)

3) The goal of the paper could be specified. "Representing the experience of developing …" is quite vague, whereas the steps of the development, refining and evaluation performed are vast. I think with a more specific description of the goal and the importance of this research the paper might better represent the research performed.

Agreed. We have rephrased the sentence to be more specific. “This paper presents the development and refinement stages, and the evaluation study of the Mobile System for Elderly Monitoring (Sistema Móvel de Assistência ao Idoso, SMAI).”

Methods / Results

4) The methods section provide little information on which theoretical background is used in testing/ how the tests are performed. Are their tasks that the users needed to perform? Which attributes of usage were measured? How were the measurements analyzed? Etc.

please see previous response

5) In the results it is often described how the research is performed, whereas I think that could better be placed at the methods sections. In my opinion, the first sentences per paragraph in the results are sentences that belong in the methods section. Examples are: p5, line 37 to 49 and p5 the section of 'clinical qualitative evaluation'. Yet, in several other lines at the results section this can be changed as well. By placing the 'how' at the methods and the outcomes of the evaluation moments at the results, the readability of the manuscript will increase.
please see previous response

6) The outcomes can also be made more concrete. For example, on p 5 in the second column, the authors say: 'some interface panels were improved in the new prototype. It would be better to have concrete examples of changed elements in the interfaces.

please see previous response

Discussion:

7) The authors say that many improvements could be made because of feedback from the caregivers. As a reader I would appreciate to see the amount of changes here (based on the data given in the results). For example, x-changes from prototype 1 to 2, y-changes from prototype 2 to 3 etc. It further remains unclear if these improvements were major or minor improvements. Would they comprise patient-safety if not improved? Perhaps there can be a categorization of issues found and improvements made. The examples given in the second and third paragraph of 'preliminary assessments' are very illustrative and interesting.

The process adopted for development is based on agile methods, with successive refinement cycles. Informal feedback from caregivers and the health team, and the information collected from the system itself already allowed several points to be improved.

Early assessments, with short periods of use, with caregivers and focus groups allowed for greater feedback, which defined the different versions as there were larger changes.

The noticeable changes mostly improved usability: facilities for the daily report interaction, confirmation buttons, main menu options most used at the top, text messaging system with more pleasant interface and notification mechanism.

Some important technical changes were transparent to caregivers, but improved use by the health care team. For example, we have developed an update mechanism that can download the latest information sent by caregivers every 20 seconds, configurable by the healthcare professional. Another major change was the change of the application server, but this was transparent to all users, who only did the update of the application using the embedded mechanism. The technical team was very proud of this move, but we did not highlight these technical points, because it would increase the text a lot and take some of the focus away.

The reporting format has also been improved for health professionals, after we have facilitated completion by the caregiver, dividing the report into tabs.

As SMAI is mainly used for the caregiver to transmit information about the patient, and no recommendation is made automatically - only a health professional can make recommendations, no change brought risks to the patient. Even the changes in how to specify medication alerts only improved the quality of the information. For example, in addition to informing that given
medication should be given every 8 hours, it was now possible to also inform that it should be
taken with breakfast or dinner.

We have a complete record of changes made throughout the project, in GitLab, the development
environment used by the developers. But, in the original text we highlighted just the most
important. The original records are much more detailed. For this new revision we have added, in
the Discussion section, a text organizing the types of changes in technical, functional and
interface, and also added two tables summarizing the main changes in Project Stages from 2 to 4,
when new versions were produced.

Minor comments

Abstract:

8) The abstract of the paper can be improved aligned with changes in structure in the paper to
make the strengths of the paper more visible / recognizable in the abstract.

Agreed. After restructuring the text, it was important to reflect the changes in the Abstract. Each
topic now better condenses the respective sections.

Introduction:

9) In the current introduction it seems as if the creation of the tool was mainly co-created by
computer science and health teams. This poses the question: Were caregivers themselves also
involved during the co-design process? I would assume that they would also be consulted in this
process since they are a main end-users.

In principle, caregivers did not participate in the design of the application. The experience of the
healthcare team and the observation of other applications was the basis of the design. The
conception was also driven by the observation of the home visiting team and the vision of the
NAI service coordination.

However, informal feedback from caregivers and more formal feedbacks during the assessments
also drove some design changes. The first short evaluations were important for operation
adjustments that could not be identified in the laboratory. Through these assessments, focus
groups and team meetings, the health team translated the points raised into functionality and
design requirements.

10) In the paper (fig 1 for example) it becomes apparent that the caregivers evaluated / are
involved from prototype 3 onwards. The manuscript could be strengthened by explaining the
caregivers' involvement in the introduction.
Agreed. Caregivers were involved in the project from the 2nd version on, during the first 15 days assessment. The hands-on training done in the second assessment is another example of the caregiver involvement. In the original text, this was only mentioned later in the “Results” section. In this review we now concentrate the conduction of the evaluations in the “Evaluation Methods” subsection, with information on how caregivers were involved.

In addition, we recorded the participation of caregivers in the Setting subsection, introduced in the restructuring of this review, within the Methods section, with the following sentence: "Caregivers engaged in the early stages of alpha-testers, with informal feedbacks, and participating in the formal assessments focus groups, retraining meetings and usability evaluation.”

Methods:

11) Design guidelines: were existing design guidelines (on designing mobile healthcare applications and mobile applications in general) examined? If so, which ones? If not, is there an explanation for this?

Before developing our mobile applications, we first evaluated the Microsoft Health Vault (MVH) to identify the main requirements of a comprehensive distributed health system. We examined closely the API, communication mechanisms and features. The system is modular, so it is possible adding new features. It includes security, access control and persistence mechanisms. However they didn’t provide the interaction options and the interfaces the NAI health team demanded and it was very web-driven, requiring many actions before getting to the main interface. So, we opted developing our own application, with specific requirements, but used the MHV as the communication and persistence engine in the first two versions of SMAI. Unfortunately in November/2015 they discontinued most of the support we used in the SMAI system, this turned into a big problem for the computing team. We had to deploy and provide our own database and application server, including access control and security. This was a major technical change. However, some solutions we included in our applications were inspired by MHV.

At the time we began our project there was no other application with the features SMAI provides. There were some health applications that allowed transmitting heart rate, blood pressure and weight, and many other applications in the fitness domain, which also inspired us in some way. But our design was driven by the NAI team requirements.

A common guideline was to make the interface simple. This was a base recommendation of the health team. All elements and interaction flow was proposed by the NAI Health team. Also, the size of the elements should be compatible with the visual comfort required by the caregiver. In that regard SMAI is completely customizable (figures below) so the visual comfort can be adjusted. This wasn't included in the text, which is already big, as mentioned by Reviewer 2 (there are many other technical details the computing team had to refrain discussing in the text).
The architecture, presentation interface and controls of our mobile applications follow the recommendations for Android 4.0, which was the version when the project was being run. However, some solutions are tailor made, as the interface to express pain or temperature. In this case there were no guidelines to follow. The computing team developed the modules, the health team approved and we launched a new version. There is also a customized, easy to use, update mechanism so any improvements were easily incorporated.

It is also worth mentioning that we didn't count on a professional visual designer.

By the end of the project evaluation we began to plan a new version of the application and mechanisms to make SMAI Caregiver available at the Google Play Store, yet maintaining the security, privacy and access control mechanisms. This is still a work in progress. Current version of Android is 9.0 and Google has made many changes to available components. For example, the Notification event largely employed on SMAI has changed.

Mona Choi (Reviewer 2):

Thank you for your effort on your manuscript.

This dealt with an interesting topic of development and implementation of mhealth application for caregivers of dementia patients, which provided simple solutions to help users.

Dear Prof. Dr. Mona Choi, please find our answers interlaced with your comments.

Major suggestions

12) This is generally well written but too long that would make readers get lost. The authors should make this paper little bit more succinct. In addition, this manuscript needs some restructure of manuscript because a part of Results section should move to Methods, which you don't have. I strongly recommend to create the section of "Evaluation Methods"

please see previous response

13) In addition, the authors should use terms, tense, upper/lower letters, and

Please see responses to items 29 and 30.

14) Citation numbering in the main text consistently throughout the manuscript, including tables and figures, even in titles, which requires very thorough English and format editing.
We have used Latex to edit the manuscript. Figure and table numbering, as also cross references and citations are handled by the compiler. If something would be missing the compiler would notify. We have revised the PDF generated by Latex to verify any reference was wrong and if table and figure numbering was inconsistent. Please point us the problem should anything is still inconsistent.

Minor suggestions

BACKGROUND

15) p. 3, left, line 20: please change "…[22] surveyed" to "…[22] reviewed" –

Agreed.

16) p. 3, left, line 61-62: Please rewrite the sentences, which are very awkward. “The prototype would be tested outside the lab for the first time. Many things could fail.”

Agreed. We tried to improve the text, substituting the sentence with: “These five caregivers would be alpha-testers, using the prototype under real conditions.” This sentence was placed closer to the beginning of the same paragraph.

17) p. 3, right, line 11-14: Please provide some examples to elaborate the case. The feedback from the caregivers was very insightful and allowed the computing team to make many other improvements in the applications. It also allowed the health team to revise their procedures.

Please see answer to item 7.

18) p. 3, right, line 17: please change "…a group of ~30" to "…about 30".

Agreed.

METHODS

19) please provide the description of IRB approval and number.

We had already included this information in the “Ethics approval and consent to participate” section, before the references. The “Hospital Universitário Pedro Ernesto Ethics Committee” has the IRB role at UERJ.
I am understanding, this information should be more complete and also mentioned in the Methods section. We downloaded some BMC papers and we noticed that this was expected. So, we have included a “Setting” subsection at the beginning of the Methods section introducing our team and mentioning the IRB approval and also completed the “Ethics approval and consent to participate” section with more information.

“This study and the consent to collect and use data information from participants was approved by Hospital Universitário Pedro Ernesto Ethics Committee (UERJ Hospital’s Institutional Review Board), 2014, April 7th, under registration CAAE: 32654014.9.0000.5259, final approval in 2017, July 17th, positive report number 2.013.410, revalidated in 2016, August 4th. The research protocol was registered in “Plataforma Brasil”, a national unified database of research records involving human beings, based on Resolution 466/2012 of the National Health Council (NHC), Brazil, respecting its guidelines and regulatory norms.

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• Approval: 7/17/2014

• Modification of Responsible Researcher Validated on 08/04/2016

• CAAE: 32654014.9.0000.5259

• Proposed Institution: Hospital Universitário Pedro Ernesto

• Approval Number: 2.013.410

20) p. 4, left, line 59-60: please delete (but not childish).

Agreed.

21) p. 4, right, line 9: please change to "SMAI are presented [26]."

Agreed. We have rephrased it to “Stutzel et al. present a broad discussion on SMAI architecture, non-functional requirements and on gamification aspects introduced in SMAI [29].”

22) p. 4, right: please change subtitles of "Caregivers’ App" "Health professional's App" to , "SMAI Caregiver Interface" and "SMAI Doctor Interface", respectively.

Agreed.
23) p. 4, left, line 6: please change "…of study" to "of education"

Agreed (page 5, right?)

24) p. 5, left, line 33: please change 28 to Twenty eight.

Agreed.

RESULTS

25) p. 6, right: there are many part that can go to Methods, for example from lines 5-11, 14-25, p. 8, left, line 52~right, line 9, right, line 57~p. 7., left, line 8, etc. Please move other parts that described methods to Methods section.

please see previous response

26) I don't think that median and IQR is necessary to be presented because it has only 5 likert scale (Tables 5 and 6 have the same issue). I suggest to delete medians and IQRs from text and tables.

Agreed. We have removed the information from the tables and from the text.

DISCUSSION

27) This section should compare and contrast your findings to relevant studies previously published. It is currently mere repeat of results section. This should be rewritten entirely.

please see previous response

CONCLUSION

28) This also needs to make a short, strong deliberation based on your findings. It just seems some part of discussion.

please see previous response
TABLES

29) please use lower/upper case letters consistently

We were not very sure about this recommendation.

We revised Tables 1 to 4 and have put all options beginning with a capital letter to be consistent with “Yes” and “No” options.

For Tables 5 and 6, we have now put in capital letter all variables and the table footnotes (for instance “SDv - standard deviation” to SDV - Standard Deviation”).

30) as well as tense (e.g., improves vs. improved; are vs. was) …

Having the questions phased in the past, present and conditional future was not random. The context was the end of the study. Most caregivers were returning the smartphones, which were being collected to undergo an inventory. Thus, some questions were related to the experience they have had during the 18 months, while some were about more permanent aspects, in the present. And one question to the health team was in the conditional future, “would recommend”.

However, we agree this was confusing in the text. We have now turned all questions to the present tense, excepting the “would recommend”.

-Table 1:

31) study should be education. Agreed.

32) Please change the title to "Demographic characteristics…” Agreed. We have changed the title of Tables 1 and 3.

33) Table 3: basic education should be education. Agreed.

FIGURES

34) please spell out abbreviation as a note if necessary.

We have scanned all figures. The graphs have self-contained x/y labels. The interface snapshots should also be self-explained. The figure describing SMAI elements has abbreviations, that were explained in the text: NAI Health professional - NAI stands for Care Center for the Elderly (“Núcleo de Atenção ao Idoso”) and LCC Team - LCC stands for Computer Science Laboratory (“Laboratório de Ciência da Computação”), which are presented in the Setting section; SMAI
Caregiver, SMAI Doctor and SMAI Web are the given names of the applications, which are explained in the text. However, we have added notes to that figure helping the reader.