

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Optimization and validation of a remote monitoring system (Onco-TreC) for home-based management of oral anticancer therapies: an Italian multicenter feasibility study.
<b>AUTHORS</b>	Passardi, Alessandro; Rizzo, Mimma; Maines, Francesca; Tondini, Carlo; Zambelli, Alberto; Vespignani, Roberto; Andreis, Daniele; Massa, Ilaria; Dianti, Marco; Forti, Stefano; Piras, Enrico; Eccher, Claudio

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Sandra Spoelstra, PhD, RN FAAN Grand Valley State University USA
<b>REVIEW RETURNED</b>	27-Oct-2016

<b>GENERAL COMMENTS</b>	<p><b>FEEDBACK:</b> Thank you for allowing me to review your paper on this very interesting topic. The following are my comments.</p> <p><b>TITLE:</b> Use of fewer words may focus the title topic; suggest deleting the words: "for a fine-tuned 2.0 system" as it did not add any meaning to the paper title.</p> <p><b>ABSTRACT:</b> Pg. 4 Ln 16 the word mobile-Health reads out of context and maybe "mobile health" would make more meaning Pg. 4 line 24-25 reword order: We plan to customize and fine-tune and existing monitoring TreC platform used in chronic diseases for the oncology setting. This will have more meaning making for readers. Pg. 4 Ln 43, maybe instead of "will contribute" change it "is expected to contribute" and you will not know until after testing is completed. Also, is it focused on medication adherence as stated above? If so add to what will be improved. Pg. 5 Ln 4 delete word individual, as inherent in words study participants.</p> <p><b>INTRODUCTION:</b> Pg. 6 Ln 6 use full word, not chemo- but chemotherapy to make clear your meaning. Pg. 6 line 14, unsure what "largely hampered by" means? And as far as I know, the side effects are not serious ADEs. Please cite if you know otherwise. Pg. 6 Ln19 unsure what "even more" means for oral cancer drugs, listing a % would be more clear. Pg. 6 Ln 24 maybe use the word "use" rather than "consumption" to make a clearer sentence. Pg. 6 Ln 28 unsure what information leaflets are; or patient-help so you mean patient completed diaries? Pg. 6 Ln 33 what do you mean "of this process" what process are</p>
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	<p>you talking about? Home-based treatment? Exactly what do these 5 key points relate to? Unsure</p> <p>Pg. 6 Ln 57 consider deleting word strong; as not all evidence is strong</p> <p>Pg. 7 Ln 4 associated with “positive health outcomes”? Many important and meaningful is unclear to me</p> <p>Pg. 7 Ln 7 Unsure what in this context means. Do you mean to enact patient-centered communication?</p> <p>Pg. 7 Ln 12 by shared to you mean between healthcare provider(s) and patient? Who is doing the sharing?</p> <p>Pg7 Ln 27 on got lost in all the abbreviations, carefully select only those abbreviations that truly add to the paper. Maybe consider not using formal site names but listing them in the acknowledgement; but rather describe the setting in your paper.</p> <p><b>AIMS AND OBJECTIVES:</b></p> <p>Page 9 Ln 21 consider dropping work “overall” implied in statement.</p> <p>Pg. 9 Ln 28 Consider dropping work “specific” as implied in statement.</p> <p>Pg. 9 #3 Line 40 above in paper you also included capability in addition to usability and acceptability here. Please clarify. Also, are you focused on medication adherence or symptoms? High value items with oral agents.</p> <p><b>METHODS:</b></p> <p>Pg. 10 Ln 7 Do you mean there are two phases to this project? What are major strands?</p> <p>Pg. 10 Ln 26—36 break into 2/3 sentences too long for reader.</p> <p>Pg. 12 Ln 7—14 again maybe describing sites rather than naming would help reader. Names have limited meaning, and what they look like would be of more interest.</p> <p>Pg. 12 Ln 16 one sentence paragraph. Check entire paper happens several times. Two sentences make a paragraph.</p> <p>Pg. 13 Ln 47, who and how will you determine life expectancy?</p> <p>Pg. 13 Ln 55 delete work clear, as inherent in word understanding</p> <p>Pg. 14 Ln 5 do you mean follow? Not cooperate.</p> <p>Pg. 14 Ln 24 delete word specific before data; and consider breaking into 2/3 sentences, too long for reader.</p> <p>Pg. 14 Ln 36 change tense from “are” to “will be”</p> <p>Pg. 14 Ln 47, shared with who?</p> <p>Pg. 14 line 49, unsure meaning of consecutive, consider deleting; unless you mean consecutively enrolled</p> <p>Pg 14 Ln 10 how will these be administered?</p> <p><b>DATA MANAGEMENT</b></p> <p>Pg 15 Lin 9, consider moving to methods as this is what the sentence is about.</p> <p>Pg 15 Ln 14—24 break into 2/3 sentences for readability</p> <p>Consider putting all sentences about statistical analysis into one paragraph rather than scattering across section.</p> <p><b>RELEVANCE</b></p> <p>Pg 17 Ln 21-26 above you say nothing in literature, yet here you saw will compare to other studies? Please clarify.</p> <p><b>REFERENCES:</b> missing several important systematic reviews detailing problems with oral agents.</p> <p><b>OVERALL:</b></p> <p>Check paper, as in some you cite word1 and others you have a space word 1. There should be no space.</p> <p>Consider how you use words mHealth eHealth in paper.</p> <p>Consider abbreviations.</p>
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	<p>Consider word choice for oral agents and use same words in entire paper.</p> <p>Consider word choice for provider, physician, professionals, etc. You use different terminology for healthcare provide in paper.</p> <p>Embed all figures within text. (Very nice figures)</p>
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<b>REVIEWER</b>	Anne Arber University of Surrey UK
<b>REVIEW RETURNED</b>	18-Nov-2016

<b>GENERAL COMMENTS</b>	<p>This is a very interesting study protocol using a user-centred design process.</p> <ul style="list-style-type: none"> <li>-Develop the user-centred design process in more detail and define how this will work throughout the research.</li> <li>-There is an age limitation identified in the inclusion criteria which means that some patients will not be able to access the system because of age. This criteria and age limitation needs to be reconsidered.</li> <li>-There are some minor typos such as assumption on page 5 which should be consumption? There are many abbreviations used throughout the article which are confusing at times.</li> <li>- The patient working group "CON-TATTO" is referred to but there is no information on the priorities of patients and families regarding mHealth.</li> <li>-IRST IRCCS approaches to patient education are referred to but no information is provided on key findings.</li> <li>- The introduction needs to make clear that this is a study protocol.</li> <li>- Identify reasons for sampling patients taking capecitabine or sunitinib.</li> </ul>
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### VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

**TITLE:** Use of fewer words may focus the title topic; suggest deleting the words: “for a fine-tuned 2.0 system” as it did not add any meaning to the paper title.

**Reply:** the title has been modified following the reviewer’s suggestion.

**ABSTRACT:**

Pg. 4 Ln 16 the word mobile-Health reads out of context and maybe “mobile health” would make more meaning

Pg. 4 line 24-25 reword order: We plan to customize and fine-tune and existing monitoring TreC platform used in chronic diseases for the oncology setting. This will have more meaning making for readers.

Pg. 4 Ln 43, maybe instead of “will contribute” change it “is expected to contribute” and you will not know until after testing is completed. Also, is it focused on medication adherence as stated above? If so add to what will be improved.

Pg. 5 Ln 4 delete word individual, as inherent in words study participants.

**Reply:** the abstract has been modified in accordance with all the reviewer’s requests.

**INTRODUCTION:**

Pg. 6 Ln 6 use full word, not chemo- but chemotherapy to make clear your meaning.

Pg. 6 line 14, unsure what “largely hampered by” means? And as far as I know, the side effects are not serious ADEs. Please cite if you know otherwise.

Pg. 6 Ln19 unsure what “even more” means for oral cancer drugs, listing a % would be more clear.  
Pg. 6 Ln 24 maybe use the word “use” rather than “consumption” to make a clearer sentence.

Pg. 6 Ln 28 unsure what information leaflets are; or patient-help so you mean patient completed diaries?

Pg. 6 Ln 33 what do you mean “of this process” what process are you talking about? Home-based treatment? Exactly what do these 5 key points relate to? Unsure

Pg. 6 Ln 57 consider deleting word strong; as not all evidence is strong

Pg. 7 Ln 4 associated with “positive health outcomes”? Many important and meaningful is unclear to me

Pg. 7 Ln 7 Unsure what in this context means. Do you mean to enact patient-centered communication?

Pg. 7 Ln 12 by shared to you mean between healthcare provider(s) and patient? Who is doing the sharing?

Pg7 Ln 27 on got lost in all the abbreviations, carefully select only those abbreviations that truly add to the paper. Maybe consider not using formal site names but listing them in the acknowledgement; but rather describe the setting in your paper.

Reply: the section has been modified in accordance with all the reviewer’s requests.

#### AIMS AND OBJECTIVES:

Page 9 Ln 21 consider dropping work “overall” implied in statement.

Pg. 9 Ln 28 Consider dropping work “specific” as implied in statement.

Pg. 9 #3 Line 40 above in paper you also included capability in addition to usability and acceptability here. Please clarify. Also, are you focused on medication adherence or symptoms? High value items with oral agents.

Reply: the section has been modified in accordance with all the reviewer’s requests.

#### METHODS:

Pg. 10 Ln 7 Do you mean there are two phases to this project? What are major strands?

Pg. 10 Ln 26—36 break into 2/3 sentences too long for reader.

Pg. 12 Ln 7—14 again maybe describing sites rather than naming would help reader. Names have limited meaning, and what they look like would be of more interest.

Pg. 12 Ln 16 one sentence paragraph. Check entire paper happens several times. Two sentences make a paragraph.

Pg. 13 Ln 47, who and how will you determine life expectancy?

Pg. 13 Ln 55 delete work clear, as inherent in word understanding

Pg. 14 Ln 5 do you mean follow? Not cooperate.

Pg. 14 Ln 24 delete word specific before data; and consider breaking into 2/3 sentences, too long for reader.

Pg. 14 Ln 36 change tense from “are” to “will be”

Pg. 14 Ln 47, shared with who?

Pg. 14 line 49, unsure meaning of consecutive, consider deleting; unless you mean consecutively enrolled

Pg 14 Ln 10 how will these be administered?

Reply: the section has been modified in accordance with the reviewer’s requests.

#### DATA MANAGEMENT

Pg 15 Lin 9, consider moving to methods as this is what the sentence is about.

Pg 15 Ln 14—24 break into 2/3 sentences for readability

Consider putting all sentences about statistical analysis into one paragraph rather than scattering across section.

Reply: the section has been modified in accordance with the reviewer’s requests.

## RELEVANCE

Pg 17 Ln 21-26 above you say nothing in literature, yet here you saw will compare to other studies?  
Please clarify.

Reply: the section has been modified in accordance with the reviewer's requests.

REFERENCES: missing several important systematic reviews detailing problems with oral agents.

Reply: we added some recent important references.

## OVERALL:

Check paper, as in some you cite word1 and others you have a space word 1. There should be no space.

Consider how you use words mHealth eHealth in paper.

Consider abbreviations.

Consider word choice for oral agents and use same words in entire paper.

Consider word choice for provider, physician, professionals, etc. You use different terminology for healthcare provider in paper.

Embed all figures within text. (Very nice figures)

Reply: the "overall" section has been modified in accordance with the reviewer's requests

Reviewer: 2

- Develop the user-centred design process in more detail and define how this will work throughout the research.

Reply: the paper has been modified in accordance with the reviewer's requests (section: METHODS > Participatory Research > Approach)

- There is an age limitation identified in the inclusion criteria which means that some patients will not be able to access the system because of age. This criteria and age limitation needs to be reconsidered.

Reply: we agree. Age limitation is not appropriate in this study. We modified the protocol criterion and the paper (section: METHODS > Prospective Study > Study Population)

- There are some minor typos such as assumption on page 5 which should be consumption? There are many abbreviations used throughout the article which are confusing at times.

Reply: the paper has been modified in accordance with the reviewer's requests.

- The patient working group "CON-TATTO" is referred to but there is no information on the priorities of patients and families regarding mHealth.

Reply: unfortunately we have too little information on the priorities of patients regarding mHealth at the moment (section: INTRODUCTION)

- IRST IRCCS approaches to patient education are referred to but no information is provided on key findings.

Reply: the paper has been modified in accordance with the reviewer's requests (section: INTRODUCTION)

- The introduction needs to make clear that this is a study protocol.

Reply: the paper has been modified in accordance with the reviewer's requests (section: INTRODUCTION)

- Identify reasons for sampling patients taking capecitabine or sunitinib.

Reply: the criterion has been better defined. The paper has been modified (section: METHODS > Prospective Study > Study Population).

### VERSION 2 – REVIEW

<b>REVIEWER</b>	Dr Anne Arber University of Surrey, UK
<b>REVIEW RETURNED</b>	05-Mar-2017

<b>GENERAL COMMENTS</b>	This is a well-written article. The authors have responded very thoroughly to all feedback from the reviewers.
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### VERSION 2 – AUTHOR RESPONSE

We are returning the above manuscript, modified in accordance with the editorial requests, for further evaluation.