

Inclusion of special populations in clinical research: important considerations and guidelines

Stuart S. Winter, Janet M. Page-Reeves, Kimberly A. Page, Emily Haozous, Angelica Solares, Carla Nicole Cordova, Richard S. Larson

Corresponding author:

Stuart S. Winter

Children's Minnesota Research Institute South Minneapolis, United States

Handling editor:

Michal Heger

Department of Experimental Surgery, Academic Medical Center, University of Amsterdam, Amsterdam, the Netherlands

Review timeline:

Received: 29 January, 2018
Editorial decision: 15 March, 2018
Revision received: 30 March, 2018
Editorial decision: 4 April, 2018
Published ahead of print: 7 April, 2018

1st Editorial decision

Date 15-Mar-2018

Ref.: Ms. No. JCTRes-D-18-00007

Inclusion of Special Populations in Clinical Research: Best Practices for a Better Future
Journal of Clinical and Translational Research

Dear author(s),

The editor and a reviewer have submitted their critical appraisal of your paper. The reviewers' comments are attached as Word documents. Based on their comments and evaluation by the editorial board, your work was FOUND SUITABLE FOR PUBLICATION AFTER MINOR REVISION.

If you decide to revise the work, please itemize the reviewers' comments and provide a point-by-point response to every comment. An exemplary rebuttal letter can be found on at <http://www.jctres.com/en/author-guidelines/> under "Manuscript preparation." Also, please use the track changes function in the original document so that the reviewers can easily verify your responses.

Your revision is due by Apr 14, 2018.

To submit a revision, go to <https://jctres.editorialmanager.com/> and log in as an Author. You will see a menu item call Submission Needing Revision. You will find your submission record there.

Yours sincerely,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Reviewers' comments:

Editor and Reviewer #1: Please see attached

There is additional documentation related to this decision letter. To access the file(s), please click the link below. You may also login to the system and click the 'View Attachments' link in the Action column.

Author's rebuttal

FEditorial review of JCTRes-D-18-00007

Please note that references to page and line numbers are made as follows: 3/9 means page 3, line 9. The comments have been formatted such that the authors simply need to copy/paste the text in their rebuttal letter and address each point of critique by adding the response behind

ANSWER:

(NOTE TO Editor: Modifications have been called out in Comments in the Marked Copy)

1. - 3/38: The multidimensional problem that is addressed through Table 1 is not overtly clear from the table or its legend. Please explicitly state the dimensions that make up the problem as pointed out by Waheed et al. or rephrase the text. In my opinion the table is complementary to the text in that paragraph (3/18 to 3/26). The way Table 1 is presented infers additional layers of complexity to the aforementioned "special populations," which are essentially restated in Table 1. Also provide more explanatory text in the table legend to contextualize the data and align it with the storyline.

ANSWER: We agree that Table 1 is not best positioned to be addressed at line 3/38. Reference to table 1 has been moved to 3/19 in the revision, as suggested by the editor. Furthermore, we have added an additional table legend, 32/808,809 which states:

"Projected shifts among US special populations predict increases in population age, a growth among Hispanic communities and a rise in urbanization."

2. - 3/60: The reference to Figure 1 is great, but the figure is not self-explanatory in some instances. This should be addressed in e.g., the figure legend or the respective text boxes. For example, the phrasing "site champion" is difficult to comprehend,

albeit defined later in the text. It is also difficult to fully appreciate how e.g., the provision of logistical support leads to gaps in the practice of special population recruitment. These are just 2 specific examples of a larger issue. Also, the figure contains the word “text” in some of the brackets. Please remove.

ANSWER: We agree that Figure 1 contains mixed messages. It has been re-formatted to show the causative features that lead to gaps in best practices. The “text” messages have been removed. A new figure legend has been included at 31/782-784:

“Figure 1: Causative features for gaps in best practices for clinical trial inclusion. Clinical trials recruitment and retention are challenged by at least six areas of deficiencies. A partial listing of specific items are addressed, but may be overcome by focused interventions. “

3. - Table 1: please use consistent punctuation and grammar throughout the table so that sentences are logical. Also make sure all abbreviations are written out at first mention (see e.g., 7/54) or that phrases are abbreviated properly at first mention.

ANSWER: We have attempted to use consistent grammar throughout the table; abbreviations have been spelled out at first use.

4. - 5/53-64: “Effective interventions” is mentioned twice.

ANSWER: Corrected

5. - 6/51-64: first column should read “...withdraw (MLTW) from the TEDDY study”.

ANSWER: Corrected

6. - 12/48-60: Please spell-check.

ANSWER: Done

7. - 13/48: Please write out CT here and throughout the paper to improve legibility.

ANSWER: Done throughout the manuscript

8. - 13/28: The section is titled “Building foundations of trust among ethnic minorities” and the issues related to this category are clearly defined. However, unlike the other sections, no solutions are provided to counter these barriers in this section. So, the section header should be rephrased to for example “Identification of trust issues among ethnic minorities.” Preferably, solutions are provided to maximally resolve the issues. I understand that some of the problem solving is partly addressed in the next section - “Accommodating Culture and Context” - but solutions to problems such as distrust of the researchers/government agencies and guinea pig mentality are addressed much later (section “Participant Awareness,” 17/11). So I suggest to change the section title for purposes of clarity and logic.

ANSWER: Done

9. - 14/40: Figure 2 needs to be reformatted because it is not legible. Moreover, the legend needs to specify that the Figure addresses solutions to the problems delineated in Figure 1. I further do not understand the positioning/significance of the special populations right outside the pentagram in juxtaposition to the presented solutions in the balloons.

ANSWER: Done (see revised Figure 2 – separate PDF file)

10. - 20/45: In the study by Brueton et al. the authors found that case management does not improve response and retention rates. Are earlier pointers provided in the current text, such as “utilizing community liaisons to help in the recruitment...” not in contrast to the research findings? Please take a good look at this because you don’t want to bring out conflicting messages that may result in significantly higher trial costs while not being effective.

ANSWER: We agree with the reviewer, and have deleted the sentence fragment about case management, which seems inconsistent with other study results.

On behalf of the authors, we are very thankful for the editorial suggestions that were provided to us. Please let us know if we can help in any other way.

2nd Editorial decision

Date: 4-Apr-2018

Ref.: Ms. No. JCTRes-D-18-00007R1

Inclusion of Special Populations in Clinical Research: Best Practices for a Better Future
Journal of Clinical and Translational Research

Dear authors,

I am pleased to inform you that your manuscript has been accepted for publication in the Journal of Clinical and Translational Research.

I would like to change one small detail in your title: "Inclusion of special populations in clinical research: important considerations and guidelines." That way the title is more drawing to the proper audience without giving off a potentially false prognosis. The 'better future' sounds utopic and pitchy, especially if the whole clinical science world starts abiding by your considerations and guidelines while Kim Jong Un and Donald Trump are pressing all sorts of hot buttons. If you agree with the title, we will change it for you in the proofs.

You will receive the proofs of your article shortly, which we kindly ask you to thoroughly review for any errors.

Thank you for submitting your work to JCTR.

Kindest regards,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Comments from the editors and reviewers: