Author’s response to reviews

Title: Clinical Trial Readiness to Solve Barriers to Drug Development in FSHD (ReSolve): protocol of a large, international, multi-center prospective study

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Author’s response to reviews:
Dear Dr. Samuel Harris, Brock Madsen and the BMC Neurology Editorial Board,

We are resubmitting our protocol manuscript entitled, “Clinical Trial Readiness to Solve Barriers to Drug Development in FSHD (ReSolve): protocol for a large, international, multi-center prospective study” for consideration for publication in BMC Neurology. This manuscript has not been previously published or submitted for consideration to any other journal.

In response to your comments:

1) It is noticed that authors Elena Carraro (EC) and Baziel van Engelen (BvE) are not mentioned in the Authors’ contributions subsection of the Declarations. Please revise and ensure all authors are accounted for using their initials alongside their individual contributions to the study/manuscript. These authors have now been added to the contributions subsection (see page 27, line 608).

2) While assessing your manuscript we found several instances where the text displayed overlap with other previously published works, in particular:

https://doi.org/10.1093/hmg/ddy293
Lines 91 – 96.

https://doi.org/10.1002/mus.26088

We sincerely apologize for that oversight. We have edited both of these sections to avoid overlap with previously published articles (see page 4, lines 91-98). Regarding the second section, we have taken out some of the detail regarding the FSHD-COM and have simply referenced the article (see page 12, lines 280-288).

3) Submission of a manuscript to a BioMed Central journal implies that materials described in the manuscript, including all relevant raw data, will be freely available to any scientist wishing to use them for non-commercial purposes, without breaching participant confidentiality. Thus, we request that you upload English language versions of all questionnaires developed specifically for use in this study as supplementary files. If the questionnaires are not yours or are already published by you, please supply references and/or links to them.
We have uploaded the exercise and fall diaries and questionnaires as supplementary files. The domain-delta questionnaire was designed as part of the FSHD-HI (now more clearly stated in our paper-page 16, line 374). We have also now added a reference that was key to the design of the FSHD-HI (see page 16, line 374); however, this questionnaire has not yet been officially published. It was purchased for the study from Chad Heatwole who holds the copyright so we are unable to upload this.

4) At this point you may remove the STROBE checklist form the file inventory as it is no longer needed at this stage of the editorial process.

This has been done.

5) Please state in the cover letter whether the maps depicted in figure 1 are your own or taken from another source. If taken from another source please acknowledge the source in the figure legend, and if it is under copyright also state the written permission given to use and adapt it.

This map is our own. It is not under copyright. It is available on the FSHD CTRN website http://www.kumc.edu/fsbd/our-sites.html which is stated in the figure legend.

6) At this stage, please upload your manuscript as a single, final, clean version that does not contain any tracked changes, comments, highlights, strikethroughs or text in different colours. All relevant tables/figures/additional files should also be clean versions. Figures (and additional files) should remain uploaded as separate files.

A single, clean version of the manuscript has been uploaded.

Sincerely,

Samantha LoRusso, MD, Jeffrey Statland, MD, and Rabi Tawil, MD, on behalf of the ReSolve Investigators of the FSHD Clinical Trial Research Network