Author's response to reviews

Title: Effects of a partially supervised conditioning programme in cystic fibrosis: an international multi-centre randomised controlled trial (ACTIVATE-CF): Study Protocol

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Effects of a partially supervised conditioning programme in cystic fibrosis: an international multi-centre randomised controlled trial: Study Protocol [NCT01744561] Helge Hebestreit, Prof; Larry C Lands, MD, PhD; Nancy Alarie; Jonathan Schaeff; Chantal Karila, MD; David M Orenstein, MD; Don S Urquhart, MD; Erik HJ Hulzebos, PhD; Lothar Stein; Christian Schindler; Susi Kriemler, MD; Thomas Radtke, PhD BMC Pulmonary Medicine

Response to Editor's comments:

Dear Cecilia Devoto,
Below we respond to your comments, which are included in this letter.

As you may be aware, it is the policy of the journal not to peer review study protocols where ethical and external funding approval have been obtained, as these processes usually involve peer review and as there is little possibility to change a protocol after enrolment begins.

Therefore, could you please respond to the following points below and provide the requested responses in your cover letter.

1. Ethical and Funding Approval Documentation

Before we can proceed with your submission, can you please forward copies of all ethical approval and funding approval for our records. These documents should be sent as email attachments to the following email address, BMCSeriesEditorial@biomedcentral.com. Please DO NOT upload these documents as additional files in the submission system. If your documents are not in English, please could you provide translated versions of the relevant parts. These should be endorsed and signed by a contactable person at the institution. Please also include the original documents. Can you please confirm in your cover letter that you have forwarded the requested documentation to BMCSeriesEditorial@biomedcentral.com.

We have sent two separate letters from the German Cystic Fibrosis Organization (Mukoviszidose e.V.) to BMCSeriesEditorial@biomedcentral.com stating that they are funding the study and that the study has undergone peer review. We have send all ethical approvals to the suggested Email address.

2. Funding

A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/ award from a charitable foundation). If a study has not received external funding, then the study protocol will be sent for peer-review with a member of our Editorial Board. If a study has received funding/assistance from a commercial organization, this should be clearly stated in the 'competing interests' section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board. Can you please confirm whether your study protocol has undergone peer-review by the funding body.

Our study protocol has undergone peer-review (see confirmation letter from the German Cystic Fibrosis Organization). Our study protocol was additionally submitted to the European Cystic Fibrosis Society-Clinical Trial Network (ECFSCTN) review board. Within this evaluation, the study protocol was revised again and the ACTIVATE-CF study (protocol Version 2) was accepted by the ECFS-CTN review board. The study was listed as one of the trials which can be performed at ECFS-CTN sites.

3. Study Status
The protocol must be for a study that is ongoing. An ‘ongoing’ study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at.

We confirm that the study is still ongoing. Detailed information for specific study centers can be found under https://clinicaltrials.gov/ct2/show/NCT01744561

4. Related Articles

Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles.

No publications have been published or submitted to any journal.

5. On the title page please include the email addresses of all authors.

Done.

6. After the Acknowledgements, please include the heading "Declarations".

Done.

7. Under the heading Ethics approval and consent to participate, please include the names of all the ethics committees that have approved the study design.

Done.

8. Authors ‘Jonathan Schaeff, Don S Urquhart, Erik HJ Hulzebos, Lothar Stein, Christian Schindler’ listed in the manuscript do not appear in the 'Author Contributions' section of the manuscript. Please include them and clarify what contributions they made to the study protocol.

We have added the requested information.

ADDITIONAL INFORMATION

We have added a list of study site investigators to the ACTIVATE-CF Working group (pages 2-5).