Author’s response to reviews

Title: Effect of a multi-ingredient based food supplement on sexual function in women with low sexual desire. Pilot study.

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Version: 1 Date: 26 Jun 2018

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Answers to Reviewers:

1. At this stage, we ask that you submit a clean version of your manuscript and do not include track changes or highlighting.

ANSWER: Already done.

2. Please include a statement on ethics approval and consent to participate in the “Ethics approval and consent to participate” section of the Declarations.

Please include the full name of the ethics committee (and the institute to which it belongs to) that approved the study and the committee’s reference number if appropriate.

If you did not need formal ethics approval please confirm that this complies with national guidelines and provide a reference which supports this. Alternatively, supply a statement that says that a local ethics committee ruled that no formal ethics approval was required in this particular case.

ANSWER: In Spain only the clinical trials with medicines are regulated by Royal Decree 1090/2015, of December 4, and Regulation (EU) No. 536/2014, without there being regulations that regulate the trials of intervention in humans with food.
The Spanish Agency for Food Safety (AECOSAN), under the Ministry of Health and Consumption, is the Spanish entity that regulates food supplements and does not establish administrative procedures prior to conducting an intervention trial in humans with food.

Therefore, no approval of the ethics committee is needed since Libicare is a food supplement (Spanish food supplement legislation attached)

However, the pilot study that has been presented has been carried out following a well-defined protocol, and in accordance with the main premises of Good Clinical Practices and the Declaration of Helsinki.

In this way, all the participants have been informed, before their inclusion, of the possible risks and benefits and of all the aspects of the study, and have signed an Informed Consent expressing their willingness to participate. Likewise, during the study, all adverse events were registered and followed, fulfilling the maximum premise of safeguarding the safety of patients.

3. In your “ethical approval and consent to participate” section of your declarations please confirm whether written consent was obtained from participants. If written consent was not obtained, please explain why not.

ANSWER: Written consent was obtained. Included as attached documents (Spanish versión and its translation)

4. As a member of the editorial board (Santiago Palacios) of this journal, in order to ensure transparency, please declare this in the Competing Interests section of the Declarations.

ANSWER: Included in the manuscript.

5. Please use initials to refer to each author's contribution in this section, for example: "FC analyzed and interpreted the patient data regarding the hematological disease and the transplant. RH performed the histological examination of the kidney, and was a major contributor in writing the manuscript. All authors read and approved the final manuscript."

ANSWER: Included in the manuscript.