Author's response to reviews

Title: Optimizing Expectations to Prevent Side Effects and Enhance Quality of Life in Breast Cancer Patients Undergoing Endocrine Therapy: Study Protocol of a Randomized Controlled Trial.

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Author's response to reviews: see over
Re: Clarification and revision of the Study-Protocol entitled: “Optimizing Expectations to Prevent Side Effects and Enhance Quality of Life in Breast Cancer Patients Undergoing Endocrine Therapy: Study Protocol of a Randomized Controlled Trial”

Dear Miss Nikka Portodo,

Thank you for your interest in our manuscript. Please find our answers to your queries in the following letter. Attached we send evidence of ethical approval and external funding for our study.

• 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). Our study ‘Clinical application of nocebo research: Optimizing breast cancer patient’s expectations to prevent side effects and decreased quality of life during endocrine therapy’ is funded by a grant of the German Research Foundation (DFG) to Dr. Nestoriuc (NE 1635/2-1).

The DFG is the self-governing organisation for science and research in Germany. It serves all branches of science and the humanities. In organisational terms, the DFG is an association under private law. Its membership consists of German research universities, non-university research institutions, scientific associations and the Academies of Science and the Humanities.

The DFG receives the large majority of its funds from the states and the Federal Government, which are represented in all Grants Committees. At the same time, the voting system and procedural regulations guarantee science-driven decisions. (www.dfg.de)

• 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.

Our study has received external funding (see above).

• 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.

Our study has not received external funding or assistance from a commercial organization, it is external funded solely by the DFG (see above).

The two authors Winfried Rief and Yvonne Nestoriuc received honoraria from Astra Zeneca, Heel, and Berlin Chemie and Atlantis Healthcare for consultation and talks about placebo effects and medication adherence that were independent from the current study.
• 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.
You will find these documents attached.

• N.B. Proof of external funding should include details of the amount of funding that was awarded for your study.
A sum of 113,452 € has been approved by the DFG (German Research Foundation) for the funding of our project (see attached funding letter).

• Could you also provide a list of any manuscripts that are under submission with other journals based on this study protocol?
At that moment there are no further manuscripts under submission.

• BioMed Central requires all controlled clinical trials to be registered in a suitable publicly accessible registry prior to consideration for publication. The trial registers that currently meet all of the ICMJE guidelines can be found at http://www.icmje.org/faq.html.
Our trial is registered at the register www.clinicaltrials.gov that meet the ICMJE guidelines.
Our trail (ClinicalTrials.gov Identifier: NCT01741883) can be found at:
http://clinicaltrials.gov/show/NCT01741883

• Kindly send us proofs of Ethical approval from both sites, as attachments to an email.
Done (see attached documents).

• Remove documents from additional files
Done.

• Confirm whether the study has been peer reviewed
The quality of our study was assessed by peer reviewers selected by the DFG Head Office.
(See the attached document and http://www.dfg.de/en/research_funding/proposal_process/quo_vadis_proposal/index.html#micro169611)

• Please revise the manuscript: remove all results from the manuscript (i.e. "feasibility" in abstract and on page 16) as only baseline demographic data can be included in a study protocol.
We now removed all feasibility results and included only preliminary baseline demographic data (page 16).

We hope that our paper is now suitable for publication.

Kind regards,
Pia v. Blanckenburg