

Author's response to reviews

Title: Patient education to prevent postoperative complications: the PEDUCAT TRIAL - (Study protocol of a cluster-randomized controlled pilot study investigating the impact of preoperative patient education on prevention of postoperative complications after major visceral surgery)

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Response to Reviewers

Dear Reviewers,

the following revisions were made in this version of our manuscript entitled “Patient education to prevent postoperative complications: the PEDUCAT TRIAL – (Study protocol of a cluster-randomized controlled pilot study investigating the impact of preoperative patient education on prevention of postoperative complications after major visceral surgery)” by Fink et al.:

1. Ethical and legal aspects in the Methods section:

   “This study is accomplished according to the Helsinki Declaration, the principles of the Good Clinical Practice (ICH-GCP) guidelines (E6) and the Federal Data protection Act. The study protocol was approved by the ethics committee of the University of Heidelberg.”

2. Subject information and informed consent in the Methods section:

   “Before being admitted to the trial, the patient must consent to participate after the nature, scope, and possible consequences of the clinical trial have been explained in a form understandable to him or her. After reading the informed consent document, the patient must give consent in writing. The investigator will not undertake any measures specifically required only for the clinical trial until valid consent has been obtained.”

Thank you very much for your consideration.

Sincerely yours,

C. Fink

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