Author’s response to reviews

Title: Makes FLASH the difference between intervention group and treatment-as-usual group in an evaluation study of a structured education and treatment programme for flash glucose monitoring devices in people with diabetes on an intensive insulin therapy: study protocol for a randomized controlled trial

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Author’s response to reviews:

Dear Ms Mader,

Thank you very much for giving us the opportunity to submit this revised version of our manuscript titled “Makes FLASH the difference between intervention group and treatment-as-usual group in an evaluation study of a structured education and treatment programme for flash glucose monitoring devices in people with diabetes on an intensive insulin therapy: study protocol for a randomized controlled trial”, and to address the comments of the reviewers. We thank the reviewers for their comments and recommendations, which have helped us improve the manuscript considerably. Please see below our specific responses to the comments.

We hope that you now find this manuscript suitable for publication in your Journal.

Best regards

Melanie Schipfer
Dear Mr Melmer,

thank you for your valuable comments to improve our manuscript. Below you will find our answers to each of the issues. We hope that these responses will clarify all doubts.

1. You wrote: “I still recommend that the authors cooperate with a professional statistician from the beginning of the study. The protocol is complex and the estimated sample size is high, it would therefore be a great pity if some interesting findings were lost by using inadequate statistical Analysis.”

We agree that it would be a pity, if some interesting findings will be lost by losing an inadequate statistical analysis. For that reason, we are working together with statistical experts in our research group who have a great background and experiences in statistical data analysis of data collected as described in our protocol to minimize the risk of loosing interesting data through the usage of inadequate statistical analysis.

2. You wrote: “Moreover, the authors should reconsider if all of the questionnaires are essential. There seems to be some redundancy in the results that the plethora of questionnaires will provide.”

The selection of questionnaires was chosen in an agreement with the same group of experts (diabetologists and diabetes educators with special experience in flash glucose monitoring) that had given valuable advices to our team in the development of FLASH, according to German and international guidelines.