Author's response to reviews

Title: Effectiveness of a PLISSIT model intervention in patients with type 2 diabetes mellitus in primary care: design of a cluster-randomised controlled trial

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Author's response to reviews: see over
Dear Sir/Madame,

We would like to submit our study protocol titled ‘Effectiveness of a PLISSIT model intervention in patients with type 2 diabetes mellitus in primary care: design of a cluster-randomised controlled trial’ for publication in *BMC Family Practice*. We requested the protocol to be transferred from *BMC Public Health* with manuscript number 1423379114168325. No changes have been made to the original submission.

Patients with type 2 diabetes mellitus are frequently affected by sexual problems, but both the patients and their care providers have difficulties with discussing these problems in diabetes care. The PLISSIT model is a frequently recommended sexual counselling model that has shown promising results in different patient groups, but has thus far never been examined in patients with diabetes. Our study describes the design of a cluster-randomised controlled trial evaluating the effectiveness of a PLISSIT-model intervention in men and women with type 2 diabetes mellitus in primary care. Primary outcomes include sexual function, satisfaction with sexual function, and quality of life. These outcome measures will be assessed at baseline and after 3 and 12 months. Our study will add important and currently missing insight into the effectiveness of PLISSIT on important patient-reported outcomes of men and women with type 2 diabetes mellitus.

We would here like to respond to the questions as asked in correspondence with Ms. J. Dalumpines. Since October 18th 2014, our study has been registered at the Dutch Trial Registry (NTR4807). The status of our study is currently ‘ongoing’ and we have no publications or papers submitted for publication at any journal. In addition, the authors declare no conflicts of interest.

We can confirm that our study underwent peer-review by our funder the Dutch Diabetes Foundation (a major funding body). Our study also received ethical approval by the Medical Ethics Committee of the VU University Medical Centre in Amsterdam, the Netherlands. We hereby confirm that the requested documents on the funding and ethical approval have been sent per e-mail to BMC series editorial.

We hope you will consider our study protocol to be of interest for the readers of *BMC Family Practice* and we look forward to your evaluation.

Yours sincerely,

Anne Rutte