Author’s response to reviews

Title: Transglucosidase improves the gut microbiota profile of type 2 diabetes mellitus patients: A randomized double-blind, placebo-controlled study

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Author’s response to reviews: see over
To,
The Editor-in-Chief
*BMC Gastroenterology*
MS: 5703470318684932

March 26, 2013

Dear Editor:

We have enclosed our revised manuscript (5703470318684932) entitled “Transglucosidase improves the gut microbiota profile of type 2 diabetes mellitus patients: A randomized double-blind, placebo-controlled study” by Makoto Sasaki, Naotaka Ogasawara, Yasushi Funaki, Mari Mizuno, Akihito Iida, Chiho Goto, Satoshi Koikeda, Kunio Kasugai, and Takashi Joh.

We hope that you will find our revised manuscript acceptable for publication in *BMC Gastroenterology*, and that the contents of our paper will be of interest to your journal’s readership.

Thank you for your consideration.

Sincerely,

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Answer to Comment

Thank you for your important comments. They were extremely helpful in improving the quality of our manuscript.

1. Firstly, we require all trials to have been registered in an appropriate trial registry. Please note that we only accept registration numbers issued by registries that meet all of the ICMJE criteria (http://www.icmje.org/publishing_10register.html). Registries which meet the requirements of the ICMJE include WHO Primary Registries are listed here (http://www.who.int/ictrp/network/primary/en/index.html). If you have already registered your trial, then please include the registration number at the end of the abstract in a revised manuscript. If you have not yet registered your trial we will require you to do so retrospectively before we can accept your manuscript.

   We have retrospectively registered our trial to UMIN-CTR, and the registration number (UMIN00001038) was described in the abstract.

2. Secondly, we require all clinical trials we publish to follow CONSORT guidelines (http://www.consort-statement.org/index.aspx?o=1031). Please revise your manuscript to fully comply with these guidelines, including completing a CONSORT checklist which should be included as an additional file in your revised manuscript. Please note that we do not consider referring back to previously published manuscripts to be an acceptable substitute for including the necessary details in this manuscript.

   We have revised our manuscript accordingly which was shown in red color sentence in the methods and results section.

3. Can we also ask you to include a power calculation in your methods section, justifying the sample size you selected for your trial.

   We have included a power calculation in the revised manuscript as follows (page 7, lines 6–9):
   “The sample size calculation was based on a previous study [2, 6], and based
on alpha of 0.05 with a power of 80%. Taking into account a drop-out of 10%, a total sample size of 66 patients will randomized.”

4. Finally, as a non-specialist reader, I found parts of your manuscript as written to be difficult to follow. In particular, it would seem desirable to me to include a paragraph in your discussion section that briefly summarises the findings from your trial.

We have included summaries in the discussion section as follows: (page 13, lines 10–13)

“In summary, we indicated that T2DM in humans is associated with compositional changes in intestinal microbiota, and TGD treatment improved metabolic condition of T2DM and fecal microbiota. These evidence suggests that there is the link between metabolic disease and bacterial population in the gut.”