

## Format for ANSWERING REVIEWERS

January 22, 2013

Dear Editor,



Please find enclosed the edited manuscript in Word format (file name: 6612-review.doc).

**Title:** EHealth monitoring in IBS patients treated with low FODMAP diet

**Author:** Pedersen N, Vegh Z, Burisch J, Jensen L, Ankersen DV, Felding M, Andersen NN, Munkholm P

**Name of Journal:** *World Journal of Gastroenterology*

**ESPS Manuscript NO:** 6612

The manuscript has been improved according to the suggestions of reviewers:

1 Format has been updated

2 Revision has been made according to the suggestions of the Editor:

(1) We defined the abbreviation "FODMAP" in the "Comments" under "Term explanation".

(2) We changed the title "Is eHealth monitoring in IBS patients treated with low FODMAP diet feasible?" to "EHealth monitoring in IBS patients treated with low FODMAP diet".

(3) The fax number of the corresponding author has been added.

(4) and (5) The type of the reference numbers has been corrected across the text

(6) Comments have been included.

(7), (8) and (9) The decomposable figures of Figures 2 and 3 are provided as a ppt format in the manuscript. The ppt file has also been uploaded separately. Figure 1 had been copied from the web-application used by the patients in this study. We deleted this figure from the manuscript, as we can't edit it. Figure 2. And 3. have been renamed to Figure 1. and 2.

3 Revision has been made according to the suggestions of the Reviewer 2:

(1) Was this study approved by an ethical committee and did the patients give informed consent?

Answer: The study was approved by the Ethical Committee, Denmark (protocol number H-2-2011-095-IBS. All patients included in this study signed an informed consent.

(2) My major concern is whether the second decline in the IBS disease score is indeed related to the introduction of the low FODMAP diet or whether it is related to the continuation of the e-monitoring application or to the natural course of IBS ? The authors need to take this time course into consideration before they will be able to draw any

definite conclusions on the e-monitoring application and the low FODMAP diet per se. Both factors need to be studied in separate groups: 1) a control group (natural course of the disease); 2) a group with the web-application for 12 weeks but without the diet and 3) a group with the web-application and the low FODMAP diet. Besides the authors need to provide evidence for the adherence of the patients to the FODMAP diet. All these factors need to be discussed in the discussion, which now only repeats the main results and discusses the topic of the web-application.

Answer: We do agree about the comments. We have an ongoing trial with randomization in the three groups as you suggest. Data will be available later.

We agree that this could be the natural disease course however all 19 patients looked the same thus we anticipate that this could be the effect from combined eHealth system and lowFODMAP.

(3) The authors need to describe the statistical test used in more detail. I could not find the test used by the authors only a description of p-values. Which test was used, did it take into consideration the repeated profile on the three measuring points of the study design?

Answer: All statistical analyses were carried out using SPSS software Version 20.0 for Windows (SPSS Inc., Chicago, IL). Standard descriptive statistics was performed, including calculation of median and range for continuous variables. Differences between the IBS-SSS and IBS-QoL values between the start and the end of the control period, between the start and the end of the LFD period and between the start of the control period and the end of the LFD period were analysed by Wilcoxon two-related-samples test. A  $p$  value of  $<0.05$  was considered statistically significant.

(4) Could the authors comment on the power of this study for the IBS group as a whole (and for the subgroups of IBS patients)? Did they calculate the power of their study or even better did they calculate the number of patients needed to show statistical differences in advance? I know this paper is presented as a case report but nevertheless it would be interesting and scientifically sound to discuss the power in the discussion as well as the lack of appropriate controls (see remark 2).

Answer:

The power of the study was not performed as we planned to report it as a case report.

(5) Please provide an additional graph showing the results over the 12-week period of the 19 individual patients.

Answer: We provided an additional graph showing the IBS-SSS and IBS-QoL values over the 12-week period of the 19 individual patients.

(6) Figure 2 and 3 only show the median I presume, they need to show the median and the 25- and 75<sup>th</sup> percentile or they can be replaced by boxplot figures

Answer: We added the 25- and 75<sup>th</sup> percentile values to the Figure 2 and 3.

(7) Please clarify the dots/circles on the X-axis in Figure 1 in the figure legend.

Answer:

The dots/circles on the X axis in Figure 1 presents the median values of the included patients at the beginning of the control period - week 0 - and at the end of the control period/at the beginning of the LFD period - week 6 - and at the end of the LFD period - week 12.

(8) Table 1: one patient received budesonide, please specify the indication and did this patient show a similar profile ?

Answer:

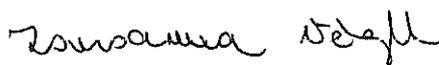
In this case, the diagnosis of IBD was suspected, but later it was not confirmed. It is a mistake in our table, because after the confirmation of the IBS diagnosis and before the inclusion in the study, this medication was abandoned. We deleted this medication from the table.

4 In order to facilitate identifying the requested changes made to the manuscript, all changes have been highlighted in red within the revised version of the paper.

5 References and typesetting were corrected

Thank you again for publishing our manuscript in the *World Journal of Gastroenterology*.

Sincerely yours,



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