OPEN PEER REVIEW

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An "Open Peer Review" process is making the details of all review process (including reviewers, associate editors, and EICs comments) as "Public" as it is agreed by EIC, Authors, and reviewers.

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- Authors' satisfactions from the review process: Increases honesty between authors and reviewers
- Education of both authors and new students
- Prevents reviewers from following their individual agendas and leading to the detection of reviewers' conflicts of interests

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Peer Review

Journal of Comprehensive Pediatrics
Article DOI: https://doi.org/10.5812/compreped.117391
Published in: Journal of Comprehensive Pediatrics: 12(4) ; e117391

Peer Review Report for "The Effect of the Yeast Probiotic *Saccharomyces boulardii* on Acute Diarrhea in Children"

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Review Timeline:

Submit Date:	20 Jul 2021
Revised Date:	10 Oct 2021
Accepted Date:	16 Oct 2021

Revision (0)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE : Reviewer

30 Jul 2021

Dear doctor

Thanks four sending me the reviewing process of this manuscript.
There are some pitfalls in the current file:
1. There are many grammatical mistakes in this file
2. They announce that the number of patients were 60 (30 cases and 30 in control group) but in line 121 the number of control group is 40 (19+21); please correct this.
3. Did they perform this study on inpatients or outpatients? please clarify in the method section. Also the didn't clarify the exact time of starting drug or placebo for

them.

4. Did they start this trial only after announcing the results of stool culture?

5. Did they discharge these patients only after full recovery of acute diarrhea?

as you know mild uncomplicated watery diarrhea doesn't need hospital admission.

6. Is their study a double blind or single blind clinical trial?

7. Is there any new point in this study?

OPEN PEER REVIEW

Revision (1)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Dear editor of journal of comprehensive pediatrics

Hello

Hereby, I send the response to dear reviewers about our original manuscript entitled: **The effect of the yeast probiotic saccharomyces boulardii on acute diarrhea in children, Manuscript ID: 117391**, as following:

Response to dear reviewer1:

Question1: There are many grammatical mistakes in this file

Response1: Grammatical mistakes corrected (highlighted).

Question2: They announce that the number of patients was 60 (30 cases and 30 in control group) but in line 121 the number of control group is 40 (19+21); please correct this

Response2: It was a typical problem and the number corrected (highlighted in results section).

Question3: Did they perform this study on inpatients or outpatients? Please clarify in the method section. Also the didn't clarify the exact time of starting drug or placebo for them.

Respose3: Study was performed on inpatients and drug or placebo started after admission (highlighted in methods and material section).

Question4*:* Did they start this trial only after announcing the results of stool culture?

Response4: yes

Question5: Did they discharge these patients only after full recovery of acute diarrhea? As you know mild uncomplicated watery diarrhea doesn't need hospital admission

Response5: After the improvement of general condition and the absence of clear dehydration, the patients were followed as outpatient.

Question 6: Is their study a double blind or single blind clinical trial?
Response6: single blind clinical trial.

Question 7: Is there any new point in this study?

Response7: Unlike many studies, our study showed that saccharomyces boulardii accelerated the recovery of acute diarrhea .

Response to dear reviewer2:

Question1: Citing references should be notice according to the journal rules (…)."

Response1: Citing references arranged according journal styles (Highlighted).

Question2: It is not appropriate to use vague words such as "efficacy". Objects and rational of study must be mentioned precisely and clear. What was novelty of study?
Response2: The objective revised (Highlighted).According the conflict of opinions about the effectiveness of S. boulardii in treating acute diarrhea, this study was conducted.

Question3: Methods section need revision, totally. What was study design? When? Number of each group? Which types of diarrhea? Age? Main demographic and characterized of subject for allocation should be mention, briefly.
Response3: method revised. The listed items are mentioned in the method section (highlighted).

Question4: We are not allowed to use any abbreviation word without definition for the first time: IQR

Response4: Item corrected.

Question5: This section needs revision. Remove unrelated content to title and aims of research, such as some part of first and second paragraphs and so on.
Response5: According to opinion of dear reviewer the unrelated contents removed from introduction section.

Question6: The background should summarize the purpose and the rationale for the study. It should neither review the subject extensively nor contains data or conclusions of the study

Response6: The abstract corrected according journal style.

Question7: What was the clinical statement of study?
Response7: The aim of this study was to evaluate the effect of yeast probiotic saccharomyces boulardii on frequency and duration of acute diarrhea in children.

Question8: I ask you the critical question: Many studies have been done in this regard. Why the authors decided to conduct this study again? What is novelty of this study? In last part of this section, objects and rational of study must be mentioned precisely and clear.
Response8: According to the conflict of opinions about the effectiveness of S. boulardii in treating acute diarrhea, this study was conducted (highlighted in last part of introduction).

Question9: What was sampling methods?
Response9: Consecutive sampling (highlighted in method section).

Question10: Eligible and allocated participants were noted in text (with number, briefly and clear). Finally, the number of subjects analyzed in each group should be stated.
Response10: Each group 30 patients (highlighted).

Question11: How many subjects were assessed for eligibility? And then how many subjects were allocated? Did you Lost to follow-up?

Response11: Study performed on 60 patients (trial group=30, control group=30) (highlighted in method section).No lost.

.**Question12:** How did you include the confounding factors in the results?
Response12: Background and confounding variables matched between groups. There was no significant difference between the two groups in terms of variables such as age, weigh, height, head circumference (up to 3 years of age), body mass index, diarrhea duration, and diarrhea frequency (is shown in table1).

Question13: Did you measure fever, vomiting and others criteria?

Response13: There was no significant difference between groups regarding temperature. Vomiting was one of our exclusion criteria (highlighted).

Question14: Did the subject receive standard diarrhea treatment? If yes describe it precisely.

Response14: yes, dehydration therapy performed as standard method.

Question15: Clearly define all potential confounders and effect modifiers. Give diagnostic criteria, if applicable.
Response 15: The variables and inclusion criteria are mentioned c in text and table1.There was no significant differences between variables before intervention.

Question 16: Describe statistical methods, used to control for confounding. Control of confounders is an important point in this study

Response 16: Statistical methods is mentioned in method section

Question 17: Did you have missing data?
Response 17: No

Question 18: Please explain confounder and test to confounder-adjusted.

Response18: Variables are shown in table1. Chi-square test and Mann–Whitney U test was used.

Question 19: To evaluate the effect of the intervention, intra group statistical analysis should be performed firstly, to extract the effect of the intervention and then compare it with the finding of control group (inter-groups statistical analysis).

Response19: These items are mentioned in result section and table1.

Question 20: Authors said: “Discontinuation of diarrhea was defined when the frequency of stool was less than 3 times/ day and the stool consistency returned to normal pattern” pl describe base on your description how many subjects recover in each groups? And then difference between groups was significant or not?

Response20: Table 2 shows that the frequency and duration of diarrhea in the trial and control groups. The frequency and duration of diarrhea was significantly less

and shorter in trial groups. Frequency of stool less than 3 times/ day was observed in 10% of trial group and 0% of control group (P=0.23).

Question 21: Authors said: “the groups did not show any significant difference in terms of weight gain before and after the intervention in each group” but p value was (p<005) (Table 3). Pl describes it precisely and clear. Did table 3 show inter-groups statistical differences (p<0.001)?!!

Response21: It was a typical problem and the sentence corrected. We measured temperature and there was no significant difference between group regarding temperature. It is shown in table 1 (Highlighted in results section).

Question 22: Did you measure fever, vomiting and others criteria?

Response22: Yes, we checked temperature (table1). Vomiting was one of our exclusion criteria.

Question 23: Paragraph 5, 6 and 7 were not suitable for this section and must be moved to introduction section.

Response23: Saccharomyces boulardii is briefly described in the introduction and further in the discussion section.

Question 24: The discussion part should be in an organized way; It must be concentrated on the new and important aspects of the study and the achieve conclusions. Discussion should emphasize on the present findings and the variations or similarities with other related studies.
In the discussion part you should write the main(s) finding(s) and specially (novelty) at first paragraph and then allude to other studies. Justify the possible reason for the consistency/ inconsistency of the results of the present study and previously published study.

Response24: The items mentioned in the discussion. The main result of the study was included at the beginning of the discussion. The cause of the discrepancies was also mentioned (Highlighted).

Question 25: Limitation and recommendation should be mentioned in the last paragraph of discussion and in last paragraph any gap, question, hypothesis or comment should be declared. I see yours limitation and recommendation but to

better and further explain the clinical statement of this study, it suggested that this comment should be declared. The authors should be noted: [According to the importance and standardization of diarrhea treatment especially in children, the best way to proper use of drugs and supplements in these subjects is to use guidelines. In medical challenges, the guidelines are very helpful, especially in the proper use of antibiotics, supplements, medical modalities and management of the difficult medical situations such as presented issue (diarrhea)]. You should be mention to this new and valuable article in your references: [A Survey of Pediatricians' Views and Practices Regarding Parents' Request for Prescribing Antibiotics: A Qualitative Study. Arch Pediatr Infect Dis. 2019 July; 7(3):e91217. doi: 10.5812/pedinfect.91217].

Response25: This well recommendation added to discussion section and references list (Highlighted).

Question 26: This section must be shown in separate section.

Response25: Conclusion separated (Highlighted).

Question 27: Show in separate subheading.

Response27: Arranged in separate subheading (Highlighted).

Question 28: No 6 and 7 were incomplete.

Response28: 6 and 7 references completed (Highlighted).

Question 29: References did not arrange according to the journal rules.
Response29: References arranged according to journal style (Highlighted).

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OPEN PEER REVIEW

Revision (1)

REFEREE : Reviewer

15 Oct 2021

All points mentioned have been changed by authors. The manuscript is now acceptable and printable.This manuscript can be useful for future scientific studies on acute diarrhea in children.
thank you