Author's response to reviews

Title: Anti-obesity Effects of Yerba Mate (Ilex Paraguariensis): A randomized, double-blind, placebo-controlled clinical trial

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Author's response to reviews: see over
Cover letter

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Editor;
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Dear Editor;

MS: 4816177331603200
Title: Anti-obesity Effects of Yerba Mate (Ilex Paraguariensis): A randomized, double-blind, placebo-controlled clinical trial

Thanks for your kindness and patience.
The authors would like to thank reviewer and editors for careful review of our manuscript and providing us with their comments and suggestion to improve the quality of the manuscript. The following responses have been prepared to address all of the reviewer’s comments.

Reply to the evaluation by referees

Reviewer: Xiao Su

1. Abstract – This is a bit too brief given that the word limit for the Journal is 350 words. More information on background should be included. For methods, the number of Yerba Mate capsules and placebo on daily basis should be provided. For results, what are the safety parameters measured?

Answer: Revised (Page 2, line 33-35, line 42-43). I didn’t specify safety parameters in the results, because the parameters were already included in abstract.

2. Background – Authors indicate that Yerba Mate modulates signaling pathways. Please
provide name of those pathways, in particular relate it to fat metabolism if any.

Answer: Revised (Page 3, line 98-100).

3. Methods – Was the 4 weeks screening period before or after the 12 weeks intervention?

Answer: Revised (Page 4, line 113, 118-120). The 12 weeks intervention followed by the 4 weeks screening.

4. Methods – Details of randomization should be provided – who randomize the subjects? How it was done, manually or use the computer software? What criteria/parameters were used in the randomization? How the two groups were balanced for the major parameters?

Answer: Revised (Page 4, line 114-117).

5. Methods – The number of different gender in each group should be provided.

Answer: Each group consists of 2 male and 13 female. The volunteers, who not only agreed to participate in this clinical trial but also were satisfied with the inclusion/exclusion criteria, were randomly assigned to each group. There was no statistically significant difference between each group.

6. Methods – Smoking is normally excluded in weight loss trial as it could alter individual’s metabolism. Authors should provide a rational to explain why it is included in their study.

Answer: Added (Page 15, line 336-339)
7. Methods – Authors should clarify the number of clinical visits per subject. From the description under the efficacy outcome measurement there seems only four not five?

Answer: Revised (Page 5, line 169).

8. Results – Last sentence in the legend for Fig 2 is not clear. Please revise.

Answer: Revised (Page 7, line 245-247).

9. Results – If there are only 25 subjects finished the study, why all Tables showed results of 15 subjects for each of treatment and placebo group.

Answer: Added (Page 6, line 207-208).

10. Results – Subtitle “Lipid metabolism” is not appropriate.

Answer: Revised (Page 10, line 257)

11. Discussion – Reference to support statements in lines 280-283 should be included.

Answer: Revised (Page 14, line 292-295).

12. Discussion – The significance of total fat mass and fat percentage reduction should be provide.

Answer: Revised (Page 14, line 289).

13. Discussion – Possible mechanism of the above should also be included in the discussion.
Discussion on why reduction of total fat mass and fat percentage observed in the study does not lead to the decreased level of TG and body weight should be more detailed. Authors cited the references on chlorogenic acid and their effects on cholesterol and weight loss. They should relate this to their study and finding.

Answer: Revised (Page 15, line 320-332).

14. line 61, “the latest WHO global projections….in 2005. This should be revised or deleted as it has passed and now we are ten years late.

Answer: Revised (Page 3, line 66-68).

15. lines 67-68 “However, only a few drugs enter and stay on ….” This sentence should be rewritten.

Answer: Revised (Page 3, line 71-72).

16. lines 80-81 “More recently, Yerba Mate tea is being consumed…” should be revised.

Answer: Revised (Page 3, line 84-85).

17. lines 206 “7 met were excluded due…”. Please revise.

Answer: Revised (Page 6, line 217-218).

18. lines 310 “…of Yerba mate on fat decrease,. should be revise.

Answer: Revised (Page 15, line 328-327).
Reply to the evaluation by referees

Reviewer: Kehua Zhou

Major Compulsory Revisions

1. Could you please provide a reference for the diagnosis of obesity in your manuscript? Your reference 1 of the Asia-Pacific perspective does not have the diagnostic criteria for obesity. Based on my understanding, BMI >= 25 and < 30 is considered as overweight. If this is the case, I recommend the authors change the relevant statements throughout the article.

Answer: Added (Page 3, line 65). World Health Organization (WHO) Regional Office for the Western Pacific Region recommend defining obesity in Asians as those with a BMI >= 25 kg/m^2. Koreans with a BMI >= 30 kg/m^2 are classified as severely obese.

2. Test supplements: 3 g/day does not equal 350 mg x 3 capsules; please check. The sentence “Subjects were instructed to bring ….dose” is unclear.

Answer: Revised (Page 5, line 162).

3. Statistical analysis: in sample size calculation, “…decrease body fat, which was calculated to be a 3 kg decrease…”, What does “body fat” refer to? How did you get the information of a 3 kg decrease: Please consider add reference(s) if available.

Answer: Added (Page 6, line 200-204), The number of subjects in this exploratory clinical study was calculated at the discretion of the investigator.

4. Statistical analysis: did you do group comparisons how did you do it? The description
of statistical methods used is unclear and the statistic methods for comparisons before
and after treatment as well as between groups seem wrong.

Answer: Revised (Page 6, line 208-212).

5. Results, I believe you need to briefly describe the findings rather than providing the
tables and figures only. The figures are difficult to understand’ do the numbers represent
the median/mean?

Answer: Revised (Page 7, line 245-247).

Minor Essential Revisions

1. Introduction: I think you need present the clear logic regarding why did you perform
the study. You mentioned polyphenols and phenolic acids; what are the relationship
between these two substances with the study objectives? I believe you may want to
briefly mention the reasons for the use of the various types of outcome measurements
for efficacy assessment. You may also want to rewrite the study objectives so readers
can better understand what are the outcome measurements.

Answer: Revised (Page 3, line 89-95).

2. Study design: how did you decide who to do the telephone screening interviews and
how many calls did you make?

Answer: Revised (Page 4, line 118-120). The telephone screening interviews are a pre-
screening step.

How did you randomly assign participants to each group?
Answer: Revised (Page 4, line 114-117).

I believe the sentence “Every 6 weeks, subjects were asked to…compliance” is redundant.

Answer: Revised (Page 4, line 126-128).

I don’t think you need to mention “A CONSORT checklist…”

Answer: Deleted (Page 4, line 130).

3. Subjects: Please provide references for the diagnosis. Many of the exclusion criteria are redundant. Some information belongs to Results.

Answer: Revised (Page 4, line 141-146).

4. Efficacy outcome measurement: please check “five clinical visits”; how did you assess abdominal fat distribution using CT?

Answer: Revised (Page 5, line 169).

5. Results, Subjects: what is “a protocol violation”?

Answer: Revised (Page 6, line 221).

We appreciate the comments from the reviewer. Thank you for reviewing our manuscript.

Sincerely,

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