Author’s response to reviews

Title: Effects of Greenselect Phytosome® on weight maintenance after weight loss in obese women: a randomized placebo-controlled study

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Replies to Reviewer 1

1. As suggested by the reviewer, we recovered the dietary histories and calculated food energy and nutrient intake using a computerized database and analysis program. This was possible for – V3 and V0 but not for the following visits. At V3 and V6 we had data derived from a questionnaire habitually used by dietitians to evaluate the adherence to the diet. Thus we included in the revised version of the manuscript the energy and macronutrient intake at –V3 and V0 and the score derived from the questionnaire on the adherence to the diet at V0, V3 and V6.

In addition we included data on physical activity levels estimated by IPAQ at –V3 and V0 and the percentage of fat-free mass at V0, V3 and V6 as a proxy of the following the given advices on the physical activity. The analysis of these data shows that the adherence to the diet decreased from V0 to V3 in both groups (and fat-free mass did not change) and remained stable from V6 to V3. This suggests that a) after the first decrease, weight remained stable till the end of supplementation in GSP group despite the decrease in the adherence to the diet, b) the vanishing of effect on weight after Globes discontinuation is not due a lower adherence to lifestyle recommendations because in GSP group the adherence to the diet and fat-free mass (proxy of physical activity) were similar between the end of supplementation and follow-up. The sentences added in "Intervention" (line 1-6 of page 6), "Measurements" (line 4-7), and “Results” (line 4-6 and 14-20) and “Discussion” (line 11-14 and 17-20 page 9) are highlighted. Not to weigh the
manuscript, we included in the questionnaire to assess adherence to diet and data on consumption of energy and macronutrients and physical activity as supplementary material.

We hope that these data can meet the objections raised by the Reviewer.

2. “if compliance was the same…..why there is a difference statistically significant on the weight loss?” Weight loss during lifestyle intervention (from –V3 to V0) was comparable in the two groups. This was stated at line 7-12 of page 7 in the original version of the manuscript.

3. We agree with the reviewer that the assessment of energy expenditure by indirect calorimetry would make results more comprehensive. We have now added at line 16-19 of the Discussion a sentence stating that energy expenditure was not assessed and future research having energy expenditure and respiratory quotient as primary endpoints, are needed to clarify the mechanisms by which Globes affect body fatness.

4. The study was single-blind because the doctor who collected women’s informed consent and opened the randomization envelopes was aware of the study group assigned. However, the dietician collecting anthropometric measures and dietary history at each visit was blind to the supplementation product. In the revised version of the manuscript, a sentence clarifying this issue has been added at page 5, line 11-13.

Replies to Reviewer 2

The reviewer recommended expanding the legends for all figures and tables.

In Table 1 the significance of differences between GSP and P group was not specified because there were no statistically significant differences between groups at –V3 and V0. For clarity, in the revised version of the manuscript, in the footnote of Table 1 a sentence stating that the comparisons between GSP and P group were NS at –V3 and at V0 has been added.

In Figure 3, the statistical significance indicates differences between V0 vs V-3, V1 vs V0, V2 vs V1, V3 vs V2 and V6 vs V3 within each group and not differences between groups; p-values
were indicated in the Figure only when significant. To avoid confusions on the presence or not of a statistical significance where p is not indicated, we have now specified in the legend to the Figure 3 that “p values refer to differences between values at a defined visit and the previous one within each group. If the difference is not significant, the p value is not indicated“. As suggested by the reviewer, “GSP” and “P group” was added in Figure 3.