Reviewer’s report

Title: Effect of a multi-ingredient based food supplement on sexual function in women with low sexual desire. Pilot study.

Version: 1 Date: 17 Sep 2018

Reviewer: Alan W Shindel

Reviewer's report:

The principle and most important limitation of this study is absence of a control group. This, with small sample sizes, renders this study at best pilot data and not truly demonstrative of a clinical effect. This may indeed be a good treatment for women in the future but this study alone cannot justify widespread use. The authors must make this explicit in the abstract conclusion and the conclusions section of the paper.

The authors should consider stating in the manuscript itself that one author has financial ties with Procare.

I don't fully understand the low sexual desire cut off. I have traditionally seen the FSFI-total cut off of 26.55 promoted as the cut off for risk of sexual dysfunction, where did 25.83 come from? The authors should also clarify in the abstract that the 25.83 is not specific to sexual desire but rather to sexual dysfunction more broadly. MOST IMPORTANTLY, sexual dysfunction cannot be diagnosed by the FSFI as it does not contain a distress component in assessment. The authors can speak of RISK of sexual dysfunction but should use caution in making an actual diagnosis. The authors should also include several more citations in the methods to bolster their claims about the capabilities of the FSFI

This study is hampered by absence of a control group.

A domain specific analysis should be considered and reported in the abstract; what specifically got better for these women?

The units of testosterone measurement are unusual. Typically ng/dL or nmol/L are utilized as units, please consider.

Please provide a citation for the statement that women produce higher amounts of estrogens than androgens. I would also take issue with the statement that this fact demonstrates how important androgens are; this is supposition.

The authors should condense their background references in the introduction; one or two paragraphs can make the case for how prevalent the problem is. The DSM section could similarly be shortened. What should receive more attention is the data to suggest that these
herbal preparations are helpful. Please discuss these in more detail, do not simply refer to existing studies en bloc and say they are helpful, provide the data to support this study on their efficacy in women.

Please state a testable hypothesis in the introduction.

Please provide more information about this herbal product. How is quality control maintained? What is the dosing of these different components? From what source are they obtained? Why these particular components and not others?

Were all participants heterosexual? Was this a requirement? What requirements existed regarding partner sexual function?

How was normality of data determined? This is essential to deciding between parametric and non-parametric statistical tests.

I believe "two tailed" is a better term than "bilateral" for hypothesis testing in the stats section.

Be aware of and correct run on sentences. The first, third, and fourth sentences of the discussion is an example, they need to be sub-divided. In general it is not a good idea to have two or more commas in a sentence, unless one is making a list of considerations (e.g. as above when I state the specific problematic sentences).

What does this study add to existing literature? The authors cite prior work that articulates the purported benefits of these herbals in women; so what makes this current work novel and/or important?

The specific limitations should be a separate paragraph, not buried at the end of a paragraph on hormone biology. The authors should expound on what could be done in the future to rectify these limitations in future work.

The authors are making an assumption about how this compound works in the second to last paragraph of the discussion; are they certain that the "Domino effect" and increasing free T and vasodilation are the drivers of these effects? Without a specific study on the components they cannot attribute specific actions to the particular components of this herbal. They may speculate but must be clear that it is speculation, not fact.

I would also recommend more caution about the "truly objective" hormonal results. Measurement of androgens in women is fraught with potential for error given low concentrations and variation. Until a control group of women is included the authors cannot conclusively demonstrate that their results are not all driven in some fashion by placebo effect.

Units must be included in table 1 (e.g. years, kg, centimeters, etc). Since all women were Caucasian this could however be eliminated and just stated in text.
What is meant by "studies" in table 1?

Were all women post-menopausal? This was not made clear. Table 1 implies that all women had undergone menopause, how was this determined?

The "no hysterectomy" row could be omitted as it is implied from the prior line.

Was number of pregnancies assessed? Number of deliveries may be better presented as whole numbers or even median, depending on normality of data.

The pie chart in figure 1 is relatively uninteresting. Would be better to include a domain-specific detail of FSFI changes.

Consider changing the y axis in the chart on testosterone levels, a maximum of 1 pg/mL would permit more distinction.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

No

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

No

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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Please indicate the quality of language in the manuscript:

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None

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