Semaine PMS and Period Support Supplement Provides Substantial Relief from Common Menstrual Cycle Symptoms

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ABSTRACT:
Menstrual cycles cause significant disruption in women's lives, leading to negative economic and personal consequences. The symptoms associated with menstrual cycles can be debilitative to the point of bed rest. Dietary supplements have previously been used to lessen the symptoms associated with the menstrual cycle and have shown promising benefits. This single-arm observation study evaluated the ability of Semaine Health Company's dietary supplement pills to improve perceptions of cramping, bloating, gastrointestinal issues, fatigue, headaches, body aches, mood swings, feeling down, skin breakouts, weight gain, breast tenderness, and appetite changes. Concurrently, this trial examined changes in blood biomarkers (both Vitamin D and C-reactive protein) that have previously been correlated to menstrual cycle symptoms. Participants completed bloodwork and a survey evaluating symptom severity at baseline, without the dietary supplement, and during the intervention while taking the supplement. Overall, perceived symptom severity decreased from baseline to intervention for all symptoms measured in the study. The symptoms that improved the most included gastrointestinal issues (75%), cramping (73%), mood swings (73%), and bloating (73%). Also, 73% of participants reported feeling better during the intervention compared to their baseline menstrual cycle. Qualitative data collected provided further evidence of improved well-being with many participants highlighting the decrease in severity of symptoms. There were no significant differences in blood biomarkers from baseline to intervention. Based on this trial, perceived well-being improved for participants during the intervention compared to baseline highlighting the beneficial use case for the dietary supplement used in this trial.

BACKGROUND:
The menstrual cycle is the series of events that occur when a woman's body prepares for the possibility of pregnancy. During the menstrual cycle, there are many changes in the body, marked most commonly by changes in hormone levels. These changes in hormone levels and the subsequent biological changes can lead to significant discomfort for women before the menstrual cycle (i.e. premenstrual syndrome) and during menstruation. Specifically, during PMS women commonly report breast tenderness, mood swings, and bloating. During menstruation, women often report pelvic cramps, bloating, and bowel issues (Meaden et al., 2005).

The symptoms caused during the menstrual cycle can bring immense challenges for women, especially women who experience severe symptoms. Menstrual cycle symptoms have long

been known to vary in severity, with some women reporting minor symptoms with no impact on their day-to-day lives, and other women reporting severe symptoms that impact their daily lives (Meaden et al., 2005). Previous research has indicated that discomfort is extremely common (Grandi et al., 2012). Women who experience severe symptoms due to their menstrual cycle are likely to seek advice about relief from medical professionals. The most commonly recommended treatments for PMS are either hormonal contraception or non-steroidal anti-inflammatory drugs (NSAIDs) (Harel, 2006; Oladosu et al., 2018).

Leading up to menstruation, higher levels of inflammation are likely to occur, leading to some of the symptoms previously discussed (Wunder et al., 2006). This increase in inflammation as women approach menstruation can be seen by changes in inflammatory markers such as C-reactive protein (CRP)(Clancy et al., 2013; Gursoy et al., 2015, Wander et al., 2008). Increases in inflammatory markers such as CRP have previously been linked to self-reported symptom severity prior to and during menstruation (Barcikowska et al., 2020; Gold et al., 2016). Low levels of Vitamin D have also been correlated with higher levels of menstrual discomfort and previous studies have demonstrated that supplementing with cholecalciferol have reduced dysmenorrhea (Bahrami et al., 2018; Lasco et al., 2012).

One avenue to lessen the symptomailty associated with menstrual discomfort is via dietary supplementation. Many supplements have previously been examined as a mode of treating symptoms of both PMS and menstrual discomfort (Shaw et al., 2018; Pirotta, 2008; Xu et al., 2019). However, many previous dietary supplement interventions have required continuous supplementation, which either leads to poor adherence to the protocol or a lack of interest in creating a new habit (Choudhry et al. 2011; Osterberg & Blaschke 2005). Due to these limitations, it is worthwhile studying supplements that provide a simpler use scenario and are intended to be consumed immediately prior to and during menstruation. This current study tests a supplement that is consumed during the menstrual cycle, which leads to a simpler use scenario as people are likely to take a supplement whenever they feel symptoms.

PURPOSE:

Semaine Health Company has designed a dietary supplement for women to consume immediately before and during menstruation to alleviate many of the negative symptoms that arise during a menstrual cycle. The goal of the supplement is to reduce inflammation that naturally occurs during the menstrual cycle so that the symptoms are lessened in severity. The dietary supplement tested in this trial includes Vitamin D (as cholecalciferol from lichen), Magnesium (as magnesium oxide complexed with sunflower lecithin), Resveratrol (*Polygonum cuspidatum* (root) extract), Silybin phytosome (*Silybum marianum* (fruit) extract/sunflower lecithin), Green tea phytosome (*Camellia sinensis* (leaf) extract/sunflower lecithin), Curcumin phytosome (*Curcuma longa* (root) extract/sunflower lecithin), Quercetin phytosome (*Sophora japonica* (flower) extract/sunflower lecithin), Indian frankincense phytosome (*Boswellia serrata*

(oleo-gum resin) extract/sunflower lecithin), Ashwagandha (*Withania somnifera* (root and leaf) extract).
Specifically, this trial examined two unique questions. The primary aim of the trial was to assess the efficacy of a dietary supplement in reducing perceived discomfort associated with menstruation. Perceived discomfort was assessed by asking participants to rate their discomfort with cramping, bloating, gastrointestinal issues, feeling tired, feeling down emotionally, feeling anxious, and headache. The secondary aim of the trial was to determine the effectiveness of the dietary supplement on blood biomarkers associated with menstrual discomfort. The two biomarkers measured in this study included CRP and 25-hydroxyvitamin D (standard biomarker for Vitamin D levels).

SUBJECTS AND METHODS:

The trial conducted was an open-label observational trial to study the effectiveness of the Semaine Health Company dietary supplement and its effect on common symptoms of normal menstrual discomfort. Female participants, aged 18-40 were recruited for the trial. 59 women were initially contacted to be a part of the study with 41 completing the blood work and 48 completing the surveys at both baseline and intervention. The participants underwent a menstrual cycle without supplementation to establish a baseline and for their next menstrual cycle, participants were given the dietary supplement. During the intervention, participants took two pills, with each major meal during the day (3 times per day for a total of 6 pills per day). During both menstrual cycles the participants were asked to complete a subjective wellbeing survey that examined their perceptions of their cramping, bloating, gastrointestinal issues, feeling tired, feeling down emotionally, feeling anxious, and headache. The subjective wellbeing scale was on a 1 to 7 Likert Scale with 1 representing "No Symptoms" and 7 representing "Very Severe- I need bed rest). Also, during both menstrual cycles, participants provided blood samples to examine both CRP and Vitamin D levels. Participants were instructed to take the blood sample on the same day of their cycle but were given a one-day buffer where the sample would still be accepted.

RESULTS

Assessing the Efficacy of the Dietary Supplement on Reducing Perceived Discomfort

Symptom	Baseline Mean	Intervention Mean	P-value from Dependent T-Test*	% Subjects Improved
Cramping	4.56	3.17	<.001	73%

Body Aches	3.52	2.44	<.001	61%
Mood Swings	4.21	2.67	<.001	73%
Feeling Down	3.94	2.67	<.001	65%
Breakouts	3.06	2.15	=.002	54%
Head Tension	3.69	2.58	<.001	63%
Bloating	4.23	2.67	<.001	73%
Weight Gain	3.04	1.96	<.001	65%
Gastrointestinal Issues	4.52	2.92	<.001	75%
Fatigue	4.46	3.13	<.001	67%
Breast Tenderness	2.90	1.73	<.001	58%
Appetite Changes	3.54	2.63	=.002	60%
Average of All Symptoms	3.81	2.56	<.001	88%

*****The dependent t-test used in this study examined differences in symptom severity from baseline to intervention. All of the tests were below the critical threshold of p <.05 indicating statistical significance.

As noted in the table above, there was a significant reduction in each symptom measured from baseline to the intervention. Over half of the participants noted an improvement for each individual symptom measured. When averaging all of the symptoms at baseline and comparing to the average symptom rating during the intervention, 88% of participants experience symptom reduction. After the conclusion of the study, participants were explicitly asked whether or not they believed that the product helped ease their symptoms. 73% of the participants (35/48) believed that the product did help ease their symptoms. Some of the qualitative responses to the prompt are below (exactly as written by the participants):

Qualitative Responses from Participants About the Supplement
Hands down. I usually get very bad cramps before I start my period and they last about two days off and on. I did not feel anyyyy cramps whatsoever. My head tension was gone and I also had bloating but not as bad as usual.
Yes, because me period before that I had to take midol constantly, which I usually do but not this past period.
Absolutely! My personal trainer couldn't believe I was on my period. Normally the bloating is
so bad she can immediately tell. Light cramps but so much better than periods prior.
While not all of my PMS symptoms improved, my cramping and physical pain went down significantly.
Yes, absolutely! My energy levels have been drastically different and my mood was not impacted by my period at all! I felt much more clear-headed,with better resolve and energy throughout the day, and waking up early with no grogginess. Definitely has turned me into someone who will seek this product!
I am surprised that I have had close to no discomfort at all regarding my cycle.
Definitely made my period more bearable and less disruptive.
This period has been much much more mild across the board than the last one.
Yes - didn't notice cramping or bloating as much as usual. Was very busy and traveling during this time so was a bit distracted but I usually have to take advil for cramps and didn't this time.
I feel that the product did ease my symptoms, but it did not erase them. I feel like they would be a great addition to traditional painkillers, but not a replacement for them.
My cramps are not as severe and I'm able to function better than I have in the past
I normally experience VERY drastic mood changes (I have major depressive disorder and periods make it worse). But I experienced no changes. Cramps were practically non-existent.
Yes, I felt a significant difference between my symptoms with and without the test product. My worst symptoms are usually breast tenderness and diarrhea and both symptoms were much milder and shortened on the product.

Assessing the effectiveness of the dietary supplement on blood biomarkers

Dependent t-tests were used to examine the differences between baseline and intervention levels of Vitamin D and CRP. There was no significant difference in levels of Vitamin D for

participants from baseline to intervention (t = .76, p = .45, Cohen's d = .118). However, mean levels of Vitamin D did increase from baseline (M = 29.83) to post-intervention (M = 31.17).
There was no significant difference in levels of CRP from baseline to the end of the intervention (t = 1.12, p = .27, Cohen's d = .18). CRP levels decreased on average from baseline measurement (M = 4.04) to post-intervention (M = 3.19).

Overall, neither Vitamin D nor CRP reached statistical levels of significance in this trial, but both measures moved in the hypothesized direction from baseline to post-intervention.

Changes in Pain Relief Consumption Across the Trial
At baseline, 15 women reported taking some form of pain reliever to reduce the symptoms associated with menstruation. However, during the intervention time period, only 4 women reported consuming medication for pain relief. This drop from 15 to 4 participants needing medication represents a 73% reduction in NSAID and other pain reliever use during the intervention compared to the baseline.

DISCUSSION:

This study provides evidence of the effectiveness of the Semaine Health Company's proprietary supplement to reduce the perceived discomfort experienced by women before and during menstruation. A majority of participants experienced improved symptoms from baseline to intervention. There was a significant reduction in all of the symptoms measured from baseline (without the supplement) to the intervention. The lower ratings were substantial and indicate that participants felt their symptoms were much improved when taking the supplement compared to not taking the supplement. The symptoms where participants experienced the most improvement included bloating (73%), cramping (73%), mood swings (73%), and GI issues (75%). These numbers indicate a significant perceived improvement from baseline to intervention, highlighting the effectiveness of the dietary supplement to improve common symptoms associated with menstruation. The qualitative data also reflected an improvement of symptoms from baseline to intervention. Many participants highlighted the supplement improved multiple symptoms that are associated with their menstrual cycle. Participants also reported that the lessening of symptoms made it easier to continue to live their daily life without the interruption normally associated with their menstrual cycle. When asked directly if they believed the product helped alleviate symptoms associated with their menstrual cycle, 73% of women in this trial reported that they felt an improvement. It is clear from the survey data and the qualitative responses provided by the participants that this product led to a significant improvement of perceived symptoms during menstruation.

There was no significant change in the blood biomarkers assessed in this study. However, both biomarkers moved in the hypothesized direction on average. Previous research has highlighted that long-term Vitamin D supplementation is necessary to significantly influence the Vitamin D blood biomarkers (Autier et al., 2012). Future research could examine a longer-term

supplementation with the product in order to see if Vitamin D levels increase and lead to decreases in menstrual symptom severity. CRP was used in this trial as a blood biomarker tracking inflammation symptoms. There was an average reduction in CRP from baseline to intervention, but it was not statistically significant. It is important to note that CRP is an inflammation biomarker that can be influenced by changes in estrogen and progesterone but also is influenced by other hormonal and biological events in the body (Wander et al., 2008). So while neither Vitamin D nor CRP were significantly changed, it does not exclude the possibility that longer-term supplementation would lead to changes in the biomarkers.

The supplement used in this trial led to a decrease in participants seeking pain relief outside of the supplement. At baseline 15 participants took either an NSAID or other pain reliever to mask the symptoms associated with menstruation. However, during the intervention, only 4 women took some form of pain relief. This is a marked improvement (73% reduction) over baseline and some participants specifically reported that they normally have to take an NSAID for pain relief, but felt the supplement provided in the intervention improved their symptoms to the point that an NSAID was unnecessary.

Overall, this product led to an improvement in all symptoms related to the menstrual cycle measured in this trial. The majority of participants also self-reported that they believed the supplement improved their outcomes compared to a menstrual cycle without the supplement. However, this trial does not demonstrate that the supplement leads to significant changes in blood biomarkers that are associated with inflammation when taken during a single menstruation. However, this could be due to the short duration of supplementation in this trial. This trial provides strong support that the dietary supplement leads to an improvement in the perceived symptoms commonly experienced during a menstrual cycle.

REFERENCES:

Autier, P., Gandini, S., & Mullie, P. (2012). A systematic review: Influence of Vitamin D supplementation on serum 25-hydroxyvitamin D concentration. *The Journal of Clinical Endocrinology & Metabolism, 97*(8), 2606-2613.

Bahrami, A., et al. (2018). High dose Vitamin D supplementation can improve menstrual problems, dysmenorrhea, and premenstrual syndrome in adolescents. *Gynecological Endocrinology, 34*(8), 659–663.

Barcikowska, Z., Rajkowska-Labon, E., Grzybowska, M. E., Hansdorfer-Korzon, R., & Zorena, K. (2020). Inflammatory markers in dysmenorrhea and therapeutic options, *International Journal of Environmental Research and Public Health, 17*(4). https://doi.org/10.3390/ijerph17041191.

Choudhry, N.K., Avorn, J., et al. (2011). Full coverage for preventive medications after myocardial infarction. *The New England Journal of Medicine, 365*(22), 2088–97.

Clancy, K.B.H., Baerwald, A.R., & Pierson, R.A. (2013). Systemic inflammation is associated with ovarian follicular dynamics during the human menstrual cycle. *PloS One, 8*(5). e64807.

Gold, E.B., Wells, C., & O'Neill Rasor, M. (2016). The association of inflammation with premenstrual symptoms. *Journal of Women's Health, 25*(9), 865–74.

Gursoy, A.Y., Caglar, G.S., Kiseli, M., Pabuccu, E., Candar, T., & Demirtas, S. (2015). CRP at early follicular phase of menstrual cycle can cause misinterpretation for cardiovascular risk assessment. *Interventional Medicine & Applied Science, 7*(4), 143–46.

Grandi, G., Ferrari, S., Xholli, A., Cannoletta, M., Palma, F., Romani, C., Volpe, A., & Cagnacci, A. (2012). Prevalence of menstrual pain in young women: What Is dysmenorrhea? *Journal of Pain Research*, *5,* 169–74.

Harel, Z. (2006). Dysmenorrhea in adolescents and young adults: Etiology and management. *Journal of Pediatric and Adolescent Gynecology, 19*(6), 363–371.

Lasco, A., Catalano, A., & Benvenga, S. (2012). Improvement of primary dysmenorrhea caused by a single oral dose of Vitamin D: Results of a randomized, double-blind, placebo-controlled study. *Archives of Internal Medicine, 172*(4), 366–367.

Meaden, P. M., Hartlage, S. A., & Cook-Karr, J. (2005). Timing and severity of symptoms associated with the menstrual cycle in a community-based sample in the Midwestern United States. *Psychiatry Research, 134*(1), 27-36.

Oladosu, F. A., Tu, F.F., & Hellman, K.M. (2018) Nonsteroidal antiinflammatory drug resistance in dysmenorrhea: Epidemiology, causes, and treatment. *American Journal of Obstetrics and Gynecology, 218*(4), 390–400.

Osterberg, L., & Blaschke, T. (2005). Adherence to medication. *The New England Journal of Medicine, 353*(5): 487–497.

Pirotta, M. (2008). Commentary on the Cochrane Review of Chinese herbal medicine for dysmenorrhea. *EXPLORE*. https://doi.org/10.1016/j.explore.2008.09.006.

Shaw, S., Wyatt, K., Campbell, J., Ernst, E., & Thompson‐Coon, J. (2018). Vitex Agnus Castus for premenstrual syndrome. *Cochrane Database of Systematic Reviews, 2018*(3).

Wander, K., Brindle, E., & O'Conor, K. A. (2008). C-reactive protein across the menstrual cycle. *American Journal of Biological Anthropology, 136*(2), 138-146.

Xu, L., Xie, T., Shen, T., & Zhang, T. (2019). Effect of Chinese herbal medicine on primary dysmenorrhea: A protocol for a systematic review and meta-analysis. *Medicine, 98*(38). e17191.