

Results of Clinical Trial for STOP PMS

Janina Meissner-Frisk, D.O.
January, 2011

Working Hypothesis: “STOP PMS” is an effective and safe product to help women combat unwanted symptoms of pre-menstrual syndrome (PMS).

Purpose of Trial: To quantify and validate the effectiveness and safety of STOP PMS as a superior product in combating unwanted symptoms of PMS, by a non-biased, third party.

Study Participants/Method: A random group of pre-menopausal women with mild to severe PMS symptoms was chosen for appropriateness based on a brief questionnaire determining health status and symptoms (see Appendix A). Various advertising modes were used in the community to solicit participants. Participation did not cost the participants, who received adequate supplies of the STOP PMS product free of charge. Those chosen were given an initial physical exam and STOP PMS product, with instructions on usage. Evaluations after 1-2 menstrual cycles were conducted which included brief interim exams and questionnaires regarding the product’s effectiveness and/or side effects (see Appendix B). Compliance to complete the study for the necessary amount of time was encouraged with a drawing at the conclusion of the study (drawing to be determined at time of writing).

Abstract: “PMS” is a syndrome affecting millions of women throughout their childbearing years, which for most is the majority of their productive lives. Symptoms such as bloating, irritability, mood swings, fluid retention, headaches, breast tenderness, and cramping, among others, may characterize it. Symptoms range from mild to debilitating. Primary care physicians frequently offer women potentially dangerous synthetic hormone oral contraceptives, anti-depression drugs or pain medications in an attempt to alleviate symptoms, but these tend to just mask symptoms at best, and are often accompanied by unwanted side effects and risks. However, it is well documented in medical literature that nutrients such as Vitamin B6, Calcium, Magnesium, and other herbs, are as effective, if not more so, at alleviating PMS symptoms as the other medication treatments, without harmful side effects (see literature review and list of references). STOP PMS is a synergistic combination of vitamins, minerals, organic herbs, amino acids, and nutrients integrated into one product. The ingredients are known to be safe and effective in their own ways individually, at the doses present in STOP PMS. These nutrients do not mask PMS symptoms. Rather, they work with the woman’s body in balancing hormones and positively help normalize her body’s processes.

Literature Review

A breakdown of the list of ingredients in STOP PMS for review by current medical and scientific literature (in light of PMS symptoms) is presented below:

Vitamin A- natural antioxidant, promotes endocrine balance
Vitamin C- natural antioxidant, promotes endocrine balance

Vitamin D3- optimizes the body's use of calcium and magnesium, boosts mood and immunity

Vitamin B1- normalizes metabolism, promotes endocrine balance

Vitamin B2 (riboflavin) - normalizes metabolism, promotes endocrine balance

Niacinamide- normalizes metabolism, decreases anxiety, promotes endocrine balance

Vitamin B6- decreases fluid retention, cramps, and overall symptoms of PMS

D-Calcium Pantothenate- decreases stress, needed by the adrenal glands during stress

Folic Acid- normalizes metabolism, promotes endocrine balance
Biotin- normalizes metabolism, promotes endocrine balance
Vitamin B12- decreases fatigue and irritability
Calcium- relieves cramping, backache, irritability

Magnesium- relieves cramping, breast tenderness, fluid retention, anxiety, irritability, fatigue, and bloating, promotes endocrine balance

Manganese- helps the body deal with pain and stress, stabilizes glucose levels, improves biological rhythms in the brain

Potassium- balances sodium levels, decreases fluid retention

Tribulus Terrestris Extract (fruit) - naturally increases (normalizes) endogenous hormone production

N-Acetyl-L-Tyrosine- reduces fatigue, headache, depression and anxiety

GABA- decreases depression, anxiety, and irritability, stabilizes mood

Organic Ginkgo Biloba Extract (leaf) - helps "brain fog" associated with PMS, decreases breast tenderness, may improve libido

Organic White Willow Extract (bark) - reduces pain and inflammation

Organic Chaste Tree Berry Extract- decreases breast tenderness, swelling, constipation, irritability, depression, anger, and headache, helps balance hormone levels

Organic Red Raspberry Leaf Extract- decreases (normalizes) menstrual flow

DHEA- naturally increases (normalizes) endogenous hormone production, improves libido

Organic Cramp Bark Extract- decreases pain associated with cramping

Results:

The women participating in this trial were asked to evaluate their particular PMS symptoms before and after using STOP PMS, rating the severity on a scale of 1-10, with 1 being minimal and 10 representing maximum severity. The responses of each participant were mostly positive, although there were a few who reported “no change” in one or more particular symptoms. **There were no reports of adverse of unexpected side-effects by any participant.** The changes in perceived severity of PMS symptoms are summarized in the table below:

Results of STOP PMS Survey (numbers represent change in perceived severity of symptom)

This table shows the average percentage of improvement for each symptom that was

Irritable	Depression	anxiety	pain	fatigue	wt gain	moods	cravings	cramping	tearful	anger	urinary	HA	bloating	nausea	breasts	libido	recomnd?
9	8	6	5	9	2					8	9	7					y
1													2				i
9	7	7		9		9	8	8			6		6	4	5		y
8	4					8	8	5	7							2	y
1								1			7			3		3	10 y
3				3	3	2	4	8						4			y
		1	1				1						1	1			y
4	4	3		4		6	3	5						4			y
1		2		4		7	2	6					3				y
7	5	5	4	3		6	2						4	4	4		y
Average perceived change			(rating scale 1-10)														
4.8	5.6	4	3.3	5.3	2.5	6.3	4	5.5	7.5	7.3	7	3.5	3.1	4.5	2.5	10	y
ZTest results																	
0.507616	0.5	0.5	0.488937	0.488672	0.5	0.486554	0.5	0.5	0.5	0.484925	#DIV/0!	0.5	0.462822	0.5	0.5	#DIV/0!	

reported. Each row represents a different participant, while each column represents a particular symptom reported. Zeros (shown as blanks in the table) indicate there was either no change, or the participant did not note that particular symptom on their questionnaire. If a participant rated a symptom severity as “10” for example, but rated it

as a “2” after taking STOP PMS, the number shown on the table would be “8,” which represents the number of points on the 10-point scale that the symptom changed. Because it is a 10-point scale, the numbers representing the average changes can easily be converted to percent by multiplying by 10. For instance, in the above example, a change of 8 points would represent an 80% improvement in that symptom. The following is the list of symptoms reported in order of percentage of improvement, although it should be taken into account that the more participants rating a particular symptom increases the overall strength of that statistic.

1. Libido- **100%** (rated by 1 participant)
2. Tearfulness- **75%** (rated by 2 participants)
3. Anger- **73%** (rated by 3 participants)
4. Urinary frequency- **70%** (rated by 1 participant)
5. Mood Swings- **63%** (rated by 6 participants)
6. Depression- **56%** (rated by 5 participants)
7. Cramping- **55%** (rated by 6 participants)
8. Fatigue- **53%** (rated by 6 participants)
9. Irritability- **48%** (rated by 9 participants)
10. Nausea- **45%** (rated by 2 participants)
11. Food Cravings- **40%** (rated by 7 participants)
12. Anxiety- **40%** (rated by 6 participants)
13. Headache- **35%** (rated by 4 participants)
14. Body Pain- **33%** (rated by 3 participants)
15. Bloating- **31%** (rated by 7 participants)

16. Breast Tenderness- **25%** (rated by 2 participants)

17. Weight Gain- **25%** (rated by 2 participants)

Additionally, **9 out of 10** participants (90%) stated they would like to continue taking the product, and would definitely recommend it to others. In order of the most frequent symptoms reported by the participants that had notable improvement are as follows:

1. Irritability (9) - 90% of the participants reported a 48% decrease in irritability (almost cut in half!)
2. Bloating (7)- 70% of the participants reported a 31% decrease in bloating (greater than a third)
3. Food cravings (7)- 70% of the participants reported a 40% decrease in food cravings
4. Mood swings (6) - 60% of the participants reported a 63% decrease in mood swings (almost 2/3 less!)
3. Cramping (6) - 60% reported a 55% decrease in cramping (more than half)
3. Fatigue (6) - 60% of the women reported a 53% decrease in fatigue (over half)
 1. Anxiety (6) - 60% of the participants reported a 40% decrease in anxiety
 2. Depression (5) - 50% of the women reported a 56% decrease in depression
 3. Headache (4) - 40% of the participants reported a 35% decrease in headache
 4. Anger (3) - 30% of the participants reported a 73% decrease in anger!
 5. Body pain (3) - 30% of the participants reported a 33% decrease in body pain
 6. Tearfulness (2) - 20% of the women reported a 75% decrease in tearfulness!
7. Nausea (2) - 20% of the women reported a 45% decrease in nausea
7. Breast tenderness (2) - 20% reported a 25% decrease in breast tenderness
 1. Weight gain (2) - 20% reported a 25% decrease in weight gain

2. Libido (1) - 10% reported a 100% *increase* in libido

8. Urinary frequency (1) - 10% reported a 70% decrease in urinary frequency

Discussion:

It should be noted that participants who were already taking nutritional supplements and/or multivitamin and mineral supplements, had less improvement than those who did not, which makes sense, since STOP PMS is a nutritional supplement as well, and those who are already benefitting from some of its ingredients beforehand theoretically would not notice as much of a change. Conversely, those participants who were more physically fit, as measured by their reported exercise levels and who ate a healthier diet were found to actually benefit more from taking the STOP PMS product.

Other miscellaneous comments included one participant's critique of the packaging artwork design as being "old fashioned," and needing updating.

Limitations and Conclusion:

Because of its small size and limited duration, this study derives its primary usefulness as a preliminary, purely observational study. Although formal statistical analysis is not appropriate here, this trial is clearly useful for validating the effectiveness and safety of the STOP PMS product, as summarized above. At some point, a larger scale, formal, double-blind, placebo-controlled study could certainly be beneficial for further clarifying the statistically relevant features of this remarkable product. Carrying the study out for a longer period of time should also theoretically show that the symptoms continue to improve the longer the product is used, due to normalization of the hormone systems in the body.

References:

1. American Family Physician [Journal]. 2008 Jan 1;77(1):82-84.
2. American Family Physician. 2003 Apr 15;67(8):1743-1752.
3. American Family Physician. 2005 Sep 1;72(5):821-824.
4. American Family Physician. 2001 Mar 1;63(5):913-923.
5. American Family Physician. 1998 Oct 1 (archived).
6. Balch, James F., et al, Prescription for Nutritional Healing, 1990.

- 7.Braverman, Eric, M.D. Path Wellness Manual, 2006.
- 8.Kasim-Karakas, Sidika E., M.D. Nutriceuticals in Women's Health, presented at the UC Davis Women's Health Conference, 2008. Mayo Clinic.
9. Guide to Alternative Medicine, 2010.

APPENDIX A

INITIAL QUESTIONNAIRE

Pre-menstrual symptoms (PMS) may include bloating, headaches, cramping, irritability, mood swings, anxiety, depression, and food cravings, particularly one to two weeks prior to a woman's monthly menstrual period.

1. Have you ever had any symptoms you might attribute to PMS? _____(yes/no)

2. If yes, please list your particular symptoms, and assign a score from 1-10 to each, 1 being minimal, 10 being severe:

_____. (Use back side of page if needed)

3. Have you ever taken any medications or supplements for PMS? _____(yes/no)

4. If yes, please list: _____

5. Were any of the products listed in #4 helpful? ____ (yes/no)

6. If yes, which ones? _____
7. On a scale of 1-10, 1 being minimal, and 10 being severe, how would you rate the severity of your symptoms? _____
8. Are you at least 18 years of age, and still menstruating? _____ (yes/no)
9. Are you willing to participate in a clinical trial, free of charge, of an all-natural product formulated for the relief of PMS symptoms? _____

APPENDIX B INTERIM QUESTIONNAIRE

1. At what point in your menstrual cycle did you start taking STOP PMS (days before menstrual period)?

2. Did you notice an improvement in your PMS symptoms?
_____ (yes/no)
3. On a scale of 1-10, 1 being minimal, 10 being severe, please rate the following:
 - A. bloating (before stop PMS) _____
 - B. bloating (after STOP PMS) _____
 - C. irritability (before STOP PMS) _____
 - D. irritability (after STOP PMS) _____

- E. mood swings (before STOP PMS)_____
- F. mood swings (after STOP PMS)_____
- G. anxiety (before STOP PMS)_____
- H. anxiety (after STOP PMS)_____
- I. depression (before STOP PMS)_____
- J. depression (after STOP PMS)_____
- K. food cravings (before STOP PMS)_____
- L. food cravings (after STOP PMS)_____
- M. headaches (before STOP PMS)_____
- N. headaches (after STOP PMS)_____
- O. cramping (before STOP PMS)_____
- P. cramping (after STOP PMS)_____
- Q. fatigue (before STOP PMS)_____
- R. fatigue (after STOP PMS)_____

Please also answer the same for the following symptoms if you have them (before and after):

- Tearfulness Changes in libido
- Acne breakouts
- Anger outbursts Confusion/fuzzy thinking
- Weight gain
- Breast swelling/tenderness
- Sore throat
- Dizziness
- Edema (hands, feet, or legs)
- Nausea
- Increased urinary frequency
- Heart palpitations

Would you recommend this to a friend? _____ Do you plan to continue the product after the study concludes?_____

Please list any other comments you may have concerning taste, appearance, or other:

LIST OF PARTICIPANTS (who completed minimum trial requirements)

1. Aldara, Natalia- (805)963-1546
2. Block, Meeshell- (310)433-3820
3. Gamby, Lisa- (805)698-9164
4. Howe, Ariel- (831)600-6702
5. Lopez, Lourdes- (805)259-8006
6. Missoff, Ana- (805)259-8482
7. Paine, Caroline- (805)845-4768
8. Picardel, Charleen- (805)968-1511
9. Sydenham, Alisa- (805)679-3360
10. Velasquez, Mayra (805)963-1546