CLINICAL TRIAL

In 2002 the company completed an IRB (Institutional Review Board) Prospective, Randomized, Placebo-Controlled Clinical Trial.

In Conclusion: Femmerol is effective in relieving a number of symptoms associated with menopause. These symptoms include hot flashes, night sweats, breast tenderness, palpitations, concentration, dizziness, vaginal dryness, excessive nervousness, joint aches and pain, and cramping. Each of these symptoms was statistically different from those on placebo.

Water retention, headaches, mood swings, irritability, and depression met the criteria for a statistical trend. Only a few parameters did not trend toward a statistical difference.

It appears that Femmerol is effective in relieving menopausal symptoms and improves ones' ability to function normally.

Based on this study, the safety of this product appears to be validated.

Dr. James Blum, Clinical Outcome Specialist, Bangor Maine USA.

Clinical Trial Summary: A Prospective, Randomized, Placebo-Controlled Clinical Trial to Test the Efficacy and Short Term Safety of Femmerol, an Herbal Blend.

Product: Femmerol

Client: Solutions for Women, LLC
315 North Village Avenue
New York, 11570
(516) 766.2242
sabina@solutionsforwomen.com
Prepared By:

Marshall-Blum, LLC
Herbal Research Clinic, LLC
James M. Blum, Ph. D., CEO

Adjunct Facility: University of Maine, Dept. of Food Sciences and Human Nutrition

Clinical Site:
Clinical Outcome Specialist
Herbal Research Clinic
268 State Street
Bangor, Maine 04401
(207) 990.4963
February 28, 2002

Independent Medical Research Center

James M. Blum, Ph. D. Study Coordinator, Epidemiologist and Biostatistician
Medical Director: Ronald Director: Ronald I. Blum, MD (No relation)
Emotional Parameters / Physical Parameters

This Institutional Review Board (IRB) approved, randomized placebo-controlled clinical trial was designed and executed to test the efficacy and short-term safety of an herbal product designed to relieve common menopausal symptoms. Equal numbers of subjects were randomized to the product or placebo groups. The trial involved women age 35-55 with hot flashes as well as other menopausal symptoms. The chief exclusions were menopause due to surgery or taking hormone replacement therapy. The women were followed up for a period of three months. Subjects were seen every month by a research nurse at our clinic. Except for blood pressure and weight, the majority of the end-points were subjective in nature. Thirty-one and nineteen subjects completed the trial respectively for the product and placebo groups. The baseline characteristics were similar between the two groups. There were a number of parameters that demonstrated that the product was effective in reducing menopausal symptoms. The following symptoms were statistically different between the two groups: hot flashes, night sweats, breast tenderness, palpitations, concentration, dizziness, vaginal dryness, excessive nervousness, joint ache and pain, and cramping. The functional status of these subjects was higher in those on product. Femmerol appeared to be safe and without any adverse events in this three month trial.

Protocol

Design:
Prospective, randomized, double blind, placebo-based, clinical trial
This trial had JRB approval (JRB Study H: 010129-001: Fox Commercial IRB, Candice Woods, Exec. Director, Springfield, IL)

Randomization determined who started on placebo and who started with the active product; randomization between groups were of equal numbers.

The duration was for three months on either product or placebo.

All subject contact was with a study coordinator or research nurse who was blinded to the randomization scheme.

Subjects were recruited from the general population of Bangor, Maine; the major exclusion criteria were women with menopause due to surgery or taking hormone replacement therapy.

Product Usage
Taken twice a day; total of six tablets—three in the morning and three in the evening.

Placebo Product
The placebo was similar in appearance (size, shape, color) to the actual product except that it only contained rice powder. Both were dispensed in unlabeled white bottles.

Inclusion Criteria
Women with moderate-to-severe menopausal symptoms, including, but not limited to: hot flashes, night sweats, cramping, excessive mood swings, depression, or difficulty sleeping, who express an interest in taking the product for reasons of reducing menopausal symptoms.

Age range: 35 – 55

Subjects who pass a compliance screening test
Subjects able to tolerate the active product and placebo
Subjects who sign consent form

Exclusion Criteria
Menopause due to surgery
Subjects on hormone replacement therapy
Subjects not meeting the age requirements
Subjects who are non-compliant with testing and taking treatment regimens
Subjects unable to tolerate specific ingredients in either regimen
Women with a history of severe gynecological pathology
Subjects with severe co-morbid disease (cardiac, pulmonary, cancer, etc.); at the discretion of the medical team
Subjects with alcohol abuse as determined by provider interviews

Cautionary Criteria
Subjects who take more than two aspirins a day
Subjects who take the blood thinners Coumadin or Heparin

Confounding Factors
Severity and complexity of symptoms (emotional, physical, or mixed)
Pre-, peri-, or post-menopausal
Age
Co-morbid conditions
Primary End Points
Emotional Parameters / Physical Parameters
Concentration
Depression
Irritability
Mood swings
Overall well being
Improved tolerance
Hot flashes
(Night) Sweating
Nervousness
Fatigue
Sleep disturbances
Dizziness
Headaches
Joint pain
Palpitations
Tender breasts
Vaginal dryness
Water retention
Cramping

Other End-Points
Emotional Parameters / Physical Parameters
Recommend product

Quality-of-Life

Analytical Methods

Methods
Answers from survey tools were coded from 1 to 10
Answers from the follow-up questionnaires were subtracted from each subjects' baseline data to create the outcome measures.
Example: Please select in the appropriate space, on the scale below, your rating for the symptoms: 1 2 3 4 5 6 7 8 9 10
0 1 2 3 4 5 6 7 8 9 10
No Hot Flashes, Severe Flashes
For example, a subject answering the question about hot flashes at baseline and final give the following responses:
Time Response
Baseline 8
Final at 3-months 2
The subtraction of the responses yields a point improvement for this subject on this question: 8 - 2 = 6 point improvement
The responses for the two groups (placebo and treatment) for each symptom were summed. This forms the basis of the results.
Differences in the means between the treatment and placebo groups were analyzed using the t-test.

Categorical Analysis
One-to-two point differences have been classified as some improvement, While three-to-four point differences as significant, and five or more point improvements as dramatic.
No Improvement
Any Improvement: 1 point or greater
Some Improvement: Specifically 1-2 point improvement
Significant Improvement: Specifically 3-4 point improvement
Dramatic Improvement: Specifically 5+ point improvement
All categories were analyzed using the Chi-Square test. Some analyses used Fisher's Exact Two-Tail t-test, due to the small cell limitations. Fisher's is another type of chi-square test that must be utilized during scenarios of small cell sizes. Note: the definition of small cell sizes refers to comparing small number of subjects for a statistical test. For example: even though thirty-one subjects completed the product phase, when we compare the numbers who rated a ?dramatic? improvement for a specific end-point, there may have been only four (4) subjects in the treatment group and none from the placebo group. This comparison involving four and none triggers the small-cell definition.

These category improvements were determined a priori by the medical advisory group.

Summary Variable
We created a summary variable consisting of all the primary end-points. This approach is often used in medical research and allows for a global comparison involving the entire scope of outcomes. This summary variable was compared, as were the other variables.
The categories for the summary variable are as follows:

No Improvement
Some Improvement: Specifically one-to-twenty point improvement

Significant Improvement: Specifically twenty-one-to-forty-nine point improvement
Dramatic Improvement: Specifically fifty or more point improvement

Statistical Significance
These criteria were set prior to the analysis.
Highly Significant: p -0.05
Significant: p -0.10
Statistical Trend: p -0.15

Randomized, Placebo-Controlled Clinical Trial Results

Subject Numbers
Thirty-one (31) subjects completed the product phase of this trial while nineteen (19) individuals completed the placebo phase of this trial. The numbers for the various endpoints, varied, since not all subjects experienced each different symptom at baseline. For example, a subject may have reported on hot flashes, mood swings, depression, but not night sweats or insomnia.

Baseline Characteristics
There are no major differences with respect to the many baseline characteristics. This includes demographics, medical and behavioral risks, education, jobs, income, and family parameters. Among the over seventy-five variables, five were different at the 0.05 level. However the expected number would be six percent and thus the actual and expected were virtually identical.

Depression
Twenty-eight (28) product subjects and eighteen (18) placebo subjects contributed to end-point.

The average mean improvement in the subjects taking product was 1.61 points while the average mean improvement for those on placebo was 0.50 points. This met the criteria for a statistical trend.

The efficacy of Femmerol with respect to relief of depression was demonstrated in that fifty-seven percent (57.1%) of the subjects taking the actual product reported some level of improvement in their symptoms while forty-four percent (44.4%) of those on placebo reported a similar level of relief.

Thirty-six (35.7%) and fourteen percent (14.3%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to seventeen (16.7%) and none (0%) on placebo.

Irritability
Thirty (30) product subjects and nineteen (19) placebo subjects contributed to this endpoint.

The average mean improvement in the subjects taking product was 2.87 points while the average mean improvement for those on placebo was 1.58 points. This met the criteria for a statistical trend ($p < 0.14$).

The efficacy of Femmerol with respect to relief of irritability was demonstrated in that seventy-three percent (73.3%) of the subjects taking the actual product reported some level of improvement in their symptoms while fifty-eight percent (5 7.9%) of those on placebo reported a similar level of relief.

Forty-seven (46.7%) and thirty percent (30%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to twenty-six (26.3%) and eleven (10.5%) on placebo.

Mood Swings

Twenty-three (23) product subjects and sixteen (16) placebo subjects contributed to this end-point.

The average mean improvement in the subjects taking product was 2.83 points while the average mean improvement for those on placebo was 1.44 points. This met the criteria for a statistical trend ($p < 0.13$).

The efficacy of Femmerol with respect to relief of mood swings was demonstrated in that seventy-four percent (73.9%) of the subjects taking the actual product reported some level of improvement in their symptoms while forty-four percent (43.8%) of those on placebo reported a similar level of relief.

Forty-four (43.5%) and thirty-five percent (34.8%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to thirty-one (3 1.3%) and thirteen (12.5%) on placebo.

Cramping

Twenty-one (21) product subjects and thirteen (13) placebo subjects contributed to this end-point.

The average mean improvement in the subjects taking product was 2.29 points while the average mean improvement for those on placebo was actually a negative 0.08 points. This did reach statistical significance ($p < 0.03$).

The efficacy of Femmerol with respect to relief of abdominal cramping was demonstrated in that forty-eight percent (47.6%) of the subjects taking the actual product reported some level of improvement in their symptoms while none (0%) of those on placebo reported a similar level of relief. This was highly significant ($p < 0.005$).

Forty-three (42.9%) and twenty-four percent (23.8%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to none on placebo ($p < 0.006$ and 0.13 respectively).

Hot Flashes

Thirty-one (31) product subjects and nineteen (19) placebo subjects contributed to this end-point.

The average mean improvement in the subjects taking product was 4.29 points while the average mean improvement for those on placebo was 1.32 points. This did reach statistical significance ($p < 0.001$).

The efficacy of Femmerol with respect to relief of hot flashes was demonstrated in that ninety-seven percent (96.8%) of the subjects taking the actual product reported some level of improvement in their symptoms while fifty-three percent (52.6%) of those on placebo reported a similar level of relief ($p < 0.00005$).

Seventy-one (71.0%) and thirty-nine percent (3 8.7%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to thirty-two (31.6%) and sixteen (15.7%) on placebo ($p < 0.006$ and 0.09 respectively).

Joint Ache and Pain

Twenty-nine (29) product subjects and nineteen (19) placebo subjects contributed to this end-point.

The average mean improvement in the subjects taking product was 1.79 points while the average mean improvement for those on placebo was 0.05 points. This did reach statistical significance ($p < 0.03$).

The efficacy of Femmerol with respect to relief of joint pain was demonstrated in that fifty-nine percent (5 8.6%) of the subjects taking the actual product reported some level of improvement in their symptoms while forty-two percent (42.1%) of those on placebo reported a similar level of relief.

Thirty-five (34.5%) and fourteen percent (13.8%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to five (5.3%) and none (0%) on placebo.

Nervousness

Nineteen (19) product subjects and sixteen (16) placebo subjects contributed to this endpoint.

The average mean improvement in the subjects taking product was 2.37 points while the average mean improvement for those on placebo was a negative 0.06 points. This did reach statistical significance ($p < 0.005$).

The efficacy of Femmerol with respect to relief of excessive nervousness was demonstrated in that sixty-three percent (63.2%) of the subjects taking the actual product reported some level of improvement in their symptoms while thirty-one percent (31.3%) of those on placebo reported a similar level of relief.

Forty-two (42.1%) and twenty-six percent (26.3%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to thirteen (12.5%) and six (6.3%) on placebo.

Vaginal Dryness

Nineteen (19) product subjects and thirteen (13) placebo subjects contributed to this endpoint.

The average mean improvement in the subjects taking product was 1.79 points while the average mean improvement for those on placebo was exactly 0.0 points. This did reach statistical significance ($p < 0.09$).

The efficacy of Femmerol with respect to relief of vaginal dryness was demonstrated in that forty-seven percent (47.4%) of the subjects taking the actual product reported some level of improvement in their symptoms while twenty-three percent (23.1%) of those on placebo reported a similar level of relief.

Thirty-two (31.6%) and sixteen percent (15.8%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to fifteen (15.4%) and eight (7.7%) on placebo.

Dizziness
Twenty-eight (28) product subjects and nineteen (19) placebo subjects contributed to this end-point.

The average mean improvement in the subjects taking product was 1.32 points while the average mean improvement for those on placebo was 0.05 points. This did reach statistical significance ($p < 0.03$).

The efficacy of Femmerol with respect to relief of dizziness was demonstrated in that forty-six percent (46.4%) of the subjects taking the actual product reported some level of improvement in their symptoms while thirty-two percent (31.6%) of those on placebo reported a similar level of relief.

Twenty-one (21.4%) and eleven percent (10.7%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to five (5.3%) and none (0) on placebo.

Headaches
Twenty-seven (27) product subjects and eighteen (18) placebo subjects contributed to this end-point.

The average mean improvement in the subjects taking product was 1.15 points while the average mean improvement for those on placebo was a negative 0.06 points. This did not reach statistical significance ($p < 0.13$), but did meet the definition of a trend.
The efficacy of Femmerol with respect to relief of headaches was demonstrated in that fifty-six percent (55.6%) of the subjects taking the actual product reported some level of improvement in their symptoms while thirty-three percent (33.3%) of those on placebo reported a similar level of relief.

Nineteen (18.5%) and eleven percent (11.1%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to eleven (11.1%) and six (5.6%) on placebo.
Insomnia
Thirty (30) product subjects and fifteen (15) placebo subjects contributed to this endpoint.

The average mean improvement in the subjects taking product was 2.07 points while the average mean improvement for those on placebo was 1.16 points. This did not reach statistical significance ($p < 0.26$).

The efficacy of Femmerol with respect to relief of insomnia was demonstrated in that sixty-seven percent (66.7%) of the subjects taking the actual product reported some level of improvement in their symptoms while forty-seven percent (47.4%) of those on placebo reported a similar level of relief
Forty-three (43.3%) and twenty percent (20.0%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to thirty-seven (36.8%) and six (5.3%) on placebo.

Concentration
Twenty-nine (29) product subjects and eighteen (18) placebo subjects contributed to this end-point.

The average mean improvement in the subjects taking product was 3.10 points while the average mean improvement for those on placebo was 1.0 points. This did reach statistical significance ($p < 0.02$).

The efficacy of Femmerol with respect to improvements in concentration was demonstrated in that seventy-two percent (72.4%) of the subjects taking the actual product reported some level of improvement in their symptoms while fifty percent (50.0%) of those on placebo reported a similar level of relief.

Fifty-two (51.7%) and thirty-eight percent (37.9%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to twenty-two (22.2%) and six (5.6%) on placebo ($p < 0.045$ and $p < 0.017$ respectively).

Palpitations

Twenty-five (25) product subjects and fourteen (14) placebo subjects contributed to this end-point. The average mean improvement in the subjects taking product was 1.80 points while the average mean improvement for those on placebo was 0.07 points. This did reach statistical significance ($p < 0.09$).

The efficacy of Femmerol with respect to palpitations was demonstrated in that forty-four percent (44.0%) of the subjects taking the actual product reported some level of improvement in their symptoms while fourteen percent (14.3%) of those on placebo reported a similar level of relief. Forty-two (42.1%) and twenty-six percent (26.3%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to seven (7.1%) and none (0%) on placebo.

Breast Tenderness

Twenty (20) product subjects and fifteen (15) placebo subjects contributed to this endpoint.

The average mean improvement in the subjects taking product was 2.00 points while the average mean improvement for those on placebo was 0.0 points. This did reach statistical significance ($p < 0.02$).

The efficacy of Femmerol with respect to relief of breast tenderness was demonstrated in that fifty-five percent (55.0%) of the subjects taking the actual product reported some level of improvement in their symptoms while twenty-seven percent (26.7%) of those on placebo reported a similar level of relief.

Twenty-eight (28.0%) and twenty-five percent (25.0%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to none (0%) on placebo ($p < 0.012$ and $p < 0.057$ respectively).

Water Retention

Twenty (20) product subjects and fourteen (14) placebo subjects contributed to this endpoint.

The average mean improvement in the subjects taking product was 2.40 points while the average mean improvement for those on placebo was 0.79 points. This did not reach statistical significance ($p < 0.15$), and missed being a trend by the slightest of margins.

The efficacy of Femmerol with respect to relief of water retention was demonstrated in that sixty percent (60.0%) of the subjects taking the actual product reported some level of improvement in

their symptoms while forty-three percent (42.8%) of those on placebo reported a similar level of relief.

Fifty (5 0.0%) and thirty percent (3 0.0%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to twenty-one (21.4%) and seven (7.1%) on placebo.

Night Sweats
Twenty-eight (28) product subjects and fifteen (15) placebo subjects contributed to this end-point.

The average mean improvement in the subjects taking product was 3.29 points while the average mean improvement for those on placebo was 1.20 points. This did reach statistical significance ($p < 0.02$).

The efficacy of Femmerol with respect to relief of night sweats was demonstrated in that eighty-six percent (85.7%) of the subjects taking the actual product reported some level of improvement in their symptoms while fifty-three percent (53.3%) of those on placebo reported a similar level of relief.

Sixty-four (64.3%) and twenty-one percent (21.4%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to thirty-three (33.3%) and thirteen (13.3%) on placebo.

Libido
Nineteen (19) product subjects and eleven (11) placebo subjects contributed to this endpoint.

The average mean improvement in the subjects taking product was 1.21 points while the average mean improvement for those on placebo was 0.27 points. This did not reach statistical significance ($p < 0.38$).

The efficacy of Femmerol with respect to improvements of libido was demonstrated in that forty-two percent (42.1%) of the subjects taking the actual product reported some level of improvement in their symptoms while thirty-six percent (3 6.4%) of those on placebo reported a similar level of relief.

Twenty-six (26.3%) and twenty-one percent (21.1%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to eighteen (18.2%) and none (0%) on placebo.

Summary Improvement
All thirty-one (31) product subjects and nineteen (19) placebo subjects contributed to this end-point.

The average mean improvement in the subjects taking product was 32.9 points while the average mean improvement for those on placebo was 9.1 points. This did reach statistical significance ($p < 0.002$).

The efficacy of Femmerol with respect to the summary outcome variable was demonstrated in that all of the subjects (100%) taking the actual product reported some level of improvement in their symptoms while sixty-eight percent (68.4%) of those on placebo reported a similar level of relief. This difference was highly statistically different ($p < 0.002$).

Sixty-one (61.3%) and thirteen percent (12.9%) of the women on product respectively reported a significant and dramatic improvement on the product, compared to twenty-one (21.0%) and five (5.3%) on placebo. The first comparison was different ($p < 0.006$).

Pulse

Seventeen (17) product subjects and twelve (12) placebo subjects contributed to this endpoint. The average mean improvement in the subjects taking product was 3.6 points while the average mean improvement for those on placebo was a negative 0.08 points. This did not reach statistical significance ($p < 0.34$).

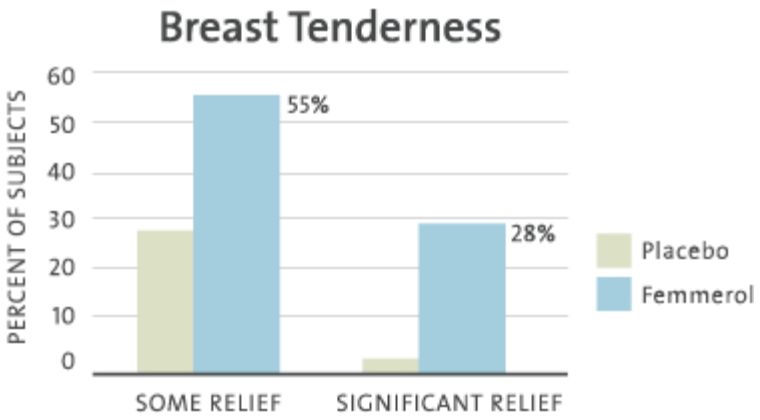
Adverse Events

There were no serious adverse events in this trial. There were subjects who reported minor gastrointestinal upsets, which abated after stopping the product. *(This has been addressed with lipid delivery)*

Conclusions

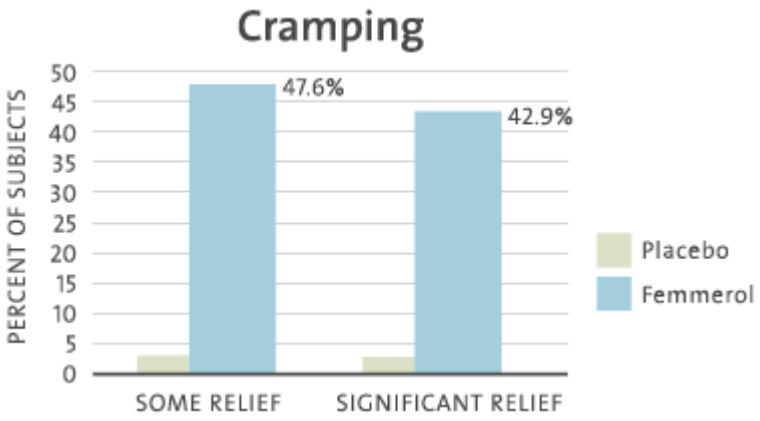
Clearly, Femmerol is extremely effective in relieving a number of common symptoms associated with common menopausal symptoms. These include hot flashes, night sweats, breast tenderness, palpitations, concentration, dizziness, vaginal dryness, excessive nervousness, joint ache and pain, and cramping. Each of these symptoms was statistically different from those on placebo. Water retention, headaches, mood swings, irritability, and depression met the criteria for a statistical trend. It appears that Femmerol is effective in relieving menopausal symptoms and improves one's ability to function normally.

Breast Tenderness



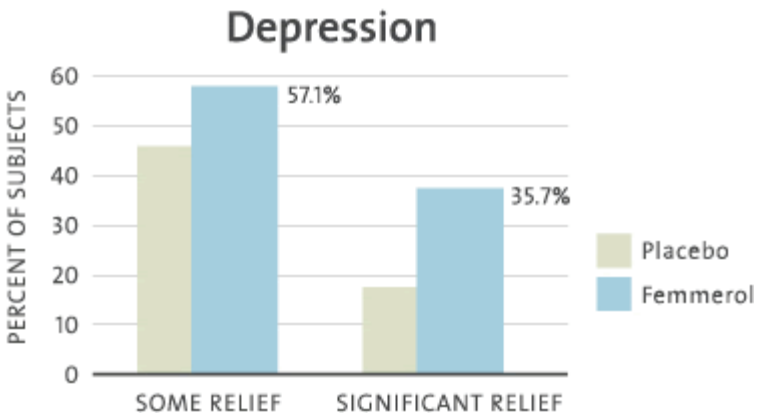
55% reported relief from breast tenderness, with 28% reporting significant and dramatic relief.

Cramping



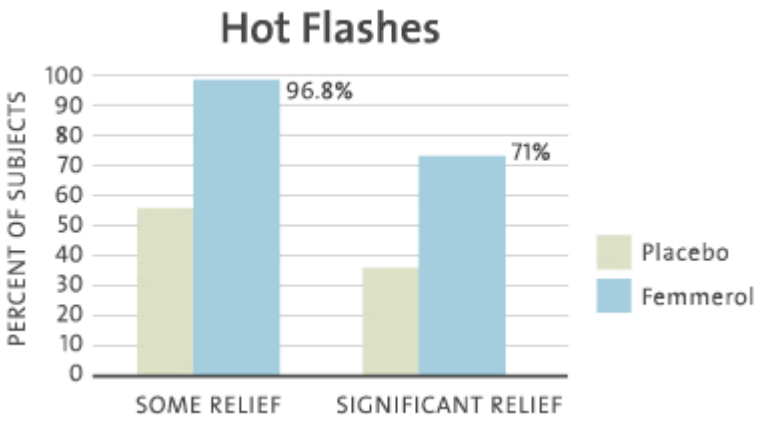
47.6% reported relief from cramping, with 42.1% reporting significant and dramatic relief.

Depression



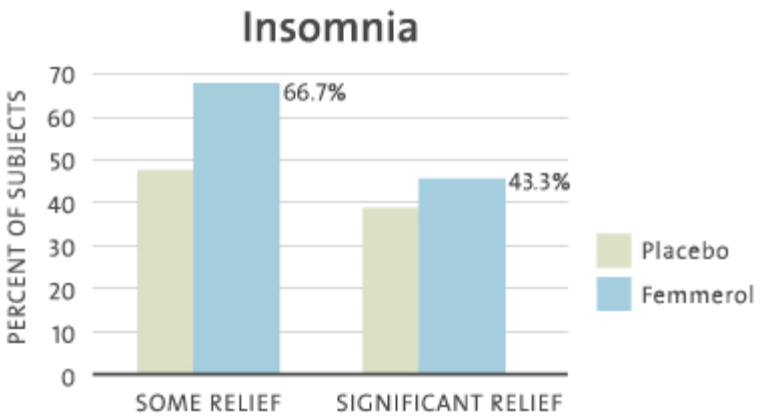
57% of women taking Femmerol reported relief from depression, with 35.7% reporting significant and dramatic relief.

Hot Flashes



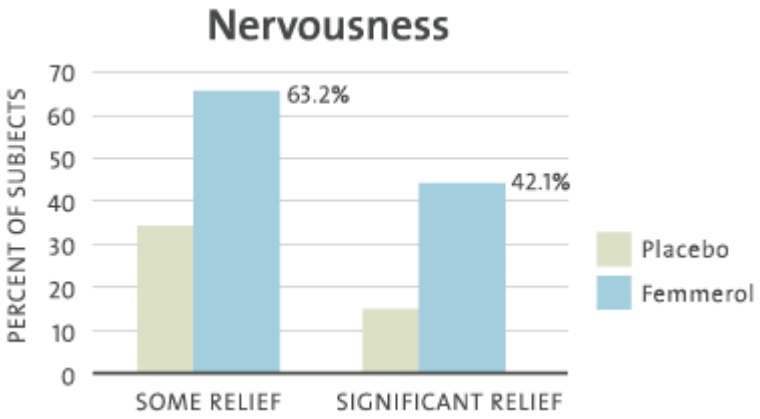
96.8% of women taking Femmerol reported relief from hot flashes, with 71% reporting significant and dramatic relief.

Insomnia



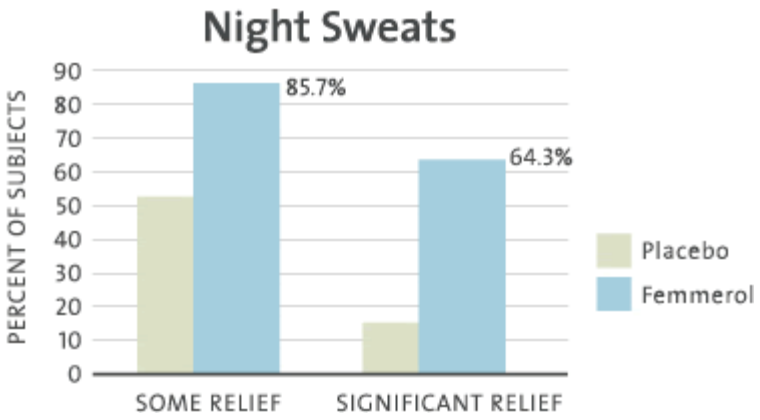
66.7% reported relief from insomnia, with 43.3% reporting significant and dramatic relief.

Nervousness



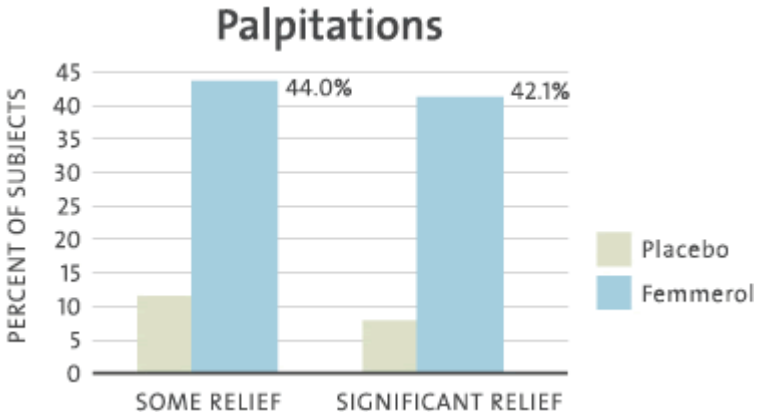
63.2% reported relief from nervousness, with 42.9% reporting significant and dramatic relief.

Night Sweats



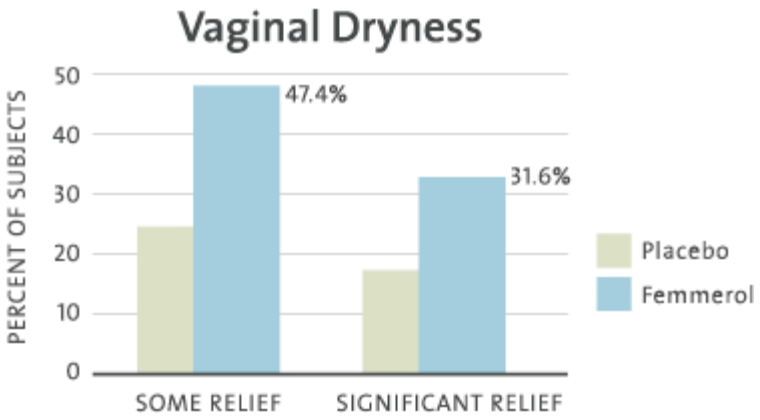
85.7% reported relief from night sweats, with 64.3% reporting significant and dramatic relief.

Palpitations



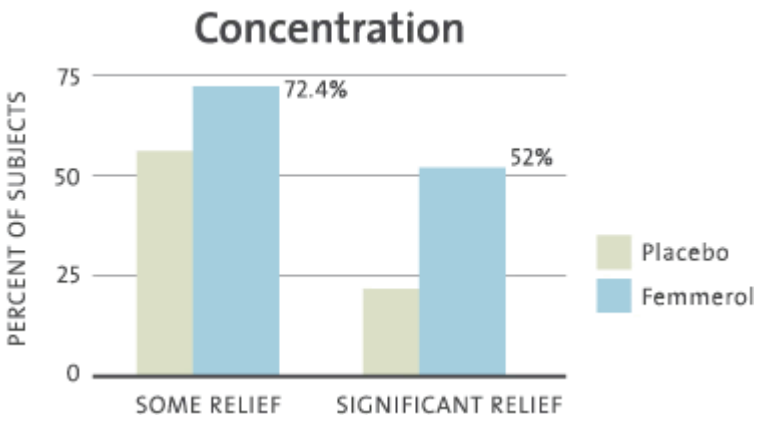
44% reported relief from palpitations, with 42.1% reporting significant and dramatic relief.

Vaginal Dryness



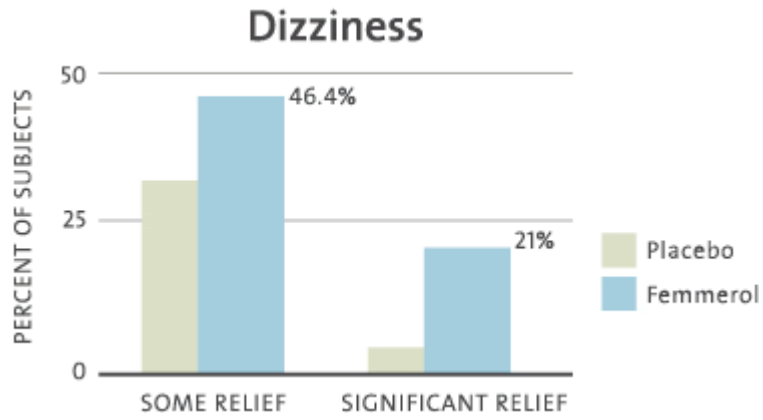
47.4% reported relief from vaginal dryness, with 31.6% reporting significant and dramatic relief.

Concentration



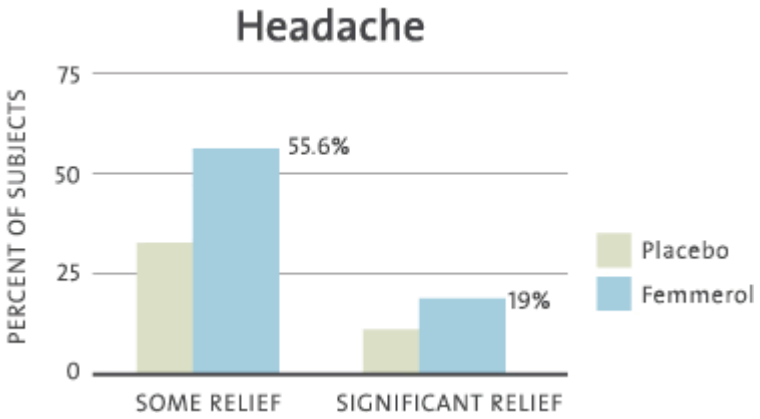
72.4% of women taking Femmerol reported improved concentration, with 51.7% reporting significant and dramatic relief.

Dizziness



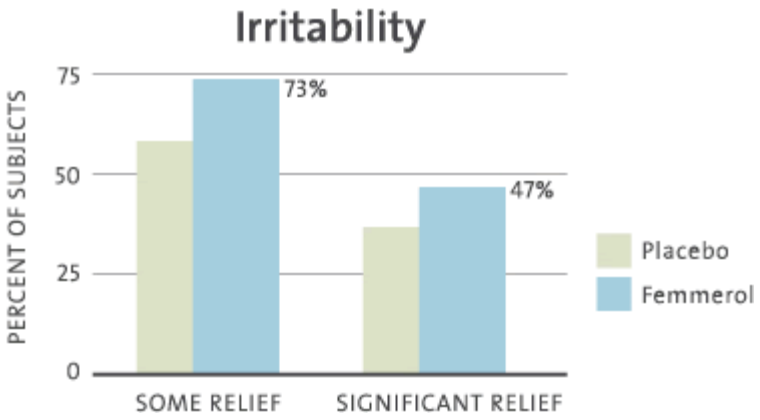
46.4% of women taking Femmerol reported relief from dizziness, with 21.4% reporting significant and dramatic relief.

Headaches



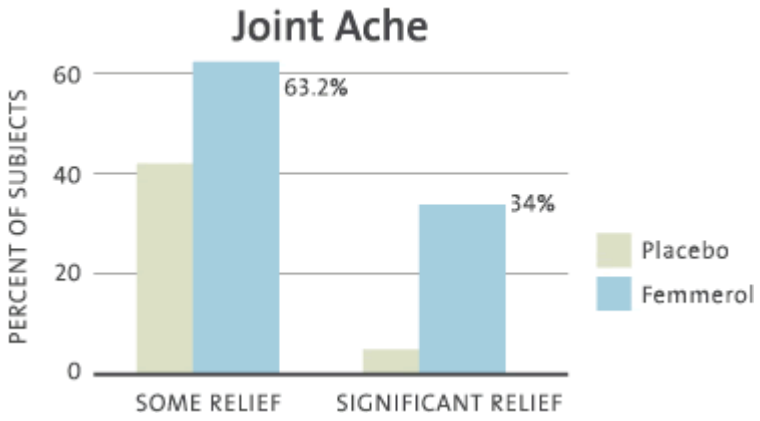
55.6% of women taking Femmerol reported relief from headaches, with 18.5% reporting significant and dramatic relief.

Irritability



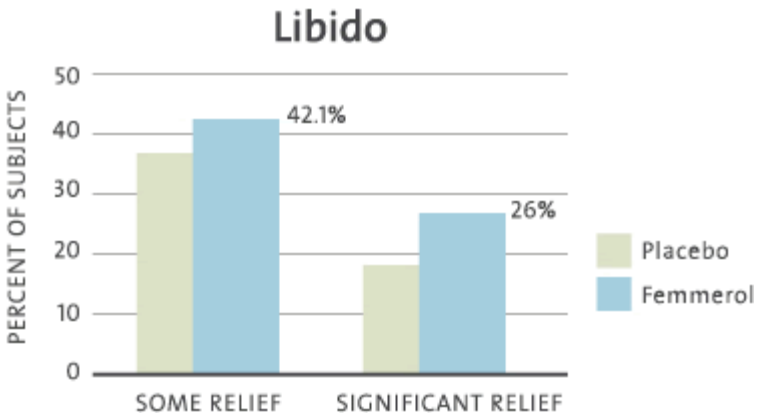
73% of women taking Femmerol reported relief from irritability, with 47% reporting significant and dramatic relief.

Joint Ache and Pain



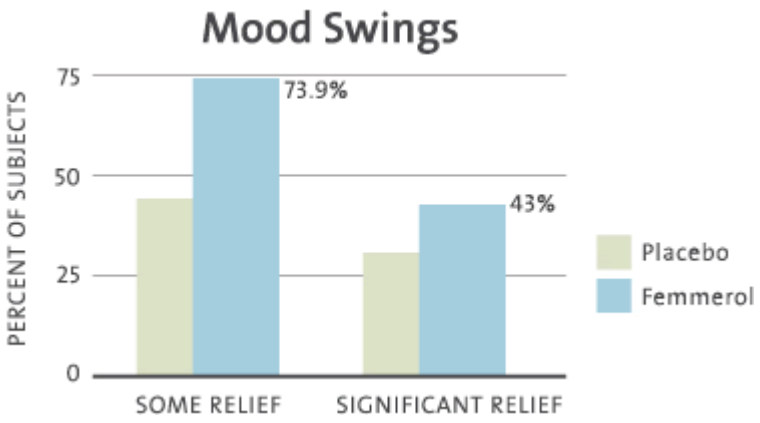
63.2% of women taking Femmerol reported relief from joint aches and pain, with 42.1% reporting significant and dramatic relief.

Libido



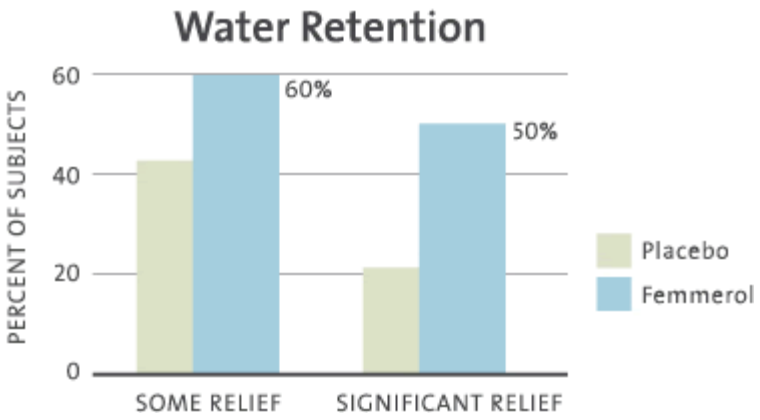
42.1% of women taking Femmerol reported improved libido, with 26.3% reporting significant and dramatic relief.

Mood Swings



73.9% of women taking Femmerol reported relief from mood swings, with 43.8% reporting significant and dramatic relief.

Water Retention



60% of women taking Femmerol reported relief from water retention, with 50% reporting significant and dramatic relief.