

The Effectiveness of Natural Products for Women's Health

8th Annual NHRI Scientific Symposium





Presented by:

"Evidence-based natural solutions to symptoms of perimenopause and menopause" Chicago, Oct. 20 2012

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Objectives

- select research in botanical and nutrient treatments for common symptoms of menopause.
- Symptom specific non-Rx options
- Dosing guidelines/adverse events

Fundamental Goals of Intervention

- Symptom relief
 -with minimal impact on increasing risks of other diseases
- Disease Prevention and Treatment
- Opportunity for changes in life
- Education about health

Categories of Treatment Intervention

- Diet, Exercise, stress management
- Nutritional supplements
- Botanical medicines
- Compounded Bio-Identical HT
- Pharmaceutical Co. BHT
- Non bio-identical hormones
- Other medications

Perimenopause/Menopause Symptoms

- Decline in fertility
- Irregular uterine bleed
- Vasomotor symptoms
- Insomnia
- Urogenital changes
- Vulvovaginal changes
- Incontinence
- Urinary tract infection

Perimenopause and Menopause Symptoms

- Mood swings, depression, anxiety
- Concentration and memory
- Sexual Function
- Weight gain, headache, palpitations, joint pain,
- Skin, eyes, hair, teeth, oral health
- Fatigue
- Oddities: burning mouth, frozen shoulder, voice impairment

Black Cohosh (Cimicifuga racemosa)



Clinical Research

Over 100 published scientific papers and presentations on the efficacy and safety of standardized black cohosh extract

Black Cohosh Breast Cancer Safety

Safety Studies

Design:

 In vitro, MCF-7 cell culture model to determine estrogen-agonist and -antagonist activity of commercially available herbal menopause preparations

Findings:

- Isopropanolic black cohosh extract had no effect on estrogen-sensitive cells in vitro.
- Results suggest safety for women with a history of breast cancer.

Bodinet C, Freudenstein J. Influence of marketed herbal menopause preparations on MCF-7 cell proliferation. *Menopause*. 2004 May-Jun;11(3):281-9.

Safety Studies

Design:

 Six-week, *in vivo* investigation of isopropanolic black cohosh extract ability to stimulate estrogen-receptor positive cells in an animal model

Findings:

- No estrogen stimulating effects were found.
- Prolactin, follicle-stimulating hormone, and luteinizing hormone levels were unchanged.

Freudenstein J, et al. Lack of promotion of estrogen-dependent mammary gland tumors in vivo by an isopropanolic Cimicifuga racemosa extract. *Cancer Res.* 2002 Jun 15;62(12):3448-52.

Black Cohosh associated with breast cancer risk reduction

 Black cohosh use was associated with a 61 percent reduction in the risk of breast cancer with an odds ratio of 0.39, 95% CI: 0.22-0.70. The breast protective effect was similar for a specific black cohosh preparation, Remifemin, odds ratio 0.47, 95%, CI: 0.27-0.82.

Int. J. Cancer 2007; 120:1523-1528.

Black Cohosh Liver Safety

New NIH Expert Panel 2008

- Analysis of case reports, adverse event reports, animal data, historical use, regulatory status.
- 30 non-duplicate reports
- All reports of liver damage were assigned possible causality, none were probably or certain causality. Clinical and animal data did not reveal unfavorable information
- NEW: should be labeled to include a cautionary statement

Black Cohosh Drug Interactions

In vitro study:

- -Black cohosh extracts increased the cytotoxicity of doxorubicin and docetaxel
- -Decreased the cytotoxicity of cisplatin
- No effect on radiation or analog cyclophosphamide

Rockwell S, et al. Breast Cancer Res Treat 2005;90(3): 233-239

Black Cohosh Dose and Safety

- Dosages: 20-40 mg St. Extract bid
- Contraindications
 - None known
 - Avoid during pregnancy and lactation
- Cautions: liver disease
- Adverse Effects
 - Occasional gastrointestinal discomfort
 - Overdose may cause vertigo, headache, nausea, vomiting, impaired vision, impaired circulation
- Drug Interactions
 - Caution if hepatotoxic drugs
 - Avoid if Cisplatin
 - Ok with tamoxifen or raloxifene

Black Cohosh

- Summary:
 - the most studied plant for menopause sx
 - does not have estrogenic action
 - Does not contain phytoestrogens
 - Safe in breast cancer patients
 - Mechanism unclear
 - Good safety profile

Ginseng and Menopause

- 384 menopausal women randomized to receive either 2 caps of Ginsana (S.E.) or placebo for 16 weeks.
- Results: Only the PGWB (psychological general well-being index (P<0.01) and its scale of depression, well being and health showed statistically significant improvement.

Wicklund I, et al. Int J Clin Pharm Res 1999;19: 89-99

Ginseng-VMI, CVD

- 72 postmenopausal women; red ginseng =given was 3 gm per day
- Kupperman index for the red ginseng group significantly reduced from 18.93 to 13.32 compared with the placebo from 15.21 to 15.10. The Menopause Rating Scale score dropped significantly from 12.45 to 8.32 in the ginseng group compared with 10.23 to 9.26 in the placebo group. The hot flash score also reduced significantly
- Red ginseng also elicited a significant decrease in total cholesterol from 138.11 to 108.82, drop in LDL; no changes in HDL cholesterol or C-reactive protein.
- Carotid intima-media thickness was significantly reduced in the red ginseng group

Menopause 2012;19(4):461-466

Ginseng Safety Issues

- For both species, occasional cases of insomnia or agitation have been reported. This is more likely to occur if consumed with caffeine. Persons with hypertension should use ginseng cautiously.
- Asian ginseng is contraindicated during pregnancy or lactation. It may also cause some women to experience menstrual abnormalities, including breast tenderness.
- For both species, caution should be observed with diabetic patients taking oral hypoglycemics or insulin. There are some reports that Asian ginseng may interfere with the actions of warfarin.

Ginseng

- Drug interactions
 - -Probable and mild

increases effect of alcohol, caffeine

- Probable and moderate

hypoglycemic drugs= theoretical enhancement of blood sugar lowering

- Unlikely

might decrease platelet aggregation= Warfarin

Hops and Menopause

RCT, 67 menopausal women were given either a placebo or a 100 mcg or 250 mcg standardized hops extract for 12 weeks. At 6 weeks, the 100 mcg dose was significantly superior to placebo, but not after 12 weeks.

There was a more rapid decrease in menopause symptoms scored for both doses of hop extract, especially the hot flush score.

Heyerick A, et al. *Maturitas 2006;54:164-175*

Hops and Menopausal Symptoms

- 36 menopausal women; RCT; placebo or hop extract x 8 weeks; switched to the opposite group for another 8 weeks.
- After 8 weeks: both groups= significant and actually higher average reductions in the placebo group.
- After 16 weeks: only hops extract in the second 8 weeks had a reduction in all outcome measures whereas the placebo group in the second 8 weeks had an increase for all outcome measures.
- Although the overall treatment efficacy of the hops treatment compared with the placebo did not show a significant effect, the time specific uses did indicate significant reductions in the KI and the VAS for the hops group, and a marginal reduction in symptoms for the MRS after 16 weeks.

Erkkola R, et al. Phytomedicine 2010;17:389-396.



Kava and Menopause RCTs

Kava extract vs placebo x 12 wks.
 Significant improvement in KI, ASI and daily symptom diary w/kava.

Warnecke. Zeitschrift Phytotherapie 1990;11

Kava extract vs placebo x 8 wks.
 Significant improvement in KI and HAMA at wks 1,4,8. DSI reduced with kava at wks 4 and 8.

Warnecke. Fortschr Med 1991;4

 Anxiety in menopause: Kava with and wo/ HRT 100 mg Kava or placebo x 6 months. Women with HRT and kava showed the greatest reduction in HAMA.

De Leo. Minerva Ginecol 2000;52

Kava and anxiety in Perimenopausal Women

- Calcium 1 gm plus Kava 100 mg vs
 Calcium 1 gm plus Kava 200 mg vs Calcium
- Rapid decline within 1 month anxiety
 Slower and less significant-depression and climacteric symptoms

Cagnacci et al. Maturitas 2003;44: 103-109

Kava Extract Safety Update

- Side effects: GI upset, skin rash, and sebaceous reaction following long-term ingestion Large amounts of traditional preparations have resulted in drowsiness and impaired reaction time.
- Kava should not be used with anxiolytics, antidepressants, or neuroleptics.
- Kava may potentiate the CNS effects of alcohol.
- Recommended dose:

45 to 7- mg kavalactones tid up to 210 kavalactones per day

Kava Extract Hepatotoxicity

- Reports from late 2001 have indicated that kava may be associated with liver damage.
- Until additional information clarifies the extent of the risk involved, it is strongly recommended that all individuals consult their physician before taking kava. In addition, based on the available information, it seems that people with liver disease and those taking medications that have the potential to damage the liver should not take kava.

Reuters, Nov. 19, 2001. http://www.reutershealth.com/frame2/eline.html *BMJ* 2001;322:139. *Dtsch Med Wochenschr* 2001;126:970–2. *Dtsch Med Wochenschr* 1998;123:1410–4. *Ann Intern Med* 2001;135:68–9 [letter].

Kudzu Pueraria mirifica

- RDBPCT
- 20, 30 or 50 mg of Pueraria mirifica in capsules or placebo, daily, for 24 weeks.
- The average vaginal dryness symptom in the treatment group decreased after 12 weeks and the maturation index increased after 24 weeks.

Manonai J, et al. Menopause 2007;14(5):919-924).

Kudzu

- N=52
- 25 mg dose vs 50 mg dose
- Both dosages were similarly effective
- A statistically significant decrease in climacteric scores was observed in both groups

Virojchaiwong P, et al. Suvithayasiri V, Itharat A. Arch Gynecol Obstet 2011 284:411-419.

Maca-GO and Postmenopausal women

2 months:

-Non significant decrease in FSH and increase in E2

-Significant increase in LH and increase in Progesterone

-No change in estradiol

Symptom relief: nervous, reduced day VMI, increased libido

8 months:

-Decreased FSH

- Increase LH
- Increased Progesterone
- Increased Estradiol

Meissner H, et al. Int J Biomedical Science 2005;1(1):33-45

Maca-GO and Perimenopause

MACA-GO results:

-reduction in body weight, blood pressure increased in HDL, iron

-74%-87% of women had a reduction in -reduced VMI, insomnia, nervousness, depression and heart palpitations dose: 1 gm bid

Meissner H, et al. Int J Biomedical Science 2006 2(2):375-394

Maca: effects on anxiety, depression, sexual dysfunction

- RCT: 14 postmenopausal women ; 3.5 gm of powdered Maca (Lepidium meyenii) vs placebo for 6 weeks.
- The Greene Climacteric Scale revealed a significant reduction in psychological symptoms including anxiety, depression and sexual dysfunction after Maca consumption compared with baseline and placebo.

Brooks N, et al. Menopause 2008;15(6):1157-1162.

Lepidium (Maca) and sexual dysfunction

- Systematic review: clinical evidence for or against the efficacy of Maca for sexual dysfunction.
- Two of these trials suggested a positive effect of Maca on sexual dysfunction or libido in menopausal women or adult men.
- One other RCT did not show effect of Maca in cyclists.
- Fourth study: assessed the effects of Maca in men with erectile dysfunction and did show significant effects.
- While the evidence is limited, there does appear to be some effectiveness of maca in improving sexual function.

Shin B, et al. BMC Complementary and Alternative Medicine 2010;10:44
- Red Clover isoflavone extract
- 40 mg vs. 160 mg isoflavones vs. placebo
- 37 postmenopausal women; 12 weeks; clinical trial **EVALUATION:**
 - Vasomotor symptoms
 - FSH, SHBG, vaginal pH, MI, HDL
 - Urinary isoflavones

RESULTS:

- No difference in flushing
- Small increase HDL

Knight, etal. Climacteric 1999;2:79-84

- Red Clover isoflavone extract
- 40 mg vs. placebo
- 51 postmenopausal women
- 12 weeks

EVALUATION:

- Symptom diary
- FSH, E2, SHBG, LFTs, Urinary isoflavone
- MI, transvaginal US

RESULTS:

- No significant difference in hot flushing
- (small at 4 and 8 weeks)

Baber etal. Climacteric 1999;2:85-92

- N=30; Postmenopausal
- 40 mg daily red clover isoflavone extract for 16 weeks

EVALUATION:

- Symptom diary
- FSH

RESULTS:

- 50% reduction in frequency vs. 20% placebo
- Also 47% reduction in severity

Jeri A. Female Patient 2002;27:35-37

- Postmenopausal women n=23
- 40 mg Red Clover extract for 2 months 3 months
 EVALUATION:
 - Menopause symptom record
 - FSH, SHBG, Lipids, glucose
 - US, estradiol, CMP, CBC

RESULTS:

- 56% reduction in hot flush frequency
- 43% reduction in hot flush severity
- 52 % reduction in severity of night sweats
- .4 mm increase in endometrial thickness
- No significant changes in metabolic markers Nachtigall, et al. 9th annual world congress on menopause 1999;17-21

Red Clover and Hot Flashes

- 30 postmenopausal women
- 80 mg red clover isoflavones or placebo daily for 12 weeks.
- 44% decrease in hot flashes in the red clover group.
- Green Climacteric Scale: 13% decrease
 with red clover and no change in placebo

Van De Weijer et al. Maturitas 2002;42:187-193

Red Clover and Hot Flashes (ICE Study)

- Red clover isoflavones no more effective than placebo in reducing incidence of hot flashes
- Promensil 82 mg/day isoflavones vs Rimostil 57 mg/day vs placebo

Tice et al, JAMA 2003;290

Red Clover and hot flashes

- RDBCT
- Black cohosh vs red clover vs placebo vs CEE/MPA
- Reductions in number of vasomotor symptoms = -black cohosh 24%
 - -Red clover 57%
 - -Placebo 63%
 - -CEE/MPA 94%

Geller S, et al. Menopause 2009;16(6):1156-1166.

Red Clover

- 109 postmenopausal women; 2 capsules daily of a red clover extract totaling 80 mg of isoflavones, or a placebo, for 3 months.
- Hospital Anxiety and Depression Scale(HADS) and the Zung's Self Rating Depression Scale (SDS).
- After taking the red clover extract, women had a significant in both of the rating scales, with a 75% reduction for anxiety and 78.3% reduction for depression using the HADS tool, and an 80.6% reduction in the total SDS score. After taking the placebo pills, the HADS and SDS scores only reduced by an average of 21.7%.

Maturitas 2010;65:258-261

Pycnogenol

- In a double-blind study, Taiwanese peri-menopausal women, aged 45-55, were given either placebo or 100 mg of Pycnogenol twice daily for 6 months.
- 155 women received the Pycnogenol and seventy-five the placebo. The Women's Health Questionnaire with 36-items was used to evaluate the climacteric symptoms at baseline, and at 1,3 and 6 months.
- BP decreased similarly in both groups. HDL increased and LDL decreased significantly from baseline with Pycnogenol, but no significant differences were seen in HDL between the two groups. However, LDL was more significantly reduced in the Pycnogenol group.
- Perimenopause symptoms of depression, vasomotor symptoms, memory, anxiety, sexual function, sleep all improved significantly (P< 0.001) with Pycnogenol as soon as one month after starting the treatment, in both severity and frequency. Most symptoms also improved with placebo, but not significantly.

Acta Obstetricia et Gynecologica. 2007;86:978-985

Sibiric Rhubarb (Rheum rhaponticum)

- RCT; 109 perimenopausal women with climacteric complaints.
- Tx: st. ext. ERr 731, from the roots of Rheum rhaponticum, also known as Sibiric Rhubarb, One tablet (250 mg), containing 4 mg of dry extract was given to women (n=54) or placebo given to the other group (n=55) for 12 weeks.
- Menopause Rating Scale II (MRS II). After 12 weeks, the MRS II total score and each MRS II symptom significantly decreased in the rhubarb extract group compared to the placebo group. (P < 0.0001). The overall menopause QOL score was also significantly better in the treatment group compared with placebo. No adverse events were observed.

Hewger M et al. Menopause; J NAMS 2006;13(5):744-759.

Sibiric Rhubarb (Rheum rhaponticum)

- A standardized extract, ERr 731
- Observational study: three hundred sixty-three menopausal women with menopausal symptoms were given 1 tablet of ERr 731, containing 4 mg, for 6 months.
- The Menopause Rating Scale; 252 women completed the study.
- Significant decrease of the total MRS score from an average of 14.7 points at baseline to 6.9 points at the end of the six months (P < .0001). This was a decrease of 7.8 points.
- Most pronounced improvement, in first 3 months of treatment/most symptomatic at baseline = <u>></u>18 points. T
- Hot flashes, irritability, sleep problems, depressive mood, and physical/mental exhaustion.

Kaszkin-Bettag M, et al. Alternative Therapies 2008;14(6):32-38.

Sibiric Rhubarb (Rheum rhaponticum)

- RCT; n=109 perimenopausal women
- ERr 731; 1 tablet,4 mg dry extract x 12 wks
- HAMA: from 27.5 points to 9.4 points
- MRS: anxiety decreased 2.2 points in tx group vs 0.3 in placebo
- Wellbeing: improved in tx group but not placebo
- WHQ: 22 point increase in tx group and decreased 7.6 points in placebo

Kaszkin-Bettag M *Menopause 2007;14(2):270-283*



SJW in Menopause

 One non placebo controlled, drug monitoring study was conducted in women with menopause symptoms and found that 900 mg of St. Johns wort for 12 weeks significantly improved psychological and psychosomatic symptoms as well as a feeling of sexual well-being.

Grube B, et al. Adv Ther 1999;16:177

Black Cohosh and SJW

Average Menopause Rating Scale score decreased 50% in the treatment group/19.6% in the placebo group. The Hamilton Depression Rating Scale score decreased 41.8% in the treatment group/12.7% in the placebo group.

In both the general menopause rating scale and in the depression scale, the St. John's wort + black cohosh group was significantly superior to the placebo group.

Uebelhack R, et al. Obstet Gynecol 2006;107:247-255

Black Cohosh/St John's wort

- Prospective, controlled open-label observational study
- N=6141 women at 1287 outpatient gyn clinics in Germany
- Dose: Remifemin 20 mg tablet bid

Remifemin plus: 3.75 mg iCR extract and 70 mg SJW (from 245 mg to 350 mg)

Results: Combination product > black cohosh only for mood symptoms

Briese V, et al. Maturitas 2007;57:405-414

SJW/Black cohosh

- Peri or postmenopausal Korean women
- Mean Kupperman index scores at 4 and 12 weeks were significantly lower in the treatment group (P < 0.002).
- average decrease in the Kupperman Index was 20 points in the treatment group and only 8.2 points in the placebo group.
- Vaginal dryness and low libido did not improve
- average hot flash scores were significantly lower in the black cohosh/St. Johns wort group.

Chung D, et al. Yonsei Med J 2007;48(2):289-294.

Hypericum P. and Menopause

- 50 women received 20 drops three times daily of St. John's wort extract (Hyperin) that contained hypericin 0.2 mg/mL and 50 women received a placebo of distilled water. The study duration was two months.
- In women taking St. John's wort, the frequency began to decline during the 1st and 2nd months, but showed more improvement during the 2nd month. Women who used St. John's wort showed more improvement in hot flash frequency than placebo. The decline in duration of hot flashes was statistically significant at week 8 and the decline was much more evident in the St. John's wort group. The severity of hot flashes was relieved in the St. John's wort group during the 2 months of treatment and was more significant in the second month. Women in the placebo group did not show any significant decrease in severity of hot flashes during the 1st month, but they did have some improvement during the 2nd month, but not as great as those women in the St. John's wort group.

Abdali K, et al. Menopause 2010;17(2): 326-331.

Vitex and SJW

- Vitex was a component of the multibotanical formula in the HALT study, and in the Cancelleiri study
- Recent menopause related study: Vitex with SJW
- RCT 16 week trial of late perimenopausal or postmenopausal women who reported hot flushes and other menopause symptoms, the herbal combination showed no significant difference from that of placebo.

van die B, et al. Menopause 2009;16(1):156-163.

Multi-botanical Formula

- Burdock root, Wild yam Motherwort, Dong quai, Licorice root
- 100% had reduction in symptoms(67% showed reduction with placebo)71% had reduction in total number of sx.(17% showed reduction with placebo)

Hudson T, et al. JNM;1997;7(1):73-77

3 Combination Korean Herbs

- Cynanchum wilfordii + Phlomis umbrosa + Angelica gigas
- RDBPCT; n=64; 12 weeks
- KMI significantly reduced

Phytotherapy Research 2011; Wiley online library



Valerian

- Postmenopausal women -aged 50 to 60 years
- 530 mg of concentrated valerian extract twice per day vs placebo twice per day, for 4 weeks.
- Overall, 30% of the women taking valerian and 4% taking placebo reported an improvement in their sleep quality

Taavoni S, Menopause 2011; 18(9): 951-955.

Omega-3 f.a. and Hot Flashes

- ethyl-eicosapentaenoic acid (E-EPA) omega-3 fatty acid or placebo for 8 weeks. The E-EPA supplementation was one capsule three times per day(350 mg of EPA/50 mg of DHA). baseline level of hot flashes =average of 2.8 per day.
- After 8 weeks, the hot flash frequency decreased in the E-EPA group by a mean of 1.58 per day and only 0.50 per day in the placebo group.
- significant reduction of 55% in hot flash frequency in the E-EPA group vs 25% decrease in the placebo group.
- greater responder rate in the E-EPA group compared with the placebo group of 58.5% vs 34.4%.
- No differences in hot flash severity and no differences were noted in the quality of life scores between the two groups.

Lucas M, et al. Menopause 2009.16(2):357-366.

EFAs- Hot flashes (and depression)

- 20 perimenopausal/menopausal women
- 2 gm/day (1 gm= 840 mg EE and 375 mg DHA for 8 weeks
- Number of hot flashes per day improved significantly from baseline-day and night
- Significant decrease in MADRS scoresresponse rate – 70%; <u>> 50%</u> decrease and remission rate of 45%

Freeman et al. Menopause 2011;18(3):279

Menopause Symptoms Integrative Clinical Solutions

Tori Hudson, N.D. Clinical Professor, NCNM/Bastyr/SCNM Medical Director, A Woman's Time Program Director, IWHIM Director Education/Research, Vitanica

Hot Flashes

- Mild to Moderate
 - Black cohosh extract 40-80 mg bid
 - Combination product ((Dong quai, licorice, burdock, motherwort, wild yam) 2 tid
 - Maca-GO Extract 2 bid
 - Pycnogenol 100 mg bid
 - Sibiric Rhubarb (ERr731) 250 mg/day

• Severe

May need Hormone Therapy or, lower dose HT + botanicals/neutraceuticals

Anxiety + Hot flashes

- Mild to Moderate
 - Kava, 70 mg kavalactones tid
 - Maca- st. extract 2 1,000 mg bid+ Kava 70 mg kavalactones tid
 - Black Cohosh 40 mg st extract bid + kava 70 mg kavalactones tid

consider :Black cohosh or Maca or combo product + GABA, L-theanine, passion flower)

Anxiety

- GABA
- L-theanine
- Inositol
- Hops, skullcap, valerian, lavender, kava

Lavender Oil extract in patients with Generalized Anxiety Disorder (GAD)

- Indication: Generalized Anxiety Disorder
- Design: Multi-center, randomized, double-blind clinical trial in comparison to lorazepam
- N = 77, 6 weeks treatment; 80 mg daily
- Results
 - Therapeutic equivalence of WS® 1265 and lorazepam
 - Anxiolytic efficacy (HAMA reduction by 11 points)
 - Improvement in quality of life (SF-36)

WS[®] 1265 improves anxiety

Mean change in HAM-A total score from baseline during the active treatment period



Lavender Oil improves anxiety and quality of life

- Randomized, double-blind, placebo-controlled, multicenter study.
- N=221, 10 weeks treatment
- Results
 - Anxiolytic efficacy (HAM-A): clear effects after 2 weeks of treatment
 - Improvement of sleep disturbances : clear effects after 4 to 6 weeks
 - Indication: Anxiety disorder
 - Improvement in Quality of life

Int Clin Psychopharmacol 2010;25:277–87.

Anxiety and Palpitations

Anxiety

- *Kava
- Lemon balm
- Valerian
- Skullcap
- Hops
- *Lavender

Palpitations

- Hawthorne
- Motherwort

Depression

- Mild Moderate
 - 1. Black cohosh 40 mg bid

+++

- SJW .3% hypericin 300 mg bid-tid 2. Maca-GO Extract 1,000 mg bid
 - +++
- SJW .3% hypericin 300 mg bid-tid

Depression

Perimenopause/PMS

 Hot flashes/mood changes + cyclic classic PMS symptoms
 Black cohosh/SJW

+++

PMS herbal formula (B6, Ca, Vitex, SJW, Mg, Ginkgo, GLA)
Insomnia

- Mild-Moderate
 - 1 of the following: Women's Phase II Black cohosh Maca-GO

+++

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Valerian 2 caps before bed
Consider L-tryptophan 1,000 mg/1500 mg h.s.
5 HTP 200 mg h.s.
Melatonin 1-10 mg h.s.
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Melatonin

Dosing

likely safe= 5 mg/day possibly safe= up to 40 mg/day for short periods likely unsafe= pregnancy preparation, pregnancy

• Adult dosing

Delayed sleep syndrome: 5 mg, 5 hours h.s.

Insomnia elderly: 30-120 minutes h.s. 0.1mg to 0.3 mg

insomnia of unknown origin: 1-5 mg h.s.

jet lag: day of travel close to target bedtime at destination and then every 24 hours for several days; 0.1 mg-5 mg

Tryptophan

- L-Tryptophan: improves sleep latency; obstructive sleep apnea; PMDD- decreases mood swings, tension, irritability; depression; SAD; smoking cessation 500 mg- 2,500mg before bed; take w/CHO
- 5 HTP: decreases time required to fall asleep and decreases number of awakenings; increases REM sleep and deep sleep of other stages 100-300 mg per day; take w/CHO

Wyatt; Biology of Psychiatry 1972 Guilleminalut. Elcectoencephalogr Clin Neurophysiol 1973

5-hydroxytryptophan (5-HTP)

- Decreases the time required to get to sleep
- Decreases night time awakenings

Wyatt; Biology of Psychiatry 1972

Guilleminalut. Elcectoencephalogr Clin Neurophysiol 1973

 Increases REM sleep and deep sleep of other stages

Summary Botanica/Neutraceutical Options

Benefits

-Especially effective for mild-moderate symptoms

-Can be used in combination with HT- able to then use lower doses of HT

-Good safety profile; low adverse events

Risks

short list of known drug interactions

short history of concomitant OTC and Rx use

Dr. Tori Hudson Resources

- Women's Encyclopedia of Natural Medicine, 2008, second edition
- www.drtorihudson.com
- www.awomanstime.com
- <u>www.instituteofwomenshealth.com</u>