

ALTERNATIVE THERAPIES IN WOMEN'S HEALTH

Science-based Information for Clinicians

Thomson American Health Consultants Home Page—www.ahcpub.com

CME for Physicians—www.cmeweb.com

THOMSON
AMERICAN HEALTH
CONSULTANTS

INSIDE

Multiple benefits of exercise for breast cancer survivors
page 36

Carbs are OK: Certainly for women
page 37

Panel of scientists evaluates genistein and soy formula
page 39

Rural older adults use CAM, but focus on 'home remedies'
page 40

Alternative Therapies in Women's Health is available on-line. For more information, go to www.ahcpub.com/online.html or call (800) 688-2421.

Evening Primrose Oil for Premenstrual and Menopausal Symptoms

By Dónal P. O'Mathúna, PhD

*Lecturer in Health Care Ethics, School of Nursing,
Dublin City University, Ireland*

Dr. O'Mathúna reports no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) CONTINUES TO be a common way for women to treat symptoms of premenstrual syndrome (PMS) and menopause. In one national survey, 43% of women ages 45-57 years used CAM.¹ Those with menopausal symptoms were almost twice as likely to use CAM, with herbal remedies being the most frequently used CAM approach to treating menopausal symptoms. Evening primrose oil is an herbal remedy commonly used to treat menopausal symptoms and PMS.

Background

Evening primrose oil is obtained from the seeds of a North American wildflower (*Oenothera biennis*).² Early English settlers brought the flower back to England where it was cultivated for its nut-flavored root. The oil also was extracted from the seeds and became known as the King's Cure-All. Surveys have found that it was still a very commonly used herbal medicine in England. Two evening primrose oil products were licensed by Britain's Medicines Control Agency. The products were available by prescription to treat atopic eczema and mastalgia (breast pain). However, in 2002 the licenses were revoked after the evidence available for its effectiveness was reviewed.³

Nonetheless, the use of evening primrose oil to treat menopausal symptoms has become more popular since problems were reported in 2001-2002 with hormone replacement therapy. Evening primrose oil contains a high proportion of essential fatty acids. The two most common types present in the oil are linoleic acid (about 65%) and gamma-linolenic acid (GLA, 8-10%).⁴ Evening primrose oil is valued primarily for its GLA. It is one of the richest plant sources of GLA, with only borage oil (24%) and black currant seed oil (16%)

EDITORIAL ADVISORY BOARD

Judith Balk, MD, MPH, FACOG
Assistant Research Professor
University of Pittsburgh
Pittsburgh, PA

Kay Ball, RN, MSA, CNOR, FAAN
Perioperative Consultant/
Educator
K & D Medical
Lewis Center, OH

Mary Hardy, MD
Associate Director,
UCLA Center for Dietary
Supplement Research:
Botanicals
Medical Director,
Cedars-Sinai Integrative
Medicine Program
Los Angeles CA

Lynn Keegan, RN, PhD, HNC, FAAN
Director,
Holistic Nursing
Consultants
Port Angeles, WA

Felise B. Milan, MD
Associate Professor
of Clinical Medicine
Albert Einstein
College of Medicine
Montefiore Medical Center
Bronx, NY

Dónal P. O'Mathúna, BS (Pharm), MA, PhD
Lecturer in Health Care
Ethics
School of Nursing
Dublin City University
Ireland

Dr. Balk (peer reviewer) reports no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

containing more GLA. GLA is converted into a number of anti-inflammatory prostaglandins in the body, which is why evening primrose oil also is recommended to treat numerous chronic inflammatory diseases.

Mechanism of Action

How evening primrose oil might treat premenstrual or menopausal symptoms is not clear. There is some preliminary evidence that women with premenstrual syndrome have lower than normal levels of GLA.⁴ Epidemiological studies have shown a connection between low dietary levels of GLA and a number of illnesses. However, a precise mechanism of action for evening primrose oil is not known.

Clinical Studies

Very few high-quality studies have been conducted using evening primrose oil for specific conditions in humans. Only one controlled study of evening primrose oil to treat menopausal symptoms was found. This 1994 study examined the impact of evening primrose oil on hot flashes and night sweats.⁵ Fifty-six women with menopausal symptoms were randomized to receive either evening primrose oil (4 g/d plus 80 mg/d vitamin E) or placebo capsules for six months. Only 35 women finished the study. Although all women showed some improvements, the researchers concluded that evening primrose oil offered no benefit over placebo. An exten-

sive review of herbal remedies used for menopausal symptoms and published at the end of 2005 failed to uncover any subsequent trials of evening primrose oil.⁶

Evening primrose oil has been one of the more popular natural therapies for PMS. A small number of open studies found some benefits from evening primrose oil. However, when studied in randomized controlled trials, evening primrose oil was found to be no more beneficial than placebo. For example, 38 women with PMS were randomly assigned to receive either 4 g/d evening primrose oil or placebo.⁷ The women took the capsules for three menstrual cycles and then crossed over to the alternative group for three more cycles. Ten PMS and menstrual symptoms were measured. All subjects in both groups showed improvements in all 10 symptoms, and in an overall PMS score, but no significant differences were found between the two groups. Another randomized controlled trial used 38 women with PMS, but administered 6 g/d evening primrose oil.⁸ Again, no significant differences were found between the two groups.

Two systematic reviews of research on evening primrose oil for PMS have been carried out. One in 1996 was unable to carry out a meta-analysis due to differences in the study designs.⁹ The authors reported that the two trials described above were the only high-quality studies. A 2001 review discussed these two trials and two other placebo-controlled trials, which also found evening primrose oil no better than placebo.¹⁰ PMS is a condition that has been found to be highly responsive to placebos, with up to 80% of subjects responding well to placebos.⁷

Anecdotal reports claim that evening primrose oil is particularly effective in reducing breast pain (mastalgia), including that associated with PMS. One of the largest studies ever conducted on mastalgia investigated this claim.³ A total of 555 women were randomized to one of four groups. Each woman took 4 g/d of capsules containing either evening primrose oil alone, evening primrose oil plus multivitamins, multivitamins alone, or placebo. After four months of blinded treatment, all groups showed an average 35% reduction in breast pain. No statistically significant differences were found between any of the four groups. The trial continued for another six months with all subjects receiving evening primrose oil, either with or without multivitamins. This phase was an open trial, with breast pain being reduced by another 50%, but with no differences between the two groups. The researchers concluded that evening primrose oil was not superior to placebo in treating mastalgia.

Adverse Effects

The most commonly reported adverse effects of

Alternative Therapies in Women's Health, ISSN 1522-3396, is published monthly by Thomson American Health Consultants, 3525 Piedmont Rd., NE, Bldg. 6, Suite 400, Atlanta, GA 30305.
VICE PRESIDENT/PUBLISHER: Brenda L. Mooney.
EDITORIAL GROUP HEAD: Lee Landenberger.
MANAGING EDITOR: Paula L. Cousins.

EDITOR: Leslie G. Coplin.
GST Registration Number: R128870672.
Application to mail at periodical postage rates is pending at Atlanta, GA 30304.
POSTMASTER: Send address changes to *Alternative Therapies in Women's Health*, P.O. Box 740059, Atlanta, GA 30374.

Copyright © 2006 by Thomson American Health Consultants. All rights reserved. No part of this newsletter may be reproduced in any form or incorporated into any information-retrieval system without the written permission of the copyright owner.

Back issues: \$45. Missing issues will be fulfilled by Customer Service free of charge when contacted within one month of the missing issue's date.

This is an educational publication designed to present scientific information and opinion to health professionals, to stimulate thought, and further investigation. It does not provide advice regarding medical diagnosis or treatment for any individual case. It is not intended for use by the layman.

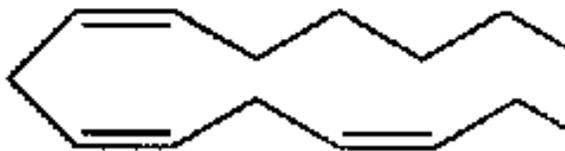


Subscriber Information
Customer Service: 1-800-688-2421.
Customer Service E-Mail: customerservice@thomson.com
Editorial E-Mail: paula.cousins@thomson.com
World-Wide Web: www.ahcpub.com
Subscription Prices
United States
\$349 per year (Student/Resident rate: \$180).
Multiple Copies
Discounts are available for multiple subscriptions.
For pricing information, call Steve Vance at (404) 262-5511.
Outside the United States
\$379 per year plus GST (Student/Resident rate: \$195 plus GST).
Accreditation
Thomson American Health Consultants (AHC) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.
Thomson American Health Consultants designates this educational activity for a maximum of 20 AMA PRA Category 1 Credit(s) [™] . Physicians should only claim credit commensurate with the extent of their participation in the activity.
This CME publication is intended for the women's health physician. It is in effect for 36 months from the date of the publication.
For CME credit, add \$50.

Questions & Comments
Please call Paula Cousins, Managing Editor, at (816) 237-1833 between 8:30 a.m. and 4:30 p.m. ET, Monday-Friday.

Gamma-linolenic acid

Gamma-linolenic acid (GLA) is an n-6 (omega-6) polyunsaturated fatty acid. It is composed of 18 carbon atoms and three double bonds. GLA is an all-cis n-6 polyunsaturated fatty acid also known as 18:3n-6; 6,9,12-octadecatrienoic acid; (Z,Z,Z)-6,9,12-octadecatrienoic acid; cis-6,cis-9,cis-12-octadecatrienoic acid; and gamolenic acid. The structural formula of GLA is:



GLA (gamma-linolenic acid)

GLA is found naturally to varying extents in the fatty acid fraction of some plant seed oils. In evening primrose seed oil, it is present in concentrations of 7-14% of total fatty acids; in borage seed oil, 20-27%; and in black currant seed oil, 15-20%. GLA is also found in some fungal sources. GLA is produced naturally in the body as the delta 6-desaturase metabolite of the essential fatty acid linoleic acid. Under certain conditions, e.g., decreased activity of the delta-6 desaturase enzyme, GLA may become a conditionally essential fatty acid. GLA is present naturally in the form of triacylglycerols. The stereospecificity of GLA varies among different oil sources. GLA is concentrated in the sn-3 position of evening primrose seed oil and black currant seed oil and in the sn-2 position in borage seed oil. GLA is concentrated evenly in both the sn-2 and sn-3 positions of fungal oil.

GLA, supplied in the form of evening primrose oil or borage seed oil, has been studied for many years for its possible effects in arthritis and other inflammatory processes. It has been shown to suppress inflammation and reduce joint tissue injury in many animal models.

Adapted from: PDR Health. Gamma-linolenic acid (GLA). Available at: www.pdrhealth.com/drug_info/nmdrugprofiles/nutsupdrugs/gam_0120.shtml. Accessed April 10, 2006.

evening primrose oil in clinical trials are gastrointestinal. These are usually mild to moderate, with nausea being the most common. The effects of long-term use have not been examined. It should be noted that the withdrawal of evening primrose oil's medical license in

Britain was not because of concerns about safety, but for lack of evidence of effectiveness. Evening primrose oil may be associated with pregnancy complications and, therefore, should not be used by pregnant women.¹¹ However, it is considered safe in children and lactating women.

Formulation

Most studies have used four 500 mg capsules taken twice daily (a total of 4 g/d evening primrose oil). Recommendations range from 2-6 g/d.

Conclusion

A relatively small number of studies have examined the effectiveness of evening primrose oil in treating PMS and menopausal symptoms. The controlled studies reveal a consistent pattern of similar effectiveness as placebo. Such symptoms are known to respond well to placebo effects, which may explain why evening primrose oil has gained a reputation for effectiveness. Such findings point to the importance of addressing symptoms of PMS and menopause holistically.

Recommendation

In spite of its popularity, evening primrose oil does not appear to be any more beneficial than placebo in treating menopausal or PMS symptoms. Some women may have very low levels of GLA in their diet, or may not produce adequate amounts within their bodies. They may receive some general health benefits from supplementing their diet with evening primrose oil. However, its usefulness in treating any particular condition associated with PMS or menopause is not supported by clinical research. ❖

References

1. Brett KM. Complementary and alternative medicine use among mid-life women. *Ann Epidemiol* 2005; 15:650.
2. Haimov-Kochman R, Hochner-Celnikier D. Hot flashes revisited: Pharmacological and herbal options for hot flashes management. What does the evidence tell us? *Acta Obstet Gynecol Scand* 2005;84:972-979.
3. Goyal A, Mansel RE; Efamast Study Group. A randomized multicenter study of gamolenic acid (Efamast) with and without antioxidant vitamins and minerals in the management of mastalgia. *Breast J* 2005;11: 41-47.
4. Hardy ML. Herbs of special interest to women. *J Am Pharm Assoc (Wash.)* 2000;40:234-242.
5. Chenoy R, et al. Effect of oral gamolenic acid from

evening primrose oil on menopausal flushing. *BMJ* 1994;308:501-503.

6. Low Dog T. Menopause: A review of botanical dietary supplements. *Am J Med* 2005;118(12 Suppl 2):98-108.
7. Khoo SK, et al. Evening primrose oil and treatment of premenstrual syndrome. *Med J Aust* 1990;153:189-192.
8. Collins A, et al. Essential fatty acids in the treatment of premenstrual syndrome. *Obstet Gynecol* 1993;81:93-98.
9. Budeiri D, et al. Is evening primrose oil of value in the treatment of premenstrual syndrome? *Control Clin Trials* 1996;17:60-68.
10. Stevinson C, Ernst E. Complementary/alternative therapies for premenstrual syndrome: A systematic review of randomized controlled trials. *Am J Obstet Gynecol* 2001;185:227-235.
11. Evening primrose oil. Natural Medicines Comprehensive Database. Available at: www.naturaldatabase.com. Accessed Nov. 25, 2005.

Multiple Benefits of Exercise for Breast Cancer Survivors

By Mary Hardy, MD

Dr. Hardy is Associate Director, UCLA Center for Dietary Supplement Research; Botanicals, and Medical Director, Cedars-Sinai Integrative Medicine Program, Los Angeles.

Dr. Hardy reports no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

Source: Ohira T, et al. Effects of weight training on quality of life in recent breast cancer survivors: The Weight Training for Breast Cancer Survivors (WTBS) study. *Cancer* 2006; [Epub ahead of print].

Abstract: Aerobic exercise training has been shown to have beneficial effects on quality of life in breast cancer survivors. However, the effects of weight training on psychological benefits are unknown. The authors sought to examine the effects of weight training on changes in quality of life and depressive symptoms in recent breast cancer survivors. A convenience sample of 86 survivors (4-36 months post treatment) was randomized into treatment and control groups. The primary outcomes were changes in quality of life (CARES short form) and depressive symptoms (CES-D) between baseline and month 6 in this randomized controlled trial. Over six months, the physical global quality-of-life score improved in the treatment group compared with the control group (standardized difference =

0.62, $P = 0.006$). The psychosocial global score also improved significantly in the treatment group compared with the control group (standardized difference = 0.52, $P = 0.02$). There were no changes in CES-D scores. Increases in upper body strength were correlated with improvements in physical global score ($r = 0.32$; $P < 0.01$) and psychosocial global score ($r = 0.30$; $P < 0.01$). Increases in lean mass were also correlated with improvements in physical global score ($r = 0.23$; $P < 0.05$) and psychosocial global score ($r = 0.24$; $P < 0.05$). The authors concluded that twice-weekly weight training for recent breast cancer survivors may result in improved quality of life, in part via changes in body composition and strength.

■ COMMENTS

DESPITE AN OVERALL INCREASE IN THE RATE OF NEW breast cancers, mortality rates have been steadily declining, about 1% a year.¹ However, even though five-year survival rates now approach 90%, breast cancer survivors remain a population at risk. Despite the war on cancer and high-tech treatment options available, modifiable risk factors still account for the majority of cancer deaths today and need to be addressed as part of secondary prevention.² Increased body weight and body fat are major risk factors for developing breast cancer, as well as increased mortality, both for primary tumors and for recurrences.^{3,4} Unfortunately, breast cancer treatment itself often leads to increases in weight and a reduction of lean body mass.⁵ The majority of survivors do not meet physical activity levels generally recommended to the healthy population.⁶ Additionally, women report significant declines in quality of life during and after treatment. For all of these reasons, clinicians should strongly support interventions that increase patient quality of life and decrease their breast cancer risk. This month's abstract considers the possible benefits of an exercise regimen for women after completing breast cancer treatment.

Eighty-six post-treatment breast cancer survivors (4-36 months after treatment) were enrolled in a randomized control trial testing the effect of a six-month weight training program.⁷ Patients were randomized in such a way that participants in both groups had equal distributions of weight and body fat. For the first three months, the exercise group was supervised by a trainer and met in small groups twice weekly. They performed a set sequence of weight-training exercises, using both machines and free weights. Participants exercised on their own for the last three months. The control group received the same intervention six months after the treatment group. Quality-of-life measures, upper and lower body strength, as well as waist circumference, body weight, and body fat were measured.

The results from this study were encouraging. Significant differences were seen between the quality-of-life scores of the treatment vs. the control group ($P = 0.02$), but even larger improvements were seen in the physical quality-of-life scores ($P = 0.006$). These changes were associated with significant gains in upper body strength ($P < 0.01$) and increases in lean body mass ($P < 0.05$).

This was generally a well-conducted study with a number of strengths, including matching groups on key variables such as weight and body fat. There were a small number of dropouts ($n = 7$) and the intervention would not be difficult to generalize to a broader population.

However, some limitations should be mentioned as well. Given how the results were reported, it was difficult to tell how much, if any, weight the patients lost and exactly how much their percent body fat changed. Despite the strong statistically significant results in quality-of-life scores, the absolute amounts were small, so the clinical significance can be questioned. However, the robust response in the control group (50% improved one or other of their quality-of-life scores vs. 80% improved in treatment group) may have overestimated the response in the average breast cancer patient. It also is important to note that the participants anecdotally reported positive results of exercise, such as improvement in sleep and energy as well as decreases in body aches and fatigue, which are difficult to reflect in quantitative data.

Therefore, we should encourage our patients to attend to issues like exercise and weight control with the same vigor that we give to their conventional care. This type of intervention can improve quality of life and lower the risk of breast cancer recurrence as well as osteoporosis and postmenopausal heart disease. Include questions about exercise in follow-up visits with breast cancer survivors. Educate patients regarding the benefits of regular aerobic exercise and weight training. Explore barriers to exercise with inactive patients and make a plan to address these barriers. Finally, prepare a list of local facilities and follow up on your recommendations at the next visit. Lifestyle modification is important after breast cancer treatment and the primary care practitioner may be in an even better position than the oncologist to motivate the breast cancer patient. It may be that a walk a day, not an apple, will keep the doctor away! ❖

References

1. Jemal A, et al. Cancer Statistics, 2006. *CA Cancer J Clin* 2006;56:106-130.
2. Danaei G, et al; Comparative Risk Assessment collaborating group (Cancers). Causes of cancer in the world: Comparative risk assessment of nine behavioural and

environmental risk factors. *Lancet* 2005;366:1784-1793.

3. Lahmann PH, et al. A prospective study of adiposity and postmenopausal breast cancer risk: The Malmö Diet and Cancer Study. *Int J Cancer* 2003;103:246-252.
4. Kroenke CH, et al. Weight, weight gain, and survival after breast cancer diagnosis. *J Clin Oncol* 2005;23:1370-1378.
5. Freedman RJ, et al. Weight and body composition changes during and after adjuvant chemotherapy in women with breast cancer. *J Clin Endocrinol Metab* 2004;89:2248-2253.
6. Irwin ML, et al. Physical activity levels among breast cancer survivors. *Med Sci Sports Exerc* 2004;36:1484-1491.
7. Ohira T, et al. Effects of weight training on quality of life in recent breast cancer survivors: The Weight Training for Breast Cancer Survivors (WTBS) study. *Cancer* 2006; [Epub ahead of print].

Carbs are OK: Certainly for Women

By Joseph E. Scherger, MD, MPH

Clinical Professor, University of California, San Diego

Dr. Scherger reports no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

Source: Howard BV, et al. Low-fat dietary pattern and weight change over 7 years: The Women's Health Initiative Dietary Modification Trial. *JAMA* 2006;295:39-49.

Abstract: The Women's Health Initiative (WHI) included a Dietary Modification Trial with the primary endpoints looking at breast and colorectal cancer. More than 48,000 postmenopausal women were randomized into either a dietary intervention with a goal of 20% calories from fat with a high intake of vegetables, fruit, and grains, or a control group simply given nutrition information. At baseline, the women had a mean age of 62.3 years, mean body mass index of 29.1 kg/m² (over-weight), and a dietary fat intake of at least 32% of total calories. This was not a weight-loss trial, but the monitoring of the two groups included measuring body weight. The intervention group lost a mean of 2.2 kg during the first year and maintained this weight over 7.5 years. The control group had modest weight gain between ages 50 and 70. Among the women in the intervention group, the lower the fat intake the greater the

weight loss. A greater intake of vegetables and fruit also resulted in greater weight loss. Grain intake was neutral with respect to weight. The authors conclude that a low-fat predominately carbohydrate eating pattern does not result in weight gain in postmenopausal women.

■ COMMENTS

THE LOW-CARB CRAZE IS FINALLY WINDING DOWN, AND this study helps bring balance and sanity back into nutritional advice. Three recent studies did report that people assigned to a low-calorie, low-carbohydrate diet (with high protein and fat content) lost more weight during a six-month period than did those assigned to a reduced-fat diet.¹⁻³ However, in the study which was extended to one year, no differences in weight loss were demonstrated.¹ The long-term health effects of a high-protein and high-fat diet have not been determined, but raise considerable cause for concern with respect to cardiac risk factors.

What have we learned from the recent dietary swings with respect to carbohydrates, fat, and protein? Some might think confusion and cynicism, and there is no solution except eating less and exercising more. I think we have learned a lot about healthy eating and some clues for weight loss and weight maintenance. This study is large and gives us limited, but important, information. A healthy diet consists of vegetables, fruits, and grains, is low in fat, and does not result in weight gain. Note that doughnuts, cookies, sodas, and candies were not included in the recommended carbohydrates. These unhealthy foods have a high glycemic index and drive hunger. Time-honored evidence demonstrates that diets high in saturated fats are not healthy. We have learned about healthy fats such as monounsaturated and polyunsaturated oils which reduce cardiac risk factors.⁴ Finally, we know that ingesting protein with each meal is beneficial in reducing the glycemic index of carbohydrates resulting in less hunger and the tendency to eat fewer overall calories, the bottom line in weight loss and maintenance.

We live in a society with an unprecedented abundance and variety of food. People vary greatly in their food tastes. Promoting healthy nutrition requires flexibility in food choices. Understanding the basic principles of healthy carbohydrates, fats, and proteins will go a long way in counteracting the epidemic of overweight and obesity. If people limited their food choices to healthy foods and kept active, we would not have today's epidemic obesity problem. This important study provides great reassurance and validation that the low-fat diet recommendation is still valid, certainly in postmenopausal women. ❖

References

1. Foster GD, et al. A randomized trial of a low-carbohydrate diet for obesity. *N Engl J Med* 2003; 348:2082-2090.
2. Samaha FF, et al. A low-carbohydrate as compared with a low-fat diet in severe obesity. *N Engl J Med* 2003;348:2074-2081.
3. Brehm BJ, et al. A randomized trial comparing a very low carbohydrate diet and a calorie-restricted low fat diet on body weight and cardiovascular risk factors in healthy women. *J Clin Endocrinol Metab* 2003;88: 1617-1623.
4. Appel LJ, et al. Effects of protein, monounsaturated fat, and carbohydrate intake on blood pressure and serum lipids: Results of the OmniHeart randomized trial. *JAMA* 2005;294:2455-2464.

CME Objectives

After reading *Alternative Therapies in Women's Health*, the health care professional will be able to:

1. evaluate alternative medicine and complementary therapies for women's health concerns;
2. identify risks and interactions associated with alternative therapies;
3. discuss alternative medicine options with patients;
4. offer guidance to patients based on latest science and clinical studies regarding alternative and complementary therapies.

CME Instructions

Physicians participate in this continuing medical education program by reading the article, using the provided references for further research, and studying the questions at the end of the article. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity, you must complete the evaluation form provided and return it in the reply envelope provided at the end of the semester to receive a certificate of completion. Upon receipt of your evaluation, a certificate will be mailed.

CME Questions

16. The essential fatty acid for which evening primrose oil is highly valued is:
- linoleic acid.
 - gamma-linolenic acid.
 - oleic acid.
 - stearic acid.
17. The most commonly used dose of evening primrose oil is:
- 4 g/d
 - 3 g/d
 - 2 g/d
 - 1 g/d
18. The evidence from randomized controlled trials shows that evening primrose oil is effective for treating:
- menopausal symptoms.
 - premenstrual syndrome.
 - breast pain.
 - None of the above
19. A recent trial examined the effect of exercise in breast cancer survivors and found that weight training improved quality of life in these patients.
- True
 - False
20. The evidence from the Women's Health Initiative Dietary Modification Trial supports which of the following dietary recommendations?
- A diet with 30% of calories from fat supports the maintenance of body weight.
 - A diet with less than 50% carbohydrates supports the maintenance of body weight.
 - A diet with 2 g of protein per pound of body weight supports the maintenance of body weight.
 - A diet low in fat and high in carbohydrates from vegetables, fruits, and grains supports the maintenance of body weight.

Answers: 16. b, 17. a, 18. d, 19. a, 20. d.

News Briefs

Panel of Scientists Evaluates Genistein and Soy Formula

A panel of scientists has concluded that unless exposure levels change, adults would be unlikely to consume sufficient daily levels of genistein to cause adverse reproductive and/or developmental effects. The Center for the Evaluation of Risks to Human Reproduction (CERHR) convened this expert panel on March 15–17, 2006, in Alexandria, VA, to evaluate genistein and soy formula.

CERHR, which was established by the National Institute of Environmental Health Sciences (NIEHS) as part of the National Toxicology Program (NTP) in 1998, selected genistein and soy formula for expert panel evaluation for several reasons. One is the availability of reproductive and developmental toxicity studies in laboratory animals and humans. The second is the availability of information on exposures in infants and women of reproductive age, and the last is public concern for effects on infant or child development.

Genistein is a phytoestrogen found in some legumes, especially soybeans. Genistein and genistin are found in many food products, especially soy-based foods such as tofu, soy milk, and soy infant formula, and in some over-the-counter dietary supplements. Soy formula is fed to infants as a supplement or replacement for human milk or cow milk.

The expert panel, composed of 14 independent scientists, reviewed and evaluated the available scientific data on genistein and soy formula in three primary areas: human exposure, reproductive toxicity, and developmental toxicity. In their deliberations, the panel considered the quality, quantity, and strength of the scientific evidence that exposure to genistein or soy formula might cause adverse effects on human reproduction and/or development of the fetus or infant. The panel also identified gaps in the available scientific data on the possible effects of genistein and soy formula and suggested areas where additional research is needed. All members of the panel served as individual experts and not as representatives of their employers or other organizations.

Here are some of the conclusions on genistein:

- Even though there is a paucity of available human data on exposure to purified genistein, the panel expressed negligible concern for reproductive and developmental effects from exposure of adults in the general population. The most highly exposed human population reported is Japanese adults with ingestion of total genistein (free and complexed) of approximately 0.43 mg/kg body weight (bw)/day. However, adverse effects in rodent studies were not observed at levels below 35–44 mg/kg bw/day.

- The panel expressed negligible concern for adverse effects in neonates and infants who may consume up to 0.01-0.08 mg/kg bw/day of genistein aglycone contained in soy formula. One member of the panel did not agree with this conclusion and felt that a higher level of concern was warranted. It is noteworthy that about 1% of total genistein in soy formula is present in its uncomplexed form.

The panel also concluded that there are insufficient human or experimental animal data available to permit a determination of the developmental or reproductive toxicity of soy infant formula.

The final expert panel reports on genistein and soy formula will be posted on the CERHR website (<http://cerhr.niehs.nih.gov>) and available in printed text from CERHR in May 2006. CERHR will solicit public comments on these reports through an announcement in the *Federal Register*. Following this comment period, CERHR will prepare two NTP/CERHR monographs, one on genistein and one on soy formula, that consist of an NTP brief, the expert panel report, and all public comments on that report. The monographs will be available to the public in PDF format on the CERHR website and in hardcopy by contacting CERHR and will be distributed to appropriate federal health and regulatory agencies.

Rural Older Adults Use CAM, but Focus on 'Home Remedies'

A survey of older adults in rural North Carolina shows that they widely use complementary medicine therapies, but tend to focus on folk or home remedies, such as taking a daily "tonic" of vinegar or using Epsom salts. The goal of the study, which is reported in the March issue of *Journal of Gerontology: Social Sciences*, was to learn more about what complementary and alternative medicine (CAM) therapies older adults are using and why.

The ELDER (Evaluating Long-term Diabetes Self-management among Elder Rural Adults) study assessed complementary medicine use among 701 rural adults older than age 65 with diabetes. Participants were selected from two rural North Carolina counties with a high proportion of ethnic minorities and people living below the poverty level.

Participants were interviewed in their homes about

their health and use of CAM therapies. Participants were asked if they had used each item for any purpose in the past year and if they had used it specifically for diabetes.

Researchers found that the majority of participants don't use CAM therapies to treat diabetes or other chronic diseases. "They are using CAM for prevention or for treating symptoms (a headache, a sore throat, a cut) but not for treating a chronic condition," wrote the authors. "CAM use among these rural older adults is largely a form of self-care."

It is common to use some of the therapies, such as vinegar or honey, as a general "tonic," says Thomas Arcury, PhD, a professor and lead researcher from Wake Forest University School of Medicine. "I've talked to older adults who'll tell you should take two tablespoons of vinegar every day in a glass of warm water because it's good for you. They aren't treating anything in particular."

The study divided CAM therapies in eight categories to better document which types of therapies are being used. The categories (and examples) are: food home remedies (honey, lemon and garlic), other home remedies (tobacco, Epsom salts, and salves), vitamins (multivitamins, folic acid, and vitamin E), minerals (calcium, magnesium, and zinc), herbs (*Ginkgo biloba*, ginseng, and echinacea), popular manufactured products (flax seed, amino acids, and glucosamine sulfate), CAM therapies (imagery, biofeedback, and energy healing), and CAM practitioners (chiropractor, herbalist, and acupuncturist).

More than half of participants used food home remedies (52%) and other home remedies (57%). Vitamins were used by 45% of participants and minerals by 17%. Interestingly, only 6% of participants used herbs for self-care.

Researchers found that ethnicity was the most important personal characteristic in predicting CAM use. African-Americans and Native Americans were 81% and 76% (respectively) more likely to use food home remedies than whites and more than twice as likely to use other home remedies.

The study was funded by the National Institute on Aging and the National Center on Minority Health and Health Disparities. ❖

In Future Issues:

Acupuncture and Obesity

Ginger and Nausea

Melatonin and Migraine Headache