

Can't Sleep? Science Is Seeking New Answers



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A good night's sleep is more than a luxury. Sleep is as important to survival as food and water. On too little, we humans don't function well—for example, we run a higher risk of accidents, we sometimes perform poorly at work or school, and our moods can turn sour.

A sleepless night or two isn't a medical emergency. However, if difficulties persist, a sleep disorder may

be involved. People with sleep disorders may have difficulty falling or staying asleep or waking up in the morning, fall asleep at inappropriate times, sleep too much, or show unusual behaviors during sleep. Important new research, including studies supported by the National Institutes of Health (NIH), has linked lack of sleep with obesity, diabetes, and other related conditions. The National Center for Complementary and Alternative Medicine (NCCAM) is supporting a number of research studies on potential treatment options for sleep disorders using complementary and alternative medicine (CAM).

"Sleep disorders are an important public health issue that is receiving serious attention from NCCAM and several other components of NIH," said NCCAM Director Stephen E. Straus, M.D.

As many as 70 million Americans—about one-quarter of the population—experience sleep disorders; half of this group have chronic sleep problems. Conventional therapies are available for most sleep disorders, but for some people they don't work well, cause unwanted side effects, or cost too much. As a result, many people turn to CAM therapies.

According to the 2002 National Health Interview Survey, 2.2 percent of all adults in the survey who used CAM did so for sleep problems. This represents approximately 1.6 million U.S. adults. CAM therapies commonly used for sleep problems include dietary supplements (such as melatonin and valerian); approaches that emphasize the interaction between the mind and the body (such as meditation); and therapies that are part of non-Western traditional medical systems (such as acupuncture and yoga).

"While some CAM products used to treat sleep disorders are already available to consumers, in most cases they have not been proven to be efficacious through rigorous research," explained Nancy J. Pearson, Ph.D., NCCAM Program Officer and member of the Trans-NIH Sleep Research Coordinating Committee. "There is very little knowledge about whether CAM therapies for sleep disorders work, and, if so, how they work. NCCAM is supporting research to help answer these questions."

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Can't Sleep?

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Types and Causes of Sleep Disorders

Sleep problems can start with a sudden event. For example, a job loss can lead to nighttime worries, which in turn can lead to trouble sleeping. When a sleep problem occurs without another identified disease or condition, it is referred to as a primary sleep disorder. However, in many cases, sleep disorders are associated with other causes. Some circumstances and illnesses that can lead to sleep problems are as follows:

- Because of lifestyles or work schedules, sleep just isn't a priority for some people. Stress from hectic schedules can make it difficult to relax and fall asleep.
- The body's internal clock programs people to feel sleepy during the nighttime and to be active during daylight hours. When that clock goes off-kilter, sleep becomes difficult. For example, travelers who fly across multiple time zones quickly get "jet lag" because they cannot maintain a regular sleep-wake schedule.
- People who work at night and try to sleep during the day are constantly fighting their internal clocks. This puts them at risk for disturbed sleep. Without

adequate rest, they are more likely to make errors or have accidents at work.

- Sleep disorders often occur in people who have a chronic disease that involves pain or infection, a neurological or psychiatric disorder, or an alcohol or substance abuse disorder. (These are sometimes called secondary sleep disorders.) For these individuals, sleep becomes difficult, potentially worsening the other medical condition, and affecting the person's health and safety, mood and behavior, and quality of life.

Sleep problems can arise during any period of life:

- In children, inadequate sleep may lead to daytime sleepiness, which can interfere with a child's ability to learn in school and perform well in other activities. Sleep-deprived children may also tend to fall or have other accidents that lead to injury. Many children who are chronically deprived of sleep may not seem sleepy and may even appear to be overactive. Chronic sleep loss in these children may be overlooked or mistakenly attributed to hyperactivity or other behavior disorders.
- Teenagers are notorious for getting too little sleep as they burn the midnight oil

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The Most Common Sleep Disorders

Below are some of the most common sleep disorders. Medications and behavioral approaches are available to help people with these disorders.

Insomnia is difficulty falling and staying asleep, as well as daytime problems associated with sleepiness. It is the most commonly reported sleep complaint. Insomnia often accompanies stress or another health condition.

Frequent loud snoring at night and daytime sleepiness are the main symptoms of **sleep apnea**. People with sleep apnea stop breathing for brief periods while asleep and then choke and gasp for breath.

People with **narcolepsy** cannot regulate their sleep/wake cycles. As a result, they may fall asleep uncontrollably—any place, any time. These "sleep attacks" are often accompanied by daytime sleepiness, episodes of muscle weakness or paralysis, and disrupted nighttime sleep.

In **restless legs syndrome**, a person has tingling sensations in the legs while sitting or lying still. They constantly stretch or move their legs to try to relieve these sensations, which interfere with sleep.



Recent surveys have shown that many people in the United States and Canada are turning to manual therapies (hands-on CAM practices, such as chiropractic manipulation and massage therapy). It is important for researchers and health care providers to better understand how these therapies affect the body. On June 9-10, NCCAM, along with four NIH institutes and the Canadian Institutes of Health Research, sponsored the **Conference on the Biology of Manual Therapies**. The conference reviewed the science explaining how manual therapies might work and identified questions for further research.

Richard Nahin, Ph.D., M.P.H., NCCAM's Senior Advisor for Scientific Coordination and Outreach, served as chair of the planning committee. He said, "There are promising preliminary studies that suggest ways manual therapies might work. However, the exact mechanisms of action are unknown for any of the treatment effects that can be attributed to manual therapies. Our hope for the conference was to help identify the most promising avenues of research."

Scientific experts from both inside and outside the field presented information on topics ranging from biomechanics to immunology. Key questions included:

- What effects do manual therapies have on the body's nervous system, immune system, and endocrine system?
- How do manual therapies affect the way the body moves and the relationships between muscles, joints, and bones?
- How should future research studies on manual therapies be designed, and what should these studies attempt to measure?
- How can state-of-the-art tools in fields such as medical imaging help researchers learn about the ways the body responds to manual therapies?

Dr. Nahin added, "A testament to the importance of this conference was the number of outstanding scientists who attended, the quality of the presentations, and the openness of discussion in the breakout groups. All of this is leading to an exciting list of recommendations. The cosponsors hope that one or more research initiatives will be developed from this list and lead to groundbreaking discoveries about how manual therapies work."

The conference recommendations will be posted on the NCCAM Web site. For more information on manual therapies, see the NCCAM backgrounder "Manipulative and Body-Based Practices: An Overview" at nccam.nih.gov/health/backgrounds/manipulative. ■

Visit nccam.nih.gov/research/announcements/active for more information on these and other NCCAM-sponsored funding opportunities.

Program Announcements **PA-05-090: Methodology and Measurement in the Behavioral and Social Sciences**

Sponsors: NCCAM and 11 other components of NIH. The study of human behavior and interactions can provide insights into the cause, treatment, and prevention of diseases. The goal of this initiative is to improve the quality of the research data in this field.

PAR-05-072 and PAR-05-073: International Research Collaboration—Basic Biomedical (072) and Behavioral, Social Sciences (073)

Sponsors: NCCAM, Fogarty International Center, and eight other components of NIH. These programs will foster research partnerships between NIH-supported U.S. scientists and their colleagues in the developing world. NCCAM's funding will support study of highly promising traditional medical practices.

PA-05-117: Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grants (T35)

Sponsors: NCCAM and 13 other components of NIH. This program will help students pursue research careers by providing training opportunities in the health-related sciences.

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Calendar of Events

September 2005 Meeting of the National Advisory Council for Complementary and Alternative Medicine: September 9. *Location:* Neuroscience Building, NIH, Bethesda, Maryland. See nccam.nih.gov/news/upcomingmeetings.

October 2005 Distinguished Lectures in the Science of Complementary and Alternative Medicine: October 28, 11 a.m. "Is Spirituality Good for Your Health? Historical Reflections on an Emerging Research Enterprise." *Speaker:* **Anne Harrington, Ph.D.**, Professor of the History of Science, Harvard University. *Location:* Masur Auditorium, Building 10, NIH, Bethesda, Maryland. See nccam.nih.gov/news/upcomingmeetings.

Fellowship

NCCAM Director's Fellowship

This fellowship is an opportunity at NIH in Bethesda, Maryland, where the awardee will perform CAM-related research through NIH's intramural program. See nccam.nih.gov/about/jobs/dir_fellowship.

Policy Updates

Research Funding Priorities

NCCAM has released priorities for funding of new research projects. See nccam.nih.gov/research/priorities.

NOT-AT-05-003 and NOT-AT-05-004: NCCAM Interim Policy and Applicant Guidance on Product Quality: Biologically Active Agents Used in Complementary and Alternative Medicine and Placebo Materials

This policy replaces NCCAM's 2003 "Policy Announcement on the Quality of Natural Products" and addresses product quality, scope of research, and Investigational New Drug applications. See nccam.nih.gov/research/policies/bioactive.

Call for Abstracts

Research Conference on Complementary and Integrative Medicine

Abstract submissions are sought for a CAM research conference cofunded by NCCAM and planned for May 2006 in Edmonton, Alberta, Canada. Submissions are due in September 2005. See imconsortium-conference2006.com. ■

NIH Conference Looks at Treatments for Menopausal Symptoms

Menopause is a natural process for women as they age. (It can also occur if a woman has certain major treatments that affect her ovaries.) There are symptoms that can occur with menopause, such as hot flashes, night sweats, vaginal dryness, and sleep problems. However, many women go through menopause with no or few symptoms, or feel that their symptoms are not troubling enough that they need to seek medical treatment. For others, symptoms can be severe and affect quality of life.

For several decades, menopausal hormone therapy, consisting of estrogen alone or combined with progestin, has been the leading conventional treatment for menopausal symptoms. However, recent studies have identified increased risks for serious health problems among women taking hormone therapy. This is one reason that many women and their health care providers have become interested in CAM treatments for menopausal symptoms.

To review what is known about managing these symptoms, NCCAM and some other components of NIH cosponsored a March 2005 conference in Bethesda, Maryland. An independent panel of experts assessed the state-of-the-science on this topic and areas where further research is needed. (To obtain the full report, see the end of this article.)

The panel observed that menopause is a normal, healthy part of a woman's life and should not be viewed as a disease. Also, some symptoms currently viewed as being menopausal might not be caused by menopause, but by aging in general and/or life changes.

The panel's review of CAM therapies focused mainly on botanicals (therapies from plants and plant products), some of which are thought to act like a weak estrogen. Black

cohoosh and soy extracts are among the most frequently studied, especially for hot flashes. But Tieraona Low Dog, M.D., who is a member of NCCAM's National Advisory Council for Complementary and Alternative Medicine, noted that clinical trials have not been rigorous enough to determine the effectiveness of these therapies. Also, more basic information is needed on black cohoosh, soy extracts, and other supplements, including their chemical components, how they are processed by the body, optimal doses, and side effects. Scientists are especially concerned about effects on the liver and on hormone-sensitive tissues such as those in the breast and uterus.

There is not much evidence on CAM therapies for menopausal symptoms, and the evidence that is available is not strong. The panel commented on other CAM therapies as follows:

- **Kava:** Effective in reducing anxiety, but there is insufficient evidence about effectiveness for hot flashes. Kava can be damaging to the liver, and the U.S. Food and Drug Administration has issued a warning about this.
- **Red clover leaf:** Believed to function as a weak estrogen, but studies have not found it effective for hot flashes.
- **Dong quai root:** Does not appear to be effective for hot flashes. Dong quai interacts with the drug warfarin, which could cause bleeding problems.
- **Ginseng root:** May be helpful for certain quality-of-life concerns, such as well-being, mood, and sleep, but does not appear to affect hot flashes.
- **Exercise, health education, and paced respiration** (a technique of slow, deep breathing): May be important for future investigation. Side effects are rare, and a

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Lecture: A Vision for Integrative Health Care

Today's health care system focuses on the treatment of flareups of chronic disease, says Ralph Snyderman, M.D., Chancellor Emeritus of Duke University and Professor of Medicine at Duke's School of Medicine. Dr. Snyderman believes the system is flawed because intervention often comes when the illness is serious, the costs are high, and the chances for cure are low.

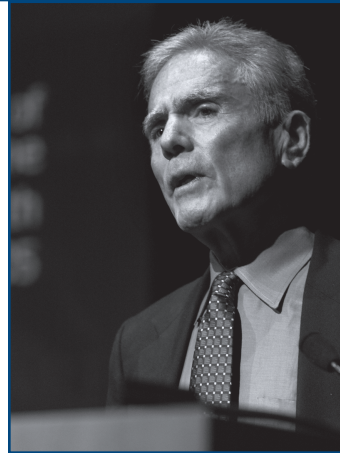
Dr. Snyderman spoke on the National Institutes of Health campus as part of NCCAM's Distinguished Lecture Series, April 22, 2005. The title of his presentation was "Integrative Medicine: A Foundation for Prospective Health Care." As CEO of Duke University Health System from 1989 to 2004, Dr. Snyderman oversaw its development from a specialty hospital to an integrated health care delivery system that offers a wide range of community-based services, from primary care and wellness services to specialized and acute care.

Dr. Snyderman called for a shift to a more "prospective" approach to health care, in which health care providers assess each individual's health risks and create an individual treatment plan. He noted that

CAM gives people potential tools to promote wellness and prevent disease.

He called for an integrative health care approach that draws on the best of evidence-based medicine but refocuses on the responsibility of the physician to involve the patient, the importance of compassion and caring, the willingness to consider nonconventional modalities with informed skepticism and scientific evaluation, and recognition of the importance of the mind-body relationship in well-being.

Dr. Snyderman's lecture has been archived on the Web and may be viewed at www.videocast.nih.gov (select "Past Events" and use "Search" to locate the lecture). The next NCCAM Distinguished Lecture will take place on October 28, 2005. (See Calendar, pg. 3, for details.) ■



Ralph Snyderman, M.D.

Treatments for Menopausal Symptoms

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few small studies have shown some benefits. However, these three therapies are not considered proven for menopausal symptoms.

NCCAM is continuing research on CAM therapies for menopausal symptoms. For example, researchers will study botanicals, looking especially at standardization (ensuring chemical consistency), characterization (better understanding of

what's in the therapies), and best dosages. This information will be useful in future clinical trials. Also, NCCAM is sponsoring an initiative to develop improved measures of hot flashes; these are expected to be useful in future studies of CAM therapies.

For the conference report, see www.consensus.nih.gov/ta/025/025MenopauseINTROpostconf.htm, call 1-888-644-2667, or write the NIH Consensus Program Information Center, P.O. Box 2577, Kensington, MD 20891. ■

Research Roundup

"Research Roundup" presents examples of NCCAM-funded research recently published in peer-reviewed journals listed in the National Library of Medicine's PubMed database.

Tai Chi May Help with Some Symptoms of Heart Failure

Chronic heart failure, a condition in which the heart cannot pump enough oxygen throughout the body, impairs the health of millions of adults. Studies show that low-intensity exercise can be helpful. Led by Harvard Medical School's Gloria Yeh, M.D., researchers there and at the New England School of Acupuncture carried out a randomized controlled trial of tai chi—a gentle, low-impact practice from traditional Chinese medicine that involves movement, breathing, and mental focusing—in people with heart failure. The control group received standard care for heart failure. The tai chi group received both standard care and 12 weeks of tai chi training. The tai chi group had significant improvements in physical condition, heart function, and quality of life; the control group did not. The report (*American Journal of Medicine*, October 15, 2004) notes that tai chi may be a useful addition to standard heart failure treatment.

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Tips for Better Sleep

Follow a regular sleep schedule. It is helpful to go to sleep and wake up at the same times as much as possible, even on weekends.

Exercise at a regular time each day, at least 3 hours before bedtime.

Get some natural, outdoor light each day.

Avoid caffeine late in the day.

Don't drink alcohol to help you sleep.

Avoid smoking.

Create a safe and comfortable place to sleep (quiet, dark, and well ventilated).

Develop a nighttime routine that helps you slow down and relax.

If you're having trouble falling asleep after about 15 minutes, get up, do a quiet activity, and return to bed when you are sleepy.

Try these tips and record your sleep and sleep-related activities in a sleep diary.

If problems continue, discuss the sleep diary with your doctor.

Source: National Institute on Aging, with credit also to the National Sleep Foundation

Can't Sleep?

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to study for exams or socialize late into the night. Body clocks actually shift during these years, so teens often stay up late and sleep beyond the morning hours. This tendency, when combined with an increased need for sleep in adolescence and an early first bell at most high schools, can put teenagers at risk for sleep disorders.

- Women going through the menopausal transition are more likely to experience sleep problems than are other women.
- Older adults' sleep is often easily disturbed by noise and other environmental factors. Older people are also more likely to have chronic health conditions or pain that make it more difficult for them to get into the deep, restful stages of sleep.
- Certain medical conditions, such as rheumatoid arthritis, Parkinson's disease, or chronic pain, may contribute to sleep problems.

NCCAM Research

NCCAM supports studies on whether certain CAM therapies might be helpful for sleep disorders. Some examples:

- University of Washington researchers are testing the herb valerian in healthy older adults who experience sleep disturbances. At Emory University, valerian is being studied in people with Parkinson's disease, and at the University of Virginia, it is being studied in people with rheumatoid arthritis.
- Researchers at Brigham and Women's Hospital in Boston are studying a program of yoga and relaxation exercises as a treatment for insomnia.
- University of Chicago researchers are studying the mechanisms of action of hops, an herb that has been used both alone and in combination with valerian for sleep problems.

- A preliminary study at Brigham and Women's Hospital will determine the mechanism of action of vitamin B12 as a treatment for a form of delayed sleep phase syndrome that affects more than half of blind individuals and is also common in sighted individuals. In delayed sleep syndrome, a person's internal body clock is out of sync, causing difficulty falling asleep until very late at night and difficulty waking up in the morning.

- Researchers at the University of Pennsylvania are comparing the effects of a low-dose melatonin supplement, a high-dose melatonin supplement, and a placebo in elderly people who have insomnia and a low level of natural melatonin in the body.

- At the University of North Carolina, researchers are investigating whether high-intensity light, installed in common areas in a nursing home, could lessen the problems of sleep/wake disorders, depressive symptoms, and agitation—all frequent, difficult issues for people with Alzheimer's disease. At Harvard University, researchers are studying the effects of blue light therapy on sleep cycles.

- At the University of Arizona, researchers are examining the impact of two different homeopathic remedies on sleep patterns in adults.

Along with supporting studies, NCCAM also participates in other activities to improve the state of scientific knowledge about treatments for sleep disorders. First, NCCAM is part of the Trans-NIH Sleep Research Coordinating Committee, which coordinates research efforts across NIH and issues a report each year. NCCAM is supporting—along with 12 other NIH institutes, centers, and offices—an initiative to stimulate research on sleep and sleep disorders.

Second, NCCAM cosponsors conferences and workshops on areas related to sleep

disorders. In 2004, NCCAM cosponsored a conference on the biology of the brain's pineal gland, which produces melatonin. In June 2005, NCCAM was one of several sponsors of the State-of-the-Science Conference on insomnia at NIH. At that conference, the invited panel of experts called for further research on commonly used CAM treatments for insomnia, including supplements like melatonin and valerian, and mind-body practices such as tai chi and yoga. Acupuncture and light therapy were also mentioned as treatments that call for additional evaluation.

Because the use of melatonin supplements by the public for sleep problems is widespread, NCCAM requested and funded a report published by the Agency for Healthcare Research and Quality that analyzed the existing scientific evidence on this topic. The authors found that melatonin appears safe for short-term use, but that it may not be effective for treating most primary sleep disorders, such as jet lag. It may offer some benefit for delayed sleep phase syndrome. How melatonin works in humans is not well understood, and more research is needed to answer many questions about this therapy.

"Many people struggle with getting enough sleep or the right kind of sleep," said Dr. Pearson. "Better sleep improves our quality of life. NCCAM, on its own and in collaboration with other institutes and

centers at NIH, is committed to supporting research to uncover potential new options from CAM for those with sleep problems." ■

For More Information

National Center on Sleep Disorders Research (NCSDR), NIH—www.nhlbi.nih.gov/about/ncsdr/index.htm
The NCSDR Web site contains publications for health professionals and the public, including an interactive quiz and fact sheets on common sleep disorders.

ClinicalTrials.gov—www.clinicaltrials.gov
Sleep clinical trials are being sponsored by a number of NIH institutes and centers, including NCCAM.

Program Announcement: PA-05-046
Research on Sleep and Sleep Disorders—nccam.nih.gov/research/announcements

National Institute of Neurological Disorders and Stroke, NIH—*Brain Basics: Understanding Sleep*—www.ninds.nih.gov/disorders/brain_basics/understanding_sleep_brain_basics.htm
Restless Legs Syndrome Fact Sheet—www.ninds.nih.gov/disorders/restless_legs/detail_restless_legs.htm

National Institute on Aging, NIH: *Sleep and Aging*—www.nihseniorhealth.gov/sleepandaging/toc.html

Office of Science Education, NIH: *Sleep, Sleep Disorders, and Biological Rhythms. Curriculum Supplement for High School*—www.science.education.nih.gov/supplements/nih3/sleep/default.htm

National Heart, Lung, and Blood Institute, NIH: *2003 National Sleep Disorders Research Plan*—www.nhlbi.nih.gov/health/prof/sleep/res_plan/index.html
Trans-NIH Sleep Research Coordinating Committee Annual Report—www.nhlbi.nih.gov/health/prof/sleep/sleep-04.htm

Agency for Healthcare Research and Quality: *Melatonin for Treatment of Sleep Disorders*—www.ahrq.gov/clinic/evrptpdfs.htm#melatonin

NIH State-of-the-Science Conference Statement on *Manifestations and Management of Chronic Insomnia in Adults*—www.consensus.nih.gov/ta/026/026InsomniaPostConfIntro.htm

Research Roundup

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Pilot Study Shows Chiropractic Care May Relieve One Type of Headache

Many people suffer from headaches regularly. Cervicogenic headache—head pain that starts in the neck area—is a common type of headache, and one CAM treatment that people seek is chiropractic manipulation.

A team of researchers at Western States Chiropractic College, Kaiser Permanente Northwest, and the National College of Naturopathic Medicine sought to find out whether there is a relationship between the number of chiropractic visits and relief from this type of headache pain. In this randomized pilot study, participants received one, three, or four treatments per week for 3 weeks. Those who had three or four treatments per week reported significantly fewer headaches at follow-up visits than those who had one treatment per week.

The authors caution that the sample size was small and note that larger studies are needed. (*Journal of Manipulative and Physiological Therapeutics*, November/December 2004).

For more findings, see the NCCAM Grantee Publications Database, at nccam.nih.gov/cgi-bin/bibliography.cgi. Sorting by "Publication Date" yields the most recent records first. ■

New from the Clearinghouse

NCCAM is continually developing new information products. The following new titles are available on the Web or from the NCCAM Clearinghouse (see pg. 2):

- *Thinking About Complementary and Alternative Medicine: A Guide for People with Cancer* (coproduced with the National Cancer Institute; www.cancer.gov/cancertopics/thinking-about-CAM)
- *Treating Type 2 Diabetes with Dietary Supplements* (nccam.nih.gov/health/diabetes)
- The first fact sheets in a new NCCAM series called Herbs at a Glance: *Black Cohosh, Echinacea, European Mistletoe, and St. John's Wort* (nccam.nih.gov/health/supplements.htm)
- A report from the *Workshop on the Safety of Black Cohosh in Clinical Studies* held in November 2004 (nccam.nih.gov/news/pastmeetings/blackcohosh_mtngsumm) ■

CAM at the NIH:

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Spotlight on Clinical Trials

A clinical trial is a research study in which a treatment or therapy is tested in people to see whether it is safe and effective. More than 100 NCCAM-funded clinical trials are currently under way, including the ones below, which were recruiting at press time. More information is available at nccam.nih.gov/clinicaltrials or from the NCCAM Clearinghouse (see pg. 2).

Effects of Electrical Acupuncture and Exercise in Older Adults with Chronic Low-Back Pain

www.clinicaltrials.gov/ct/show/NCT00101387

Many older adults experience chronic low-back pain, which can limit activities and worsen one's quality of life. Conventional treatments are available, but older people are more likely to have side effects from them. This study will look at how a type of electrical acupuncture—with or without exercise—may affect pain, physical function, use of health care facilities, and social interactions.

Mistletoe Extract and Gemcitabine for the Treatment of Solid Tumor Cancers

www.clinicaltrials.gov/ct/show/NCT00044161

Mistletoe extract has been used in Europe either alone or together with conventional cancer therapies. Data from studies suggest it may stimulate the immune system and help cancer patients feel better. This study is looking at how different doses of mistletoe extract combined with gemcitabine (an anti-cancer drug) affect how gemcitabine works in people with advanced solid tumors. ■

New Online Continuing Education Series

NCCAM has launched a new Online Continuing Education Series in complementary and alternative medicine (CAM). These online seminars offer both health care professionals and the public an opportunity to learn more about CAM therapies and the state-of-the-science about them. Video lectures are presented by experts on topics such as herbs and dietary supplements, acupuncture, and chiropractic and spinal manipulation. Health care professionals can earn Continuing Medical Education credits. To access the series (which is free of charge), go to nccam.nih.gov/videolectures.