

COMPLEMENTARY AND ALTERNATIVE MEDICINE GOALS AND OBJECTIVES

Course Description

“Complementary and Alternative Medicine” is a home study continuing education course for rehabilitation professionals. This course presents updated information about Complementary and Alternative Medicine (CAM) including sections on statistical usage, alternative medical systems, mind body medicine, biologically based practices, energy therapies, manipulative and body based practices, consumer issues, and research.

Course Rationale

The purpose of this course is to present current information about Complementary and Alternative Medicine. Both therapists and therapy assistants will find this information pertinent and useful when providing care for individuals who receive, or may benefit from, non-traditional health care.

Course Goals and Objectives

Upon completion of this course, the therapist or assistant will be able to

1. recognize current statistical demographic trends of CAM usage in the U.S..
2. differentiate between the various categories of CAM
3. identify and differentiate the practices that are categorized as alternative medicine systems.
4. identify and differentiate the practices that are categorized as mind body medicine.
5. identify and differentiate the practices that are categorized as biologically based practices.
6. identify and differentiate the practices that are categorized as energy therapies.
7. identify and differentiate the practices that are categorized as manipulative and body based practices.
8. locate and review current research data and information specific to each of the various CAM therapies.
9. recognize consumer issues relating to CAM

Course Instructor

Michael Niss, DPT

Target Audience

Physical therapists, physical therapist assistants, occupational therapists, and occupational therapist assistants

Course Educational Level

This course is applicable for introductory learners.

Course Prerequisites

None

Criteria for issuance of Continuing Education Credits

A documented score of 70% or greater on the written post-test.

Continuing Education Credits

Four (4) hours of continuing education credit (4 NBCOT PDUs/4 contact hours)
AOTA - .4 AOTA CEU, Category 1: Domain of OT – Client Factors, Context

Determination of Continuing Education Contact Hours

“Complementary and Alternative Medicine” has been established to be a 4 hour continuing education program. This determination is based on an accepted standard for home-based self-study courses of 10-12 pages of text (12 pt font) per hour. The complete instructional text for this course is 49 pages (excluding Post-Test).

COMPLEMENTARY AND ALTERNATIVE MEDICINE

**COMPLEMENTARY AND ALTERNATIVE MEDICINE
COURSE OUTLINE**

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To take the post-test for CE credit, go to: WWW.CHEAPCEUS.COM

Introduction

Complementary and alternative medicine (CAM) is a group of diverse medical and health care systems, practices, and products that are not presently considered to be a part of conventional medicine. People use CAM therapies in a variety of ways. CAM therapies used alone are often referred to as "alternative." When used in addition to conventional medicine, they are often referred to as "complementary."

While some scientific evidence exists regarding some CAM therapies, for most there are key questions that are yet to be answered through well-designed scientific studies--questions such as whether these therapies are safe and whether they work for the diseases or medical conditions for which they are used. The list of what is considered to be CAM changes continually, as those therapies that are proven to be safe and effective become adopted into conventional health care and as new approaches to health care emerge.

The Use of Complementary and Alternative Medicine in the United States

The most comprehensive and reliable findings to date on Americans' use of CAM were released by the National Center for Complementary and Alternative Medicine (NCCAM) and the National Center for Health Statistics (NCHS, part of the Centers for Disease Control and Prevention). (Barnes; 2004) They came from the NCHS's National Health Interview Survey (NHIS), an annual study in which tens of thousands of Americans are interviewed about their health- and illness-related experiences. It included detailed questions on CAM. It was completed by 31,044 adults aged 18 years or older from the U.S. civilian noninstitutionalized population.

The survey included questions on various types of CAM therapies commonly used in the United States. These included provider-based therapies, such as acupuncture and chiropractic, and other therapies that do not require a provider, such as natural products, special diets, and megavitamin therapy.

CAM Therapies Included in the Survey

- Acupuncture
- Ayurveda
- Biofeedback
- Chelation therapy
- Chiropractic care
- Deep breathing exercises
- Diet-based therapies
 - Vegetarian diet
 - Macrobiotic diet

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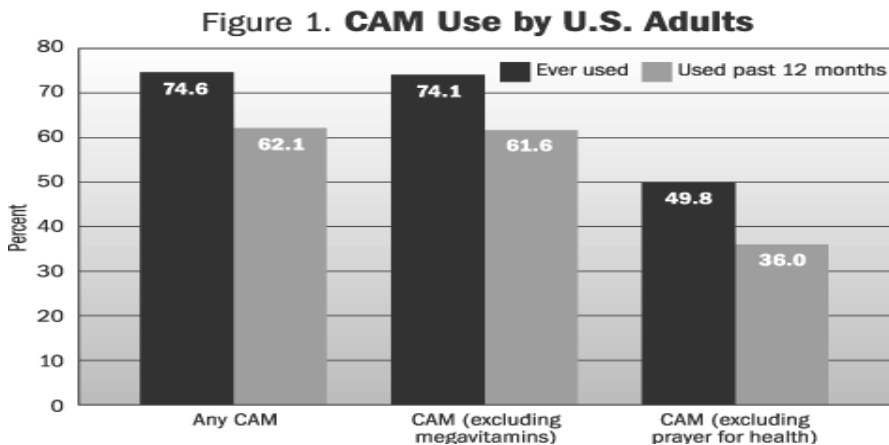
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- Atkins diet
- Pritikin diet
- Ornish diet
- Zone diet
- Energy healing therapy
- Folk medicine
- Guided imagery
- Homeopathic treatment
- Hypnosis
- Massage
- Meditation
- Megavitamin therapy
- Natural products
(nonvitamin and nonmineral, such as herbs and other products from plants, enzymes, etc.)
- Naturopathy
- Prayer for health reasons
 - Prayed for own health
 - Others ever prayed for your health
 - Participate in prayer group
 - Healing ritual for self
- Progressive relaxation
- Qi gong
- Reiki
- Tai chi
- Yoga

How Many People Use CAM

In the United States, 36% of adults are using some form of CAM. When megavitamin therapy and prayer specifically for health reasons are included in the definition of CAM, that number rises to 62%. (Figure 1)



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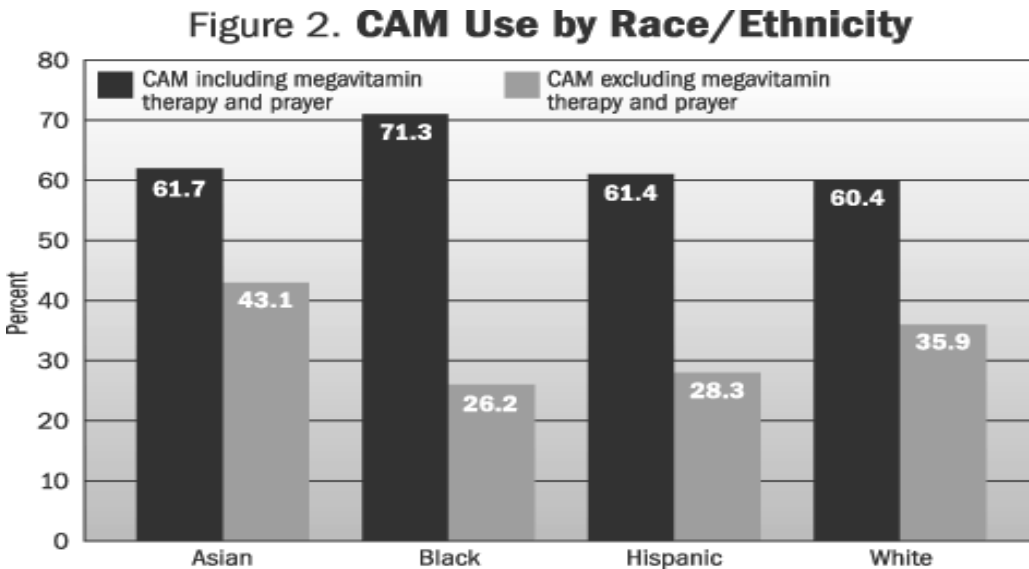
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Who Uses CAM Most

CAM use spans people of all backgrounds. But, according to the survey, some people are more likely than others to use CAM. Overall, CAM use is greater by:

- Women than men
- People with higher educational levels
- People who have been hospitalized in the past year
- Former smokers, compared with current smokers or those who have never smoked

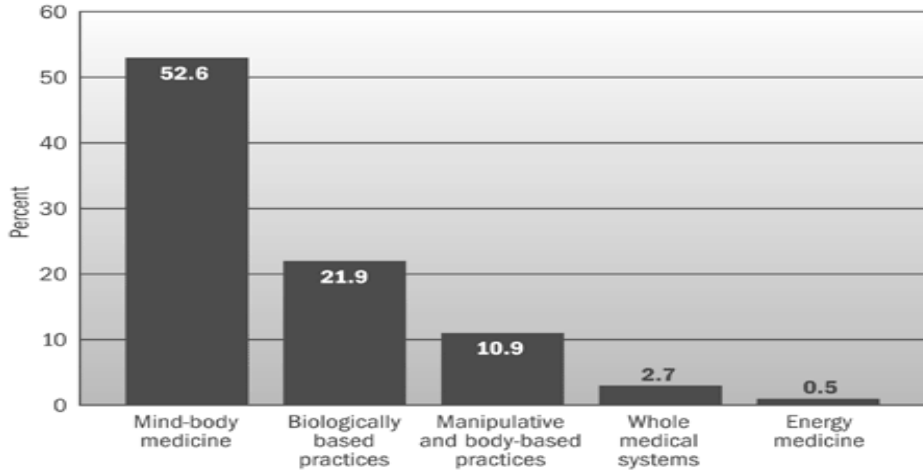
This survey was the first to yield substantial information on CAM use by minorities, and the major findings so far are shown in figure 2.



CAM Domains Used the Most

When prayer is included in the definition of CAM, the domain of mind-body medicine is the most commonly used domain (53%). (See figure 3.) When prayer is not included, biologically based therapies (22%) are more popular than mind-body medicine (17%).

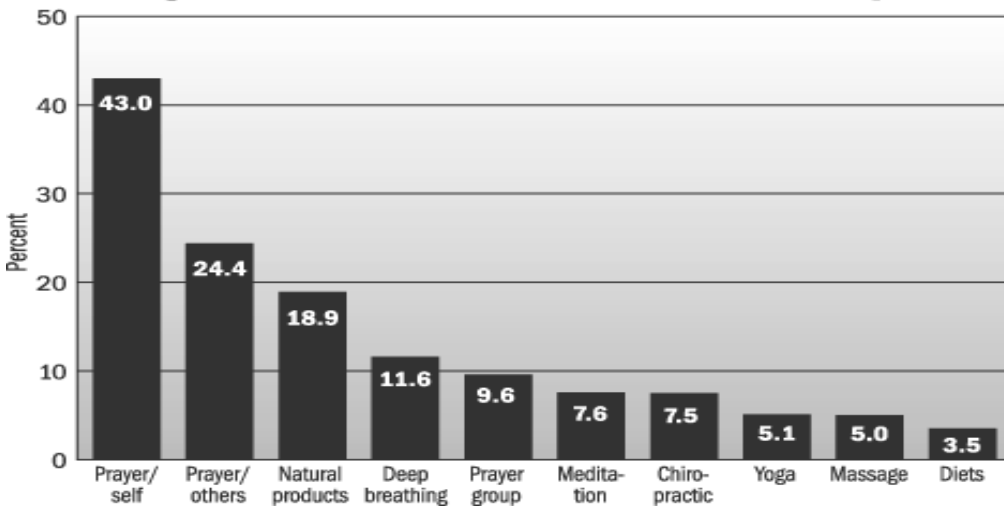
Figure 3. CAM Use by Domain and Whole Medical Systems



CAM Therapies Used the Most

Prayer specifically for health reasons was the most commonly used CAM therapy. (See figure 4.) Most people who use CAM use it to treat themselves, as only about 12% of the survey respondents sought care from a licensed CAM practitioner.

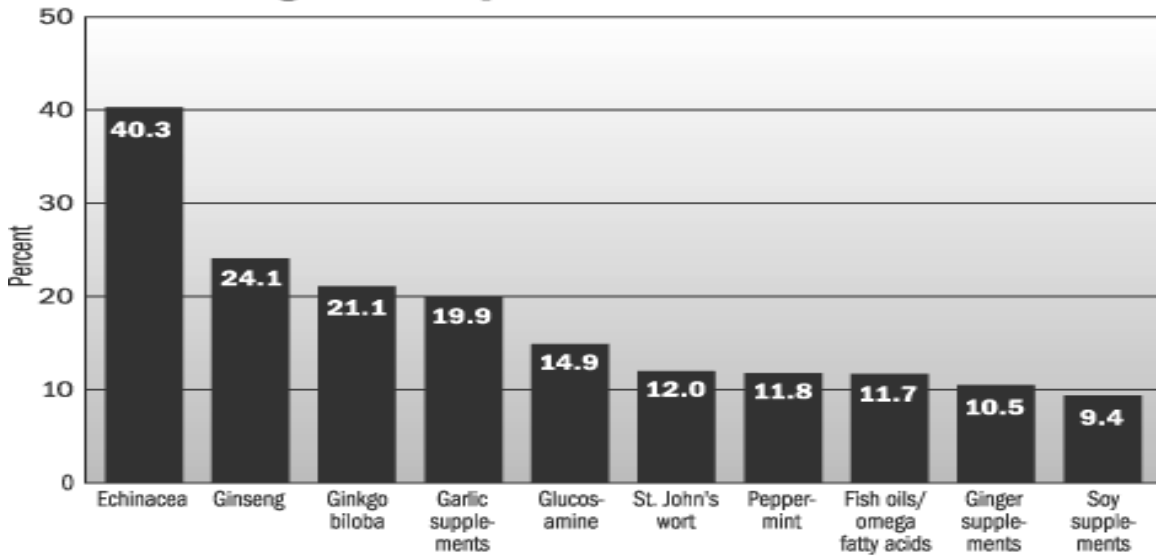
Figure 4. 10 Most Common CAM Therapies



Use of Natural Products

As shown in figure 4, about 19% (or one-fifth) of the people surveyed used natural products. See figure 5 for the most commonly used natural products and for the percentages of natural product users who took those products.

Figure 5. Top 10 Natural Products*

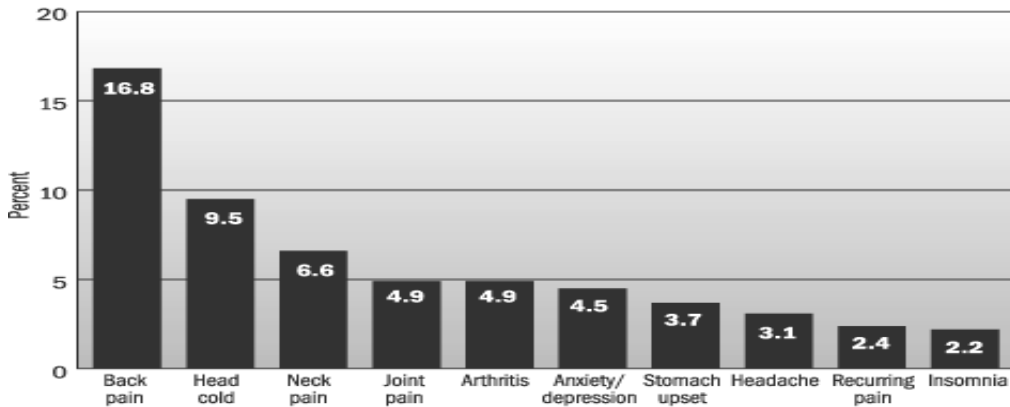


*The percentage for each product represents its rate of use among U.S. adults who use natural products.

Health Conditions Prompting CAM Use

People use CAM for a wide array of diseases and conditions. According to the survey, Americans are most likely to use CAM for back, neck, head, or joint aches, or other painful conditions; colds; anxiety or depression; gastrointestinal disorders; or sleeping problems. (See figure 6.) It appears that CAM is most often used to treat and/or prevent musculoskeletal conditions or other conditions involving chronic or recurring pain.

Figure 6. Disease/Condition for Which CAM Is Most Frequently Used*



*These figures exclude the use of megavitamin therapy and prayer.

Reasons for Using CAM

The survey asked people to select from five reasons to describe why they used CAM. (See figure 7.) Results were as follows (people could select more than one reason):

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CAM would improve health when used in combination with conventional medical treatments: 55%

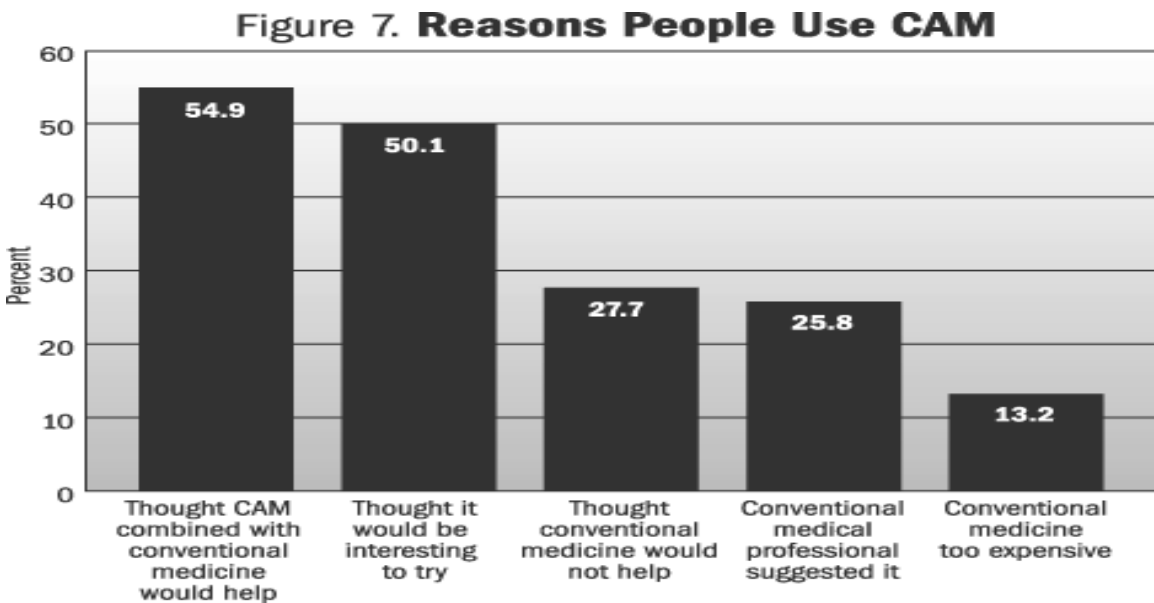
CAM would be interesting to try: 50%

Conventional medical treatments would not help: 28%

A conventional medical professional suggested trying CAM: 26%

Conventional medical treatments are too expensive: 13%

The survey found that most people use CAM along with conventional medicine rather than in place of conventional medicine.



Spending on CAM

The NHIS did not include questions on spending on health care, but the report authors cited spending figures from national surveys. Those surveys found the following:

The U.S. public spent an estimated \$36 billion to \$47 billion on CAM therapies.

Of this amount, between \$12 billion and \$20 billion was paid out-of-pocket for the services of professional CAM health care providers.

These fees represented more than the public paid out-of-pocket for all hospitalizations and about half of what it paid for all out-of-pocket physician services.

\$5 billion of out-of-pocket spending was on herbal products.

Categories of CAM

NCCAM classifies CAM therapies into five categories, or domains:

1. Alternative Medical Systems

Alternative medical systems are built upon complete systems of theory and practice. Often, these systems have evolved apart from and earlier than the conventional medical approach used in the United States. Examples of alternative medical systems that have developed in Western cultures include homeopathic medicine and naturopathic medicine. Examples of systems that have developed in non-Western cultures include traditional Chinese medicine and Ayurveda.

2. Mind-Body Interventions

Mind-body medicine uses a variety of techniques designed to enhance the mind's capacity to affect bodily function and symptoms. Some techniques that were considered CAM in the past have become mainstream (for example, patient support groups and cognitive-behavioral therapy). Other mind-body techniques are still considered CAM, including meditation, prayer, mental healing, and therapies that use creative outlets such as art, music, or dance.

3. Biologically Based Therapies

Biologically based therapies in CAM use substances found in nature, such as herbs, foods, and vitamins. Some examples include dietary supplements, herbal products, and the use of other so-called natural but as yet scientifically unproven therapies (for example, using shark cartilage to treat cancer).

4. Energy Therapies

Energy therapies involve the use of energy fields. They are of two types:

Biofield therapies are intended to affect energy fields that purportedly surround and penetrate the human body. The existence of such fields has not yet been scientifically proven. Some forms of energy therapy manipulate biofields by applying pressure and/or manipulating the body by placing the hands in, or through, these fields. Examples include qi gong, Reiki, and Therapeutic Touch.

Bioelectromagnetic-based therapies involve the unconventional use of electromagnetic fields, such as pulsed fields, magnetic fields, or alternating-current or direct-current fields.

5. Manipulative and Body-Based Methods

Manipulative and body-based methods in CAM are based on manipulation and/or movement of one or more parts of the body. Some examples include chiropractic or osteopathic manipulation, and massage.

Alternative Medical Systems

Introduction

Alternative medical systems involve complete systems of theory and practice that have evolved independently from or parallel to allopathic (conventional) medicine. Many are traditional systems of medicine that are practiced by individual cultures throughout the world. Major Eastern whole medical systems include traditional Chinese medicine (TCM) and Ayurvedic medicine, one of India's traditional systems of medicine. Major Western whole medical systems include homeopathy and naturopathy. Other systems have been developed by Native American, African, Middle Eastern, Tibetan, and Central and South American cultures.

Traditional Chinese Medicine

TCM is a complete system of healing that dates back to 200 B.C. in written form. Korea, Japan, and Vietnam have all developed their own unique versions of traditional medicine based on practices originating in China. In the TCM view, the body is a delicate balance of two opposing and inseparable forces: yin and yang. Yin represents the cold, slow, or passive principle, while yang represents the hot, excited, or active principle. Among the major assumptions in TCM are that health is achieved by maintaining the body in a "balanced state" and that disease is due to an internal imbalance of yin and yang. This imbalance leads to blockage in the flow of qi (or vital energy) and of blood along pathways known as meridians. It is believed that there are 12 main meridians and 8 secondary meridians and that there are more than 2,000 acupuncture points on the human body that connect with them. TCM practitioners typically use herbs, acupuncture, and massage to help unblock qi and blood in patients in an attempt to bring the body back into harmony and wellness.

Treatments in TCM are typically tailored to the subtle patterns of disharmony in each patient and are based on an individualized diagnosis. The diagnostic tools differ from those of conventional medicine. There are three main therapeutic modalities:

1. Acupuncture and moxibustion (moxibustion is the application of heat from the burning of the herb moxa at the acupuncture point)
2. Chinese Materia Medica (the catalogue of natural products used in TCM)
3. Massage and manipulation

Although TCM proposes that natural products catalogued in Chinese Materia Medica or acupuncture can be used alone to treat virtually any illness, quite often they are used together and sometimes in combination with other modalities (e.g., massage, moxibustion, diet changes, or exercise).

Acupuncture

Acupuncture is one of the oldest, most commonly used medical procedures in the world. Originating in China more than 2,000 years ago, acupuncture began to become better known in the United States in 1971, when New York Times reporter James Reston wrote about how doctors in China used needles to ease his pain after surgery.

The term acupuncture describes a family of procedures involving stimulation of anatomical points on the body by a variety of techniques. American practices of acupuncture incorporate medical traditions from China, Japan, Korea, and other countries. The acupuncture technique that has been most studied scientifically involves penetrating the skin with needles that are manipulated by the hands or by electrical stimulation.

Acupuncture needles are metallic, solid, and hair-thin. People experience acupuncture differently, but most feel no or minimal pain as the needles are inserted. Some people are energized by treatment, while others feel relaxed. Improper needle placement, movement of the patient, or a defect in the needle can cause soreness and pain during treatment. This is why it is important to seek treatment from a qualified acupuncture practitioner.

The U.S. Food and Drug Administration (FDA) approved acupuncture needles for use by licensed practitioners in 1996. The FDA requires that sterile, nontoxic needles be used and that they be labeled for single use by qualified practitioners only.

Relatively few complications from the use of acupuncture have been reported to the FDA in light of the millions of people treated each year and the number of acupuncture needles used. Still, complications have resulted from inadequate sterilization of needles and from improper delivery of treatments. Practitioners should use a new set of disposable needles taken from a sealed package for each patient and should swab treatment sites with alcohol or another disinfectant before inserting needles. When not delivered properly, acupuncture can cause serious adverse effects, including infections and punctured organs.

The report from a Consensus Development Conference on Acupuncture held at the National Institutes of Health (NIH) states that acupuncture is being "widely" practiced--by thousands of acupuncturists, physicians, dentists, and other practitioners--for relief or prevention of pain and for various other health conditions.(NIH Consensus Panel; 2004) In terms of the evidence at that time, acupuncture was considered to have potential clinical value for nausea/vomiting and dental pain, and limited evidence suggested its potential in the treatment of other pain disorders, paralysis and numbness, movement disorders, depression, insomnia, breathlessness, and asthma.

Preclinical studies have documented acupuncture's effects, but they have not been able to fully explain how acupuncture works within the framework of the Western system of medicine.

It is proposed that acupuncture produces its effects by the conduction of electromagnetic signals at a greater-than-normal rate, thus aiding the activity of pain-killing biochemicals, such as endorphins and immune system cells at specific sites in the body. In addition, acupuncture may alter brain chemistry by changing the release of neurotransmitters and neurohormones and affecting the parts of the central nervous system related to sensation and involuntary body functions, such as immune reactions and processes whereby a person's blood pressure, blood flow, and body temperature are regulated.

Chinese Materia Medica

Chinese Materia Medica is a standard reference book of information on medicinal substances that are used in Chinese herbal medicine. Herbs or botanicals usually contain dozens of bioactive compounds. Many factors--such as geographic location, harvest season, post-harvest processing, and storage--could have a significant impact on the concentration of bioactive compounds. In many cases, it is not clear which of these compounds underlie an herb's medical use. Moreover, multiple herbs are usually used in combinations called formulas in TCM, which makes the standardization of herbal preparations very difficult. Further complicating research on TCM herbs, herbal compositions and the quantity of individual herbs in a classic formula are usually adjusted in TCM practice according to individualized diagnoses.

In the past decades, major efforts have been made to study the effects and effectiveness of single herbs and of combinations of herbs used in classic TCM formulas. The following are examples of such work:

Artemisia annua. Ancient Chinese physicians identified that this herb controls fevers. In the 1970s, scientists extracted the chemical artemisinin from *Artemisia annua*. Artemisinin is the starting material for the semi-synthetic artemisinins that are proven to treat malaria and are widely used. (Klayman dL; 1985)

Tripterygium wilfordii Hook F (*Chinese Thunder God vine*). Thunder God vine has been used in TCM for the treatment of autoimmune and inflammatory diseases. The first small randomized, placebo-controlled trial of a Thunder God vine extract in the United States showed a significant dose-dependent response in patients with rheumatoid arthritis. (Tao X.; 2002) In larger, uncontrolled studies, however, renal, cardiac, hematopoietic, and reproductive toxicities of Thunder God vine extracts have been observed.

Ayurvedic Medicine

Ayurveda, which literally means "the science of life," is a natural healing system developed in India. Ayurvedic texts claim that the sages who developed India's original systems of meditation and yoga developed the foundations of this medical system. It is a comprehensive system of medicine that places equal emphasis on the body, mind, and spirit, and strives to restore the innate harmony of the individual. Some of the primary Ayurvedic treatments include diet, exercise, meditation, herbs, massage, exposure to sunlight, and controlled breathing. In India, Ayurvedic treatments have been developed for various diseases (e.g., diabetes, cardiovascular conditions, and neurological disorders). However, a survey of the Indian medical literature indicates that the quality of the published clinical trials generally falls short of contemporary methodological standards with regard to criteria for randomization, sample size, and adequate controls.

Naturopathy

Naturopathy is a system of healing, originating from Europe, that views disease as a manifestation of alterations in the processes by which the body naturally heals itself. It emphasizes health restoration as well as disease treatment. The term "naturopathy" literally translates as "nature disease." Today naturopathy, or naturopathic medicine, is practiced throughout Europe, Australia, New Zealand, Canada, and the United States. There are six principles that form the basis of naturopathic practice in North America (not all are unique to naturopathy):

1. The healing power of nature
2. Identification and treatment of the cause of disease
3. The concept of "first do no harm"
4. The doctor as teacher
5. Treatment of the whole person
6. Prevention

The core modalities supporting these principles include diet modification and nutritional supplements, herbal medicine, acupuncture and Chinese medicine, hydrotherapy, massage and joint manipulation, and lifestyle counseling. Treatment protocols combine what the practitioner deems to be the most suitable therapies for the individual patient.

As of this writing, virtually no research studies on naturopathy as a complete system of medicine have been published. A limited number of studies on botanicals in the context of use as naturopathic treatments have been published. For example, in a study of 524 children, echinacea did not prove effective in treating colds. (Taylor JA, et al; 2003) In contrast, a smaller, double-blind trial of an herbal extract solution containing echinacea, propolis (a resinous product

collected from beehives), and vitamin C for ear pain in 171 children concluded that the extract may be beneficial for ear pain associated with acute otitis media. (Sarrell EM; 2003) A naturopathic extract known as Otikon Otic Solution (containing *Allium sativum*, *Verbascum thapsus*, *Calendula flores*, and *Hypericum perforatum* in olive oil) was found as effective as anesthetic ear drops and was proven appropriate for the management of acute otitis media-associated ear pain. (Sarrell EM; 2001) Another study looked at the clinical effectiveness and cost-effectiveness of naturopathic cranberry tablets--versus cranberry juice and versus a placebo--as prophylaxis against urinary tract infections (UTIs). Compared with the placebo, both cranberry juice and cranberry tablets decreased the number of UTIs. Cranberry tablets proved to be the most cost-effective prevention for UTIs. (Strothers L; 2002)

Homeopathy

In the late 1700s, Samuel Hahnemann, a physician, chemist, and linguist in Germany, proposed a new approach to treating illness. This was at a time when the most common medical treatments were harsh, such as bloodletting, purging, blistering, and the use of sulfur and mercury. At the time, there were few effective medications for treating patients, and knowledge about their effects was limited.

Hahnemann was interested in developing a less-threatening approach to medicine. The first major step reportedly was when he was translating an herbal text and read about a treatment (cinchona bark) used to cure malaria. He took some cinchona bark and observed that, as a healthy person, he developed symptoms that were very similar to malaria symptoms. This led Hahnemann to consider that a substance may create symptoms that it can also relieve. This concept is called the "similia principle" or "like cures like." The similia principle had a prior history in medicine, from Hippocrates in Ancient Greece--who noted, for example, that recurrent vomiting could be treated with an emetic (such as ipecacuanha) that would be expected to make it worse--to folk medicine. Another way to view "like cures like" is that symptoms are part of the body's attempt to heal itself--for example, a fever can develop as a result of an immune response to an infection, and a cough may help to eliminate mucus--and medication may be given to support this self-healing response.

Hahnemann tested single, pure substances on himself and, in more dilute forms, on healthy volunteers. He kept meticulous records of his experiments and participants' responses, and he combined these observations with information from clinical practice, the known uses of herbs and other medicinal substances, and toxicology, eventually treating the sick and developing homeopathic clinical practice.

Hahnemann added two additional elements to homeopathy:

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A concept that became "potentization," which holds that systematically diluting a substance, with vigorous shaking at each step of dilution, makes the remedy more, not less, effective by extracting the vital essence of the substance. If dilution continues to a point where the substance's molecules are gone, homeopathy holds that the "memory" of them--that is, the effects they exerted on the surrounding water molecules--may still be therapeutic.

A concept that treatment should be selected based upon a total picture of an individual and his symptoms, not solely upon symptoms of a disease. Homeopaths evaluate not only a person's physical symptoms but her emotions, mental states, lifestyle, nutrition, and other aspects. In homeopathy, different people with the same symptoms may receive different homeopathic remedies.

Hans Burch Gram, a Boston-born doctor, studied homeopathy in Europe and introduced it into the United States in 1825. European immigrants trained in homeopathy also made the treatment increasingly available in America. In 1835, the first homeopathic medical college was established in Allentown, Pennsylvania. By the turn of the 20th century, 8 percent of all American medical practitioners were homeopaths, and there were 20 homeopathic medical colleges and more than 100 homeopathic hospitals in the United States.

In the late 19th and early 20th centuries, numerous medical advances were made, such as the recognition of the mechanisms of disease; Pasteur's germ theory; the development of antiseptic techniques; and the discovery of ether anesthesia. In addition, a report (the so-called "Flexner Report") was released that triggered major changes in American medical education. Homeopathy was among the disciplines negatively affected by these developments. Most homeopathic medical schools closed down, and by the 1930s others had converted to conventional medical schools.

In the 1960s, homeopathy's popularity began to revive in the United States. Over 6 million Americans reported that they had used homeopathy in the preceding 12 months. The World Health Organization noted in 1994 that homeopathy had been integrated into the national health care systems of numerous countries, including Germany, the United Kingdom, India, Pakistan, Sri Lanka, and Mexico. Several schools of practice exist within homeopathy.

Persons using homeopathy do so to address a range of health concerns, from wellness and prevention to treatment of injuries, diseases, and conditions. Studies have found that many people who seek homeopathic care seek it for help with a chronic medical condition. Many users of homeopathy treat themselves with homeopathic products and do not consult a professional.

Since homeopathy is administered in minute or potentially nonexistent material dosages, there is a skepticism in the scientific community about its efficacy. Nonetheless, the medical literature provides evidence of ongoing research in the field. Studies of homeopathy's effectiveness involve three areas of research:

1. Comparisons of homeopathic remedies and placebos
2. Studies of homeopathy's effectiveness for particular clinical conditions
3. Studies of the biological effects of potencies, especially ultra-high dilutions

Several systematic reviews and meta-analyses evaluated clinical trials of the effectiveness of homeopathic remedies as compared with placebo. The reviews found that, overall, the quality of clinical research in homeopathy is low. But when high-quality studies were selected for analysis, a surprising number showed positive results. (Jonas WB; 2003, Mathie RT; 2003, Cucherat M, et al; 2000)

Overall, clinical trial results are contradictory, and systematic reviews and meta-analyses have not found homeopathy to be a definitively proven treatment for any medical condition.

Summary

While whole medical systems differ in their philosophical approaches to the prevention and treatment of disease, they share a number of common elements. These systems are based on the belief that one's body has the power to heal itself. Healing often involves marshalling multiple techniques that involve the mind, body, and spirit. Treatment is often individualized and dependent on the presenting symptoms. To date, NCCAM's research efforts have focused on individual therapies with adequate experimental rationale and not on evaluating whole systems of medicine as they are commonly practiced. (NCCAM; 2004)

Mind-Body Medicine

Introduction

Mind-body medicine focuses on the interactions among the brain, mind, body, and behavior, and the powerful ways in which emotional, mental, social, spiritual, and behavioral factors can directly affect health. It regards as fundamental an approach that respects and enhances each person's capacity for self-knowledge and self-care, and it emphasizes techniques that are grounded in this approach.

Definition

Mind-body medicine typically focuses on intervention strategies that are thought to promote health, such as relaxation, hypnosis, visual imagery, meditation, yoga, biofeedback, tai chi, qi gong, cognitive-behavioral therapies, group support,

autogenic training, spirituality, and prayer. The field views illness as an opportunity for personal growth and transformation, and health care providers as catalysts and guides in this process.

Mind-body interventions constitute a major portion of the overall use of CAM by the public. Five relaxation techniques and imagery, biofeedback, and hypnosis, taken together, were used by more than 30 percent of the adult U.S. population. Prayer was used by more than 50 percent of the population. (Wolsko PM, et al; 2004)

Background

The concept that the mind is important in the treatment of illness is integral to the healing approaches of traditional Chinese and Ayurvedic medicine, dating back more than 2,000 years. It was also noted by Hippocrates, who recognized the moral and spiritual aspects of healing, and believed that treatment could occur only with consideration of attitude, environmental influences, and natural remedies (ca. 400 B.C.). While this integrated approach was maintained in traditional healing systems in the East, developments in the Western world by the 16th and 17th centuries led to a separation of human spiritual or emotional dimensions from the physical body. This separation began with the redirection of science, during the Renaissance and Enlightenment eras, to the purpose of enhancing humankind's control over nature. Technological advances (e.g., microscopy, the stethoscope, the blood pressure cuff, and refined surgical techniques) demonstrated a cellular world that seemed far apart from the world of belief and emotion. The discovery of bacteria and, later, antibiotics further dispelled the notion of belief influencing health. Fixing or curing an illness became a matter of science (i.e., technology) and took precedence over, not a place beside, healing of the soul. As medicine separated the mind and the body, scientists of the mind formulated concepts, such as the unconscious, emotional impulses, and cognitive delusions, that solidified the perception that diseases of the mind were not "real," that is, not based in physiology and biochemistry.

In the 1920s, Walter Cannon's work revealed the direct relationship between stress and neuroendocrine responses in animals. Coining the phrase "fight or flight," Cannon described the primitive reflexes of sympathetic and adrenal activation in response to perceived danger and other environmental pressures (e.g., cold, heat). Hans Selye further defined the deleterious effects of stress and distress on health. At the same time, technological advances in medicine that could identify specific pathological changes, and new discoveries in pharmaceuticals, were occurring at a very rapid pace. The disease-based model, the search for a specific pathology, and the identification of external cures were paramount, even in psychiatry.

During World War II, the importance of belief reentered the web of health care. On the beaches of Anzio, morphine for the wounded soldiers was in short supply,

and Henry Beecher, M.D., discovered that much of the pain could be controlled by saline injections. He coined the term "placebo effect," and his subsequent research showed that up to 35 percent of a therapeutic response to any medical treatment could be the result of belief. (Beecher H; 1959) Investigation into the placebo effect and debate about it are ongoing.

Since the 1960s, mind-body interactions have become an extensively researched field. The evidence for benefits for certain indications from biofeedback, cognitive-behavioral interventions, and hypnosis is quite good, while there is emerging evidence regarding their physiological effects. Less research supports the use of other, more clearly CAM approaches, like meditation and yoga. The following is a summary of relevant studies.

Mind-Body Interventions and Disease Outcomes

Over the past 20 years, mind-body medicine has provided considerable evidence that psychological factors can play a substantive role in the development and progression of coronary artery disease. There is evidence that mind-body interventions can be effective in the treatment of coronary artery disease, enhancing the effect of standard cardiac rehabilitation in reducing all-cause mortality and cardiac event recurrences for up to 2 years. (Rutledge JC, et al; 1999)

Mind-body interventions have also been applied to various types of pain. Clinical trials indicate that these interventions may be a particularly effective adjunct in the management of arthritis, with reductions in pain maintained for up to 4 years and reductions in the number of physician visits. (Luskin FA, et al; 2000) When applied to more general acute and chronic pain management, headache, and low-back pain, mind-body interventions show some evidence of effects, although results vary based on the patient population and type of intervention studied.(Astin JA; 2003)

Evidence from multiple studies with various types of cancer patients suggests that mind-body interventions can improve mood, quality of life, and coping, as well as ameliorate disease- and treatment-related symptoms, such as chemotherapy-induced nausea, vomiting, and pain. (Mundy EA, et al; 2003) Some studies have suggested that mind-body interventions can alter various immune parameters, but it is unclear whether these alterations are of sufficient magnitude to have an impact on disease progression or prognosis. (Irwin MR, et al; 2003)

Mind-Body Influences on Immunity

There is considerable evidence that emotional traits, both negative and positive, influence people's susceptibility to infection. Following systematic exposure to a respiratory virus in the laboratory, individuals who report higher levels of stress or

negative moods have been shown to develop more severe illness than those who report less stress or more positive moods. (Cohen S, et al; 2003) Recent studies suggest that the tendency to report positive, as opposed to negative, emotions may be associated with greater resistance to objectively verified colds. These laboratory studies are supported by longitudinal studies pointing to associations between psychological or emotional traits and the incidence of respiratory infections. (Smith A; 2001)

Meditation and Imaging

Meditation, one of the most common mind-body interventions, is a conscious mental process that induces a set of integrated physiological changes termed the relaxation response. Functional magnetic resonance imaging (fMRI) has been used to identify and characterize the brain regions that are active during meditation. This research suggests that various parts of the brain known to be involved in attention and in the control of the autonomic nervous system are activated, providing a neurochemical and anatomical basis for the effects of meditation on various physiological activities. (Lazr SW, et al; 2000) Recent studies involving imaging are advancing the understanding of mind-body mechanisms. For example, meditation has been shown in one study to produce significant increases in left- sided anterior brain activity, which is associated with positive emotional states. Moreover, in this same study, meditation was associated with increases in antibody titers to influenza vaccine, suggesting potential linkages among meditation, positive emotional states, localized brain responses, and improved immune function. (Davidson RJ, et al; 2003)

Physiology of Expectancy (Placebo Response)

Placebo effects are believed to be mediated by both cognitive and conditioning mechanisms. Until recently, little was known about the role of these mechanisms in different circumstances. Now, research has shown that placebo responses are mediated by conditioning when unconscious physiological functions such as hormonal secretion are involved, whereas they are mediated by expectation when conscious physiological processes such as pain and motor performance come into play, even though a conditioning procedure is carried out.

Positron emission tomography (PET) scanning of the brain is providing evidence of the release of the endogenous neurotransmitter dopamine in the brain of Parkinson's disease patients in response to placebo. (Fuente-Fernandez R, et al; 2002) Evidence indicates that the placebo effect in these patients is powerful and is mediated through activation of the nigrostriatal dopamine system, the system that is damaged in Parkinson's disease. This result suggests that the placebo response involves the secretion of dopamine, which is known to be important in a number of other reinforcing and rewarding conditions, and that there may be mind-body strategies that could be used in patients with

Parkinson's disease in lieu of or in addition to treatment with dopamine-releasing drugs.

Stress and Wound Healing

Individual differences in wound healing have long been recognized. Clinical observation has suggested that negative mood or stress is associated with slow wound healing. Basic mind-body research is now confirming this observation. Matrix metalloproteinases (MMPs) and the tissue inhibitors of metalloproteinases (TIMPs), whose expression can be controlled by cytokines, play a role in wound healing. Using a blister chamber wound model on human forearm skin exposed to ultraviolet light, researchers have demonstrated that stress or a change in mood is sufficient to modulate MMP and TIMP expression and, presumably, wound healing. (Yang EV, et al; 2002) Activation of the hypothalamic-pituitary-adrenal (HPA) and sympathetic-adrenal medullary (SAM) systems can modulate levels of MMPs, providing a physiological link among mood, stress, hormones, and wound healing. This line of basic research suggests that activation of the HPA and SAM axes, even in individuals within the normal range of depressive symptoms, could alter MMP levels and change the course of wound healing in blister wounds.

Surgical Preparation

Mind-body interventions are being tested to determine whether they can help prepare patients for the stress associated with surgery. Initial randomized controlled trials--in which some patients received audiotapes with mind-body techniques (guided imagery, music, and instructions for improved outcomes) and some patients received control tapes--found that subjects receiving the mind-body intervention recovered more quickly and spent fewer days in the hospital. (Tusek DL, et al; 1997)

Behavioral interventions have been shown to be an efficient means of reducing discomfort and adverse effects during percutaneous vascular and renal procedures. Pain increased linearly with procedure time in a control group and in a group practicing structured attention, but remained flat in a group practicing a self-hypnosis technique. The self-administration of analgesic drugs was significantly higher in the control group than in the attention and hypnosis groups. Hypnosis also improved hemodynamic stability. (Lang EV, et al; 2000)

Conclusion

Evidence from randomized controlled trials and, in many cases, systematic reviews of the literature, suggest that:

Mechanisms may exist by which the brain and central nervous system influence immune, endocrine, and autonomic functioning, which is known to have an impact on health.

Multicomponent mind-body interventions that include some combination of stress management, coping skills training, cognitive-behavioral interventions, and relaxation therapy may be appropriate adjunctive treatments for coronary artery disease and certain pain-related disorders, such as arthritis.

Multimodal mind-body approaches, such as cognitive-behavioral therapy, particularly when combined with an educational/informational component, can be effective adjuncts in the management of a variety of chronic conditions.

An array of mind-body therapies (e.g., imagery, hypnosis, relaxation), when employed presurgically, may improve recovery time and reduce pain following surgical procedures.

Neurochemical and anatomical bases may exist for some of the effects of mind-body approaches.

Mind-body approaches have potential benefits and advantages. In particular, the physical and emotional risks of using these interventions are minimal. Moreover, once tested and standardized, most mind-body interventions can be taught easily. Finally, future research focusing on basic mind-body mechanisms and individual differences in responses is likely to yield new insights that may enhance the effectiveness and individual tailoring of mind-body interventions. In the meantime, there is considerable evidence that mind-body interventions, even as they are being studied today, have positive effects on psychological functioning and quality of life, and may be particularly helpful for patients coping with chronic illness and in need of palliative care.

Biologically Based Practices

Definition

The CAM domain of biologically based practices includes, but is not limited to, botanicals, animal-derived extracts, vitamins, minerals, fatty acids, amino acids, proteins, prebiotics and probiotics, whole diets, and functional foods.

Dietary supplements are a subset of this CAM domain. In the Dietary Supplement Health and Education Act (DSHEA) of 1994, Congress defined a dietary supplement as a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these

products may include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and they can occur in many forms, such as tablets, capsules, softgels, gelcaps, liquids, or powders.

The Food and Drug Administration (FDA) regulates dietary supplements differently than drug products (either prescription or over-the-counter).

First, drugs are required to follow defined good manufacturing practices (GMPs). The FDA is developing GMPs for dietary supplements. However, until they are issued, companies must follow existing manufacturing requirements for foods.

Second, drug products must be approved by the FDA as safe and effective prior to marketing. In contrast, manufacturers of dietary supplements are responsible only for ensuring that their products are safe. While the FDA monitors adverse effects after dietary supplement products are on the market, newly marketed dietary supplements are not subject to pre-market approval or a specific post-market surveillance period.

Third, while DSHEA requires companies to substantiate claims of benefit, citation of existing literature is considered sufficient to validate such claims. Manufacturers are not required, as they are for drugs, to submit such substantiation data to the FDA; instead, it is the Federal Trade Commission that has primary responsibility for monitoring dietary supplements for truth in advertising. An Institute of Medicine (IOM) report on the safety of dietary supplements recommends a framework for cost-effective and science-based evaluation by the FDA.

History and Demographic Use

Dietary supplements reflect some of humankind's first attempts to improve the human condition. The personal effects of the mummified prehistoric "Ice Man" found in the Italian Alps in 1991 included medicinal herbs. By the Middle Ages, thousands of botanical products had been inventoried for their medicinal effects. Many of these, including digitalis and quinine, form the basis of modern drugs.

Interest in and use of dietary supplements have grown considerably in the past two decades. Consumers state that their primary reason for using herbal supplements is to promote overall health and wellness, but they also report using supplements to improve performance and energy, to treat and prevent illnesses (e.g., colds and flu), and to alleviate depression. According to a national survey on Americans' use of CAM, use of supplements may be more frequent among Americans who have one or more health problems, who have specific diseases such as breast cancer, who consume high amounts of alcohol, or who are obese.

COMPLEMENTARY AND ALTERNATIVE MEDICINE

Supplement use differs by ethnicity and across income strata. On average, users tend to be women, older, better educated, live in one- or two-person households, have slightly higher incomes, and live in metropolitan areas.

Use of vitamin and mineral supplements, a subset of dietary supplements, by the U.S. population has been a growing trend since the 1970s. National surveys indicate that 40 to 46 percent of Americans reported taking at least one vitamin or mineral supplement at some time within the month surveyed. (Radimer K, et al; 2004)

Sales of dietary supplements are an estimated \$18.7 billion per year, with herbs/botanical supplements accounting for an estimated \$4.3 billion in sales. Consumers consider the proposed benefits of herbal supplements less believable than those of vitamins and minerals. Recently sales of herbs have experienced negative growth. This is attributed to consumers' waning confidence and confusion. Within the herbal category, however, formulas led single herbs in sales; products became increasingly condition-specific; and sales of women's products actually increased by approximately 25 percent.

In contrast to dietary supplements, functional foods are components of the usual diet that may have biologically active components (e.g., polyphenols, phytoestrogens, fish oils, carotenoids) that may provide health benefits beyond basic nutrition. Examples of functional foods include soy, nuts, chocolate, and cranberries. These foods' bioactive constituents are appearing with increasing frequency as ingredients in dietary supplements. Functional foods are marketed directly to consumers. Sales are now over \$16.2 billion annually. Unlike dietary supplements, functional foods may claim specific health benefits. The Nutrition Labeling and Education Act (NLEA) of 1990 delineates the permissible labeling of these foods for health claims. Whole diet therapy has become an accepted practice for some health conditions. However, the popularity of unproven diets, especially for the treatment of obesity, has risen to a new level as the prevalence of obesity and metabolic syndrome among Americans has increased and traditional exercise and diet "prescriptions" have failed. Popular diets today include the Atkins, Zone, and Ornish diets, Sugar Busters, and others. The range of macronutrient distributions of these popular diets is very wide. The proliferation of diet books is phenomenal. Recently, food producers and restaurants have been targeting their marketing messages to reflect commercially successful low-carbohydrate diets.

Public need for information about dietary supplements, functional foods, and selected strict dietary regimens has driven research on the effectiveness and safety of these interventions and the dissemination of research findings.

Research

Range of Studies

Research on dietary supplements spans the spectrum of basic to clinical research and includes ethnobotanical investigations, analytical research, and method development/validation, as well as bioavailability, pharmacokinetic, and pharmacodynamic studies. However, the basic and preclinical research is better delineated for supplements composed of single chemical constituents (e.g., vitamins and minerals) than for the more complex products (e.g., botanical extracts). There is an abundance of clinical research for all types of dietary supplements. Most of this research involves small phase II studies.

The literature on functional foods is vast and growing; it includes clinical trials, animal studies, experimental in vitro laboratory studies, and epidemiological studies. Much of the current evidence for functional foods is preliminary or not based on well-designed trials. However, the foundational evidence gained through other types of investigations is significant for some functional foods and their "health-promoting" constituents.

An important gap in knowledge concerns the role of diet composition in energy balance. Popular diets low in carbohydrates have been purported to enhance weight loss. Shorter-term clinical studies show equivocal results. In addition, mechanisms by which popular diets affect energy balance, if at all, are not well understood. Although numerous animal studies assessing the impact of diet composition on appetite and body weight have been conducted, these studies have been limited by availability and use of well-defined and standardized diets. The research on weight loss is more abundant than that on weight maintenance.

Primary Challenges

Many clinical studies of dietary supplements are flawed because of inadequate sample size, poor design, limited preliminary dosing data, lack of blinding even when feasible, and/or failure to incorporate objective or standardized outcome instruments. In addition, the lack of reliable data on the absorption, disposition, metabolism, and excretion of these entities in living systems has complicated the selection of products to be used in clinical trials. This is more problematic for complex preparations (e.g., botanicals) than for products composed of single chemicals.

The lack of consistent and reliable botanical products represents a formidable challenge both in clinical trials and in basic research. Most have not been sufficiently characterized or standardized for the conduct of clinical trials capable of adequately demonstrating safety or efficacy, or predicting that similarly prepared products would also be safe and effective in wider public use. Consequently, obtaining sufficient quantities of well-characterized products for evaluation in clinical trials would be advantageous. Several issues regarding the choice of clinical trial material require special attention, for example:

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- Influences of climate and soil
- Use of different parts of the plants
- Use of different cultivars and species
- Optimal growing, harvesting, and storage conditions
- Use of the whole extract or a specific fraction
- Method of extraction
- Chemical standardization of the product
- Bioavailability of the formulation
- Dose and length of administration

Some nonbotanical dietary supplements, such as vitamins, carnitine, glucosamine, and melatonin, are single chemical entities. Botanicals, however, are complex mixtures. Their specific active ingredients may be identified, but are rarely known for certain. Usually, there is more than one of these ingredients, often dozens. When active compounds are unknown, it is necessary to identify marker or reference compounds, even though they may be unrelated to biological effects.

Qualitative and quantitative determinations of the active and marker compounds, as well as the presence of product contaminants, can be assessed by capillary electrophoresis, gas chromatography, liquid chromatography-mass spectrometry, gas chromatography-mass spectrometry, high-performance liquid chromatography, and liquid chromatography-multidimensional nuclear magnetic resonance. Fingerprinting techniques can map out the spectrum of compounds in a plant extract.

New applications of older techniques and new analytical methods continue to be developed and validated. However, there remains a limited number of analytical tools that are precise, accurate, specific, and robust. Steps are currently being taken to apply molecular tools, such as DNA fingerprinting, to verify species in products, while transient expression systems, and microarray and proteomic analyses, are beginning to be used to define the cellular and biological activities of dietary supplements.

Particular attention should be paid to the issues of complex botanicals and clinical dosing. Quality control of complex botanicals is difficult, but must be accomplished, because it is not ethical to administer an unknown product to patients. The use of a suboptimal dose that is safe but ineffective does not serve the larger goals of research community, or public health. Although the trial would indicate only that the tested dose of the intervention was ineffective, the public might conclude that all doses of the intervention are ineffective, and patients would be denied a possible benefit from the intervention. Overdosing, on the other hand, might produce unnecessary adverse effects. Phase I/II studies should be conducted first to determine the safety of various doses, and the

optimal dose should then be tested in a phase III trial. As a result, maximum benefit would be seen in the trial; also, any negative result would be definitive.

To a great extent, the difference between a dietary supplement and a drug lies in the use of the agent, not in the nature of the agent itself. If an herb, vitamin, mineral, or amino acid is used to resolve a nutritional deficiency or to improve or sustain the structure or function of the body, the agent is considered a dietary supplement. If the agent is used to diagnose, prevent, treat, or cure a disease, the agent is considered a drug. This distinction is key when the FDA determines whether proposed research on a product requires an investigational new drug (IND) exemption. If the proposed investigation of a lawfully marketed botanical dietary supplement is to study its effects on diseases (i.e., to cure, treat, mitigate, prevent, or diagnose a disease and its associated symptoms), then the supplement is more likely to be subject to IND requirements.

Similarly, little attention has been paid to the quality of probiotics. Quality issues for probiotic supplements may include:

- Viability of bacteria in the product
- Types and titer of bacteria in the product
- Stability of different strains under different storage conditions and in different product formats
- Enteric protection of the product

Therefore, for optimal studies, documentation of the type of bacteria (genus and species), potency (number of viable bacteria per dose), purity (presence of contaminating or ineffective microorganisms), and disintegration properties must be provided for any strain to be considered for use as a probiotic product. Speciation of the bacteria must be established by means of the most current, valid methodology.

Many of the challenges identified for research on dietary supplements, including issues of composition and characterization, are applicable to research on functional foods and whole diets. In addition, challenges of popular diet research include adherence to the protocol for longer-term studies, inability to blind participants to intervention assignment, and efficacy versus effectiveness.

Summary of Evidence

Over the past few decades, thousands of studies of various dietary supplements have been performed. To date, however, no single supplement has been proven effective in a compelling way. Nevertheless, there are several supplements for which early studies yielded positive, or at least encouraging, data.

For a few dietary supplements, data have been deemed sufficient to warrant large-scale trials. For example, multicenter trials have concluded or are in

progress on ginkgo (*Ginkgo biloba*) for prevention of dementia, glucosamine hydrochloride and chondroitin sulfate for osteoarthritis of the knee, saw palmetto (*Serenoa repens*)/African plum (*Prunus africana*) for benign prostatic hypertrophy, vitamin E/selenium for prevention of prostate cancer, shark cartilage for lung cancer, and St. John's wort (*Hypericum perforatum*) for major and minor depression. The results of one of the depression studies showed that St. John's wort is no more effective for treating major depression of moderate severity than placebo. Other studies of this herb, including its possible value in treatment of minor depression, are under way.

The Agency for Healthcare Research and Quality has produced a number of evidence-based reviews of dietary supplements, including garlic, antioxidants, milk thistle, omega-3 fatty acids, ephedra, and S-adenosyl-L-methionine (S-AMe). The following are examples of findings from some of these reviews:

Analysis of the literature shows generally disappointing results for the efficacy of antioxidant supplementation (vitamins C and E, and coenzyme Q10) to prevent or treat cancer. Because this finding contrasts with the benefits reported from observational studies, additional research is needed to understand why these two sources of evidence disagree. (AHRQ 04-E002; 2004)

Similarly, the literature on the roles of the antioxidants vitamins C and E and coenzyme Q10 for cardiovascular disease also shows discordance between observational and experimental data. Therefore, the thrust of new research into antioxidants and cardiovascular disease should be randomized trials. (AHRQ 03-E043; 2003)

The clinical efficacy of milk thistle to improve liver function is not clearly established. Interpretation of the evidence is hampered by poor study methods or poor quality of reporting in publications. Possible benefit has been shown most frequently, but not consistently, for improvement in aminotransferase levels. Liver function tests are overwhelmingly the most common outcome measure studied. Available evidence is not sufficient to suggest whether milk thistle is more effective for some liver diseases than others. Available evidence does suggest that milk thistle is associated with few, and generally minor, adverse effects. Despite substantial *in vitro* and animal research, the mechanism of action of milk thistle is not well defined and may be multifactorial. (AHRQ 01-E025; 2001)

The review of S-AMe for the treatment of depression, osteoarthritis, and liver disease identified a number of promising areas for future research. For example, it would be helpful to conduct

- (1) additional review studies, studies elucidating the pharmacology of S-AMe, and clinical trials;

- (2) studies that would lead to a better understanding of the risk-benefit ratio of SAME compared to that of conventional therapy;
- (3) good dose-escalation studies using the oral formulation of SAME for depression, osteoarthritis, or liver disease; and
- (4) larger clinical trials once the efficacy of the most effective oral dose of SAME has been demonstrated.(AHRQ 02-E034; 2002)

Two high-quality randomized controlled trials provide good evidence that cranberry juice may decrease the number of symptomatic urinary tract infections in women over a 12-month period. It is not clear if it is effective in other groups. The fact that a large number of women dropped out of these studies indicates that cranberry juice may not be acceptable over long periods of time. Finally, the optimal dosage or method of administration of cranberry products (e.g., juice or tablets) is not clear.(Jepson RG, et al; 2004)

There has been some study of other popular dietary supplements. For example, valerian is an herb often consumed as a tea for improved sleep, and melatonin is a pineal hormone touted for the same purpose.(Kunz D, et al; 2004) Small studies suggest that these two supplements may relieve insomnia, and there may be little harm in a trial course of either one. Echinacea has long been taken to treat or prevent colds; other supplements currently used for colds include zinc lozenges and high doses of vitamin C. As yet, only moderate-sized studies have been conducted with echinacea or zinc, and their outcomes have been conflicting. (Marshall I; 2004, Melchart D, et al; 2003) Large trials of high doses of oral vitamin C showed little, if any, benefit in preventing or treating the common cold.(Douglas RM; 2004)

Because of widespread use, often for centuries, and because the products are "natural," many people assume dietary supplements to be inert or at least innocuous. Yet, studies show clearly that interactions between these products and drugs do occur. For example, the active ingredients in ginkgo extract are reported to have antioxidant properties and to inhibit platelet aggregation. (Foster S; 1996) Several cases have been reported of increased bleeding associated with ginkgo's use with drugs that have anticoagulant or antiplatelet effects.

St. John's wort induces a broad range of enzymes that metabolize drugs and transport them out of the body. It has been shown to interact with a number of drugs that serve as substrates for the cytochrome P450 CYP3A enzymes responsible for metabolism of approximately 60 percent of current pharmaceutical agents. (Wilson TM, et al; 2002)

Other dietary supplements shown to potentiate or interfere with prescription drugs include garlic, glucosamine, ginseng (*Panax*), saw palmetto, soy, valerian, and yohimbe. (De Smet PA; 2002)

In addition to interacting with other agents, some herbal supplements can be toxic. Misidentification, contamination, and adulteration may contribute to some of the toxicities. But other toxicities may result from the products themselves. For example, in 2001, extracts of kava were associated with fulminant liver failure. More recently, the FDA banned the sale of ephedra after it was shown to be associated with an increased risk of adverse events.

Given the large number of dietary supplement ingredients; that dietary supplements are assumed to be safe in general; and that the FDA is unlikely to have the resources to evaluate each ingredient uniformly, the Institute of Medicine offers a framework for prioritizing evaluation of supplement safety. Among the IOM's recommendations are:

All federally supported research on dietary supplements conducted to assess efficacy should be required to include the collection and reporting of all data on the safety of the ingredient under study.

The development of effective working relationships and partnerships between the FDA and NIH should continue. The FDA and NIH should establish clear guidelines for cooperative efforts on high-priority safety issues related to the use of dietary supplements.

Energy Therapies

Introduction

Energy medicine is a domain in CAM that deals with energy fields of two types:

Veritable, which can be measured

Putative, which have yet to be measured

The **veritable** energies employ mechanical vibrations (such as sound) and electromagnetic forces, including visible light, magnetism, monochromatic radiation (such as laser beams), and rays from other parts of the electromagnetic spectrum. They involve the use of specific, measurable wavelengths and frequencies to treat patients.

In contrast, **putative** energy fields (also called biofields) have defied measurement to date by reproducible methods. Therapies involving putative energy fields are based on the concept that human beings are infused with a subtle form of energy. This vital energy or life force is known under different names in different cultures, such as qi in traditional Chinese medicine (TCM), ki in the Japanese Kampo system, doshas in Ayurvedic medicine, and elsewhere as prana, etheric energy, fohat, orgone, odic force, mana, and homeopathic resonance. Vital energy is believed to flow throughout the material human body,

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but it has not been unequivocally measured by means of conventional instrumentation. Nonetheless, therapists claim that they can work with this subtle energy, see it with their own eyes, and use it to effect changes in the physical body and influence health.

Practitioners of energy medicine believe that illness results from disturbances of these subtle energies (the biofield). For example, more than 2,000 years ago, Asian practitioners postulated that the flow and balance of life energies are necessary for maintaining health and described tools to restore them. Herbal medicine, acupuncture, acupressure, moxibustion, and cupping, for example, are all believed to act by correcting imbalances in the internal biofield, such as by restoring the flow of qi through meridians to reinstate health. Some therapists are believed to emit or transmit the vital energy (external qi) to a recipient to restore health.

Examples of practices involving putative energy fields include:

- Reiki and Johrei, both of Japanese origin

- Qi gong, a Chinese practice

- Healing touch, in which the therapist is purported to identify imbalances and correct a client's energy by passing his or her hands over the patient

- Prayer specifically for health purposes--such as intercessory prayer, in which a person intercedes through prayer on behalf of another

In the aggregate, these approaches are among the most controversial of CAM practices because neither the external energy fields nor their therapeutic effects have been demonstrated convincingly by any biophysical means. Yet, energy medicine is gaining popularity in the American marketplace and has become a subject of investigations at some academic medical centers. A National Center for Health Statistics survey indicated that approximately 1 percent of the participants had used Reiki, 0.5 percent had used qi gong, 4.6 percent had used some kind of healing ritual, and approximately 30 percent had had others pray for their health. (Barnes P, et al; 2004)

Veritable Energy Medicine

There are many well-established uses for the application of measurable energy fields to diagnose or treat diseases: electromagnetic fields in magnetic resonance imaging, cardiac pacemakers, radiation therapy, ultraviolet light for psoriasis, laser keratoplasty, and more. There are many other claimed uses as well. The ability to deliver quantifiable amounts of energies across the electromagnetic spectrum is an advantage to studies of their mechanisms and clinical effects. For example, both static and pulsating electromagnetic therapies have been employed.

Magnetic Therapy

Magnets have been used for many centuries in attempts to treat pain. By various accounts, this use began when people first noticed the presence of naturally magnetized stones, also called lodestones. Other accounts trace the beginning to a shepherd noticing that the nails in his sandals were pulled out by some stones. By the third century A.D., Greek physicians were using rings made of magnetized metal to treat arthritis and pills made of magnetized amber to stop bleeding. In the Middle Ages, doctors used magnets to treat gout, arthritis, poisoning, and baldness; to probe and clean wounds; and to retrieve arrowheads and other iron-containing objects from the body.

In the United States, magnetic devices (such as hairbrushes and insoles), magnetic salves, and clothes with magnets applied came into wide use after the Civil War, especially in some rural areas where few doctors were available. Healers claimed that magnetic fields existed in the blood, organs, or elsewhere in the body and that people became ill when their magnetic fields were depleted. Thus, healers marketed magnets as a means of "restoring" these magnetic fields. Magnets were promoted as cures for paralysis, asthma, seizures, blindness, cancer, and other conditions. The use of magnets to treat medical problems remained popular well into the 20th century. More recently, magnets have been marketed for a wide range of diseases and conditions, including pain, respiratory problems, high blood pressure, circulatory problems, arthritis, rheumatism, and stress.

Static magnets have been used for centuries in efforts to relieve pain or to obtain other alleged benefits (e.g., increased energy). They are usually made from iron, steel, rare-earth elements, or alloys. Typically, the magnets are placed directly on the skin or placed inside clothing or other materials that come into close contact with the body. Static magnets can be unipolar (one pole of the magnet faces or touches the skin) or bipolar (both poles face or touch the skin, sometimes in repeating patterns). Some magnet manufacturers make claims about the poles of magnets--for example, that a unipolar design is better than a bipolar design, or that the north pole gives a different effect from the south pole. These claims have not been scientifically proven. Numerous anecdotal reports have indicated that individuals have experienced significant, and at times dramatic, relief of pain after the application of static magnets over a painful area.

Although the literature on the biological effects of magnetic fields is growing, there is a limited amount of data from well-structured, clinically sound studies. However, there is growing evidence that magnetic fields can influence physiological processes. It has recently been shown that static magnetic fields affect the microvasculature of skeletal muscle. (Morris CE; 2003) Microvessels that are initially dilated respond to a magnetic field by constricting, and microvessels that are initially constricted respond by dilating. These results suggest that static magnetic fields may have a beneficial role in treating edema or ischemic conditions, but there is no proof that they do.

Electromagnets were approved by the FDA in 1979 to treat bone fractures that have not healed well. Researchers have been studying electromagnets for painful conditions, such as knee pain from osteoarthritis, chronic pelvic pain, problems in bones and muscles, and migraine headaches. However, these uses of electromagnets are still considered experimental by the FDA and have not been approved. Currently, electromagnets to treat pain are being used mainly under the supervision of a health care provider and/or in clinical trials.

An electromagnetic therapy called TMS (transcranial magnetic stimulation) is also being studied by researchers. In TMS, an insulated coil is placed against the head, near the area of the brain to be examined or treated, and an electrical current generates a magnetic field into the brain. Currently, TMS is most often used as a diagnostic tool, but research is also under way to see whether it is effective in relieving pain. A type of TMS called rTMS (repetitive TMS) is believed by some to produce longer lasting effects and is being explored for its usefulness in treating chronic pain, facial pain, headache, and fibromyalgia pain. A related form of electromagnetic therapy is rMS (repetitive magnetic stimulation). It is similar to rTMS except that the magnetic coil is placed on or near a painful area of the body other than the head. This therapy is being studied as a treatment for musculoskeletal pain.

Pulsating electromagnetic therapy has also been used for treating osteoarthritis, migraine headaches, multiple sclerosis, and sleep disorders. Some animal and cell culture studies have been conducted to elucidate the basic mechanism of the pulsating electromagnetic therapy effect, such as cell proliferation and cell-surface binding for growth factors. However, detailed data on the mechanisms of action are still lacking.

The kinds of magnets marketed to consumers are generally considered to be safe when applied to the skin. Reports of side effects or complications have been rare. One study reported that a small percentage of participants had bruising or redness on their skin where a magnet was worn.

Manufacturers often recommend that static magnets not be used by the following people:

Pregnant women, because the possible effects of magnets on the fetus are not known.

People who use a medical device such as a pacemaker, defibrillator, or insulin pump, because magnets may affect the magnetically controlled features of such devices.

People who use a patch that delivers medication through the skin, in case magnets cause dilation of blood vessels, which could affect the delivery of

the medicine. This caution also applies to people with an acute sprain, inflammation, infection, or wound.

There have been rare cases of problems reported from the use of electromagnets. Because at present these are being used mainly under the supervision of a health care provider and/or in clinical trials, readers are advised to consult their provider about any questions.

Millimeter Wave Therapy

Low-power millimeter wave (MW) irradiation elicits biological effects, and clinicians in Russia and other parts of Eastern Europe have used it in past decades to treat a variety of conditions, ranging from skin diseases and wound healing to various types of cancer, gastrointestinal and cardiovascular diseases, and psychiatric illnesses. In spite of an increasing number of in vivo and in vitro studies, the nature of MW action is not well understood. It has been shown, for example, that MW irradiation can augment T-cell mediated immunity in vitro. (Logani MK, et al; 2004) However, the mechanisms by which MW irradiation enhances T-cell functions are not known. Some studies indicate that pretreating mice with naloxone may block the hypoalgesic and antipruritic effects of MW irradiation, suggesting that endogenous opioids are involved in MW therapy-induced hypoalgesia. Theoretical and experimental data show that nearly all the MW energy is absorbed in the superficial layers of skin, but it is not clear how the energy absorbed by keratinocytes, the main constituents of epidermis, is transmitted to elicit the therapeutic effect. (Szabo I, et al; 2003) It is also unclear whether MW yields clinical effects beyond a placebo response.

Sound Energy Therapy

Sound energy therapy, sometimes referred to as vibrational or frequency therapy, includes music therapy as well as wind chime and tuning fork therapy. The presumptive basis of its effect is that specific sound frequencies resonate with specific organs of the body to heal and support the body. Music therapy has been the most studied among these interventions, with studies dating back to the 1920s, when it was reported that music affected blood pressure.¹¹ Other studies have suggested that music can help reduce pain and anxiety. Music and imagery, alone and in combination, have been used to entrain mood states, reduce acute or chronic pain, and alter certain biochemicals, such as plasma beta-endorphin levels.¹² These uses of energy fields truly overlap with the domain of mind-body medicine.

Light Therapy

Light therapy is the use of natural or artificial light to treat various ailments, but unproven uses of light extend to lasers, colors, and monochromatic lights. High-intensity light therapy has been documented to be useful for seasonal affective disorder, with less evidence for its usefulness in the treatment of more general forms of depression and sleep disorders. Hormonal changes have been detected after treatment. Although low-level laser therapy is claimed to be useful

for relieving pain, reducing inflammation, and helping to heal wounds, strong scientific proof of these effects is still needed.

Putative Energy Fields

The concept that sickness and disease arise from imbalances in the vital energy field of the body has led to many forms of therapy. In traditional Chinese medicine, a series of approaches are taken to rectify the flow of qi, such as herbal medicine, acupuncture (and its various versions), qi gong, diet, and behavior changes.

Therapeutic Touch and Related Practices

Numerous other practices have evolved over the years to promote or maintain the balance of vital energy fields in the body. Examples of these modalities include Therapeutic Touch, healing touch, Reiki, Johrei, vortex healing, and polarity therapy. All these modalities involve movement of the practitioner's hands over the patient's body to become attuned to the condition of the patient, with the idea that by so doing, the practitioner is able to strengthen and reorient the patient's energies.

Many small studies of Therapeutic Touch have suggested its effectiveness in a wide variety of conditions, including wound healing, osteoarthritis, migraine headaches, and anxiety in burn patients. In one meta-analysis of 11 controlled Therapeutic Touch studies, 7 controlled studies had positive outcomes, and 3 showed no effect; in one study, the control group healed faster than the Therapeutic Touch group. (Winstead-Fry P; 1999) Similarly, Reiki and Johrei practitioners claim that the therapies boost the body's immune system, enhance the body's ability to heal itself, and are beneficial for a wide range of problems, such as stress-related conditions, allergies, heart conditions, high blood pressure, and chronic pain. (Gallob R; 2003) However, there has been little rigorous scientific research. Overall, these therapies have impressive anecdotal evidence, but none has been proven scientifically to be effective.

Distant Healing

Proponents of energy field therapies also claim that some of these therapies can act across long distances. For example, the long-distance effects of external qi gong have been studied in China and summarized in the book *Scientific Qigong Exploration*, which has been translated into English. The studies reported various healing cases and described the nature of qi as bidirectional, multifunctional, adaptable to targets, and capable of effects over long distances. But none of these claims has been independently verified.

Another form of distant healing is intercessory prayer, in which a person prays for the healing of another person who is a great distance away, with or without that person's knowledge. Review of eight nonrandomized and nine randomized clinical trials published between 2000 and 2002 showed that the majority of the

more rigorous trials do not support the hypothesis that distant intercessory prayer has specific therapeutic effects. (Ernst E; 2003)

Physical Properties of Putative Energy Fields

There has always been an interest in detecting and describing the physical properties of putative energy fields. Kirlian photography, aura imaging, and gas discharge visualization are approaches for which dramatic and unique differences before and after therapeutic energy attunements or treatments have been claimed. However, it is not clear what is being detected or photographed. Early results demonstrated that gamma radiation levels markedly decreased during therapy sessions in 100 percent of subjects and at every body site tested, regardless of which therapist performed the treatment. Recently replicated studies identified statistically significant decreases in gamma rays emitted from patients during alternative healing sessions with trained practitioners.

It has been hypothesized that the body's primary gamma emitter, potassium-40 (K40), represents a "self-regulation" of energy within the body and the surrounding electromagnetic field. The body's energy adjustment may result, in part, from the increased electromagnetic fields surrounding the hands of the healers. Furthermore, an extremely sensitive magnetometer called a superconducting quantum interference device (SQUID) has been claimed to measure large frequency-pulsing biomagnetic fields emanating from the hands of Therapeutic Touch practitioners during therapy.

In one study, a simple magnetometer measured and quantified similar frequency-pulsing biomagnetic fields from the hands of meditators and practitioners of yoga and qi gong. These fields were 1,000 times greater than the strongest human biomagnetic field and were in the same frequency range as those being tested in medical research laboratories for use in speeding the healing process of certain biological tissues. (Sisken BF; 1995) This range is low energy and extremely low frequency, spanning from 2 Hz to 50 Hz. However, there are considerable technical problems in such research. For example, SQUID measurement must be conducted under a special shielded environment, and the connection between electromagnetic field increases and observed healing benefits reported in the current literature is missing.

Other studies of putative energies suggested that energy fields from one person can overlap and interact with energy fields of other people. For example, when individuals touch, one person's electrocardiographic signal is registered in the other person's electroencephalogram (EEG) and elsewhere on the other person's body. (Russek L; 1996) In addition, one individual's cardiac signal can be registered in another's EEG recording when two people sit quietly opposite one another.

Additional Theories

Thus far, electromagnetic energy has been demonstrated and postulated to be the energy between bioenergy healers and patients. However, the exact nature of this energy is not clear. Among the range of ideas emerging in this field is the theory of a Russian researcher who hypothesized that "torsion fields" exist and that they can be propagated through space at no less than 10^9 times the speed of light in vacuum; that they convey information without transmitting energy; and that they are not required to obey the superposition principle. (Panov V; 1997)

There are other extraordinary claims and observations recorded in the literature. For example, one report claimed that accomplished meditators were able to imprint their intentions on electrical devices (IIED), which when placed in a room for 3 months, would elicit these intentions, such as changes in pH and temperature, in the room even when the IIED was removed from the room. (Tiller WA; 2004) Another claim is that water will crystallize into different forms and appearances under the influence of written intentions or types of music. (Emoto M; 2004)

For research, questions remain about which of the above theories and approaches can be and should be addressed using existing technologies, and how.

Manipulative and Body-Based Practices

Introduction

Under the umbrella of manipulative and body-based practices is a heterogeneous group of CAM interventions and therapies. These include chiropractic and osteopathic manipulation, massage therapy, Tui Na, reflexology, rolfing, Bowen technique, Trager bodywork, Alexander technique, Feldenkrais method, and a host of others. Surveys of the U.S. population suggest that between 3 percent and 16 percent of adults receive chiropractic manipulation in a given year, while between 2 percent and 14 percent receive some form of massage therapy. (Ni H, et al; 2002) U.S. adults make an estimated 192 million visits to chiropractors and 114 million visits to massage therapists. Visits to chiropractors and massage therapists combined represented 50 percent of all visits to CAM practitioners. Data on the remaining manipulative and body-based practices are sparser, but it can be estimated that they are collectively used by less than 7 percent of the adult population.

Manipulative and body-based practices focus primarily on the structures and systems of the body, including the bones and joints, the soft tissues, and the circulatory and lymphatic systems. Some practices were derived from traditional systems of medicine, such as those from China, India, or Egypt, while others were developed within the last 150 years (e.g., chiropractic and osteopathic

manipulation). Although many providers have formal training in the anatomy and physiology of humans, there is considerable variation in the training and the approaches of these providers both across and within modalities. For example, osteopathic and chiropractic practitioners, who use primarily manipulations that involve rapid movements, may have a very different treatment approach than massage therapists, whose techniques involve slower applications of force, or than craniosacral therapists. Despite this heterogeneity, manipulative and body-based practices share some common characteristics, such as the principles that the human body is self-regulating and has the ability to heal itself and that the parts of the human body are interdependent. Practitioners in all these therapies also tend to tailor their treatments to the specific needs of each patient.

Definitions

Alexander technique: Patient education/guidance in ways to improve posture and movement, and to use muscles efficiently.

Bowen technique: Gentle massage of muscles and tendons over acupuncture and reflex points.

Chiropractic manipulation: Adjustments of the joints of the spine, as well as other joints and muscles.

Craniosacral therapy: Form of massage using gentle pressure on the plates of the patient's skull.

Feldenkrais method: Group classes and hands-on lessons designed to improve the coordination of the whole person in comfortable, effective, and intelligent movement.

Massage therapy: Assortment of techniques involving manipulation of the soft tissues of the body through pressure and movement.

Osteopathic manipulation: Manipulation of the joints combined with physical therapy and instruction in proper posture.

Reflexology: Method of foot (and sometimes hand) massage in which pressure is applied to "reflex" zones mapped out on the feet (or hands).

Rolfing: Deep tissue massage (also called structural integration).

Trager bodywork: Slight rocking and shaking of the patient's trunk and limbs in a rhythmic fashion.

Tui Na: Application of pressure with the fingers and thumb, and manipulation of specific points on the body (acupoints).

Chiropractic

Chiropractic is a form of spinal manipulation, which is one of the oldest healing practices. Spinal manipulation was described by Hippocrates in ancient Greece. In 1895, Daniel David Palmer founded the modern profession of chiropractic in Davenport, Iowa. Palmer was a self-taught healer and a student of healing philosophies of the day. He observed that the body has a natural healing ability that he believed was controlled by the nervous system. He also believed that subluxations, or misalignments of the spine interrupt or interfere with this "nerve flow." Palmer suggested that if an organ does not receive its normal supply of impulses from the nerves, it can become diseased. This line of thinking led him to develop a procedure to "adjust" the vertebrae, the bones of the spinal column, with the goal of correcting subluxations.

Some chiropractors continue to view subluxation as central to chiropractic health care. However, other chiropractors no longer view the subluxation theory as a unifying theme in health and illness or as a basis for their practice.

Patients may or may not experience side effects from chiropractic treatment. Effects may include temporary discomfort in parts of the body that were treated, headache, or tiredness. These effects tend to be minor and to resolve within 1 to 2 days.

Range of Studies

The majority of research on manipulative and body-based practices has been clinical in nature, encompassing case reports, mechanistic studies, biomechanical studies, and clinical trials. A cursory search in PubMed for research published in the last 10 years identified 537 clinical trials, of which 422 were randomized and controlled. Similarly, 526 trials were identified in the Cochrane database of clinical trials. PubMed also contains 314 case reports or series, 122 biomechanical studies, 26 health services studies, and 248 listings for all other types of clinical research published in the last 10 years. On the other hand, for this same time period, there have been only 33 published articles of research involving in vitro assays or employing animal models.

Primary Challenges

Different challenges face investigators studying mechanisms of action than those studying efficacy and safety. The primary challenges that have impeded research on the underlying biology of manual therapies include the following:

- Lack of appropriate animal models

- Lack of cross-disciplinary collaborations

- Lack of research tradition and infrastructure at schools that teach manual therapies

- Inadequate use of state-of-the-art scientific technologies

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Clinical trials of CAM manual therapies face the same general challenges as trials of procedure-based interventions such as surgery, psychotherapy, or more conventional physical manipulative techniques (e.g., physical therapy). These include:

Identifying an appropriate, reproducible intervention, including dose and frequency. This may be more difficult than in standard drug trials, given the variability in practice patterns and training of practitioners.

Identifying an appropriate control group(s). In this regard, the development of valid sham manipulation techniques has proven difficult.

Randomizing subjects to treatment groups in an unbiased manner. Randomization may prove more difficult than in a drug trial, because manual therapies are already available to the public; thus, it is more likely that participants will have a preexisting preference for a given therapy.

Maintaining investigator and subject compliance to the protocol. Group contamination (which occurs when patients in a clinical study seek additional treatments outside the study, usually without telling the investigators; this will affect the accuracy of the study results) may be more problematic than in standard drug trials, because subjects have easy access to manual therapy providers.

Reducing bias by blinding subjects and investigators to group assignment. Blinding of subjects and investigators may prove difficult or impossible for certain types of manual therapies. However, the person collecting the outcome data should always be blinded.

Identifying and employing appropriate validated, standardized outcome measures.

Employing appropriate analyses, including the intent-to-treat paradigm.

Preclinical Studies

The most abundant data regarding the possible mechanisms underlying chiropractic manipulation have been derived from studies in animals, especially studies on the ways in which manipulation may affect the nervous system. For example, it has been shown, by means of standard neurophysiological techniques, that spinal manipulation evokes changes in the activity of proprioceptive primary afferent neurons in paraspinal tissues. Sensory input from these tissues has the capacity to reflexively alter the neural outflow to the autonomic nervous system. Studies are under way to determine whether input from the paraspinal tissue also alters pain processing in the spinal cord.

Animal models have also been used to study the mechanisms of massage-like stimulation. (Lund I; 2002) It has been found that antinociceptive and

cardiovascular effects of massage may be mediated by endogenous opioids and oxytocin at the level of the midbrain.

Although animal models of chiropractic manipulation and massage have been established, no such models exist for other body-based practices. Such models could be critical if researchers are to evaluate the underlying anatomical and physiological changes accompanying these therapies.

Clinical Studies: Mechanisms

Biomechanical studies have characterized the force applied by a practitioner during chiropractic manipulation, as well as the force transferred to the vertebral column, both in cadavers and in normal volunteers. (Swenson R; 2003) In most cases, however, a single practitioner provided the manipulation, limiting generalizability. Additional work is required to examine interpractitioner variability, patient characteristics, and their relation to clinical outcomes.

Studies using magnetic resonance imaging (MRI) have suggested that spinal manipulation has a direct effect on the structure of spinal joints; it remains to be seen if this structural change relates to clinical efficacy.

Clinical studies of selected physiological parameters suggest that massage therapy can alter various neurochemical, hormonal, and immune markers, such as substance P in patients who have chronic pain, serotonin levels in women who have breast cancer, cortisol levels in patients who have rheumatoid arthritis, and natural killer (NK) cell numbers and CD4+ T-cell counts in patients who are HIV-positive. (Field T; 2002) However, most of these studies have come from one research group, so replication at independent sites is necessary. It is also important to determine the mechanisms by which these changes are elicited.

Despite these many interesting experimental observations, the underlying mechanisms of manipulative and body-based practices are poorly understood. Little is known from a quantitative perspective. Important gaps in the field, as revealed by a review of the relevant scientific literature, include the following:

- Lack of biomechanical characterization from both practitioner and participant perspectives

- Little use of state-of-the-art imaging techniques

- Few data on the physiological, anatomical, and biomechanical changes that occur with treatment

- Inadequate data on the effects of these therapies at the biochemical and cellular levels

- Only preliminary data on the physiological mediators involved with the clinical outcomes

Clinical Studies: Trials

Numerous clinical trials have been conducted on the use of spinal manipulation for low-back pain, and there are abundant systematic reviews and meta-analyses of the efficacy of spinal manipulation for both acute and chronic low-back pain. (Assendelft WJ; 2003) These trials employed a variety of manipulative techniques. Overall, manipulation studies of varying quality show minimal to moderate evidence of short-term relief of back pain. Information on cost-effectiveness, dosing, and long-term benefit is scant. Although clinical trials have found no evidence that spinal manipulation is an effective treatment for asthma, (Hondras MA; 2004) hypertension (Goertz CH, et al; 2002), or dysmenorrhea, (Proctor ML, et al; 2004) spinal manipulation may be as effective as some medications for both migraine and tension headaches (Astin JA; 2002) and may offer short-term benefits to those suffering from neck pain. (Hurwitz DL; 2002) Studies have not compared the relative effectiveness of different manipulative techniques.

Although there have been numerous published reports of clinical trials evaluating the effects of various types of massage for a variety of medical conditions (most with positive results), these trials were almost all small, poorly designed, inadequately controlled, or lacking adequate statistical analyses. For example, many trials included co-interventions that made it impossible to evaluate the specific effects of massage, while others evaluated massage delivered by individuals who were not fully trained massage therapists or followed treatment protocols that did not reflect common (or adequate) massage practice.

There have been very few well-designed controlled clinical trials evaluating the effectiveness of massage for any condition, and only three randomized controlled trials have specifically evaluated massage for the condition most frequently treated with massage--back pain.(Cherkin DC, et al; 2003) All three trials found massage to be effective, but two of these trials were very small. More evidence is needed.

Risks

There are some risks associated with manipulation of the spine, but most reported side effects have been mild and of short duration. Although rare, incidents of stroke and vertebral artery dissection have been reported following manipulation of the cervical spine. Despite the fact that some forms of massage involve substantial force, massage is generally considered to have few adverse effects. Contraindications for massage include deep vein thrombosis, burns, skin infections, eczema, open wounds, bone fractures, and advanced osteoporosis.

Utilization

In the United States, manipulative therapy is practiced primarily by doctors of chiropractic, some osteopathic physicians, physical therapists, and physiatrists. Doctors of chiropractic perform more than 90 percent of the spinal manipulations

in the United States, and the vast majority of the studies that have examined the cost and utilization of spinal manipulation have focused on chiropractic.

Individual provider experience, traditional use, or arbitrary payer capitation decisions--rather than the results of controlled clinical trials--determine many patient care decisions involving spinal manipulation. More than 75 percent of private payers and 50 percent of managed care organizations provide at least some reimbursement for chiropractic care. Congress has mandated that the Department of Defense (DOD) and the Department of Veterans Affairs provide chiropractic services to their beneficiaries, and there are DOD medical clinics offering manipulative services by osteopathic physicians and physical therapists. The State of Washington has mandated coverage of CAM services for medical conditions normally covered by insurance. The integration of manipulative services into health care has reached this level despite a dearth of evidence about long-term effects, appropriate dosing, and cost-effectiveness.

Although the numbers of Americans using chiropractic and massage are similar, massage therapists are licensed in fewer than 40 states, and massage is much less likely than chiropractic to be covered by health insurance. Like spinal manipulation, massage is most commonly used for musculoskeletal problems. However, a significant fraction of patients seek massage care for relaxation and stress relief.

Cost

A number of observational studies have looked at the costs associated with chiropractic spinal manipulation in comparison with the costs of conventional medical care, with conflicting results. Smith and Stano found that overall health care expenditures were lower for patients who received chiropractic treatment than for those who received medical care in a fee-for-service environment. (Smith M; 1997) Carey and colleagues found chiropractic spinal manipulation to be more expensive than primary medical care, but less expensive than specialty medical care. (Carey TS, et al; 1995) Two randomized trials comparing the costs of chiropractic care with the costs of physical therapy failed to find evidence of cost savings through chiropractic treatment. (Cherkin DC, et al; 1998, Skargren EI, et al; 1998) The only study of massage that measured costs found that the costs for subsequent back care following massage were 40 percent lower than those following acupuncture or self care, but these differences were not statistically significant. (Cherkin DC, et al; 2001)

Patient Satisfaction

Although there are no studies of patient satisfaction with manipulation in general, numerous investigators have looked at patient satisfaction with chiropractic care. Patients report very high levels of satisfaction with chiropractic care. Satisfaction with massage treatment has also been found to be very high.

Consumer Issues

Safety of CAM Therapies

Each treatment needs to be considered on its own. However, here are some issues to think about when considering a CAM therapy.

Many consumers believe that "natural" means the same thing as "safe." This is not necessarily true. For example, think of mushrooms that grow in the wild: some are safe to eat, while others are poisonous.

Individuals respond differently to treatments. How a person might respond to a CAM treatment depends on many things, including the person's state of health, how the treatment is used, or the person's belief in the treatment.

For a CAM product that is sold over the counter, such as a dietary supplement, safety can also depend on a number of things:

The components or ingredients that make up the product.

Where the components or ingredients come from.

The quality of the manufacturing process (for example, how well the manufacturer is able to avoid contamination).

The manufacturer of a dietary supplement is responsible for ensuring the safety and effectiveness of the product before it is sold. The U.S. Food and Drug Administration (FDA) cannot require testing of dietary supplements prior to marketing. However, while manufacturers are prohibited from selling dangerous products, the FDA can remove a product from the marketplace if the product is dangerous to the health of Americans. Furthermore, if in the labeling or marketing of a dietary supplement a claim is made that the product can diagnose, treat, cure, or prevent disease, such as "cures cancer," the product is said to be an unapproved new drug and is, therefore, being sold illegally. Such claims must have scientific proof.

For CAM therapies that are administered by a practitioner, the training, skill, and experience of the practitioner affect safety. However, in spite of careful and skilled practice, all treatments--whether CAM or conventional--can have risks.

Efficacy of CAM Therapies

Statements that manufacturers and providers of CAM therapies may make about the effectiveness of a therapy and its other benefits can sound reasonable and promising. However, they may or may not be backed up by scientific evidence.

Before beginning a CAM treatment, it is a good idea for patients to ask the following questions:

1. Is there scientific evidence (not just personal stories) to back up the statements? Ask the manufacturer or the practitioner for scientific articles or the results of studies. They should be willing to share this information, if it exists.
2. Does the Federal Government have anything to report about the therapy?

Visit the FDA online at www.fda.gov to see if there is any information available about the product or practice. Information specifically about dietary supplements can be found on FDA's Center for Food Safety and Applied Nutrition Web site at www.cfsan.fda.gov. Or visit the FDA's Web page on recalls and safety alerts at www.fda.gov/opacom/7alerts.html.

Check with the Federal Trade Commission (FTC) at www.ftc.gov to see if there are any fraudulent claims or consumer alerts regarding the therapy. Visit the Diet, Health, and Fitness Consumer Information Web site at www.ftc.gov/bcp/menu-health.htm.

3. How does the provider or manufacturer describe the treatment? The FDA advises that certain types of language may sound impressive but actually disguise a lack of science. Be wary of terminology such as "innovation," "quick cure," "miracle cure," "exclusive product," "new discovery," or "magical discovery." Watch out for claims of a "secret formula." If a therapy were a cure for a disease, it would be widely reported and prescribed or recommended. Legitimate scientists want to share their knowledge so that their peers can review their data. Be suspicious of phrases like "suppressed by Government" or claims that the medical profession or research scientists have conspired to prevent a therapy from reaching the public. Finally, be wary of claims that something cures a wide range of unrelated diseases (for example, cancer, diabetes, and AIDS). No product can treat every disease and condition.

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POST-TEST

1. According to the National Health Interview Survey (NHIS), what percentage of Americans seek care from a licensed CAM practitioner?
 - A. 5
 - B. 12
 - C. 18
 - D. 23

2. Ayurveda is included in Which CAM category?
 - A. Alternative Medicine System
 - B. Mind Body Intervention
 - C. Biologically Based Therapy
 - D. Manipulative and Body Based Method

3. Traditional Chinese Medicine teaches that there are _____ main meridians in the human body.
 - A. 8
 - B. 12
 - C. 200
 - D. 2000

4. Which of the following is NOT one of the principles of Naturopathy?
 - A. The healing power of nature
 - B. Treatment of the whole person
 - C. The doctor as student
 - D. Prevention

5. The systematic diluting and vigorous shaking of a substance to extract its vital essence is known as _____.
 - A. extraction
 - B. potentization
 - C. minimalization
 - D. homeopathes

6. Research by Henry Beecher showed that up to 35% of a therapeutic response to any medical treatment could be as a result of
 - A. immunological suppression
 - B. hemolytic integration
 - C. neurological transference
 - D. placebo effect

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7. Which of the following is TRUE?
 - A. The FDA currently requires dietary supplements to follow defined good manufacturing practices.
 - B. Manufacturers of dietary supplements must ensure that their products are safe and effective.
 - C. Newly marketed dietary supplements are subject to FDA pre-market approval.
 - D. None of the above

8. Any substance that claims to diagnose, prevent, treat, or cure a disease is classified by the FDA as a
 - A. dietary supplement
 - B. drug
 - C. probiotic
 - D. functional food

9. Which of the following is NOT a putative energy practice?
 - A. Magnetism
 - B. Johrei
 - C. Qi Gong
 - D. Healing Touch

10. Which of the following is a manipulative body based practice that includes slight rocking and shaking of the patient's trunk and limbs in a rhythmic fashion?
 - A. Alexander Technique
 - B. Bowen Technique
 - C. Trager Bodywork
 - D. Tui Na