

STRATEGIC OBJECTIVE 3

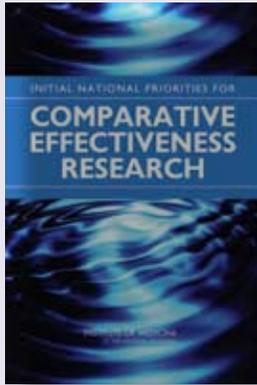
INCREASE UNDERSTANDING OF “REAL WORLD” PATTERNS AND OUTCOMES OF CAM USE AND ITS INTEGRATION INTO HEALTH CARE AND HEALTH PROMOTION

Two defining features of CAM in the United States are its widespread use by the public and a relative paucity of research evidence regarding efficacy or safety to guide decisionmaking about that use by individuals, health care providers, and health policymakers. Indeed, NCCAM was established in 1998 because Congress believed that a concerted research effort at the NIH was needed to address these gaps in scientific evidence and public information.

Research Opportunities and Needs

CAM's extensive use by both adults and children in the general population presents opportunities to use tools and methods of the disciplines of observational, survey, epidemiology, outcomes, health services, and effectiveness research to help address a number of information needs about CAM interventions, practices, and disciplines, including:

- The frequency and characteristics of CAM use
- How and why individuals and health care providers decide whether or not to use CAM approaches
- The benefits, risks, and cost-effectiveness of CAM use in the general population
- The potential role of CAM interventions, practices, or disciplines in supporting healthy lifestyles and well-being.



IOM* Priorities for Comparative Effectiveness Research Involving CAM Approaches

- Compare the effectiveness of mindfulness-based interventions (e.g., yoga, meditation, deep-breathing training) and usual care in treating anxiety and depression, pain, cardiovascular risk factors, and chronic diseases
- Compare the effectiveness of acupuncture for various indications using a cluster-randomized trial
- Compare the effectiveness of dietary supplements and usual care in the treatment of selected high-prevalence conditions
- Establish a prospective registry to compare the effectiveness of treatment strategies for low-back pain without neurological deficit or spinal deformity

*Institute of Medicine (part of the National Academies)

Information about these and related matters derived from rigorous population-based research has significant potential to help in (1) identifying and shaping research priorities and initiatives, (2) building evidence needed to advance research on specific promising interventions, practices, or disciplines, and (3) informing and shaping health care policy. With respect to health policy, it is noteworthy that 4 of the top 100 topics identified by the Institute of Medicine as priorities for comparative effectiveness research involve CAM approaches.

Strategies

Strategy 3.1: Support survey and epidemiological research to:

- Better understand patterns of adult and pediatric CAM use both at the national level and within specific demographic subpopulations
- Better understand decision-making processes of individuals and practitioners regarding CAM use
- Study the safety and risks of adult and pediatric CAM use
- Develop data needed to inform future research hypotheses or studies.

Since its inception NCCAM has supported a variety of epidemiological studies of CAM use. Most prominent have been the population-based NHIS surveys, carried out in 2002 and 2007, and many secondary analyses of the public-use data sets derived from them. This body of work has been extremely important in shaping understanding of CAM use at both the national level and within specific populations. That understanding has, in turn, been instrumental in shaping NCCAM's strategic thinking and research priorities. For example, NHIS data regarding CAM use have pointed toward the first two overarching goals of this strategic plan (better strategies for symptom management and better strategies for healthier lifestyles). And together with clinical trial data and evidence-based recommendations suggesting the potential usefulness of several specific CAM practices (spinal manipulation, acupuncture, and massage), NCCAM is targeting research on chronic back pain as a high priority for future investment.

Observational data are instrumental in identifying research priorities, informing the hypotheses and designs of intervention studies, and shaping public information activities.

Observational data inform both the hypotheses and the designs of specific CAM research projects. For example, they help justify the need for a particular study, establish feasibility and accrual potential, or permit evidence-based estimates of sample size.

Understanding the scope and nature of public use of CAM and the decision-making processes behind that use is critically important in shaping the communication and public information activities of NCCAM and other organizations. For example, they help define priorities across a spectrum of health conditions and CAM approaches. They also shape content so that it best addresses the questions and needs of the end users.



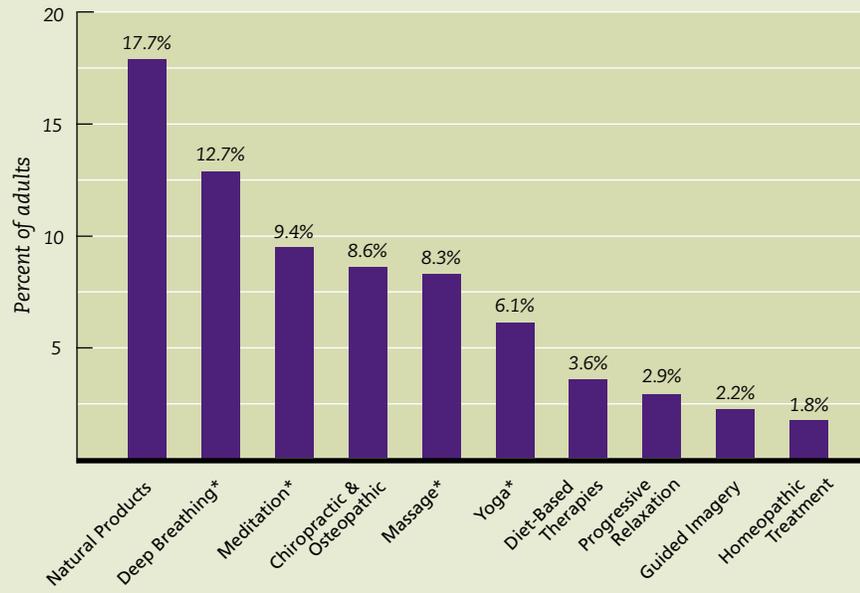
Specific Use of CAM in the United States, 2007

***Therapies with significant increases between 2002 and 2007**

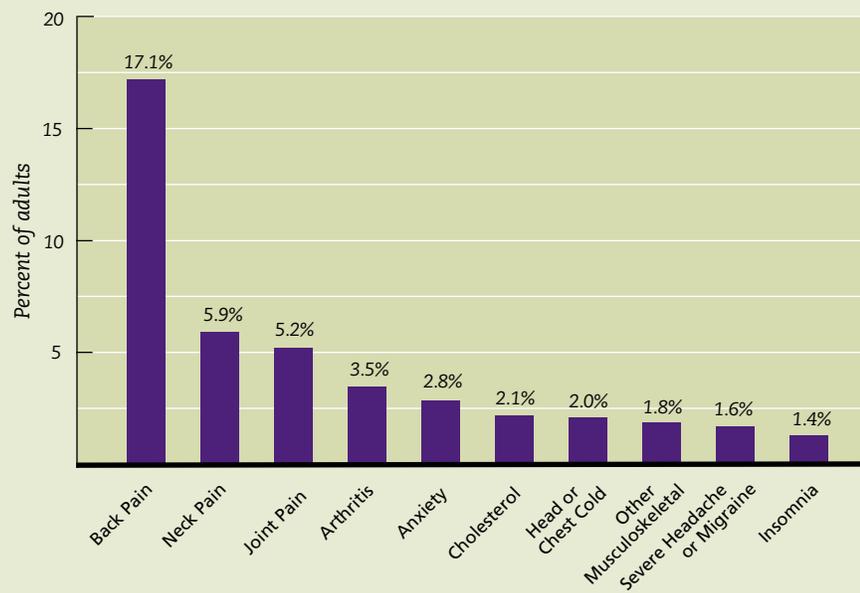
	2002	2007
Deep breathing	11.6%	12.7%
Meditation	7.6%	9.4%
Massage	5.0%	8.3%
Yoga	5.1%	6.1%

Source: Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Reports #12. *Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*. December 2008.

10 Most Common CAM Therapies Among Adults

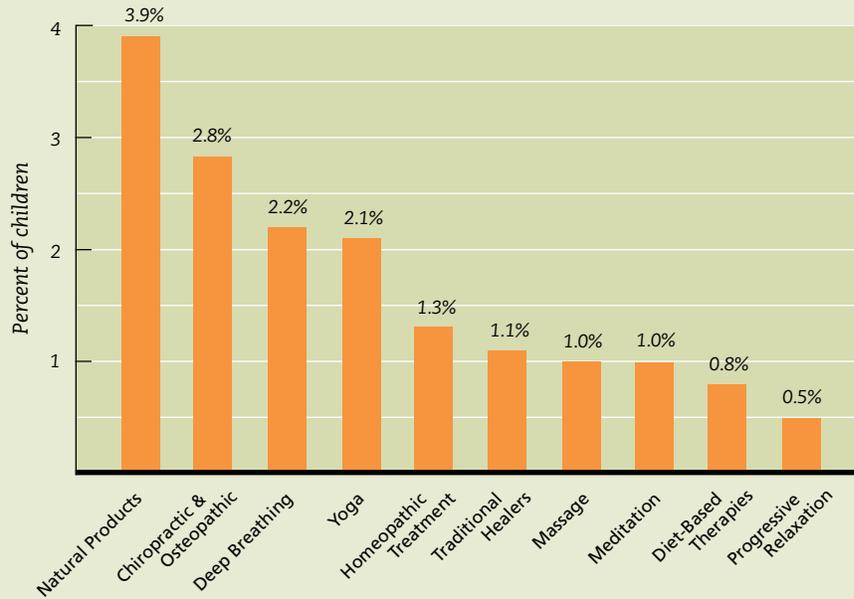


Diseases/Conditions for Which CAM Is Most Frequently Used Among Adults



Source: Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Reports #12. *Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*. December 2008.

10 Most Common CAM Therapies Among Children



Source: Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Reports #12. *Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*. December 2008.

Diseases/Conditions for Which CAM Is Most Frequently Used Among Children



Source: Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Reports #12. *Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*. December 2008.



Going forward, NCCAM will continue to build upon the body of both directed and investigator-initiated observational research that addresses the need for better understanding of (1) patterns of CAM use and the decision-making processes that drive this use and (2) the safety of CAM interventions, in both adults and children.

Strategy 3.2: Develop research examining the contributions of specific promising CAM approaches to better treatment and health promotion using the real-world methods and tools of the disciplines of observational, outcomes, health services, and effectiveness research.

It is important to seek out opportunities to take scientific advantage of the extensive use of CAM in the general population to help address the gaps in evidence that confront the public and health care providers. The disciplines of observational, outcomes, health services, and effectiveness research offer a number of tools, methods, and pragmatic study designs for gathering useful evidence regarding CAM interventions and disciplines on a larger scale than typical clinical trials.

For example, some specific CAM interventions or disciplines are covered by some health insurance providers and not covered by others. It should be possible to take scientific advantage of this natural experiment to develop insight into the safety, effectiveness, and cost-effectiveness of these approaches.

Health provider networks, practice-based clinical research networks, and integrative medicine practices provide important venues in which to develop real-world evidence across a broad array of outcome measures regarding the effects and effectiveness of CAM approaches and their integration into strategies for treatment and health promotion. Practice-based research provides an important setting in which to study the complex interplay of intervention, the patient-provider relationship, and other important contextual and environmental factors involved in health care and health promotion. Indeed, many CAM and integrative care practices actively seek to employ these factors. Population-based and practice-based research strategies also offer great potential for developing evidence regarding the effectiveness of CAM-related interventions in engaging individuals in health-promoting behaviors and practices (see strategy 3.3, below).

The methods and approaches of observational, outcomes, and effectiveness research also offer potential to address the concern that CAM research often fails to reflect practice in the real world. For example, studies are sometimes criticized because clinical trial protocols do not allow for the kind of individualization of treatment that a typical CAM practitioner might employ or because the experimental design focuses on a specific aspect of a multifaceted approach to care. Similar challenges confront other disciplines of health care research that employ individualized interventions or complicated and multifaceted systems of care. There is broad interest within the biomedical and behavioral research communities in applying effectiveness and outcomes approaches, including comparative effectiveness and pragmatic trial designs, to such questions. There is also broad interest in developing and validating better patient-oriented outcome measures for such research.

Pursuing these approaches in the context of CAM and integrative medicine practice will require collaboration with experts who confront similar challenges and opportunities in studying outcomes of procedures or multicomponent interventions introduced into and adapted in clinical practice (e.g., surgery, psychotherapy, and behavioral change). This research will also require creative leveraging of the capacities and resources of insurers and health care and clinical research networks.

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Strategy 3.3: Conduct research on the potential of CAM interventions, practices, or disciplines to support healthy lifestyle behaviors and behavior change.

Many CAM disciplines, systems of traditional medicine, and integrative medicine practices place a strong emphasis on preventive health strategies, including better dietary practices and regular physical exercise. In addition, CAM and integrative medicine practitioners often claim a high degree of success in supporting healthy behavior, using CAM-inclusive interventions and practices to facilitate behavior change and support sustained motivation.

Although limited in scope, an emerging body of interesting data suggests that users of CAM have a greater degree of health consciousness, in that they are more likely to engage in activities widely accepted as health promoting. For example, preliminary data suggest that CAM users are more likely to exercise regularly than non-CAM users. Other data suggest that individuals who see both CAM and conventional medical providers are more proactive about their health than are those who see only CAM or only conventional medicine providers.

These claims and preliminary findings are noteworthy because of the widely recognized need for better or more individualized strategies for promoting healthy behavior and positive health behavior change. They merit further investigation initially aimed at verifying this preliminary evidence and exploring the observed associations. If confirmed, translational research toward subsequent intervention trials testing evidence-based hypotheses would be warranted.

Going forward, NCCAM will work with its stakeholder communities to develop initiatives for research exploring these associations and, if appropriate, designing the methods and translational tools needed to develop this area of investigation further.

Can Yoga or Mindfulness Meditation Assist in Promoting Weight Loss and Healthier Eating Habits?

Obesity is epidemic: 65 percent of Americans are overweight or obese. Overeating often reflects dysregulation of physiological, emotional, and behavioral systems. Chronic stress responses may drive eating patterns that lead to obesity and appear to favor central fat deposition, which is closely linked to the metabolic syndrome and complications such as increased cholesterol, hypertension, and insulin resistance.

Most weight-loss programs focus heavily on diet, but do little to address the impact of stress on food intake and metabolism, and most individuals gradually return to former patterns of overeating. Recent research suggests that the addition of yoga or mindfulness meditation practices may be associated with greater psychological well-being, less disordered eating, greater weight loss, and improved metabolic function.

These preliminary results warrant further investigation into the short- and long-term effectiveness of meditative practices in enhancing weight-loss programs and maintaining healthier eating habits. An important element of this research direction is translational research to validate a panel of outcome measures and to define the frequency, duration, and other characteristics of the intervention. This work is needed to prepare for larger clinical trials and to facilitate comparison of the results of different studies.

