

## STRATEGIC OBJECTIVE 1

### ADVANCE RESEARCH ON MIND AND BODY INTERVENTIONS, PRACTICES, AND DISCIPLINES

The term CAM includes a large and diverse group of interventions, practices, and disciplines that are based in physical procedures or techniques administered or taught to others by a trained practitioner or teacher. They are used to improve health and well-being and in the treatment of illness or symptoms such as chronic pain or stress.

These interventions, practices, and disciplines are grouped together in this plan as mind and body\* approaches because, from a research perspective, they all share a set of characteristics that create similar challenges in designing rigorous and definitive clinical investigations of their benefit and safety. For example, (1) it is generally difficult or impossible to mask practitioners and/or participants

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\*Terminology: As used in this plan, *mind and body* encompasses interventions from the three domains of mind/body medicine, manipulative and body-based practices, and energy medicine.

#### Examples of CAM Mind and Body Interventions

- Acupuncture
- Breath practices
- Meditation
- Guided imagery
- Progressive relaxation
- Tai chi
- Yoga
- Spinal manipulation
- Massage therapy
- Feldenkrais method
- Alexander technique
- Pilates
- Hypnosis
- Trager psychophysical integration
- Reiki
- Healing touch
- Qi gong
- Craniosacral therapy
- Reflexology

## Specific and Nonspecific Outcomes

Many of the challenges of studying mind and body interventions are illustrated in the current state of research on acupuncture. Centuries of experience suggesting that acupuncture can be helpful in treating pain have stimulated considerable interest in scientific investigation of this ancient treatment, even though traditional teachings based on meridians and the flow of “qi” are difficult to reconcile with contemporary understanding of anatomy and neurophysiology.

The accumulated data from many clinical trials in a variety of pain conditions present a complicated picture. In efficacy-design trials where comparison has been made between “real” acupuncture and a “sham” treatment designed to be subjectively identical, differences have generally been small and not statistically significant. On the other hand, in effectiveness-design trials for a variety of conditions where acupuncture has been compared to standard care, acupuncture generally produces superior pain relief. For example, results from a series of large randomized trials supported by the German government comparing “real” and “sham” acupuncture show minimal differences in relief of pain from osteoarthritis and low-back pain. However, acupuncture plus standard care (following clinical practice guidelines) was found to yield a statistically significant and clinically meaningful superiority to standard care alone.

Thus, the current body of efficacy research provides little clinical evidence for specific effects of “real” acupuncture. At the same time the observation of substantial pain relief in effectiveness-design studies cannot be dismissed.

Research is warranted to better understand (1) the specific and the nonspecific effects involved and (2) whether either or both can be better and more intentionally employed to improve upon current strategies for treating pain. Finally, future clinical research on acupuncture must be carefully designed to ensure that controls are optimally suited for the research question being addressed.



## Research Challenges and Needs

Investigators studying mind and body interventions face a number of scientifically interesting and important challenges. Foremost among them is the need to carefully define the most important research questions to be addressed, to choose appropriate experimental controls and study designs to address these questions, and to determine and validate key study design features such as the optimal frequency or duration of the intervention to be studied and measures of effect and outcome.

## Understanding the Engagement of Major Pathways of Emotion Regulation by Meditative Practices



Clinical and laboratory studies of mindfulness meditation are yielding a growing body of evidence that meditation affects the mind, the brain, the body, and behavior in ways that have potential to treat many health problems and to promote healthy behavior.

For example, recent research suggests that systematic mindfulness training and other meditation practices influence areas of the brain involved in regulating awareness, attention, and emotion. Brain-imaging studies suggest that more mindful people may be better able to regulate emotional reactions or have improved self-awareness. Other research suggests that mindfulness training is associated with changes in the physical structure of the brain. Several studies suggest that meditative practices can positively affect immune function. Many of the beneficial physical effects of mindfulness training could be attributable to learning how to cope better with stress.

Ongoing NIH-supported research is investigating the use of mindfulness training in treating specific pain conditions, overeating and obesity, irritable bowel syndrome, insomnia, myocardial ischemia, and substance abuse. Mindfulness meditation is also being explored as a means of facilitating and sustaining healthy behavior change, such as smoking cessation and healthier eating habits.

- **Build a solid biological foundation for translational research needed to carry out clinical studies.**

Developing insight into biological and physiological effects and mechanisms of action of mind and body interventions is critically important in developing translational research tools and designing and executing maximally informative clinical research. It also is a crucial component of the scientific evidence base guiding clinical practice and public use and has significant potential to inform other fields of biomedical research.

## **Strategy 1.2: Support translational research to build a solid biological foundation for studies of efficacy or effectiveness of mind and body interventions or disciplines.**

Rigorous study of all clinical interventions requires well-established methodology that has undergone careful preliminary assessment and feasibility testing. Large clinical studies are an essential component of the evidence base regarding clinical efficacy or effectiveness. To implement such studies, treatment algorithms must be developed and validated and feasibility of accrual must be established. Methods need to be in place to measure consistency and fidelity of protocol implementation, control for practitioner variability, and monitor adherence of participants. In addition, well-characterized and meaningful clinical and laboratory outcome measures are needed to accurately assess the scope and magnitude of effects or to definitively discern a lack thereof.

Investing in development of good translational tools is essential. This investment will increase the quality and quantity of evidence garnered from large-scale clinical research, and it will help ensure that clear conclusions can be drawn from the outcomes observed. It will also augment abilities to compare results across different studies, which is essential in building a clinically useful evidence base.

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### **Mind and Body Translational Research Needs: Selected Examples**

- Developing and validating methods to assess and document interactions between providers and patients/clients so consistency can be measured or interventions reproducibly applied to other populations
- Developing and validating better objective outcome measures relevant to particular CAM interventions
- Developing and validating better measures of subjective outcomes
- Studying nonspecific contextual factors important in the interaction between CAM professionals and their patients or clients
- Defining the optimal frequency or duration of a particular CAM intervention for study in subsequent, more definitive clinical trials
- Assessing feasibility and accrual potential—e.g., implementing a particular treatment algorithm; determining the ability to recruit sufficient participants

## Better Strategies for Managing Back Pain

By any measure, low-back pain is a huge public health problem. It affects approximately 25 percent of adults. While acute back pain usually resolves completely within weeks, pain becomes a chronic problem in 10 to 15 percent of cases. Costs associated with back and neck pain account for a large proportion of, and are increasing more rapidly than, overall health care expenditures.

Individuals searching for relief from chronic back pain pursue many treatment options, including opioids, injections, surgery, physical therapy, spinal manipulation, yoga, exercise therapy, acupuncture, massage, and cognitive-behavioral therapy. Often patients try different approaches, sometimes in consultation with a provider and sometimes on their own, as they search for helpful strategies. Chronic back pain is, by far, the most frequent health problem for which Americans turn to CAM. While data suggest that some interventions, both conventional and CAM, help some individuals, there is broad agreement among health care providers that none are fully satisfactory.

There is an emerging consensus that developing improved strategies for managing chronic back pain will require fresh thinking informed by:

- A better understanding of natural history and prognostic factors
- Improved diagnostic criteria and tools
- Application of state-of-the-art technologies to better elucidate biomechanics, central nervous system responses, emotional and cognitive influences, behavior, and genetics
- Pragmatic trials and outcomes research.

