

National Center for Complementary and Alternative Medicine

U.S. Department of Health and Human Services
Interagency Autism Coordinating Committee

May 4, 2009



Topics

- NCCAM's history and mission
- Data on CAM use in America
- Achievements of ten years of NCCAM research – and lessons learned
 - in mind body research
 - in natural product research
- Challenges of CAM research
- N of one trials



Legislative language

“The general purposes of the National Center for Complementary and Alternative Medicine (NCCAM) are the conduct and support of basic and applied research...research training, and other programs with respect to identifying, investigating, and validating complementary and alternative treatment, diagnostic, and prevention modalities, disciplines and systems.”

P.L. 105-277

October 1998

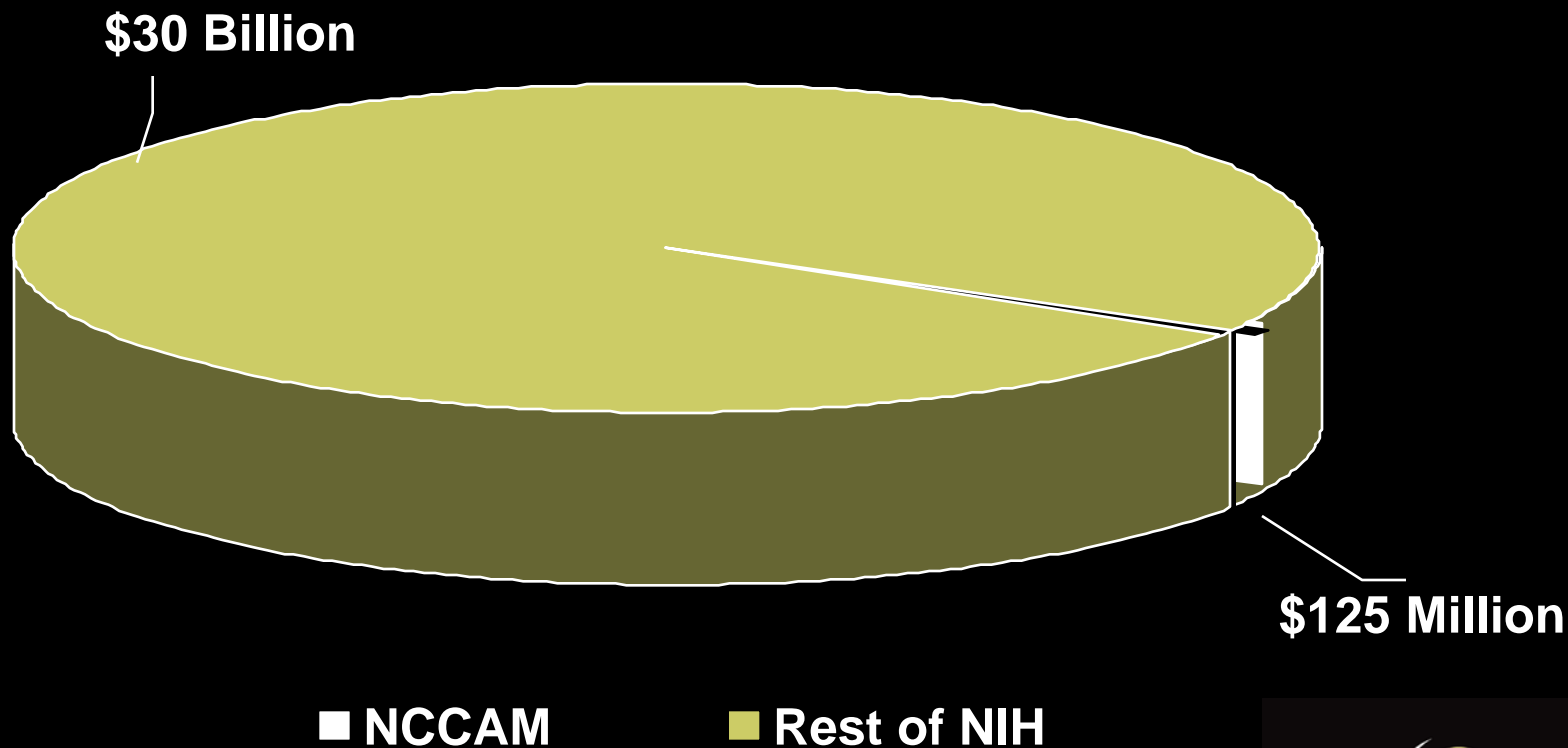


NCCAM: Mission

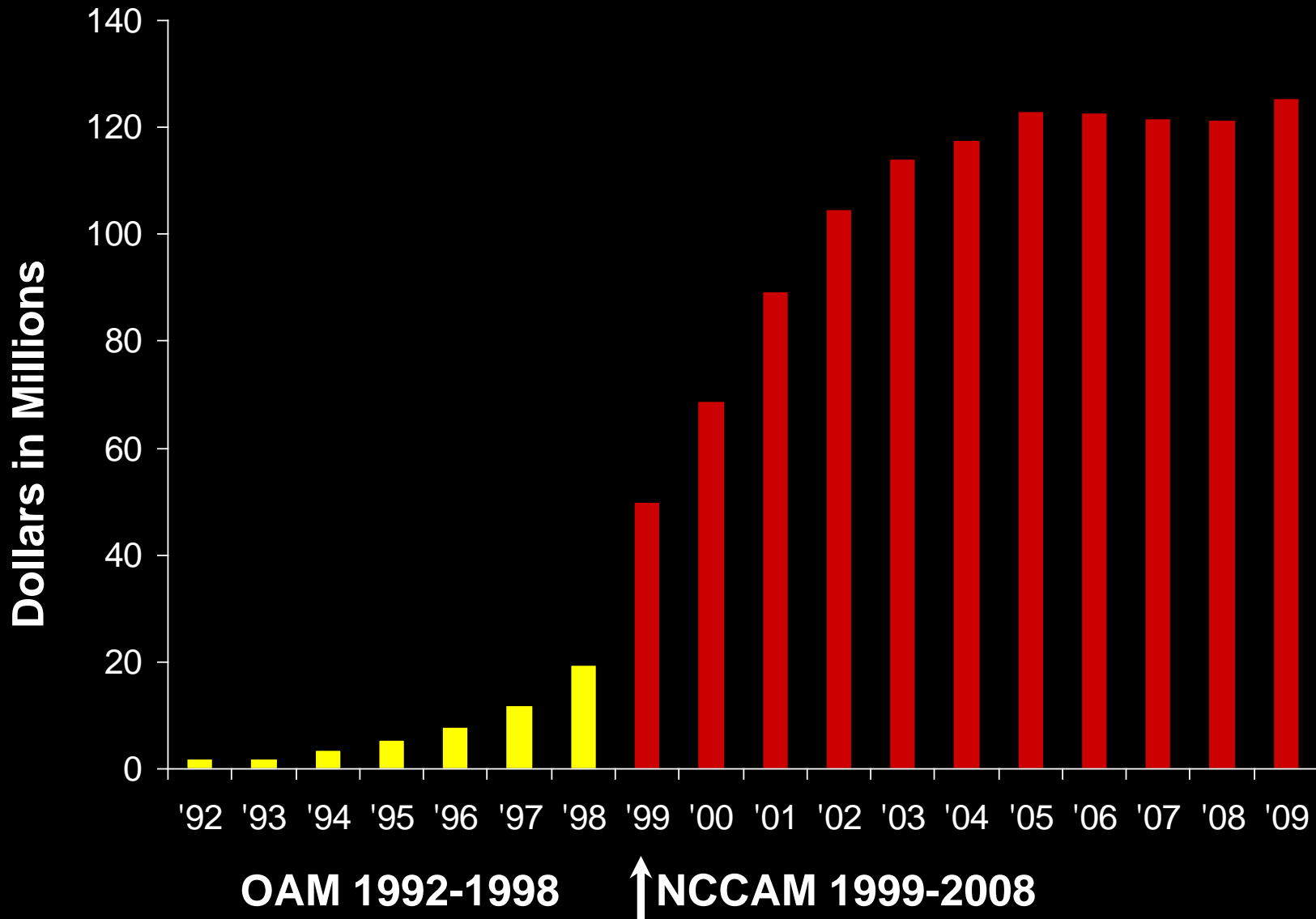
- Explore complementary and alternative healing practices *using rigorous scientific methods* and develop the evidence for safety and efficacy of CAM approaches
- Support the development of the next generation of CAM researchers
- Disseminate authoritative information to the public and professionals



NCCAM's Budget: 0.4% of the NIH Total



NCCAM's Appropriations History



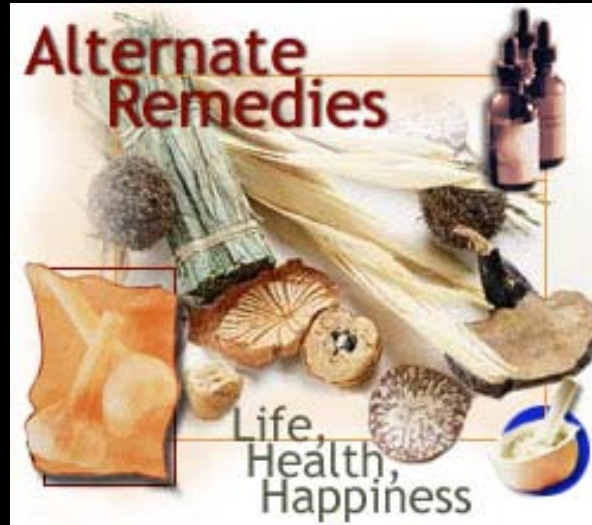
NCCAM is a TEAM PLAYER

Examples

- Ginkgo Evaluation of Memory Study (GEMS) – NCCAM, NIA, NINDS, NHLBI, NIH ODS
- Glucosamine/chondroitin Arthritis Intervention Trial (GAIT) – NCCAM, NIAMS
- St. John's Wort for Major Depression of Moderate Severity – NCCAM, NIMH, NIH ODS
- National Health Interview Survey – NCCAM and CDC
- Systematic evidence-based reviews – NCCAM and AHRQ



NHIS CAM Modules: 2002 and 2007



- 2007 Survey: 36 different CAM therapies for 81 different diseases/conditions
- Sample of 23,000 adults



NHIS CAM Module



The 2007 NHIS collected CAM information on a subset of 23,393 adults and 9,417 children

This sample is representative of the civilian, non-institutionalized U.S. population

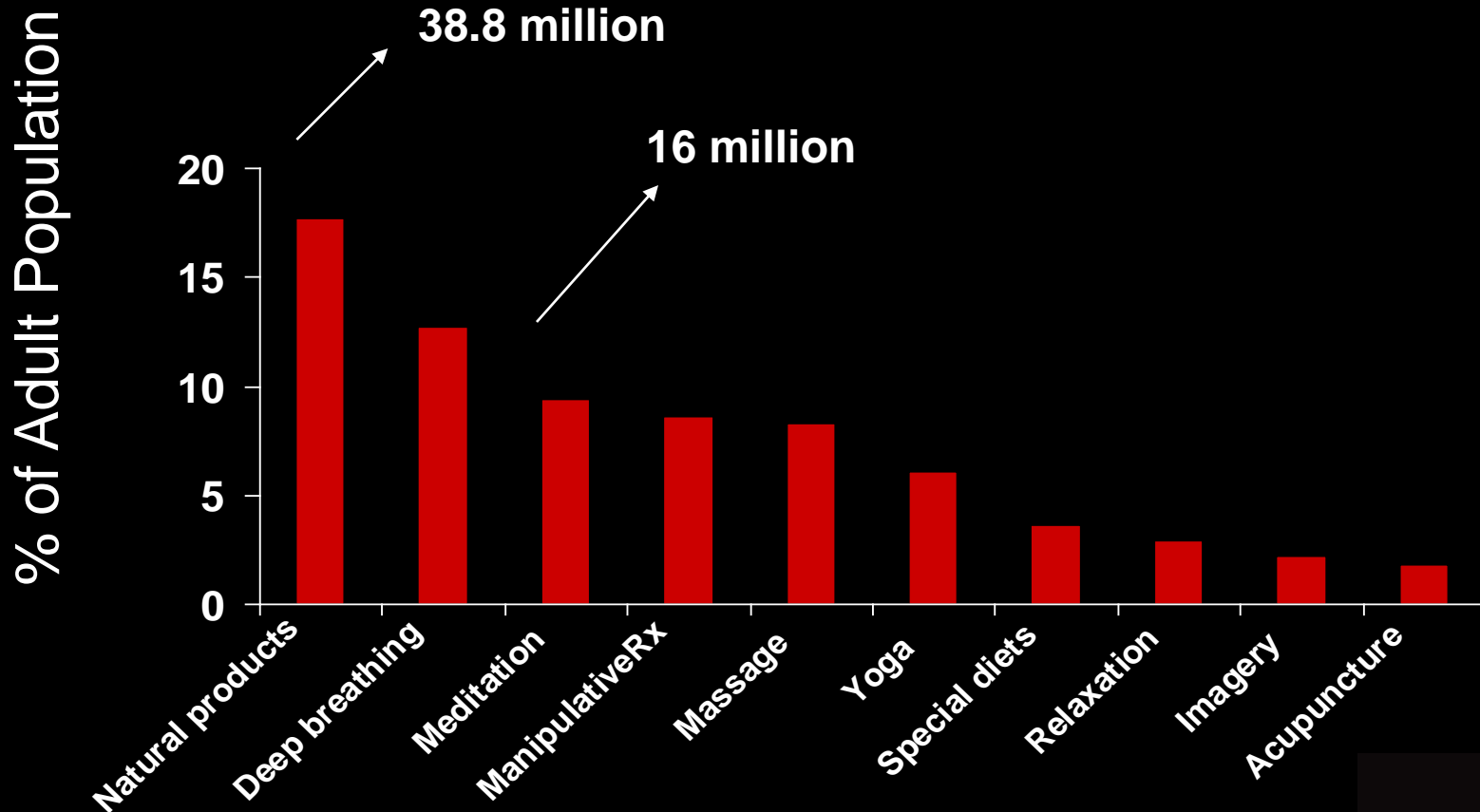


NHIS CAM Module Survey: Demographics of CAM Use, 2007

- Approx 40% of American public use CAM, consistent with earlier surveys
- 1 in 9 U.S. children use CAM
- Widespread in all demographic groups
- Women > men
- West > Midwest > Northeast > South
- Greater use in people with higher education levels



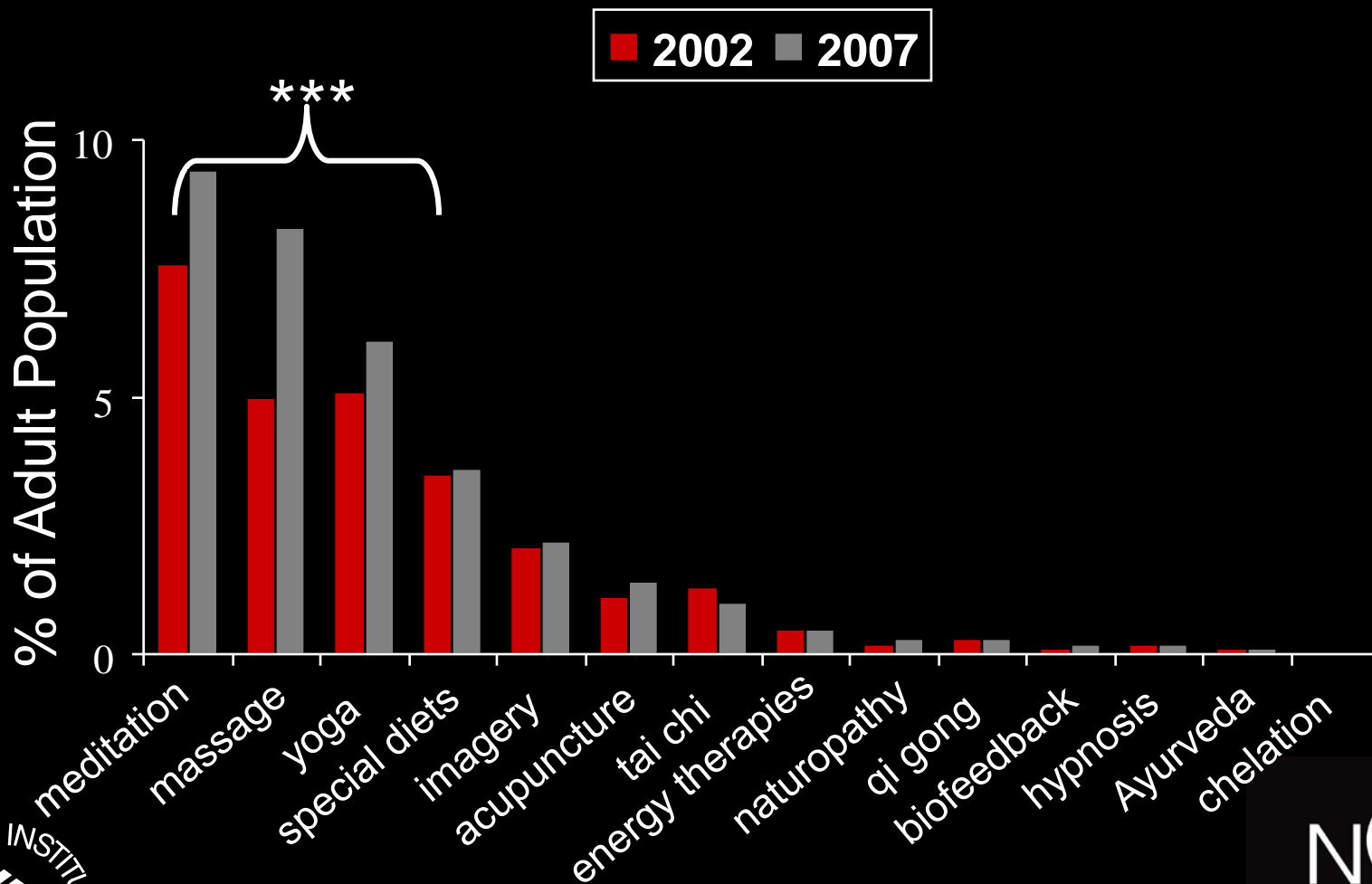
Adult Use of Selected CAM Therapies: United States, 2007



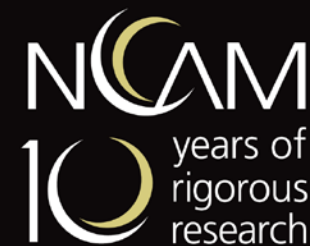
Barnes et al., 2008



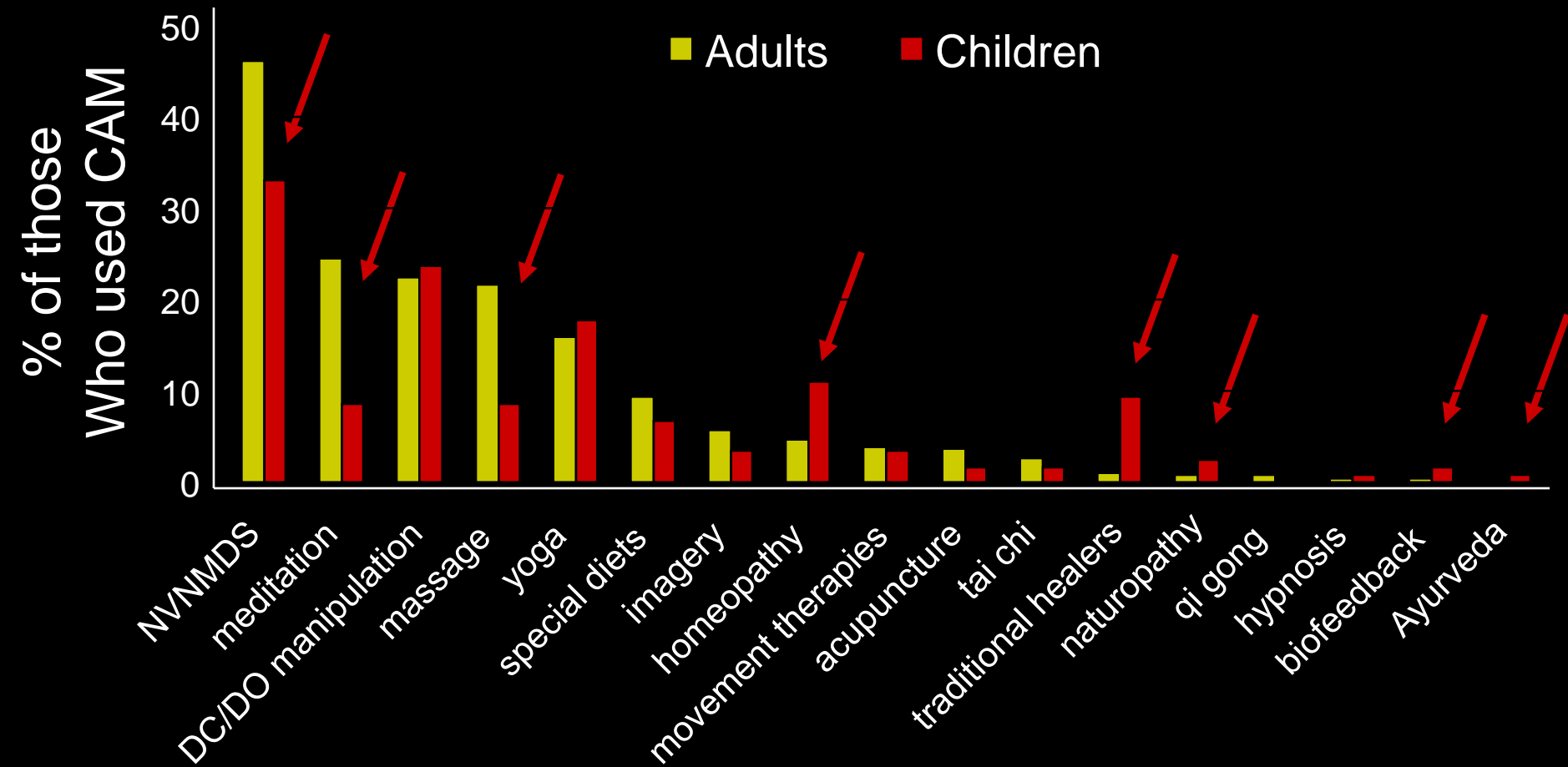
Adult Use of Selected CAM Therapies: 2002 vs. 2007



Barnes et al. 2004, 2008



Use of Selected CAM Therapies: Adults vs. Children



Barnes et al., 2008

Why do people turn to complementary or alternative medicine?

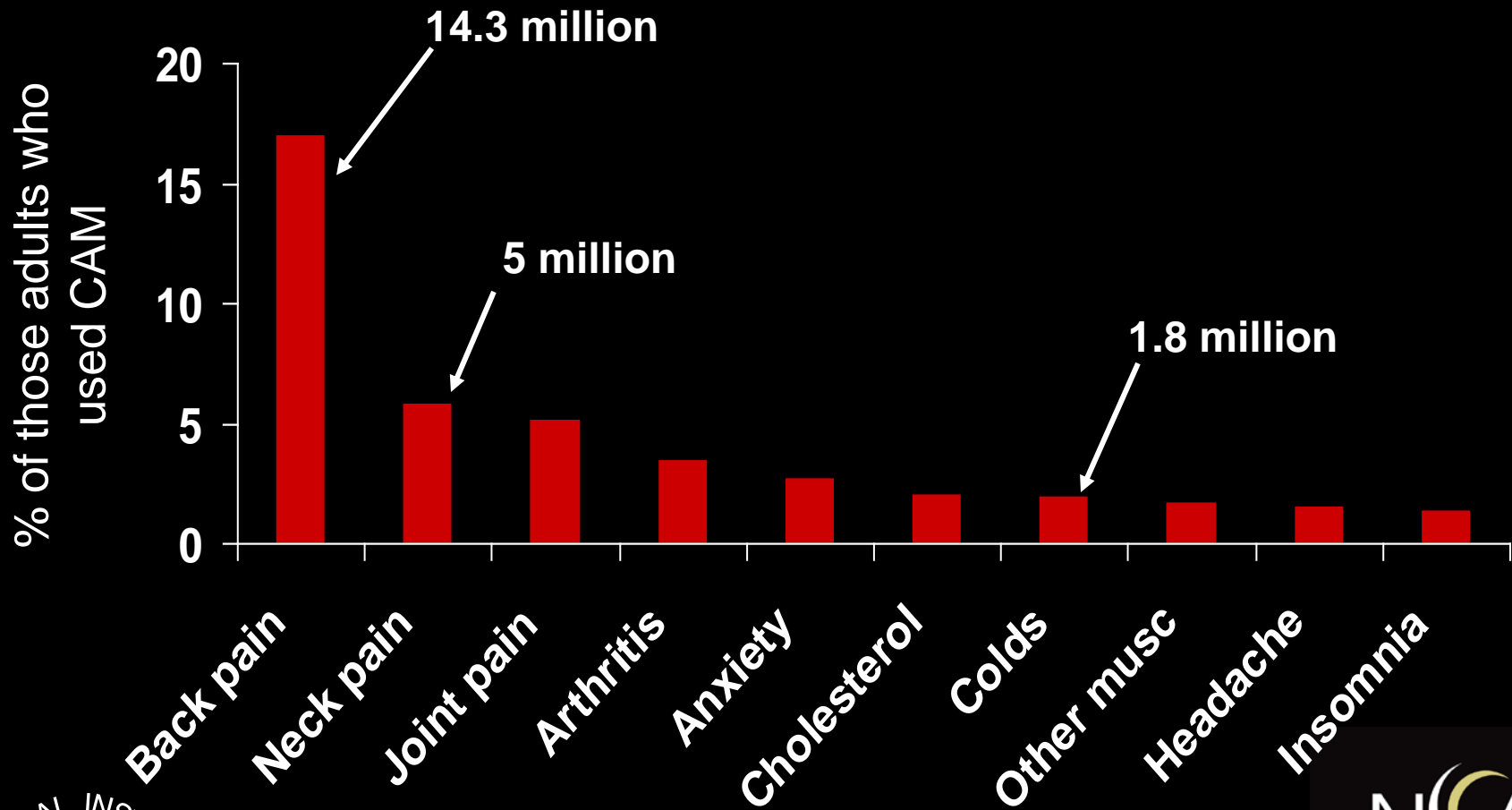
To promote health and wellness

To treat specific health conditions and symptoms

(Mostly as an adjunct to conventional care)



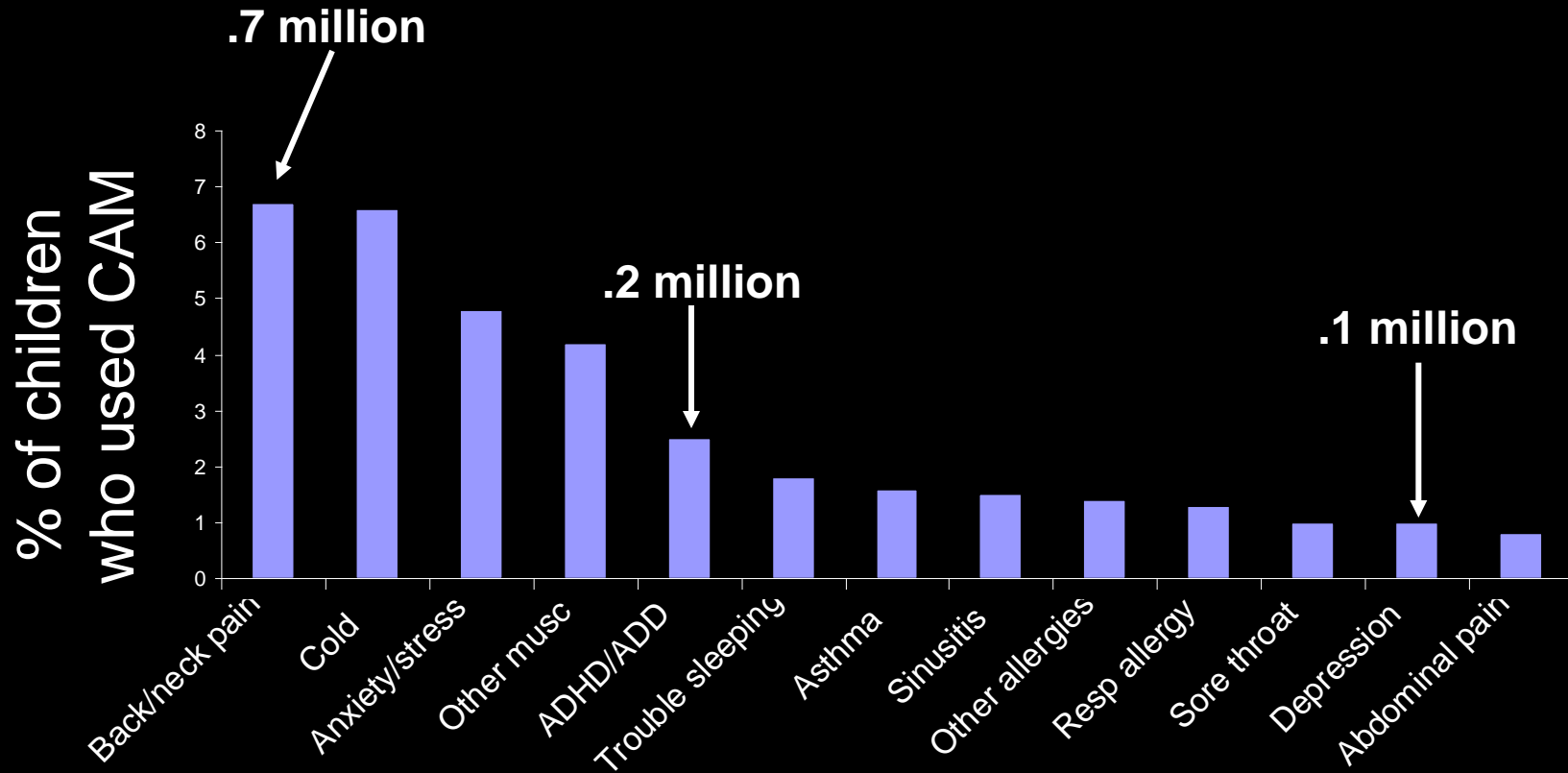
Adult Use of CAM for Selected Health Conditions



Barnes et al., 2008



Children's Use of CAM for Selected Diseases

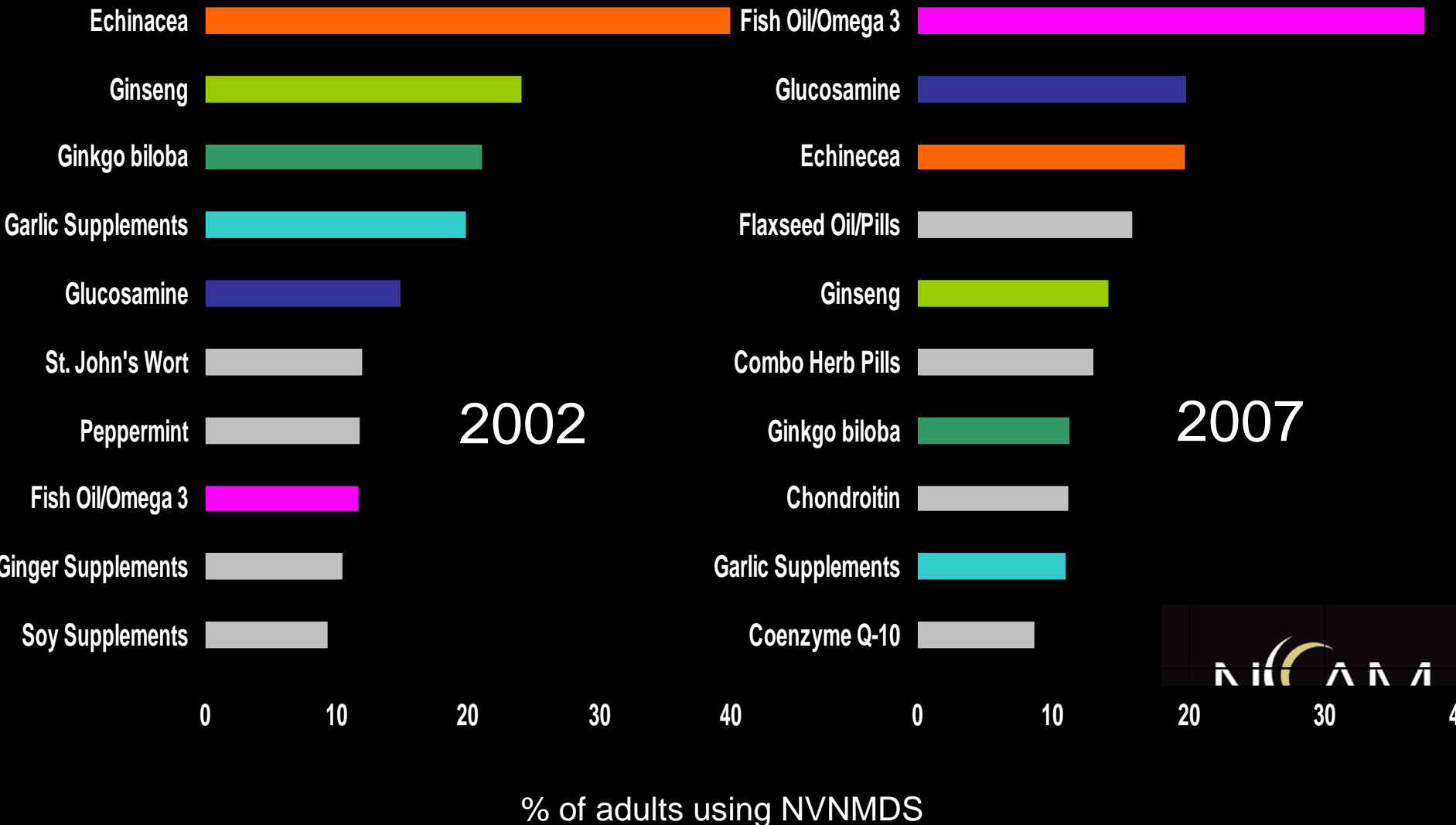


Barnes et al., 2008



Top Herbal Medicines and Other NVNMDS:

NVNMDS = non-vitamin/non-mineral dietary supplements



What do the numbers tell us?

- Complementary and alternative health practices, especially natural products, meditation, massage, manipulative therapies, and yoga are widely used by the American public, including children
- Chronic pain, especially back pain, is the most common reason
- Media coverage and public interest is strong
- NIH Research influences the public



NCCAM: Our Research Expertise

Studying Real World Health Practices

CHALLENGES

- Need to partner with disease experts
- Need careful product characterization
- Need strong preliminary data



Preliminary data needed for major RCT's of CAM interventions:

- Strong biological hypothesis
- Well described intervention
- 'Proof of concept' preliminary clinical data
- Good chemistry of any natural products (ADME) and marker(s) to verify biological effect *in vivo*
- Maximally sensitive outcome measures and trial design



NCCAM: The CAM Research Paradigm

How does
it work?

Do we have the
tools to study it
in people?

What are the
specific effects?

Is it better
treatment?

*Basic
Science*

*Translational
Research*

*Efficacy
Studies*

*Effectiveness
Research*



Cheat death.

The antioxidant power of
pomegranate juice:



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NCCAM Research: Areas of promise in mind and body CAM approaches

- Benefits of mindfulness meditation for stress reduction and quality of life - for examples for Alzheimer care givers
- Benefits of yoga and Tai chi for balance and avoiding falls in elderly people
- Insight into of central mechanisms of reassurance and expectancy
- Contribution of acupuncture and other mind and body practices to pain management



NCCAM: Achievements in natural product research

- Implementation, in partnership with other IC's, of 6 major high-quality RCTs of widely used natural products
- Rigorous processes to assess quality and consistency of herbal and other natural products used in NCCAM research
(PIWG: Product Integrity Working Group)



Autism Spectrum Disorders: CAM for Symptom Management

- Numerous provider and parent reports suggest that certain CAM practices show promise to contribute to symptom management
- Limited scientific evidence
- Children's safety paramount



NCCAM: Expertise in studying untested therapies already in use by the public

- CAM research, as a scientific discipline, has advanced dramatically in the last ten years
- NCCAM has established a CAM research enterprise at the Nation's premier biomedical research institutions
- Partnerships with CAM practitioners are critical to our efforts
- NCCAM has special expertise in applying rigorous scientific inquiry to health and wellness promotion practices already in use
- Experience has taught us that the evidence base for a particular therapy's use must be developed incrementally



First Steps: The road from anecdote to proven efficacy

“The plural of anecdote is not evidence.” S. Straus

- Therapies are in current use without scientific proof of safety, efficacy, or effectiveness
- How do we find out if they work?
 - Investigator-initiated research
 - Collaborations with NIH Institutes and Centers and other Federal agencies with specific expertise



Study of Omega-3 Fatty Acids for Children with Autism Spectrum Disorders

- Double-blind, placebo-controlled, RCT
- Comparing omega-3 fatty acids with placebo to assess effects on
 - Aggression and irritability
 - Functional ability



Credit: NLM MedlinePlus

PI: Sherie Novotny, M.D.
Robert Wood Johnson Medical School



n-of-1 Trials

- Randomized, double-blind, placebo-controlled crossover comparison trials in a single patient
- Patient-centered approach to testing therapeutic efficacy for symptom management
- Useful in patients with chronic diseases or conditions to test short term effects



n-of-1 Controlled Trials

- What are they?
- How are they designed?
- Could they be useful in determining the role of CAM in the management of symptoms associated with Autism Spectrum Disorders?



n-of-1 Trials: Role in testing CAM therapies for Autism Spectrum Disorders?

- Develops “proof of concept” data required before larger-scale studies are conducted
- Helps determine if, when (e.g., response variations), and how a therapy might be used effectively for symptom management
- Encourages provider, parent, patient partnerships



CAM and Autism

- Complementary and alternative health approaches have substantial promise to contribute to practical management of symptoms and burden of ASD on patients and their families
- NCCAM welcomes opportunity to partner in trans-NIH Autism Coordinating Committee



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1.888.644.6226
nccam.nih.gov

