

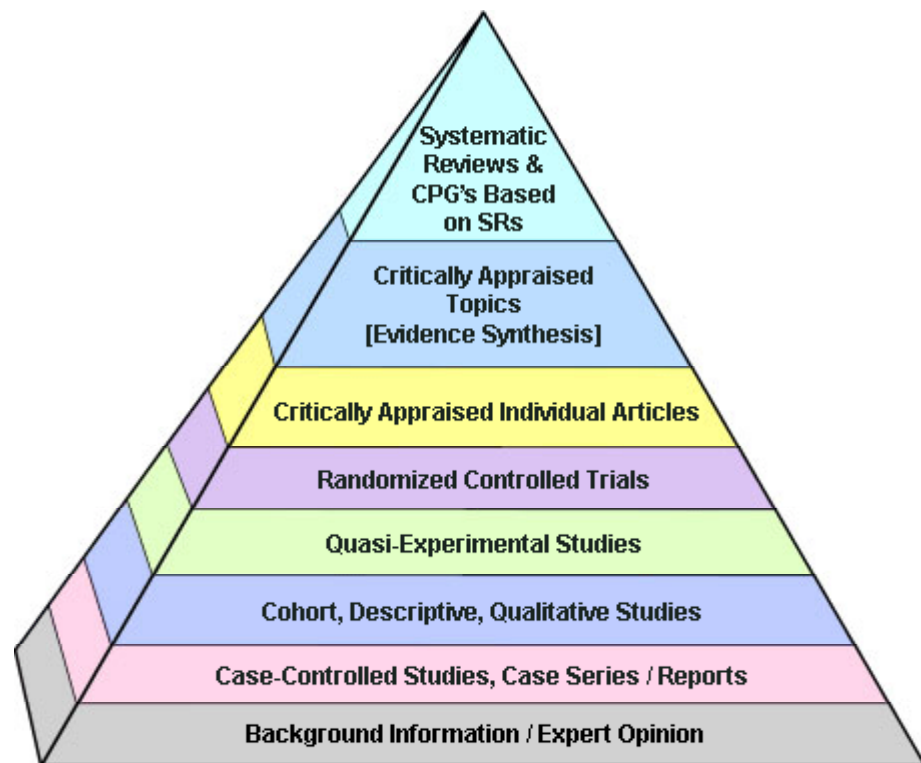
Quick Reference Guide: Sound Research, and Challenges thereof, in CAM

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Evidence-based medicine (EBM) requires the integration of the best research evidence with clinical expertise and understanding of a patient's unique values and circumstances.¹ The best research evidence is synonymous with the gold standard for sound scientific research, and constitutes well-designed, reproducible, double-blind, randomized control trials (RCTs). Applying this standard to complementary and alternative medicine (CAM) research is the ideal case. Few would refute significant results that have been independently reproduced under such conditions. Because CAM addresses the whole person versus the typical reductionist approach by conventional medicine, well-designed CAM studies require comparatively more time, effort and cost to set-up and measure outcomes. The budget set aside for CAM research by the National Institutes of Health (NIH) has been criticized, however, because while strict research guidelines have been adhered to, the CAM therapies studied thus far have shown little or no promising effects compared to placebo.² Face-value criticisms aside, this poor track record is likely due to under-funding issues for CAM, described in more detail under

"Some challenges to consider with CAM Research".

The pyramid to the right visually represents the strength of evidence in research. Lowest tier being background information/expert opinion, highest tier being systematic reviews & Clinical Practice Guidelines (CPG), such as Cochrane reviews - a key resource in EBM consisting of a database of systematic reviews and meta-analyses which summarize and interpret the results of medical research. Currently, the evidence-base for many CAM therapies is anecdotal, and ranges between the "Case-Reports" tier to even below the expert opinion tier. In order for effective CAM therapies to be demonstrated as such, and accepted by a wide-spread population, much research needs to be done. The following sections highlight important considerations for CAM research, as well as some challenges.



<http://library.upstate.edu/evidence/pyramid/#systematic>

¹ Straus, et.al., *Evidence-Based Medicine: How to Practice and Teach EBM*, 3rd ed., Elsevier 2005

² Brown, David, Critics Object to 'Pseudoscience' Center, Washington Post, May 17, 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/03/16/AR2009031602139.html>

Considerations for Sound Research

Peer-reviewed Journals: When gathering information in the field of study/interest, and when considering where to publish research, peer-reviewed journals are indispensable. Top tier, peer-reviewed medical Journals include *Journal of the American Medical Association (JAMA)*, *The New England Journal of Medicine (NEJM)*, and *The Lancet*. Also, journals that endorse the CONSORT - Consolidated Standards of Reporting Trials (see <http://www.consort-statement.org/about-consort/consort-endorsement/consort-endorsers---journals/>) - abide by peer-review requirements.

The CONSORT Statement: The CONSORT statement is a minimum set of recommendations for reporting randomized trials. The statement adheres to evidence-based research, and consists of a 25-item checklist and a participant flow diagram. The checklist guides the researcher on reporting how the trial was designed, analyzed, and interpreted; the flow diagram allows the progress of all participants to be thoroughly tracked throughout the trial. For a copy of the check-list and flow-diagram, visit <http://www.consort-statement.org>.

Well-Designed Study: A well-designed study includes a statistically significant population of targeted, eligible subjects, thoroughly considers the best way to devise (a) control or sham treatment(s), and carefully considers how blinding will occur. The anticipation and planning for any possible caveats or criticisms is critical, and the researcher must diligently work to at least minimize, or preferably eradicate, any potential doubts about the experimental design.

Reproducibility: Indicates the capacity for the study to be wholly replicated by an independent, qualified researcher.

Double-Blind: Indicates that neither the researcher nor the subjects know who is receiving the control/sham treatment(s) and who is receiving the test treatment, minimizing confounding factors such as the *reinterpretation effect* and *observer bias*, thereby allowing the *placebo effect* to be accurately distinguished and compared to the test treatmentⁱ.

Randomized Control Trial: Indicates subjects have been randomly assigned to receive control/sham treatment(s) or the test treatment, minimizing allocation bias, which could otherwise lead to design artifacts.

Some challenges to consider with CAM Research

Funding: Designing and executing sound studies requires large sums of money. The CAM portion (budget published by NCCAM & OCCAM)ⁱⁱ is less than 1% of the total NIH 2011 \$31 billion research budget. At about \$250 million for CAM research, this pales in comparison to the billions of dollars that go into commercial pharmaceutical development and research each year. Insufficient funding in the area of CAM detracts from the number of bright, qualified researchers that might otherwise consider doing research in CAM. Furthermore, the success rate for cancer drugs for example, with billions of dollars going into research each year, is about 0.1%. Assuming the success rate to be similar for CAM, these limited dollars mean the discovery and acceptance of evidence-based CAM treatments will likely be particularly slow, unless we discover a sound, economical way to distinguish CAM treatments that are worthy of undergoing rigorous research studies, and/or if more money is set aside for CAM research.

Amorphous Nature: Many CAM therapies cannot easily be "put into a box", and thereby present an increased level of difficulty when applying the gold standard of sound research. In most cases, CAM therapies do not take a reductionist approach as conventional medicine does. The consideration of the whole person involves many more confounding and multivariable factors. These additional factors lead to larger, more complex studies, meaning more money is needed to create a well-designed study.

Lack of Current Scientific Basis: Many CAM therapies lack plausible scientific mechanisms. While this does not exclude these therapies from being shown effective empirically, it makes it more difficult to justify funding versus a therapy for which a plausible, hard scientific hypothesis exists.

Lack of Well-Designed Studies: Few well-designed studies exist for CAM therapies; evidence is mostly based on anecdotes – often addressing different conditions via one specific type of therapy. Because anecdotal information does not account for the reinterperation effect, observer bias, or the placebo effect (among other possible confounding factors), it falls on a low tier of the evidence pyramid. It is difficult to justify spending large sums of money on rigorous studies for a therapy based only on anecdotes and get results that are no better than placebo.

In conclusion, while many difficult challenges are faced in CAM research, the goal of getting effective CAM therapies to the top of the evidence pyramid is not insurmountable. According to the Center of Disease Control and Prevention, chronic illness accounts for seventy-percent of all deaths in the United States. Truly, in the area of chronic illness, conventional medicine falls short. As a result of this short-coming, forty-percent of Americans have turned to CAM. Just because a particular CAM therapy has not undergone the rigors of sound research does not mean it is ineffective. Any CAM therapy considered, of course, must be demonstrated to do no harm, and ideally should be openly discussed with a physician. Fortunately, more and more conventional practitioners are now eager and willing to listen to the alternative choices patients are making to manage and treat illnesses. Also, more CAM practitioners are interested in quality research so more patients can be helped by their therapies.

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- *Reinterperation Effect:* The tendency of a subject to reinterpret his/her symptoms as less severe due to a perceived treatment.
- *Observer Bias:* The tendency of the researcher to erroneously observe improvements, due to a perceived treatment.
- *Placebo Effect:* Improvement of subjects due to perceived treatment.

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- NCCAM = National Center for Complementary and Alternative Medicine
- OCCAM = Office of Cancer Complementary and Alternative Medicine