

WHAT ABOUT THE EVIDENCE FOR FUNCTIONAL MEDICINE?

For many years, the conventional medical establishment has promoted a narrow view of clinical research—that without randomized, double-blind, placebo-controlled (RDBPC) clinical trials we cannot know what works. Such trials do indeed tell us which agents *among those measured* have the most overall success across many patients. But the more accurate statement would be that without RDBPC trials we cannot know whether agent X has a greater impact than agent Y *on the particular populations studied*. The data are grouped, analyzed, and interpreted with this goal in mind.

RDBPC studies play a significant role in evaluating and comparing efficacy of new pharmaceutical treatments, especially when it is important to rule out placebo effects, but they have many inherent limitations which constrain their ability to inform medical decision making.^{i,ii}

- The subjects in clinical trials are usually screened to exclude patients with multiple conditions. That means research subjects rarely resemble the patients actually treated in physicians' offices.
- The decision about which interventions to study is extremely biased: 70% of U.S. research dollars is provided by pharmaceutical companies.ⁱⁱⁱ That means that many potentially effective approaches are never formally studied and those that are published are frequently shown later on to have faulty and even biased findings.^{iv,v}
- Therapies that do not involve drugs but that do involve multiple individualized interventions (e.g., diet and exercise) do not fit the RDBPC research model.^{vi,vii,viii}
- Most important, what such trials do NOT tell us is how to create an individualized, patient-centered therapeutic plan that will work for a person with a unique combination of existing conditions, genetic influences, environmental exposures, and lifestyle choices.^{ix}

When people ask to see “the evidence for Functional Medicine,” they often mean, “Where are your RDBPC trials, comparing Functional Medicine to conventional medicine in a clinical setting?” We’d like to see those also; for many of the reasons summarized above, they do not exist. To advance the goal of collecting useful data in clinical settings on real patients (not carefully selected research subjects without co-morbidities), IFM has begun developing pilot projects in collaboration with institutions that provide care to patients. At the same time, we are exploring research models that can address individualized, multifaceted, whole-systems care.^{x,xi} And we are working with leaders in academic medicine to help transform medical education so that doctors of the future will have Functional Medicine skills. Does that mean there is not yet any evidence for Functional Medicine? Not at all. There is a vast array of evidence to consider:

- Understanding the causes of disease requires extensive knowledge about the physiology and biochemistry of the human body. The scientific community has made incredible strides in helping practitioners understand not only the most basic of biological functions (assimilation, defense and repair, energy production, biotransformation and elimination,

communication, transport, and structural integrity) but also how environment and lifestyle influences, moving continuously through an individual's genetic heritage, psychosocial experiences, and personal beliefs, can impair those functions. Using that knowledge to find the sources of each patient's problems is powerful science!

- Scientific support for the Functional Medicine approach to treatment can be found in a large and rapidly expanding evidence base about the therapeutic effects of **nutrition** (including both dietary choices and the clinical use of vitamins, minerals, and other nutrients such as fish oils)^{xii,xiii,xiv}; **botanicals**^{xv,xvi,xvii}; **exercise**^{xviii} (aerobics, strength training, flexibility); **stress management**^{xix}; **detoxification**^{xx,xxi,xxii}; **acupuncture**^{xxiii,xxiv,xxv}; **manual medicine** (massage, manipulation)^{xxvi,xxvii,xxviii}; and **mind/body techniques**^{xxix,xxx,xxxi} such as meditation, guided imagery, and biofeedback.

IFM invests considerable resources in reviewing, analyzing, and presenting the scientific foundation of Functional Medicine to health practitioners. Our landmark publication, *The Textbook of Functional Medicine*, explores the evidence underlying biochemical individuality, the web-like interactivity of physiological factors, the influences on healthy aging, the effects of genetics, environment, and lifestyle on individual health, and the common dysfunctions that, if left untended, drive us toward disease. It is extensively researched (thousands of citations) and carefully explains how this evidence can be applied to clinical practice. IFM also ensures that all curriculum presented at our continuing medical education activities includes the most recent and relevant research regarding the topics discussed.

Making healthcare choices—and making sure they are effective—involves the Functional Medicine clinician and patient in a relationship where science and art, information and belief, attention and insight, communication and trust all have value. Functional Medicine practitioners are taught to integrate what they know from their previous education and clinical experience with what they learn about Functional Medicine—how to seek the underlying causes of disease and how to craft a personalized, systems-oriented therapeutic plan for each unique patient using evidence and insight, art and science.

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