A critical eye for vetting (Neuropathy) medical claims

Dr. Kristy Townsend

Associate Professor, The Ohio State University

Disclaimers

- Today's discussion is a reflection of my personal advice as a scientist, and how I vet medical information for myself to determine accuracy of claims versus the status of the medical research literature.
- I am *not* a medical doctor, and nothing today should be considered medical advice
- My opinions do not reflect those of my employer(s)

The History of Snake Oil Sales

- "quack remedy or panacea"
- The original form of snake oil in the 1800s came from China, was high in omega-3 fatty acids, and *was* effective
- Later in 19th century, "patent mediciness" were advertised at the back of newspapers, tonics promising to cure a variety of ailments
- At the 1893 World's Exposition in Chicago, Clark Stanley "the rattlesnake king" claimed he had healing rattlesnake oil learned from Hopi medicine men. *Problem: Stanley's snake oil contained NO snake oil at all…*
- Led to the Pure Food and Drug Act of 1906 to regulate sale of patent medicines
- Snake oil then became a symbol of fraudulent cures

Made from the oil of the Chinese water snake, which is rich in the omega-3 acids that help reduce inflammation, snake oil in its original form was effective, especially when used to treat arthritis and bursitis.

Jagrap/Flickr

https://www.npr.org/sections/codeswitch/2013/08/26/215761377/a-history-of-snake-oil-salesmen

"Caveat Emptor" – *Buyer Beware* with medical claims

- The risks of poor, inaccurate, or simply wrong medical/scientific information regarding diseases:
  - Lost time in seeking an effective treatment or therapeutic
  - $$ spent on ineffective products
  - Potential health risks for products that make conditions worse instead of better; serious side effects/toxicity
  - Patients lacking a clear and accurate understanding of their physiology and pathophysiology

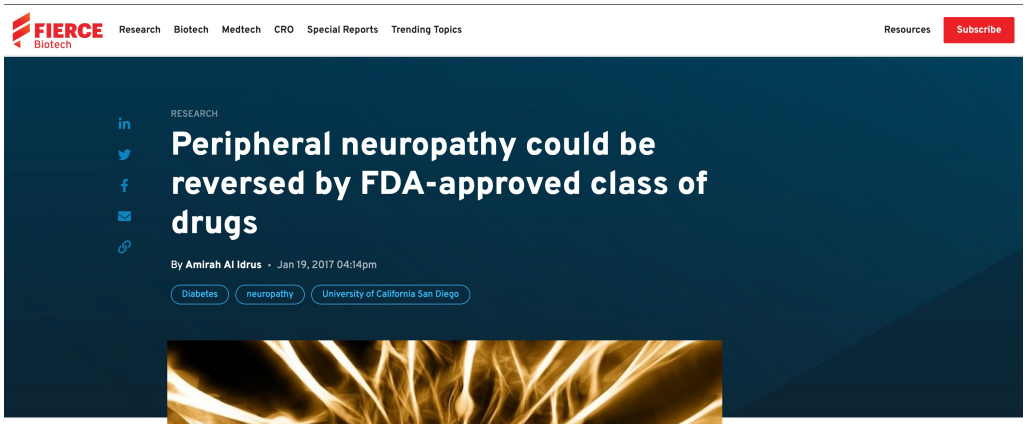
There is (A LOT of) money to be made selling products/services outside the mainstream medical establishment – and salespeople sometimes use fraudulent practices to dupe vulnerable patients, who may have an existing distrust of or lack of faith in medical professionals.

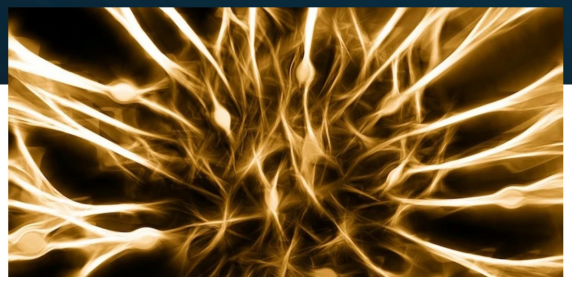
Article

Miracle Health Claims

People spend billions of dollars a year on health-related products and treatments that not only are unproven and often useless, but also sometimes are dangerous. The products promise quick cures and easy solutions for a variety of problems, from obesity and arthritis to cancer and AIDS. But the "cures" don't deliver, and people who buy them are cheated out of their money, their time, and even their health. That's why it's important to learn how to evaluate claims for products related to your health.

Comparing the Headlines





Actual Study:

- Mouse model (not human)
- Treatments improved depletion of sensory nerve terminals, thermal hypoalgesia, and nerve conduction slowing in model of diabetes
- " a variety of antimuscarinic drugs are approved for clinical use against other conditions, prompt translation of this therapeutic approach to clinical trials is *feasible*"

Comparing the Headlines

Actual Study:

- N=17 humans with Long COVID, 69% female, 94% Caucasian, 19% Latino
- 59% had more than one test confirming neuropathy

Know your source:
Caveat Emptor (buyer beware)

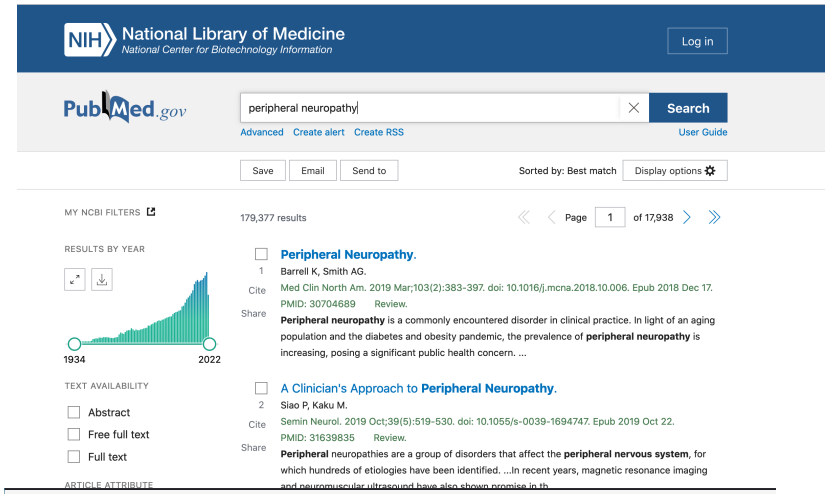
https://pubmed.ncbi.nlm.nih.gov/

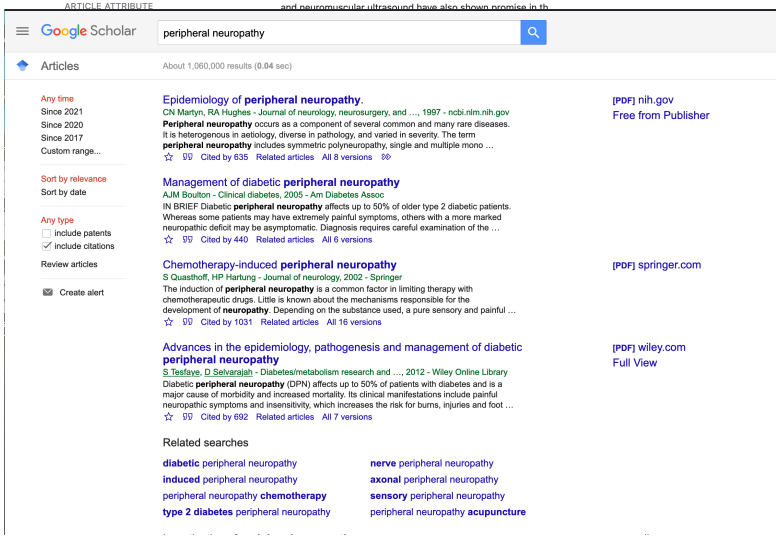
Scientific Organizations
(ie: AAAS, NIH)

Scientific Publications
(research articles, science news outlets, etc.)

Respected Professional Bodies
(major research hospitals, scientific societies, research universities)

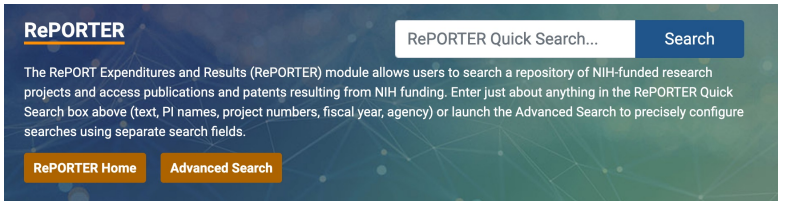
Trained and Practicing Experts





Caveat Emptor – how to find and vet research

- Look at the source and the intent behind sharing the information – is a product being sold, or is the goal to disseminate reputable & current evidence-based information?
  - Even on PubMed, not all journals are peer-reviewed and/or reputable ("predatory journals")
  - Even in peer-reviewed and reputable journals, not all studies are well-designed and well-executed (& not all peer reviewers are created equal!)
  - Not all studies are reproduced and hold up with time and further study
  - Caveats: low sample size, model system doesn't apply to humans, etc.
- Reliable sources:
  - Twitter – follow the researchers and clinicians themselves!
  - Science communicators/journalists
  - University press, hospital newsletters



- Finding what is current/ongoing:
  - Scientific/Medical Conferences – often online news coverage, posted talks (not yet peer-reviewed!)
  - Funded Grants
  - Clinical Trials

Even with rigorous research…research can be wrong

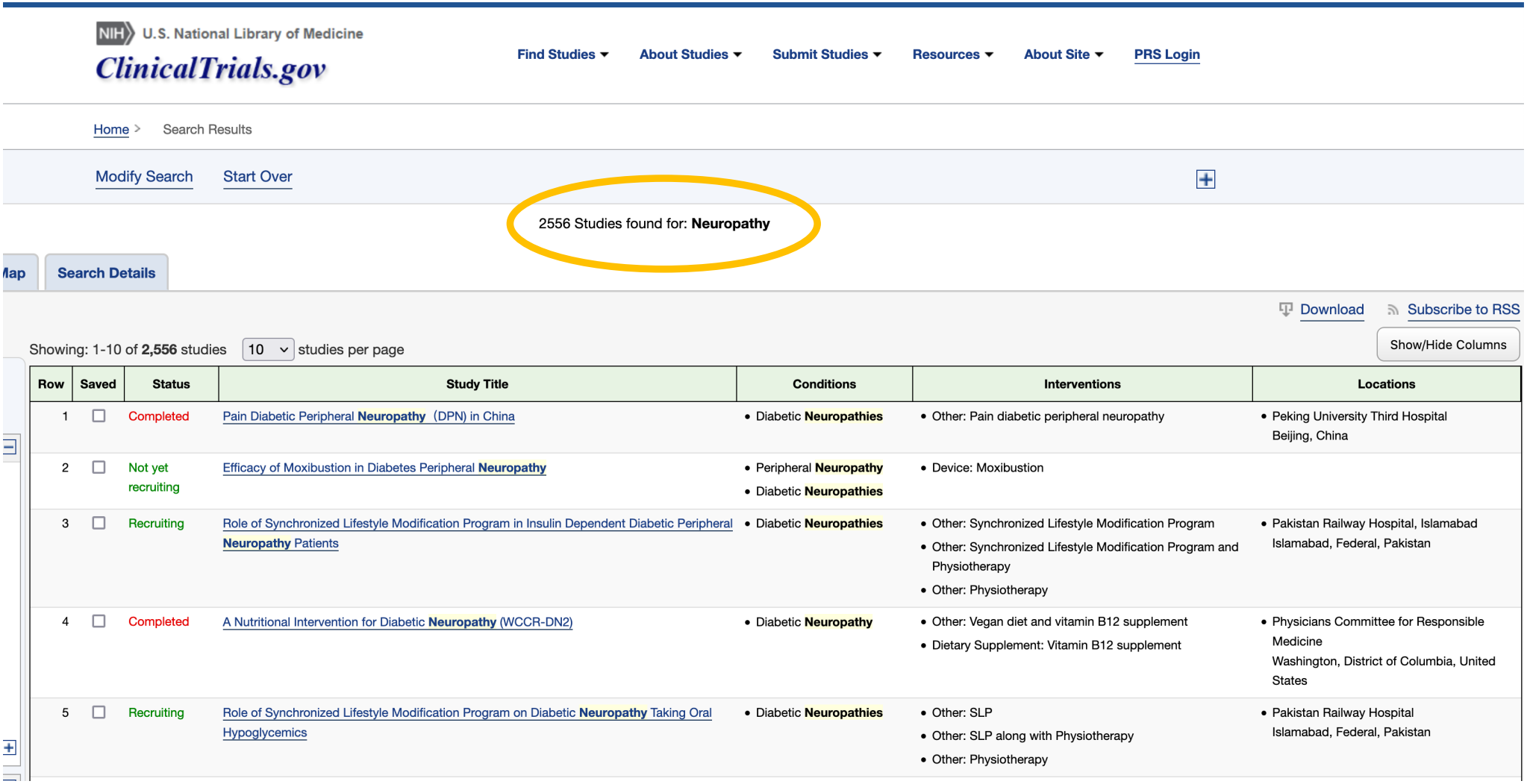
- Science is self-correcting
- Meta-analyses assess numerous studies across time, different labs
- Replication → increases likelihood a finding is real

How to ID Fraudulent Claims: https://quackwatch.org/

Quackwatch, which is operated by Stephen Barrett, M.D., is a network of Web sites and mailing lists maintained by the Center for Inquiry (CFI). The sites focus on health frauds, myths, fads, fallacies, and misconduct. Their main goal is to provide quackery-related information that is difficult or impossible to get elsewhere. To help visitors with special areas of interest, there are sites that cover autism, chiropractic, dentistry, multilevel marketing, and many other problematic areas. The Internet Health Pilot site provides links to hundreds of reliable health sites. Casewatch contains a large library of legal cases, licensing board actions, government sanctions, and regulatory actions against questionable medical products. All of these can be accessed through the "Visit Our Affiliated Sites" drop-down menu above. Their contents can be searched all at once through our search page. We also offer a Health Fraud Discussion List with more than 550 members and Consumer Health Digest, a free weekly e-mail newsletter that summarizes scientific reports, legislative developments, enforcement actions, and other information relevant to consumer protection and consumer decision-making. Its primary focus is on health, but occasionally it includes non-health scams.

About Quackwatch

- Mission Statement
- Tips for Navigating Our Web Sites
- Frequently Asked Questions (FAQs)
- Who Funds Quackwatch?
- Quackwatch Acts as a Healthcare Watchdog (badcredit.org)
- Quackwatch Compiles Trustworthy Information (DatingNews.com)
- Quackwatch: Vigilance Against Questionable Healthcare Claims and Their Financial Implications (cardrates.com)
- How to Become a Quackwatch Advisor
- Honors and Awards (70+) Given to Quackwatch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ClinicalTrials.gov
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About Studies
Submit Studies
Resources
About Site
PRS Login
Home > Search Results
Modify Search
Start Over
2556 Studies found for: Neuropathy
Search Details
Download
Subscribe to RSS
Showing: 1-10 of 2,556 studies
10
studies per page
Show/Hide Columns
Row
Saved
Status
Study Title
Conditions
Interventions
Locations
1
Completed
Pain Diabetic Peripheral Neuropathy (DPN) in China
• Diabetic Neuropathies
• Other: Pain diabetic peripheral neuropathy
• Peking University Third Hospital Beijing, China
2
Not yet recruiting
Efficacy of Moxibustion in Diabetes Peripheral Neuropathy
• Peripheral Neuropathy
• Diabetic Neuropathies
• Device: Moxibustion
3
Recruiting
Role of Synchronized Lifestyle Modification Program in Insulin Dependent Diabetic Peripheral Neuropathy Patients
• Diabetic Neuropathies
• Other: Synchronized Lifestyle Modification Program
• Other: Synchronized Lifestyle Modification Program and Physiotherapy
• Other: Physiotherapy
• Pakistan Railway Hospital, Islamabad Islamabad, Federal, Pakistan
4
Completed
A Nutritional Intervention for Diabetic Neuropathy (WCCR-DN2)
• Diabetic Neuropathy
• Other: Vegan diet and vitamin B12 supplement
• Dietary Supplement: Vitamin B12 supplement
• Physicians Committee for Responsible Medicine Washington, District of Columbia, United States
5
Recruiting
Role of Synchronized Lifestyle Modification Program on Diabetic Neuropathy Taking Oral Hypoglycemics
• Diabetic Neuropathies
• Other: SLP
• Other: SLP along with Physiotherapy
• Other: Physiotherapy
• Pakistan Railway Hospital Islamabad, Federal, Pakistan

Clinical Trials

- Informed Consent
- Institutional Review Board (IRB); Human Subjects Protection
- Four phases to establish ***safety*** and ***efficacy*** of medical treatments using rigorously designed, executed, and analyzed studies
- Data is disseminated and peer-reviewed

WHY DO **RESEARCHERS** DO DIFFERENT KINDS OF **CLINICAL STUDIES?**

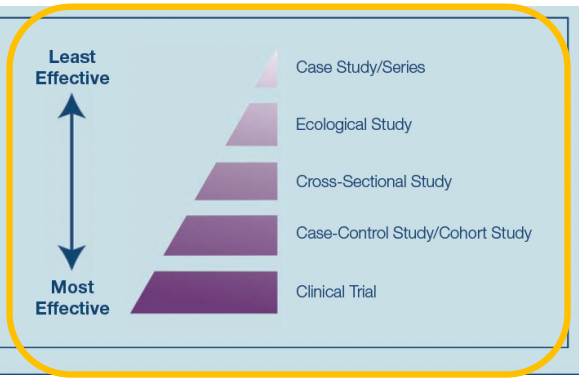
Clinical research is the study of health and illness in people.

Scientists may have many reasons for doing a clinical study, such as:

- **To explore the cause of a disease or a set of symptoms**
- **To test if a treatment will help with a symptom or condition**
- **To learn how a certain behavior affects people's health**

How good are these kinds of studies at showing cause and effect?

The strength of a study depends on its size and design. New results may confirm earlier findings, contradict them, or add new aspects to scientists' understanding. In the end, cause and effect are usually hard to establish without a well-designed clinical trial.



Different types of clinical studies are used in different circumstances. Depending on what is known and what isn't, scientists may even study the same research question using different kinds of studies and in different groups of people. Here are different types of clinical studies and why they might be used.

Observational Studies

In many studies, researchers do not do experiments or test new treatments; they *observe*. Observational studies help researchers understand a situation and come up with hypotheses that can be put to the test in clinical trials. Observational studies can find associations between things but can't prove that one thing causes another. Types include:

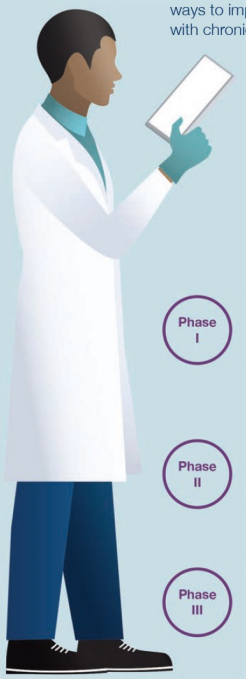
Case Study/Case Series
A detailed description of one or more patients. By documenting new and unusual cases, researchers start to generate hypotheses about causes or risk factors.

Ecological Study
Compares the rate of a disease or condition for groups of people, such as towns in different climates or with different average incomes.

Cross-Sectional Study
A snapshot of many people at one moment in time. These studies can show how common a condition is and help identify factors associated with it.

Case-Control Study
A group of people who have a condition is compared to a control group of people who don't. Possible causes or risk factors can emerge.

Cohort Study
A large group of people is observed over time. Some eventually develop a disease or condition. Researchers can learn how often the condition occurs and find possible causes or risk factors.



Clinical Trials

In these studies, researchers test new ways to prevent, detect, or treat disease. Treatments might be new drugs or combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments. Clinical trials can also test other aspects of care, such as ways to improve the quality of life for people with chronic illnesses.

A well-designed clinical trial is the gold standard for proving that a treatment or medical approach works, but clinical trials can't always be used. For example, scientists can't randomly assign people to live in different places, or ask people to start smoking or eating an unhealthy diet. Clinical trials are conducted in phases:

Phase I
- Purpose: Find out whether a medical approach (e.g., drug, diagnostic test, device) is safe, identify side effects, and figure out appropriate doses.
- Number of people: Typically fewer than 100

Phase II
- Purpose: Start testing whether a medical approach works. Continue monitoring for side effects; get information that goes into designing a large, phase III trial.
- Number of people: Typically 100-300

Phase III
- Purpose: Prove whether a medical approach works; continue monitoring side effects.
- Number of people: As many as needed or able to enroll—can be 1,000 or more

Phase IV
- Purpose: When a medical approach is being marketed, continue gathering information on its effects.
- Number of people: Thousands

Critical Assessment of Claims: who were the enrolled patients?

- Statistics, power of the sample size (how many? was it enough?)
- Sex differences (male/female biological differences)
- Regional differences, relevance across race/ethnicity
- Genetics

FDA Approval

FDA Approval: What it means

FDA approval of a drug means that data on the drug's effects have been reviewed by CDER, and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population. The drug approval process takes place within a structured framework that includes:

- ***Analysis of the target condition and available treatments***—FDA reviewers analyze the condition or illness for which the drug is intended and evaluate the current treatment landscape, which provide the context for weighing the drug's risks and benefits. For example, a drug intended to treat patients with a life-threatening disease for which no other therapy exists may be considered to have benefits that outweigh the risks even if those risks would be considered unacceptable for a condition that is not life threatening.
- ***Assessment of benefits and risks from clinical data***—FDA reviewers evaluate clinical benefit and risk information submitted by the drug maker, taking into account any uncertainties that may result from imperfect or incomplete data. Generally, the agency expects that the drug maker will submit results from two well-designed clinical trials, to be sure that the findings from the first trial are not the result of chance or bias. In certain cases, especially if the disease is rare and multiple trials may not be feasible, convincing evidence from one clinical trial may be enough. Evidence that the drug will benefit the target population should outweigh any risks and uncertainties.
- ***Strategies for managing risks***—All drugs have risks. Risk management strategies include an FDA-approved drug label, which clearly describes the drug's benefits and risks, and how the risks can be detected and managed. Sometimes, more effort is needed to manage risks. In these cases, a drug maker may need to implement a Risk Management and Mitigation Strategy (REMS).

https://www.fda.gov/drugs/development-approval-process-drugs

U.S. Food and Drug Administration

Drug Approval Process

What is a drug as defined by the FDA?

A drug is any product that is intended for use in the diagnosis, cure mitigation, treatment , or prevention of disease; and that tis intended to affect the structure or any function of the body.

PRE-CLINICAL

Drug Sponsor's Discovery and Screening Phase

Drug Developed

Drug sponsor develops a new drug compound and seeks to have it approved by FDA for sale in the United States.

1

Animals Tested

Sponsor must test new drug on animals for toxicity. Multiple species are used to gather basic information on the safety and efficacy of the compound being investigated/researched.

2

IND Application

The sponsor submits an Investigational New Drug (IND) application to FDA based on the results from intial testing that include, the drug's composition and manufacturing, and develops a plan for testing the drug on humans.

IND REVIEW

FDA reviews the IND to assure that the proposed studies, generally referred to as clinical trials, do not place human subjects at unreasonable risk of harm. FDA also verifies that there are adequate informed consent and human subject protection.

FDA's Center for Drug Evaluation and Research (CDER) evaluates new drugs before they can be sold.

The center's evaluation not only prevents quackery, but also provides doctors and patients the information they need to use medicines wisely. CDER ensures that drugs, both brand-name and generic, are effective and their health benefits outweigh their known risks.

CLINICAL

Drug Sponsor's Clinical Studies/Trials

3

PHASE 1

20-80

The typical number of healthy volunteers used in Phase 1; this phase emphasizes safety. The goal here in this phase is to determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted.

4

PHASE 2

100's

The typical number of patients used in Phase 2; this phase emphasizes effectiveness. This goal is to obtain preliminary data on whether the drug works in people who have a certain disease or condition. For controlled trials, patients receiving the drug are compared with similar patients receiving a different treatment--usually a placebo, or a different drug. Safety continues to be evaluated, and short-term side effects are studied.

At the end of Phase 2, FDA and sponsors discuss how large-scale studies in Phase 3 will be done.

5

PHASE 3

1000's

The typical number of patients used in Phase 3. These studies gather more information about safety and effectiveness, study different populations and different dosages, and uses the drug in combination with other drugs.

Why aren’t all health claims regulated?

- FTC/FDA cracking down on food and supplement health claims
  - Seeking ***Significant Scientific Agreement (SSA)***
- Many treatments and therapies outside the insurance system, or considered alternative/complementary can slip through the cracks

Report Scams

If you believe you’ve responded to a scam, file a complaint with:

- the FTC
- your state Attorney General

Characteristics of Pseudoscience

1. Is **UNFALSIFIABLE** (can't be proven wrong): Makes vague or unobservable claims
2. Relies heavily on **ANECDOTES**, personal experiences, and testimonials
3. **CHERRY PICKS** confirming evidence while ignoring/minimizing disconfirming evidence
4. Uses **TECHNOBABBLE**: Words that sound scientific but don't make sense
5. Lacks **PLAUSIBLE MECHANISM**: No way to explain it based on existing knowledge
6. Is **UNCHANGING**: Doesn't self-correct or progress
7. Makes **EXTRAORDINARY/EXAGGERATED CLAIMS** with insufficient evidence
8. Professes **CERTAINTY**: Talks of "proof," with great confidence
9. Commits **LOGICAL FALLACIES**: Arguments contain errors in reasoning
10. Lacks **PEER REVIEW**: Goes directly to the public, avoiding scientific scrutiny
11. Claims there's a **CONSPIRACY** to suppress their ideas

Are you a CRITICAL THINKER?

Critical thinkers...

- ✓ Are aware their thinking is **flawed** and **prone to errors**
- ✓ Think about **how they think**
- ✓ Are **curious** and **inquisitive**
- ✓ Separate their **identity** from their **beliefs**
- ✓ Welcome **criticism** from others
- ✓ Use **evidence** to arrive at conclusions and maintain a healthy level of **skepticism**
- ✓ Avoid **black-and-white thinking** and are comfortable with **ambiguity** and **uncertainty**
- ✓ Are **humble**

https://thinkingispower.com/

Available online at www.sciencedirect.com
ScienceDirect
Journal of Prosthodontic Research 55 (2011) 1–6
Journal of Prosthodontic Research
www.elsevier.com/locate/jpor

Industry Sponsored Research – is it biased?

Review

Fifteen common mistakes encountered in clinical research

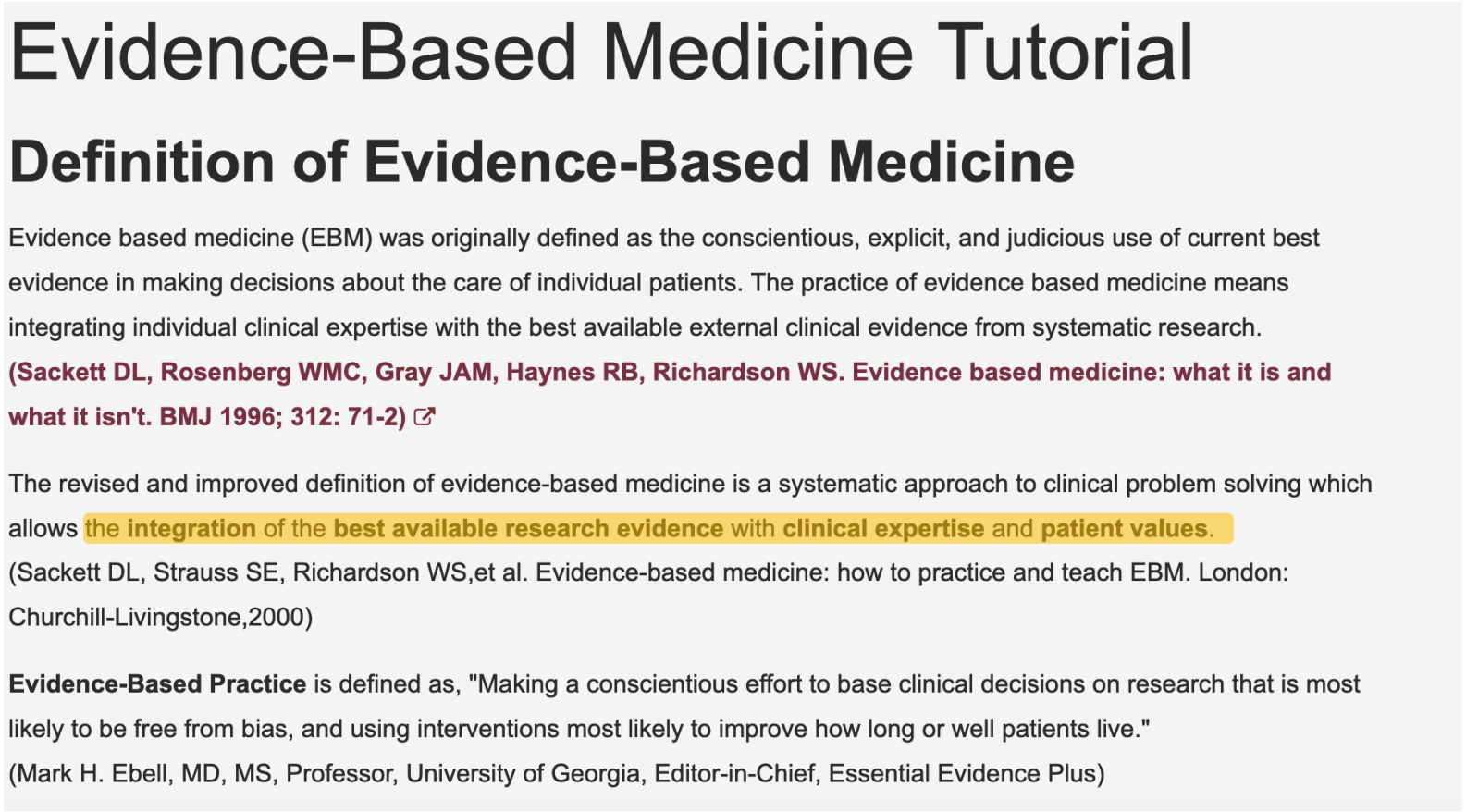
Glenn T. Clark DDS, MS[a,1,*], Roseann Mulligan DDS, MS[b,1]

[a] Orofacial Pain and Oral Medicine Center, Herman Ostrow School of Dentistry, University of Southern California, Los Angeles, CA 90089-0641, USA
[b] Community Dentistry Programs and Hospital Affairs, Herman Ostrow School of Dentistry,

The Physician Payments Sunshine Act (PPSA)--also known as section 6002 of the Affordable Care Act (ACA) of 2010--requires medical product manufacturers to disclose to the Centers for Medicare and Medicaid Services (CMS) any payments or other transfers of value made to physicians or teaching hospitals. It also requires certain manufacturers and group purchasing organizations (GPOs) to disclose any physician ownership or investment interests held in those companies.

Contents

Evidence Based Medicine – Look to the Experts



Evidence-Based Medicine Tutorial

Definition of Evidence-Based Medicine

Evidence based medicine (EBM) was originally defined as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.
(Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ 1996; 312: 71-2)

The revised and improved definition of evidence-based medicine is a systematic approach to clinical problem solving which allows the **integration** of the **best available research evidence** with **clinical expertise** and **patient values**.
(Sackett DL, Strauss SE, Richardson WS,et al. Evidence-based medicine: how to practice and teach EBM. London: Churchill-Livingstone,2000)

Evidence-Based Practice is defined as, "Making a conscientious effort to base clinical decisions on research that is most likely to be free from bias, and using interventions most likely to improve how long or well patients live."
(Mark H. Ebell, MD, MS, Professor, University of Georgia, Editor-in-Chief, Essential Evidence Plus)

- https://med.fsu.edu/medicalInformatics/ebmTutorial

The Placebo Effect

Harvard Health Publishing
HARVARD MEDICAL SCHOOL

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RECENT BLOG ARTICLES

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Warming up to the cold: Staying active in any weather

MENTAL HEALTH

The power of the placebo effect

December 13, 2021

Treating yourself with your mind is possible, but there is more to the placebo effect than positive thinking.

Your mind can be a powerful healing tool when given the chance. The idea that your brain can convince your body a fake treatment is the real thing — the so-called placebo effect — and thus stimulate healing has been around for millennia. Now science has found that under the right circumstances, a placebo can be just as effective as traditional treatments.

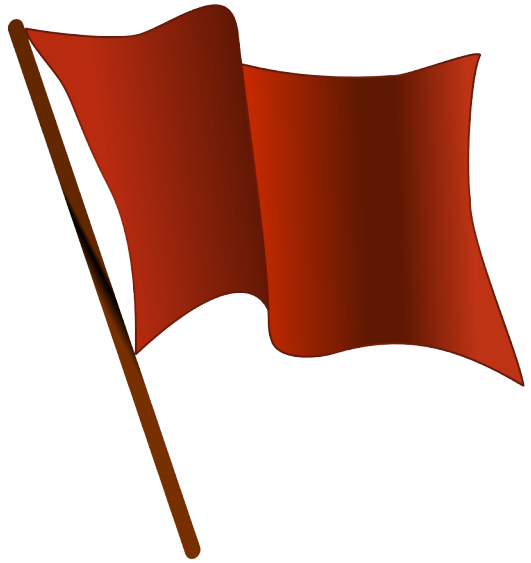
"The placebo effect is more than positive thinking — believing a treatment or procedure will work. It's about creating a stronger connection between the brain and body and how they work together," says Professor Ted Kaptchuk of Harvard-affiliated Beth Israel Deaconess Medical Center, whose research focuses on the placebo effect.

Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

Program in Placebo Studies

For many years, the placebo effect was considered to be no more than a nuisance variable that needed to be controlled in clinical trials. Only recently have researchers redefined it as the key to understanding the healing that arises from medical ritual, the context of treatment, the patient-provider relationship and the power of imagination, hope and expectation.

Be on the lookout for ”red flags” when vetting online sources of medical information
(*Especially: Ads, Sponsored Content, Social Media posts*)



I genuinely thought
I had neuropathy for life.

I followed my doctor's health advice
and I took my meds.

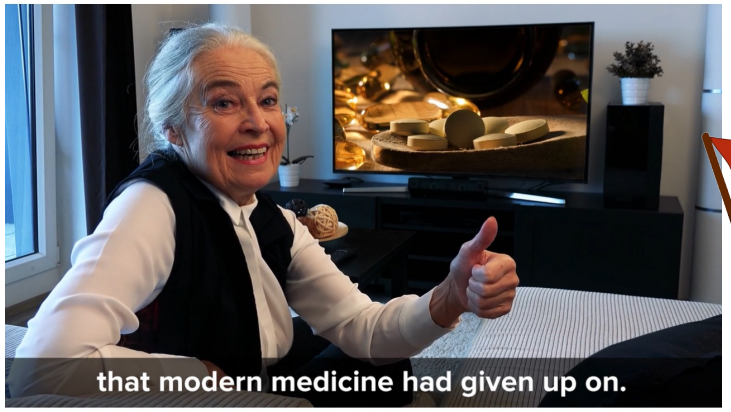
and yet it was incredibly simple to do.

The real reason we get neuropathy

Well, I found out one thing that turned my worries into hope…

Sounds a little odd I know.

that these apparently different conditions all have, at their source a single cause.



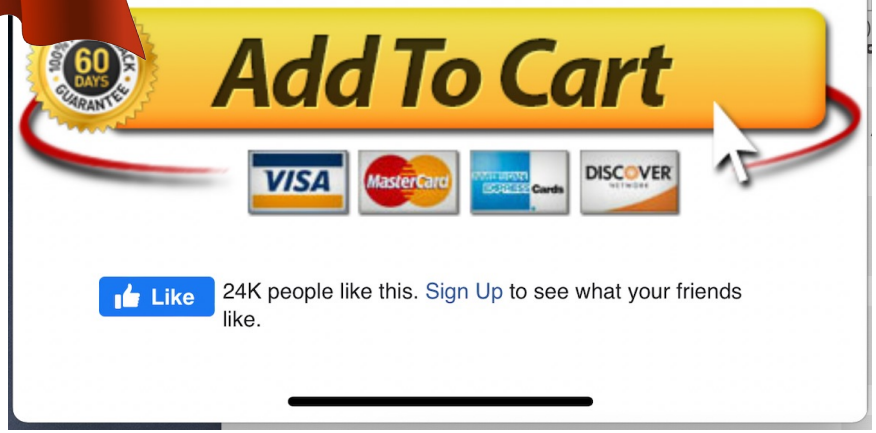
I mean, at that time
I was very skeptical about
alternative treatments.

But as I watched the documentary
it was clear the results of natural
treatments were very, very
impressive.

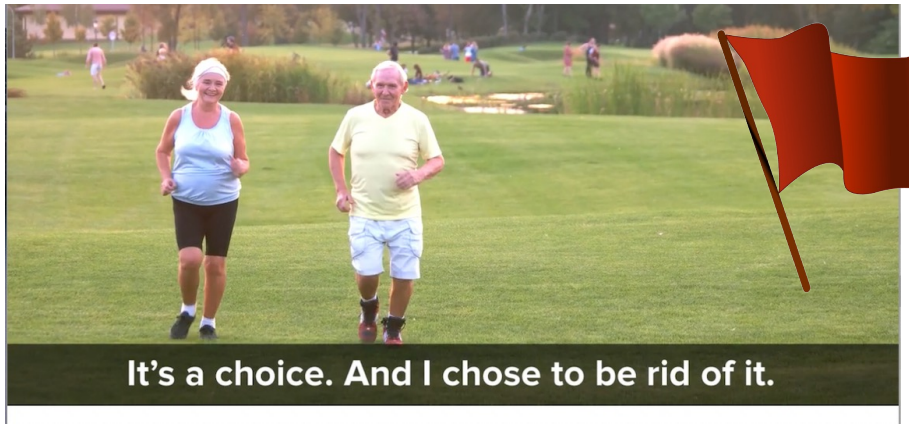
National Center for Complementary and Integrative Health

https://www.nccih.nih.gov/

But my nerve pains were getting so bad I was prepared to take that leap of faith.



Yep, the gut. I found that a bit weird too when I first heard it.



The Research Behind the Claims: Minimal number of studies, inconclusive evidence, too early in testing potential therapies

J Headache Pain. 2020; 21(1): 103.
Published online 2020 Aug 17. doi: 10.1186/s10194-020-01170-x
PMCID: PMC74
PMID: 328(

Gut microbiota regulates neuropathic pain: potential mechanisms and therapeutic strategy

Binbin Lin,# Yuting Wang,# Piao Zhang,# Yanyan Yuan, Ying Zhang, and Gang Chen

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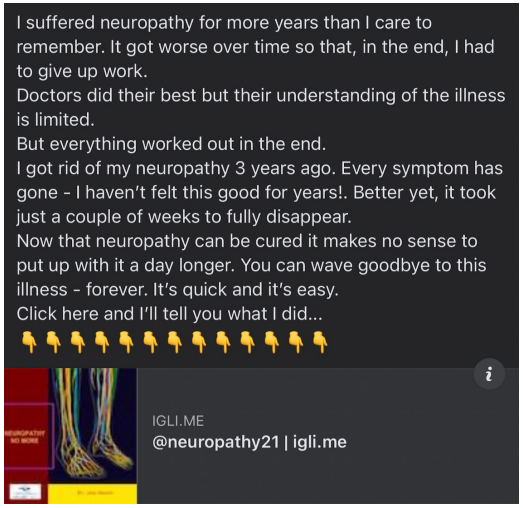

What has science shown about the effectiveness of probiotics for health conditions?

A great deal of research has been done on probiotics, but much remains to be learned about whether they're helpful and safe for various health conditions.

Probiotics have shown promise for a variety of health purposes, including prevention of **antibiotic-associated diarrhea** (including diarrhea caused by *Clostridium difficile*), prevention of **necrotizing enterocolitis** and **sepsis** in premature infants, treatment of **infant colic**, treatment of **periodontal disease**, and induction or maintenance of remission in **ulcerative colitis**.

However, in most instances, we still don't know which probiotics are helpful and which are not. We also don't know how much of the probiotic people would have to take or who would be most likely to benefit. Even for the conditions that have been studied the most, researchers are still working toward finding the answers to these questions.

The following sections summarize the research on probiotics for some of the conditions for which they've been studied.

https://www.nccih.nih.gov/health/probiotics-what-you-need-to-know

Be on the lookout for anecdotal evidence
(claims of N=1 success)

How would you critically vet these social media claims?