

## **"Clinical Research in Complementary and Integrative Medicine: A Practical Training Book"**

**Claudia M. Witt and Klaus Linde, 2011, 166 pages, Elsevier, \$84.95**

**Review by Norman M. Goldfarb**

"Clinical Research in Complementary and Integrative Medicine: A Practical Training Book" is an excellent introduction to clinical research on treatments outside the bounds of conventional Western medicine. Such research presents challenges that are uncommon when investigating conventional therapies.

The authors estimate that there are approximately 100 million users of complementary and alternative medicine (CAM) in the E.U., as well as a significant fraction of the population in the U.S. and elsewhere. CAM consists of treatments like chiropractic, homeopathy, aromatherapy, and natural herbal medications. Integrative medicine combines conventional treatments with CAM treatments. The popularity of unconventional treatments calls for research to assess their effectiveness and safety.

In addition, CAM treatments can generate strong placebo effects, so their study could provide insights into increasing the placebo effects of conventional treatments — and placebos, for that matter. The placebo effect clearly exists across a remarkable range of conditions, is poorly understood, and does not cause pharmacological or surgical complications.

Given the very limited funding available for research on unconventional treatments, it should focus on the most plausible treatments and be conducted in a legitimate and definitive manner. Studies not only test their research hypothesis but also the credibility of CAM research in general. This book is a big step in that direction.

The authors are well aware of the challenges:

Most complementary treatments only become scientifically evaluated after their use has become so widespread that they cannot be ignored any longer. This has important implications:

- Providers have already treated many patients and are convinced that their treatments are beneficial. So, providers are often reluctant to agree that their patients may be randomized to treatment and placebo, respectively.
- If a treatment has been available over a long period of time and from large numbers of providers, there is likely to be some diversification, i.e., different providers apply the therapy in a slightly, or sometimes very different manner. The question then arises whether the results of a study done in one style can be extrapolated to another style. Patients treated with complementary medicine often actively choose "their" therapy and develop strong preferences or have strong beliefs. However, results from studies done in such subjects may not apply to patients not actively seeking complementary medicine. And, if a study is done in the latter group, it is at least questionable whether it is only relevant to "believers."
- Finally, if an experimental study finds a negative result, will CAM providers and patients accept "statistical findings" that contradict their direct personal experience? A drug that does not show efficacy in phase III never becomes

available, but can health authorities ban a widely practised complementary therapy if a randomized trial is negative?

...Finally, the aim of research in complementary medicine is often problematic. In conventional medicine, the ultimate goal of research is (or at least, should be) improvement of patient care. However, the goal of research in complementary medicine seems very often to be to prove to the world that your view is correct (i.e., that your therapy is effective if you are a convinced provider, or that it is rubbish if you are a skeptic).

Prior beliefs seem to be particularly strong in the discussion of complementary therapies and any study will be criticized, regardless of its results.

The book includes 11 chapters:

- Introduction
- Basic Study Design
- Basic Statistics
- Planning
- Study and Data Management
- Data Analysis
- Publication
- Qualitative Research
- Economic Studies
- Single-Case Research
- A Brief Look at Other Study Designs

The book devotes only one paragraph to human subjects protection and regulatory compliance.

The book is available in bookstores.

### **Reviewer**

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