

Evidence of effectiveness but not efficacy

-

**why many complementary therapies
are so hard to accept for biomedicine**

Klaus Linde

Institute for General Practice, Technical University of Munich

"Background and aims"

My impression

- Integration of CAM into health care practice proceeding (at least in most in western industrialized countries)
- Scientific and academic debate on some major therapies heats up again
- Both proponents and adversaries (and those in between) claim their view is based on evidence from randomized clinical trials (RCTs)

My aims for today

- To explore why it is so hard for biomedicine to accept CAM therapies

Evidence from RCTs

- Efficacy: evidence of specific effects from placebo-controlled RCTs
- Effectiveness: evidence of an overall benefit from RCTs with more naturalistic comparator groups (no treatment, usual care/usual care alone, other treatment)

Overview of my presentation

- The general problem of interpreting evidence
(Example: Do homeopathic remedies have clinical effects over placebo)
- The problem of specific effects, placebo, and of the dominance of efficacy over effectiveness
- Summary and conclusions

An attempt to summarize evidence from RCTs on homeopathy with as little interpretation as possible

Efficacy (effects over placebo)

- If you pool all available trials
 - homeopathy > placebo^{1,3(2)}
 - better and larger trials tend to yield less positive findings^{1,2}
- If analyzed per condition
 - few trials
 - inconsistent results^{1,4}

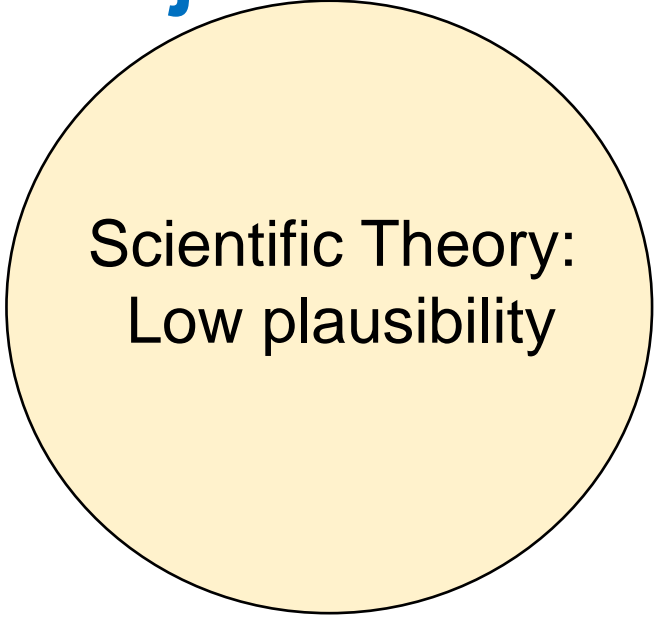
Effectiveness

- Few (mostly small) RCTs available, some evidence from observational studies

¹Linde et al. Lancet 1997;350:834; ²Shang et al. Lancet 2005;366:726; ³Mathie et al. Syst Rev 2014;3:142 & 2017;6:63

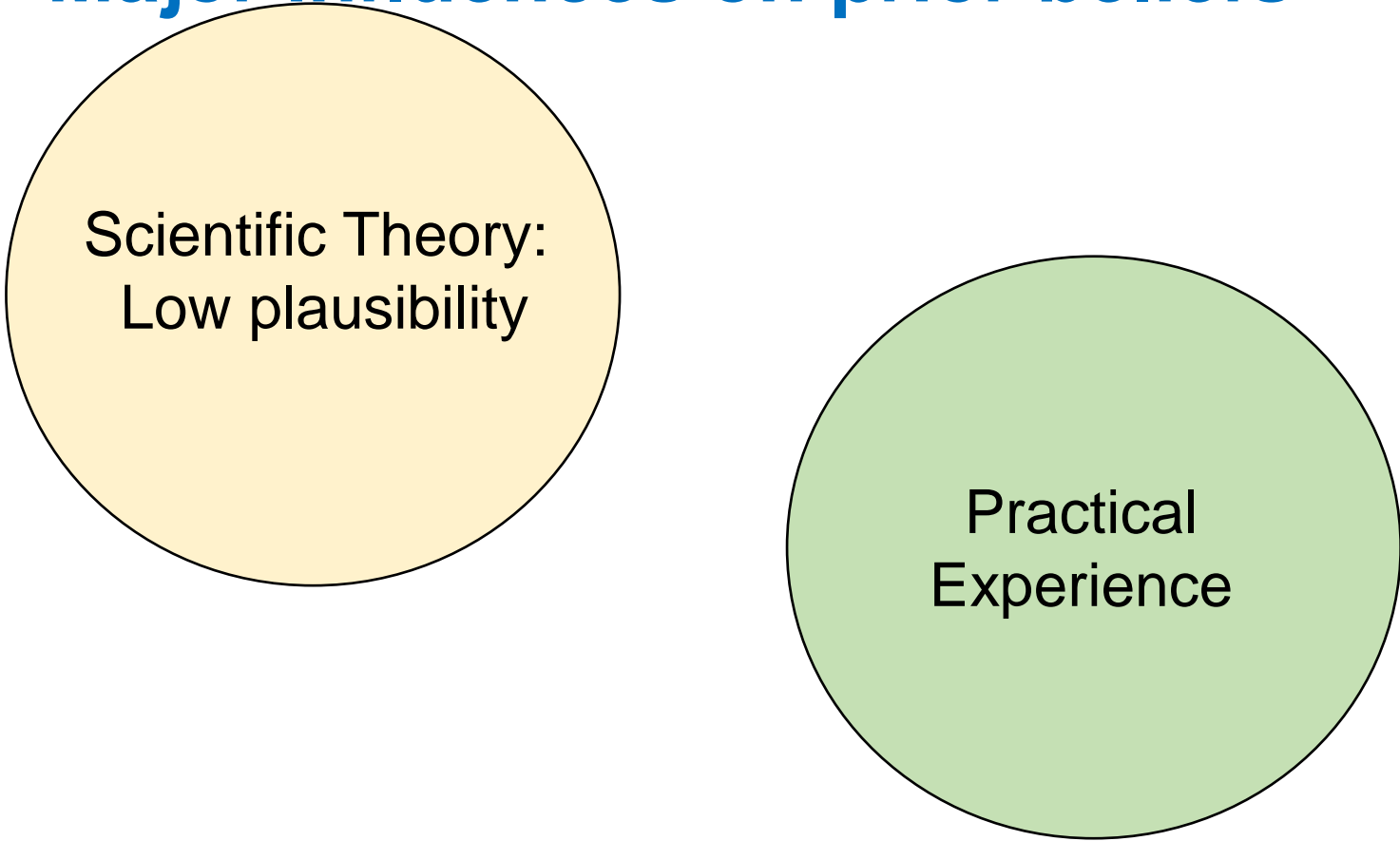
⁴<https://www.nhmrc.gov.au/health-topics/complementary-medicines/homeopathy-review> (Australian report)

Major influences on prior beliefs



Scientific Theory:
Low plausibility

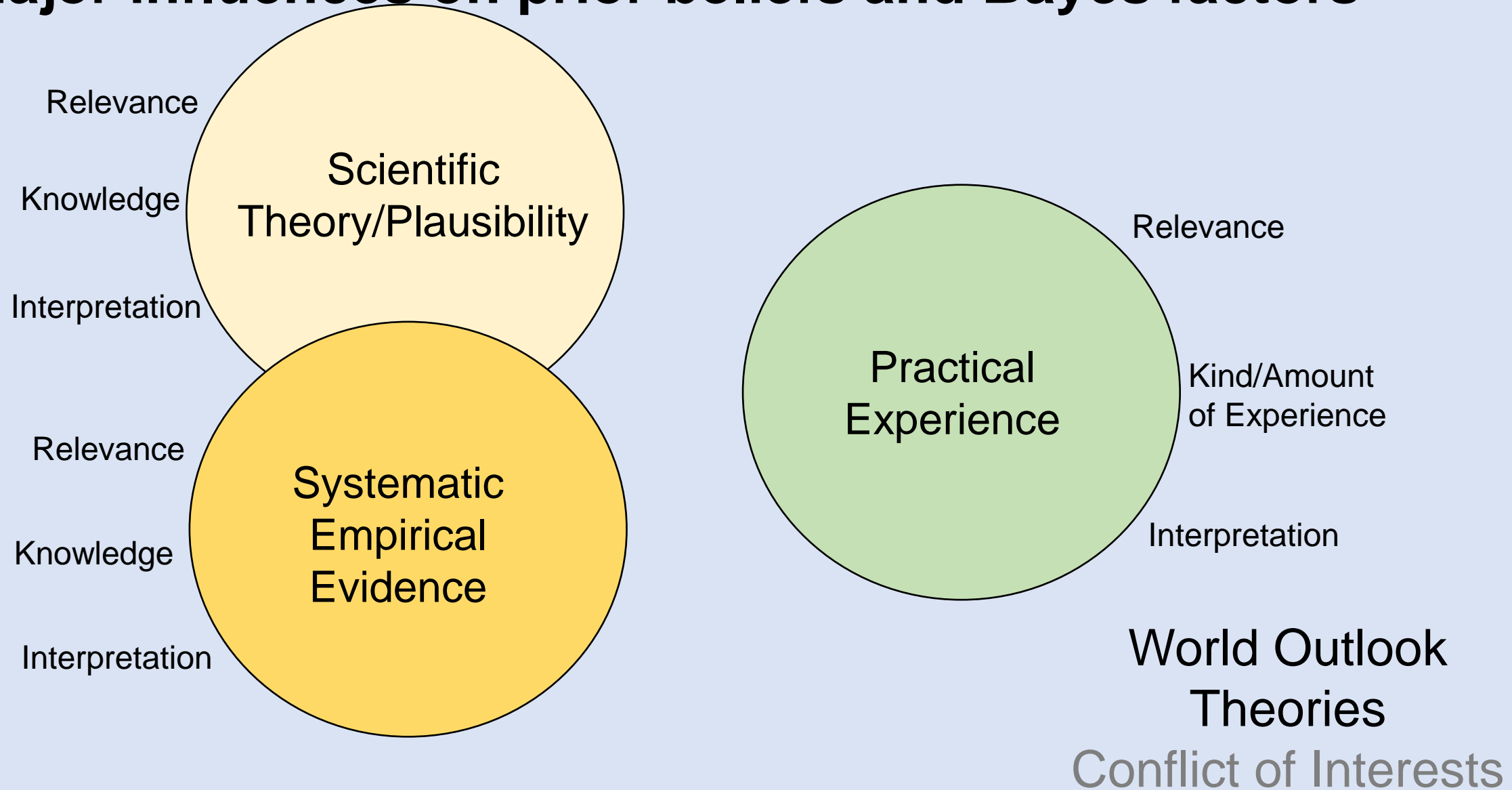
Major influences on prior beliefs



Scientific Theory:
Low plausibility

Practical
Experience

Major influences on prior beliefs and Bayes factors



You are here: [Home](#) / [EVIDENCE](#) / The evidence for homeopathy

The evidence for homeopathy

There is a growing body of published research in good quality peer-reviewed journals showing that homeopathy has a positive effect.

This section of the website gives you a straightforward introduction to the kinds of evidence that exist for homeopathy and the range of **conditions with positive evidence**.

More research needed



Homeopathic research is still in its infancy. The body of

FIND A PRACTITIONER

Search By:

- | | |
|--------------------------------------|--|
| <input type="checkbox"/> Doctors | <input type="checkbox"/> Physiotherapist |
| <input type="checkbox"/> Pharmacists | <input type="checkbox"/> Podiatrist |
| <input type="checkbox"/> Vets | <input type="checkbox"/> Nurse/Midwife |
| <input type="checkbox"/> Dentists | <input type="checkbox"/> Osteopath |

FIND

CLEAR

[sign in](#)[become a supporter](#)[subscribe](#)[search](#)[jobs](#)[dating](#)[more ▾](#)[International edition ▾](#)

theguardian

[UK](#)[world](#)[sport](#)[football](#)[opinion](#)[culture](#)[business](#)[lifestyle](#)[fashion](#)[environment](#)[tech](#)[travel](#)[all sections](#)[home](#) > [opinion](#)[columnists](#)

Homeopathy

Opinion

There is no scientific case for homeopathy: the debate is over

Edzard Ernst

Pharmacists who sell homeopathic remedies as anything other than placebos are putting their customers' health at risk



56k 2,196

Thursday 12 March 2015
10.43 GMT



Advertisement

We have to accept that different groups interpret evidence on controversial topics very differently (unless it is really unequivocal (???)).

Is it likely that further placebo-controlled trials or meta-analyses of such trials will settle the debate???

Overview of my presentation

- The general problem of interpreting evidence
(Example: Do homeopathic remedies have clinical effects over placebo)
- The problem of specific effects, placebo, and of the dominance of efficacy over effectiveness
- Summary and conclusions

Legitimization (medical profession)

Why do we allow a physician to

- ask us to take off our clothes (coercion)?
- to stick needles into our body or even cut out an organ (bodily injury)?

Legitimization (medical professions)

Our situation ¹

- We feel bad or worry about our health
- We cannot solve the problem alone

The physician has expert knowledge and skills and we rely that ¹

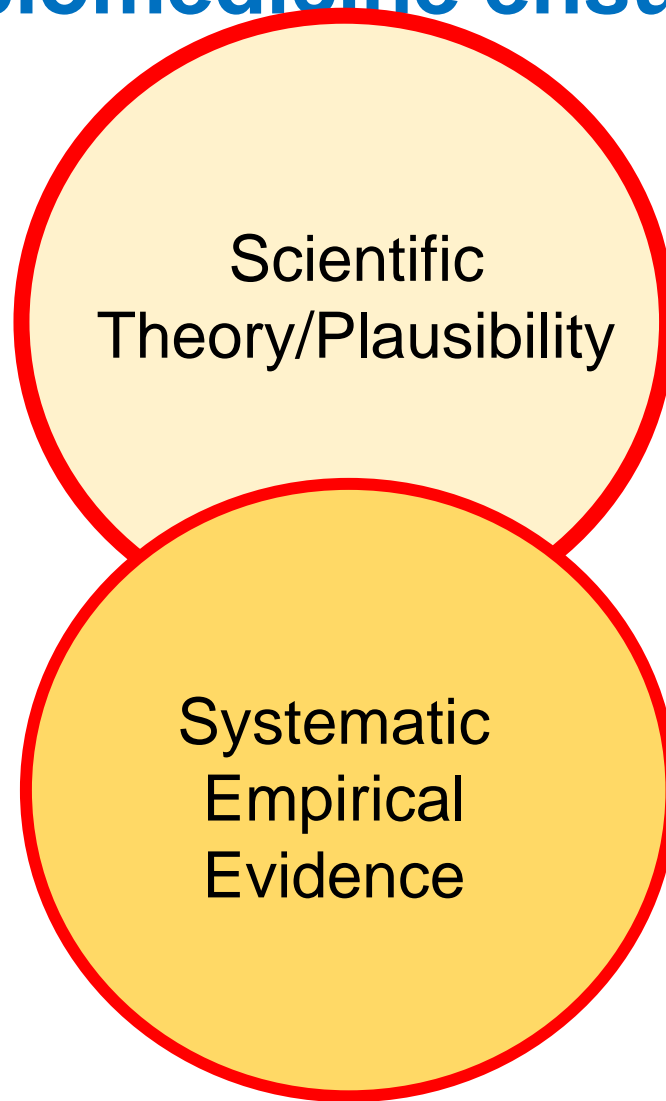
- our well-being is primacy
- **what she/he does is the one correct thing to do (functional specificity)**
- she/he acts in affectively neutral

Therapeutic ideal: act only when necessary and with specific therapies ²

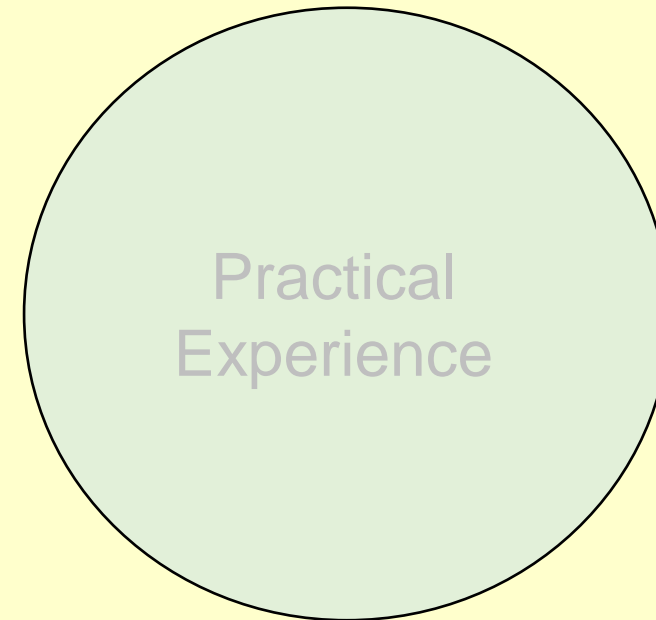
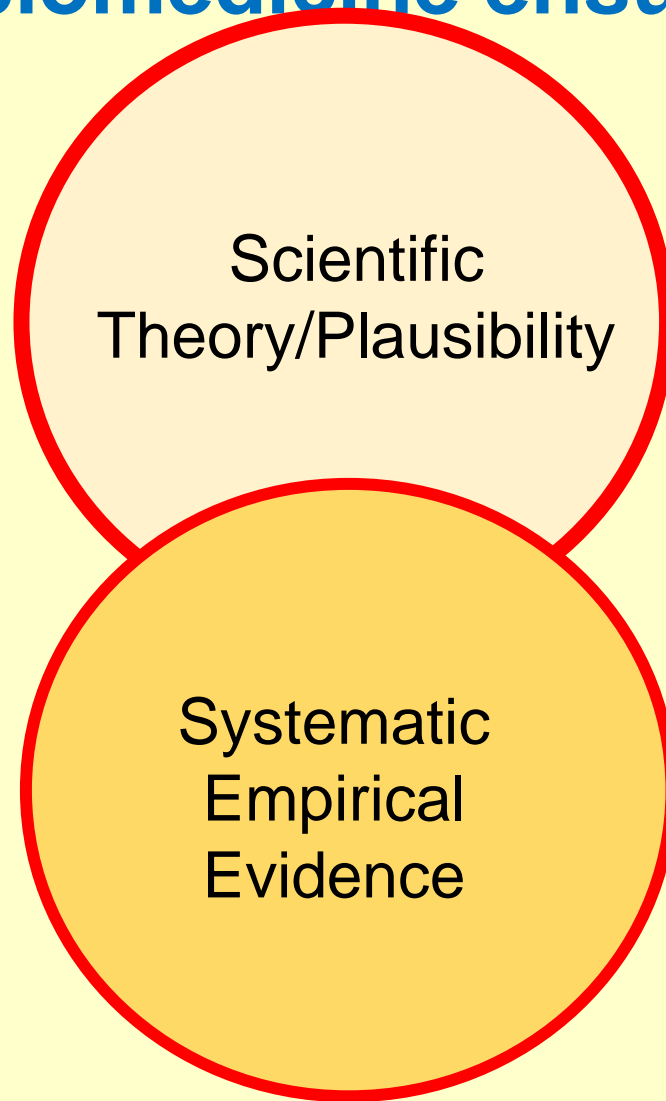
¹Parsons T. The Social System. The Case of Modern Medical Practice. 1964

²Comaroff J. Sociol Rev 1976;24:79-96

How biomedicine ensures functional specificity



How biomedicine ensures functional specificity



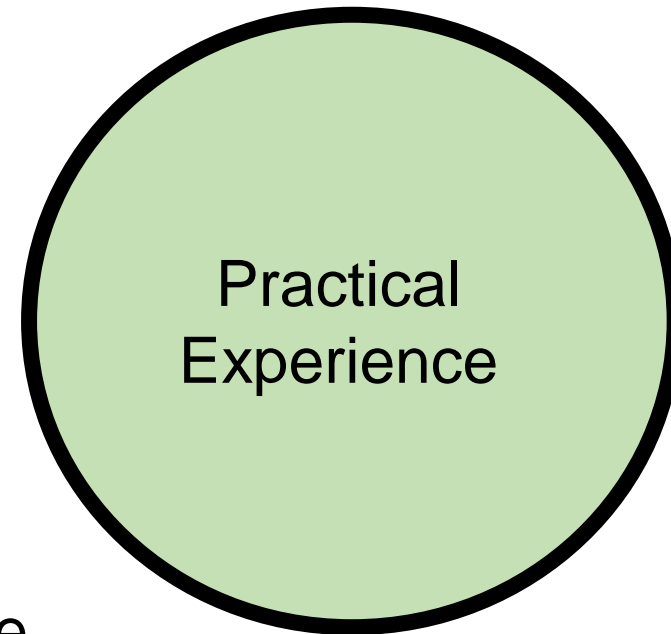
Academic and professional
authority and power

In routine practice positive practical experience is often sufficient evidence of specific effects for the patient and the doctor

But things get problematic

- on the professional level
- when public money is spent
- when there are safety concerns

And much of conventional medicine not based on solid trial evidence has more scientific plausibility and more academic authority/power



Why is the request stronger in case of CAM?

Controversial
Theory/Low
Plausibility

The lower the plausibility, the more need of strong evidence for efficacy (specific effects over placebo)

Controversial
Empirical
Evidence?

Beware of the placebo trap!!!

Controversial
Theory/Low
Plausibility

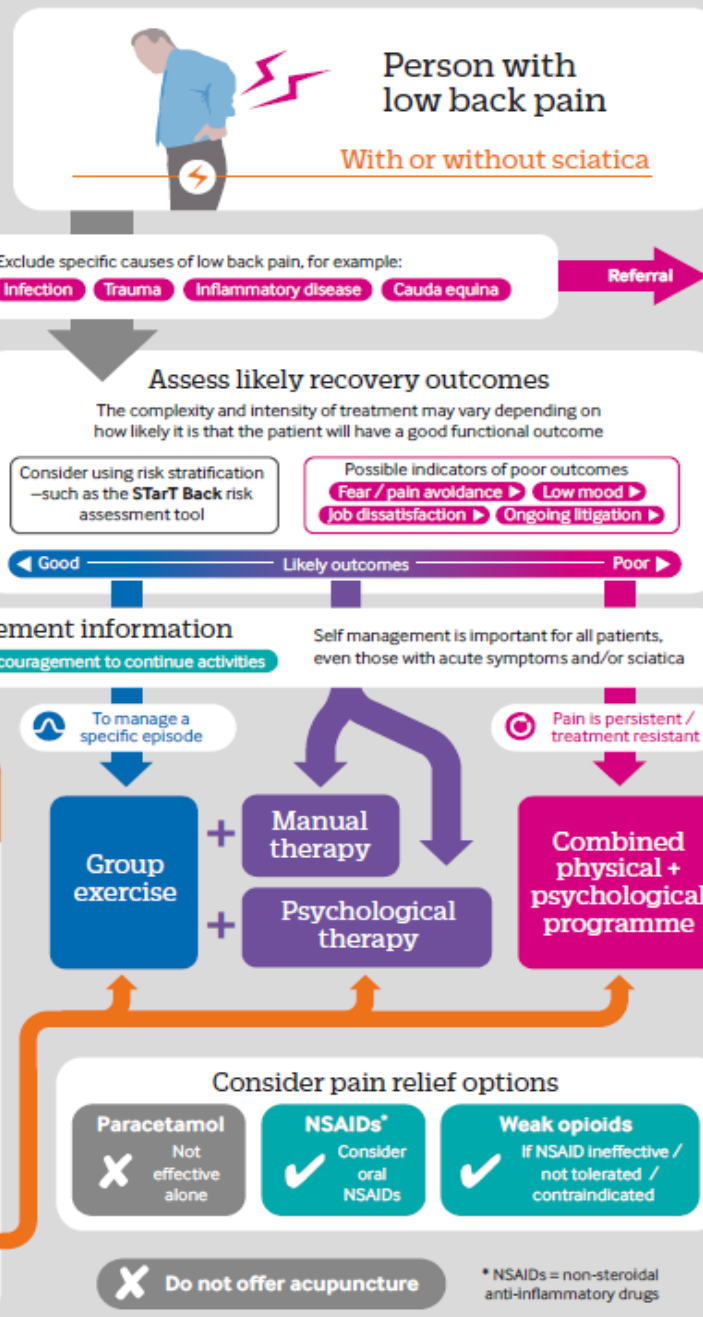
Placebo-controlled trials investigate whether the postulated mechanism of action makes a clinical difference! They directly link (scientific) theory and empirical evidence! If the mechanism is not fully clear, defining an adequate placebo is impossible!

Controversial
Empirical
Evidence?

Visual summary

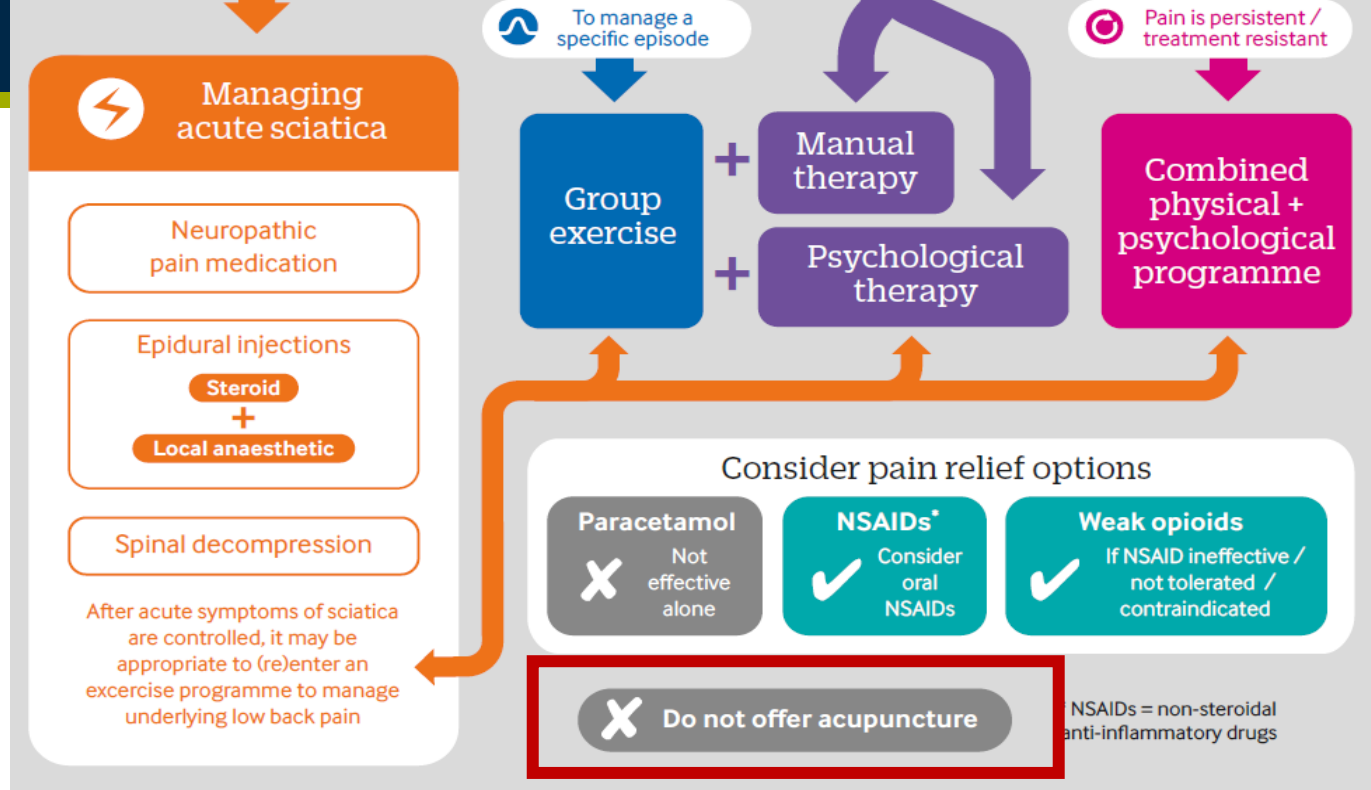
Managing low back pain and sciatica

A brief overview the new NICE guidelines, from the perspective of a patient presenting in primary care.



Low back pain and sciatica in over 16s: assessment and management (2016)

<https://www.nice.org.uk/guidance/ng59>



- Acupuncture had the most robust evidence for effects over usual care (effectiveness)
- It was the only non-drug therapy which had any reasonable evidence of effects over sham (efficacy/specific effects)!!!! But the size of these effects was below the pre-defined threshold for clinical relevance

The reasoning of the guideline development group (GDG)

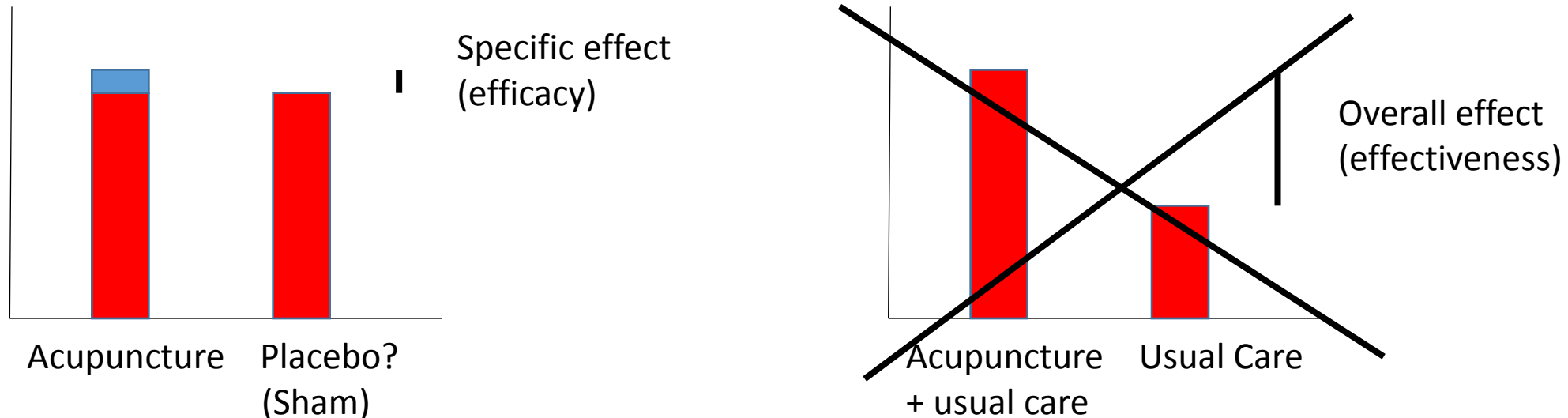
The GDG first discussed the necessity of a body of evidence to show specific intervention effects, that is, over and above any contextual or placebo effects. It was therefore agreed that if placebo-controlled evidence (or sham acupuncture) is available, this should inform decision making in preference to contextual effects, but

that the effect sizes compared with usual care would be important to consider if effectiveness relative to placebo, or sham, has been demonstrated. This approach is consistent with that taken in the recent osteoarthritis NICE guideline.

<https://www.nice.org.uk/guidance/ng59>

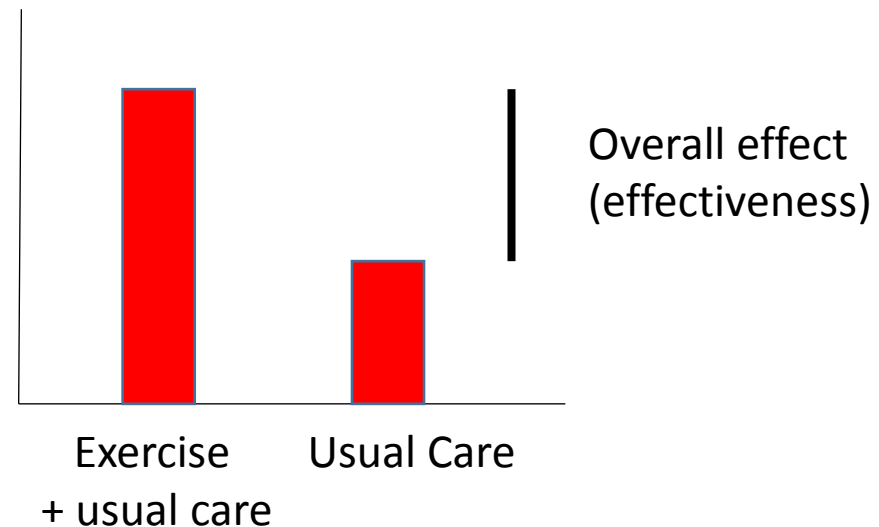
The logic (???) of the GDG

- If there is placebo-controlled(???) evidence (efficacy) ignore evidence over usual care (effectiveness - where specific and „contextual“ effects cannot be separated)
Actually there WAS evidence of specific effects, but there were too small



The logic (???) of the GDG

- If there is placebo-controlled(???) evidence (efficacy) ignore evidence over usual care (effectiveness - where specific and „contextual“ effects cannot be separated)
Actually there WAS evidence of specific effects, but there were too small
- If there is no placebo-controlled evidence (efficacy), then evidence of effectiveness is sufficient

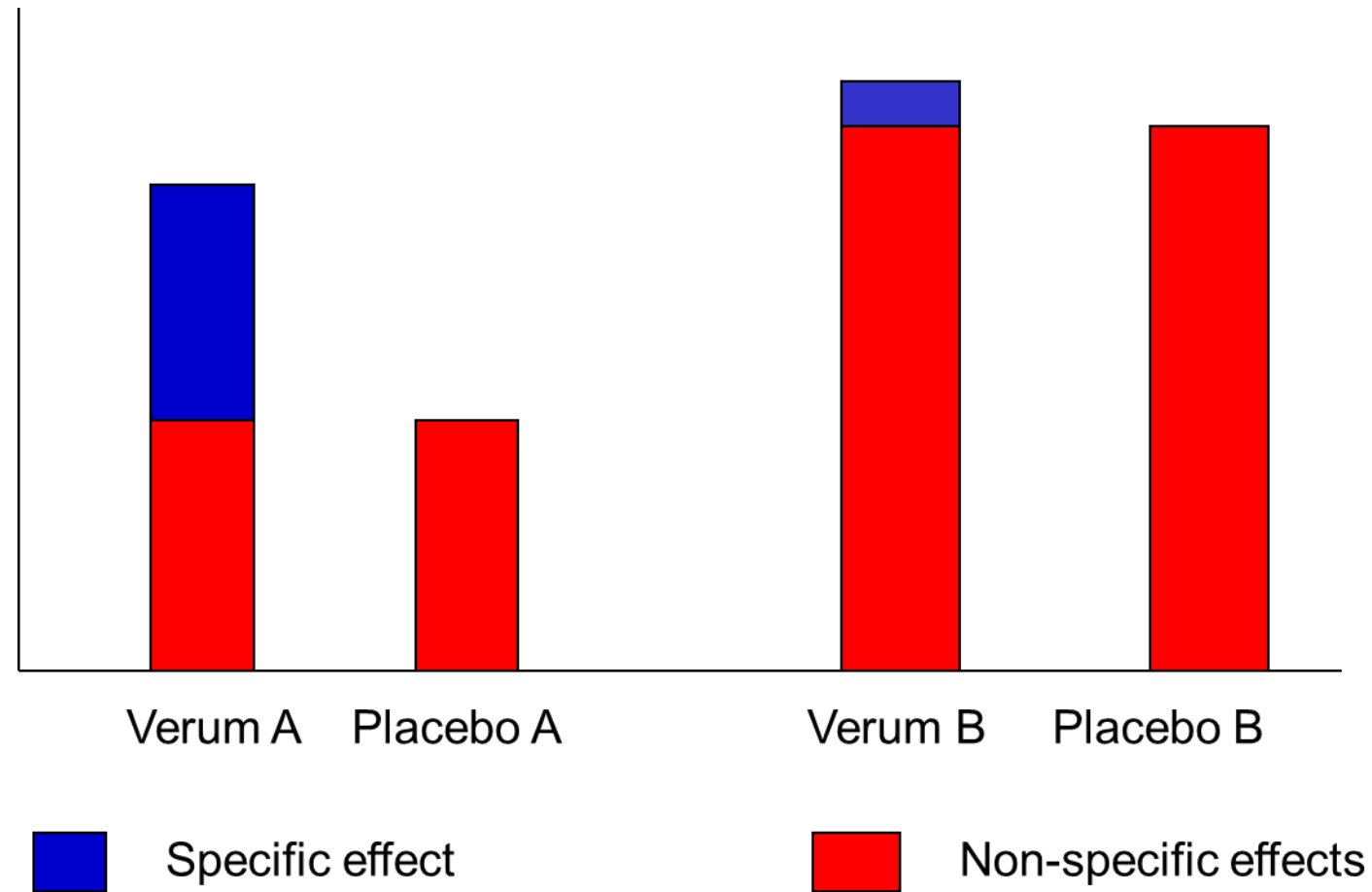


Functional specificity is fundamental for legitimate care

BUT

**Is the primary goal of health care
being science-based or being effective?**

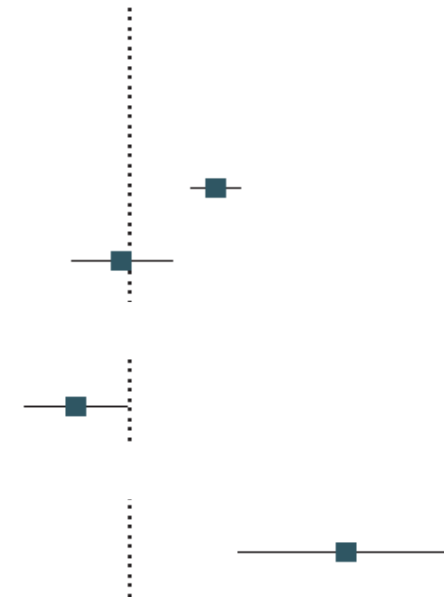
Accumulating evidence that the placebo paradox is reality in case of acupuncture. Which treatment would you prefer?



Accumulating evidence „the placebo paradox“ can be real: The example of acupuncture and drugs in migraine prophylaxis

Pharmacological drug
compared with:

Pharmacological placebo	1.79 (0.08)	[1.55-2.08]
Sham acupuncture	0.95 (0.17)	[0.68-1.33]
Acupuncture	0.70 (0.17)	[0.50-0.98]
No treatment	4.35 (0.37)	[2.10-8.99]



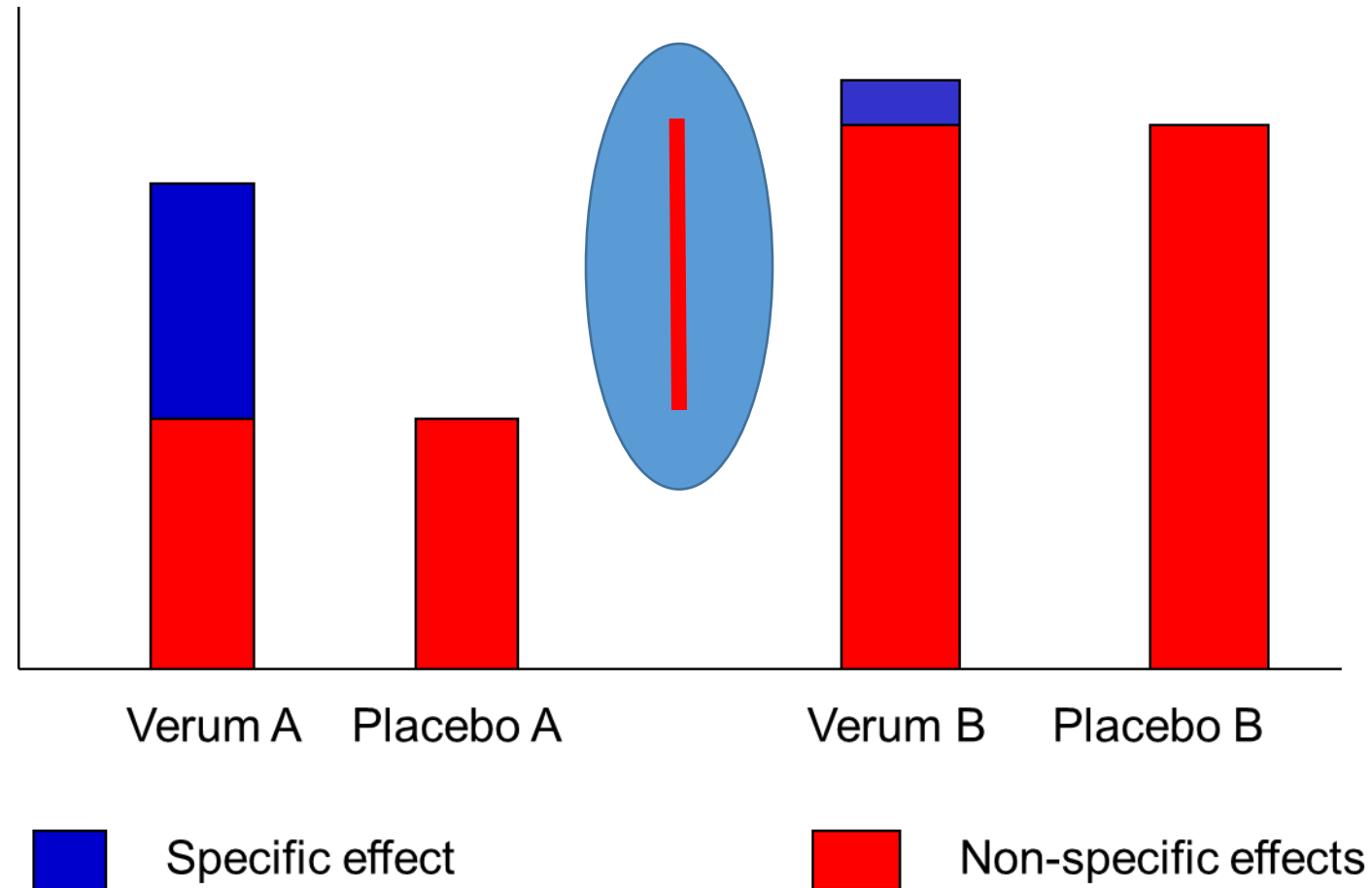
Meissner et al. JAMA Intern Med 2013;173:1941
Linde et al. Cochrane Library 2016

**Functional specificity is fundamental
Effectiveness is fundamental**

BUT

**Many CAM therapies should re-consider the focus of
their traditional theories of specific effects...**

...because we need a good explanation for this difference!



My time is up Summary & Conclusions (I)

- Evidence from RCTs is NOT interpreted in an empty space. It depends on what we/science currently know/believe and what else we consider important
- Functional specificity is central to legitimizing a therapy. Believing in functional specificity is crucial for a provider! Explaining and showing this remains important for CAM therapies! If you fail this is a problem!
- I think it is ok that more evidence of effectiveness is needed when evidence of efficacy is weak and the plausibility of "specific" effects is low. But how much evidence of effectiveness is then needed????
- While more evidence from RCTs is always nice, the major challenge is on the level of theories

My time is up Summary & Conclusions (II)

- While placebo/sham *controls* have a role the concept of placebo *interventions* and placebo *effects* is often highly misleading and an obstacle to logic thinking
- In my view quite a number of CAM therapies are quite reductionistic and mechanistic in their theories. **Do not commit the same error as biomedicine!**
- Apart for mind-body therapies/lifestyle therapies theories in textbooks of CAM therapies rarely reflect the current state in science (neurosciences, psychology, sociology, anthropology, bio-psycho-social model, ...). **Do not commit the same error as biomedicine!**
- Many CAM therapies have components/aspects which are likely to strengthen "placebo/context" – try to include these aspects better into the theories (then, maybe, they are no longer placebo but specific effects)

Thank you for listening!
Thanks to all the many homeopaths, acupuncturists,
naturopaths, other CAM people, CAM researchers, skeptics,
EBM people, lab researchers, general practitioners for the
countless discussions...

Some of the books that strongly influenced my view:

Sociology of Science - B. Latour: Science in Action, 1987; Pandora's Hope, 1997
 An Anthropological Analysis of Medicine - B. Good: Medicine, Rationality and Experience, 1994
 Non-specific effects in Psychotherapy - B. Wampold & Z. Imel: The Great Psychotherapy Debate. 2nd ed. 2015
 Evolutionary Perspective on Placebo Effects - F. Benedetti: The Patients' Brain, 2011
 Specifics of General Practice - R. Braun: Wissenschaftliches Arbeiten in der Allgemeinmedizin, 1988

Some of the texts that strongly influenced my view:

T. Parsons in The Social System, 1964: Chapter The Case of Modern Medical Practice
 J. Comaroff: A Bitter Pill to Swallow - Placebo Therapy in General Practice. Sociol Rev 1976;24:79-96
 K.M. Agledahl et al.: Clinical Essentialising. Med Health Care Philos 2010;13:107 & Courteous but not Curious. J Med Eth 1022;37:650
 M.D. Sullivan: Placebo Controls and Epistemic Control in Orthodox Medicine. J Med Philosophy 1993;18:213.

Many other articles by Grünbaum, Goodman, Howick, Walach, Hyland, Heusser, and so many others...

If anyone is aware of a good epistemological text on the role of practical experience in natural sciences, please tell me!

