

# Evaluation of complementary/ alternative medicine

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# DR. ERNST'S®



**TISANE AMINCISSANTE  
à base de plantes**

**HERBAL TEA FOR WEIGHT  
MANAGEMENT**

LOT 03D01

EXP03/2008



## 24 Filtrette®

PPS-11-06 Köln-5-2

# Outline of my lecture

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- Background
- Evaluation of CAM
  - 1) Efficacy/effectiveness
  - 2) Safety
- Obstacles
- The dilemma
- Conclusion

# Background

# The range of complementary medicine

ACUPUNCTURE - diagnosis + therapy

AROMATHERAPY - mainly therapy

CHIROPRACTIC - diagnosis + therapy

HEALING (faith, spiritual, etc) - diagnosis + therapy

HERBALISM (phytotherapy) - diagnosis + therapy

HOMOEOPATHY - diagnosis + therapy

IRIDOLOGY- diagnosis only

KINESIOLOGY- diagnosis + therapy

MASSAGE - diagnosis + therapy

OSTEOPATHY- diagnosis + therapy

REFLEXOLOGY- diagnosis + therapy

- physical
- pharmacological
- undefined "energies"

# CAM: common features

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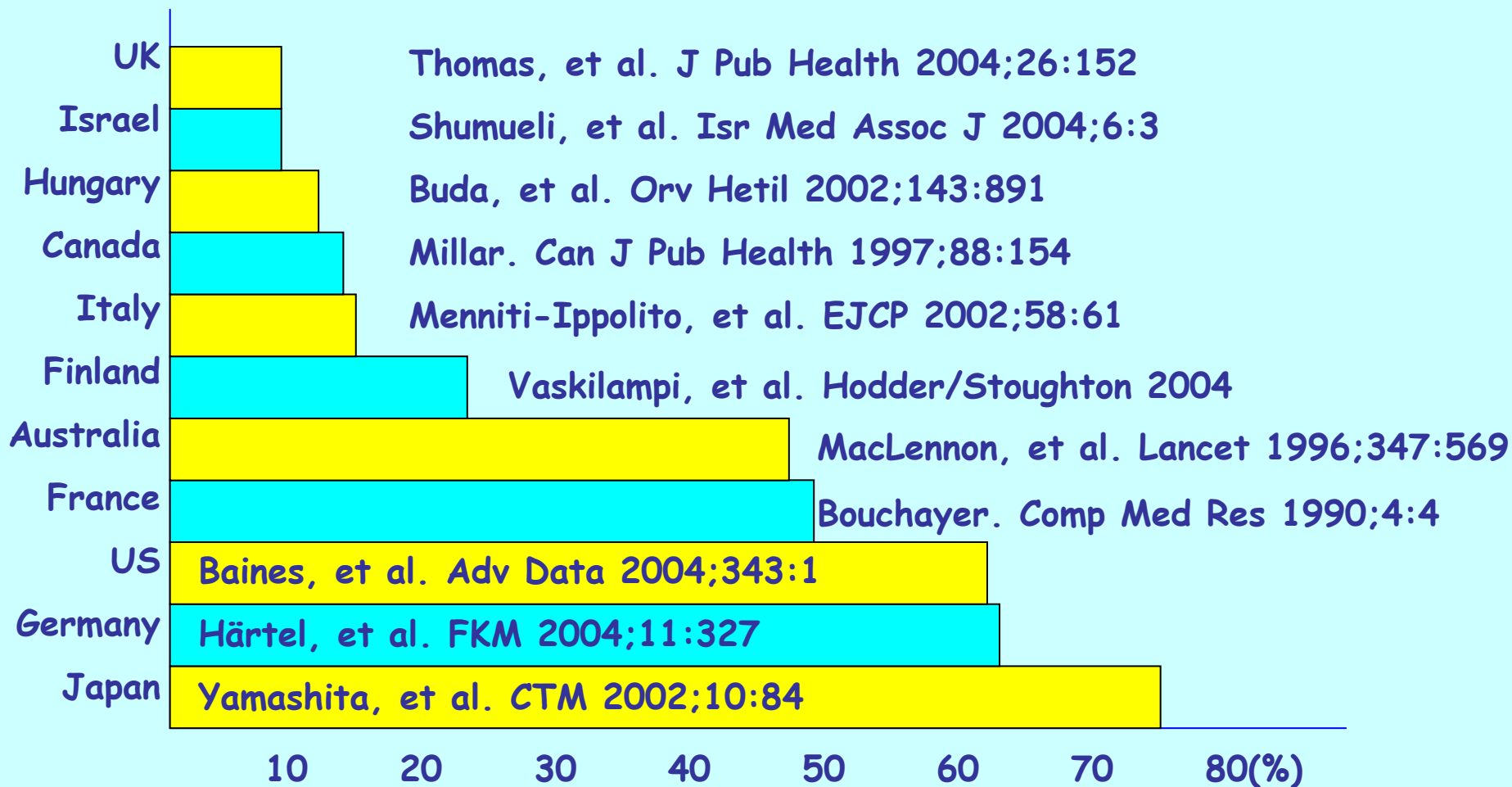
- Emphasis on holism, "energy" etc
- 'Natural' treatments
- 'Safe' treatments
- Individualisation
- Self-healing properties of body
- Long tradition of usage
- Private healthcare

Why does it  
matter?





# One-year prevalence of CAM-use in general populations



Why is CAM  
so popular?

# Positive

- Philosophical congruence
- Locus of control
- Therapeutic relationship

# Negative

- Desperation
- Rejection of science
- Rejection of establishment

# Evaluation of CAM

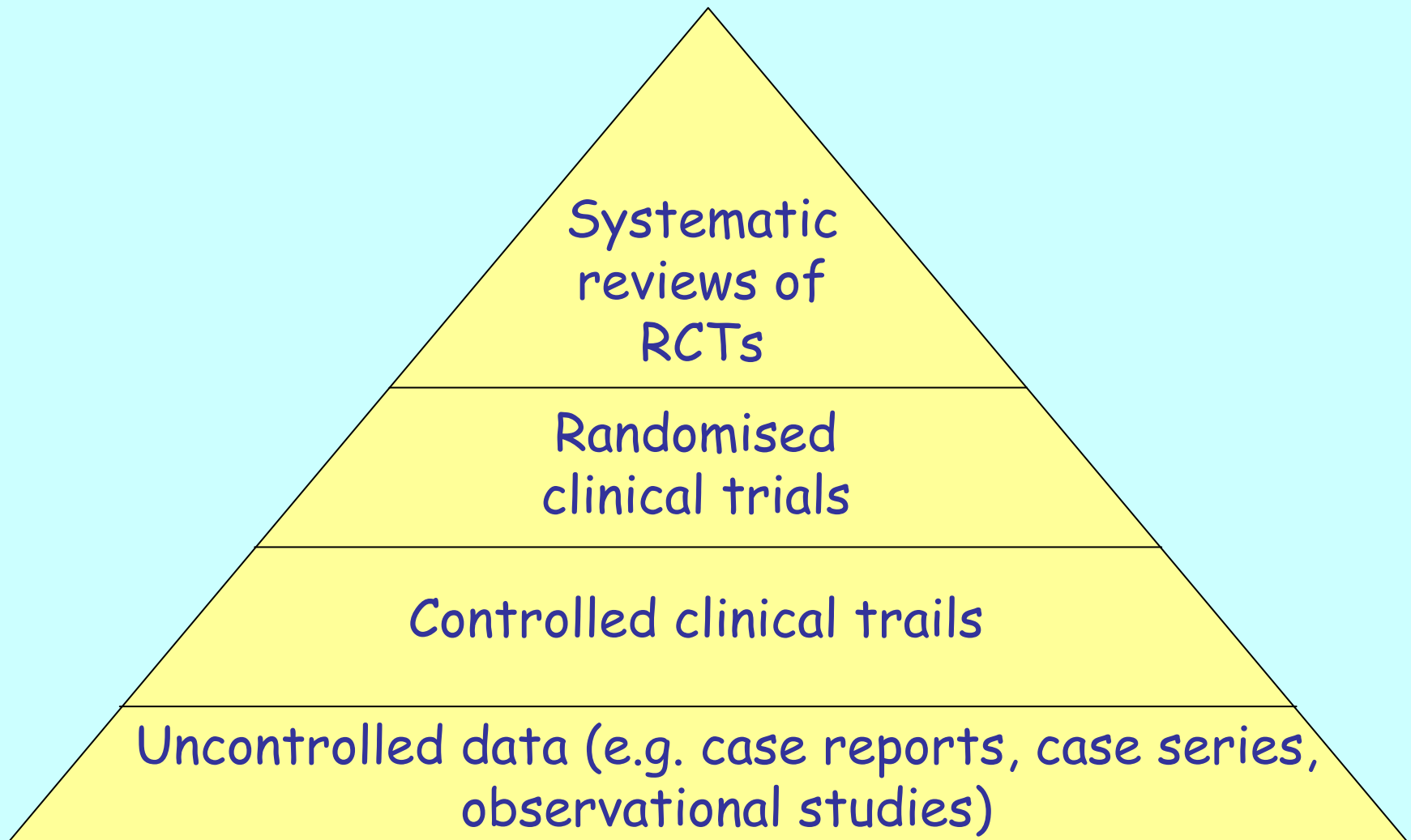
# Aim of evaluation

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Which form of CAM generates more than harm in which condition?

# 1. Efficacy/ Effectiveness

# Hierarchy of evidence

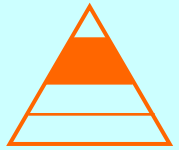


# RCTs of CAM: potential problems

- Placebos not possible
- Double-blinding not possible
- Patients with strong preference may not agree to randomisation
- Treatments are complex, individualised etc.
- Adequate endpoints do not exist
- Therapeutic effects are small
- Therapeutic effects are slow
- Investigators are not impartial
- The notion that CAM defies science
- Funds are scarce



# Spiritual healing for chronic pain

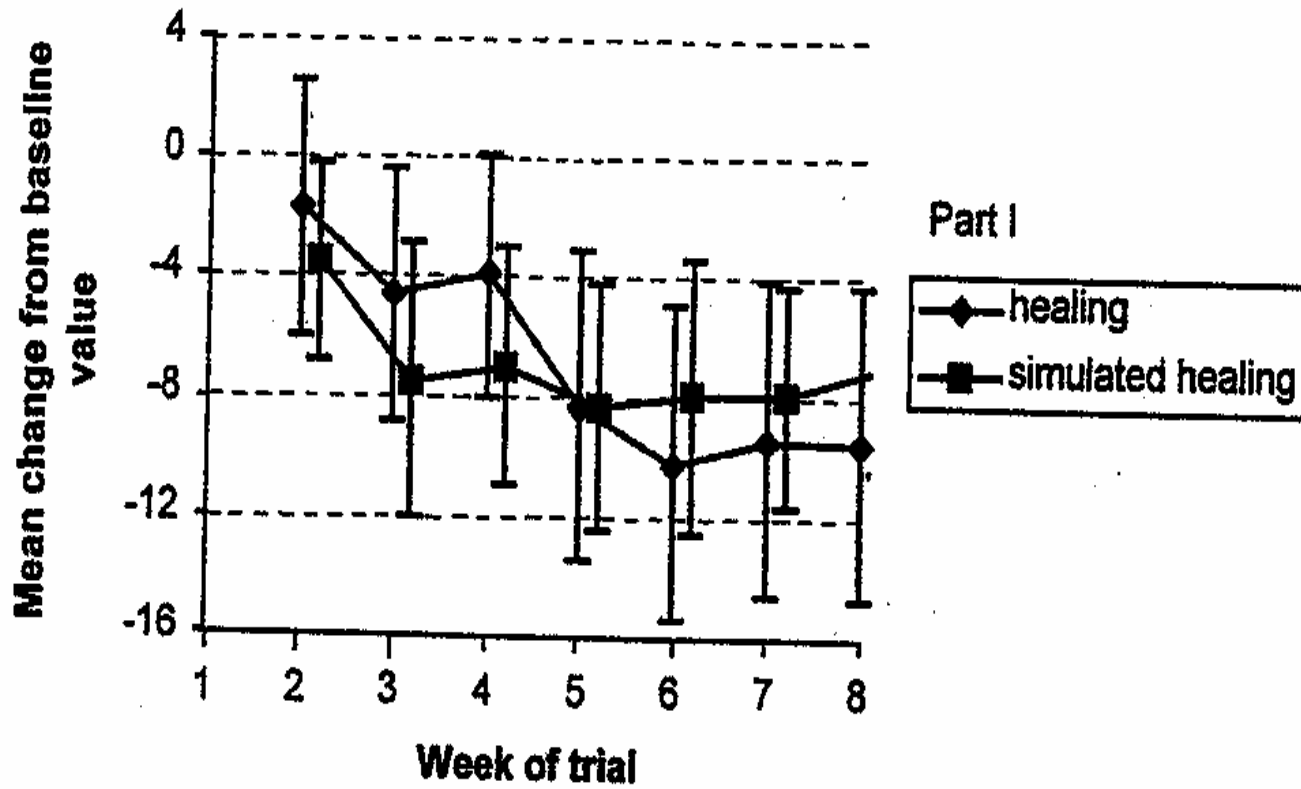


**Design:** double-blind RCT with 4 parallel arms

**Sample:** 120 patients with idiopathic chronic pain

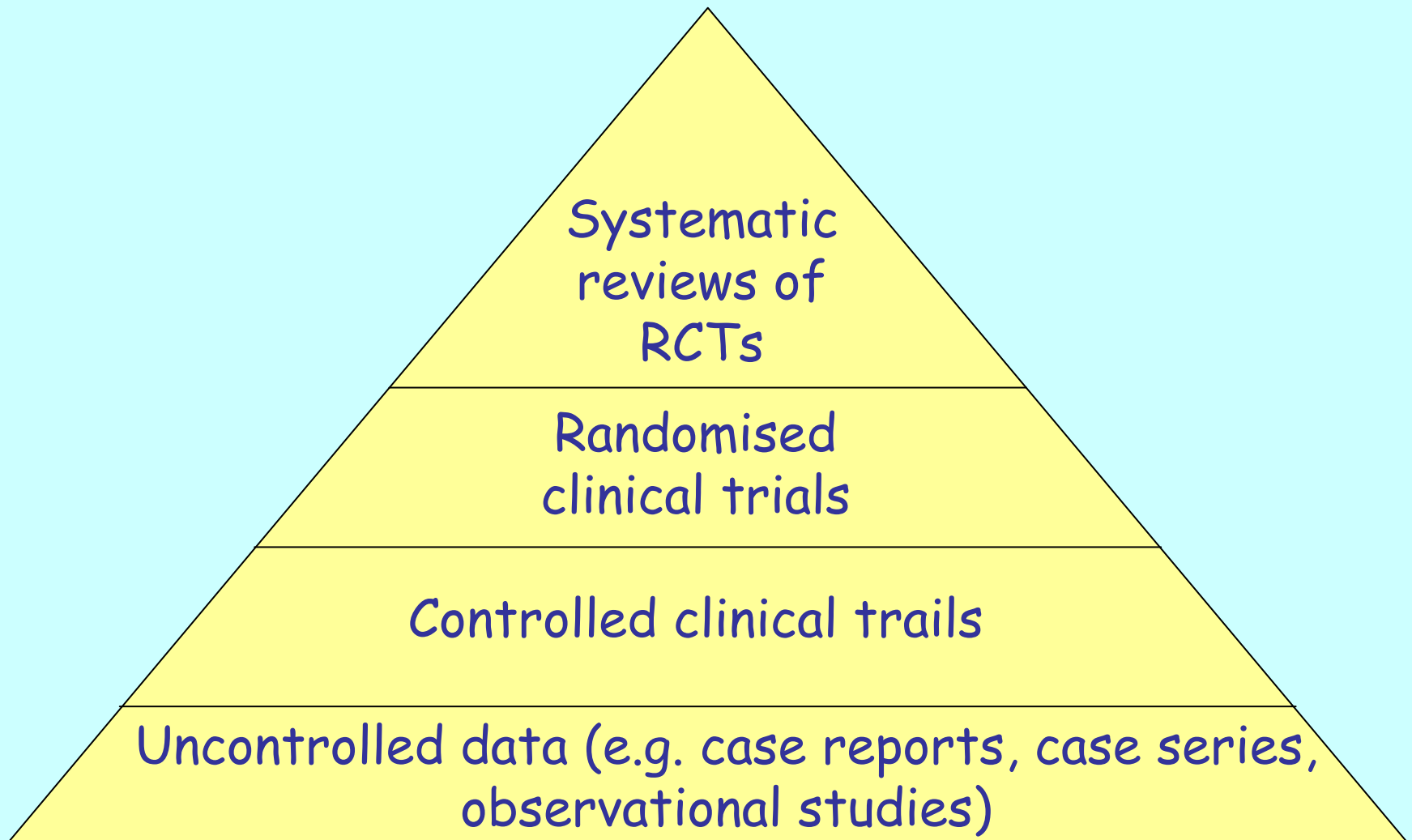
**Intervention:** A) face to face healing by 5 experienced healers  
B) face to face simulated healing by 5 actors  
C) distant healing by 5 (hidden) healers  
D) stimulated distant healing with no human presence

**Result:** Primary outcome measure (pain, McGill) decreased in all groups with no significant inter-group differences



- Random bias
- Selection bias

# Hierarchy of evidence



# SRs of Spiritual healing

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(n = 23 RCTs)

The methodological limitations of several studies make it difficult to draw definitive conclusions... However, .. 57% of trials showed a positive treatment effects, the evidence thus far merits further study.

Astin et al. *Ann Intern Med* 2000; 134: 903

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(n = +17 studies)

[The new trials]...shift the weight of the evidence against the notion that distant healing is more than a placebo.

Ernst. *WKW* 2003: 241

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# Systematic reviews of CAM: potential problems

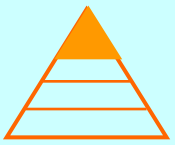
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- Primary data are flawed
- Primary data are scarce
- Publication bias
- Heterogeneity
- Investigators are not impartial
- Funds are scarce

# (Cochrane) Reviews of CAM Modalities

	Cochrane	Non-Cochrane	Total
Non-herbal supplements	71	46	117
Herbal remedies	23	79	102
Acupuncture	10	69	79
Chiropractic	2	33	35
Homeopathy	4	34	38
Other	53	171	224
Total	163	332	495

# Ginkgo for dementia



Design: systematic review

Sample: 10 RCTs

Results:

- Methodological quality was often excellent
- Totality of this evidence suggest efficacy in delaying clinical deterioration



# 2. Safety



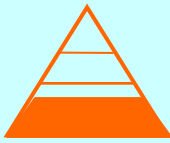
"Looks like he died of natural causes."

# Evaluating the safety of CAM: potential problems

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- General opinion (CAM is safe)
- Safety is not an issue in CAM research
- CAM community is not cooperative
- There is no 'post-marketing' surveillance
- There are no reliable data
- Investigators are not impartial
- Funds are non-existent

# Adverse effects of CAM



## Survey of large sample of British CAM users

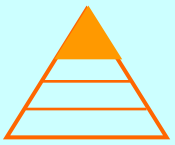
Therapy	reporting	adverse effects
Spinal manipulation	15.8 %	(~50%)
Acupuncture	12.5 %	(7-11%)
Homoeopathy	9.8 %	(~20%)
Herbal medicine	7.6 %	(depends)

# Specific research question

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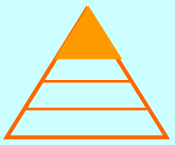
- Ginkgo biloba has been associated with complications of bleeding
- Does ginkgo affect haemostasis
  - as a monotherapy?
  - through herb-drug interactions?

# Ginkgo: case reports of bleeding



- Design:** systematic review
- Searches:** 5 electronic databases
- Inclusion:** clinical reports of bleeding associated with ginkgo monopreparations
- Results:**
- 12 articles were found
  - methodological quality often poor
  - likelihood of causality was low
- Conclusions:** "causality between ginkgo biloba intake and bleeding is unlikely"

# Ginkgo: RCTs testing effects on coagulation

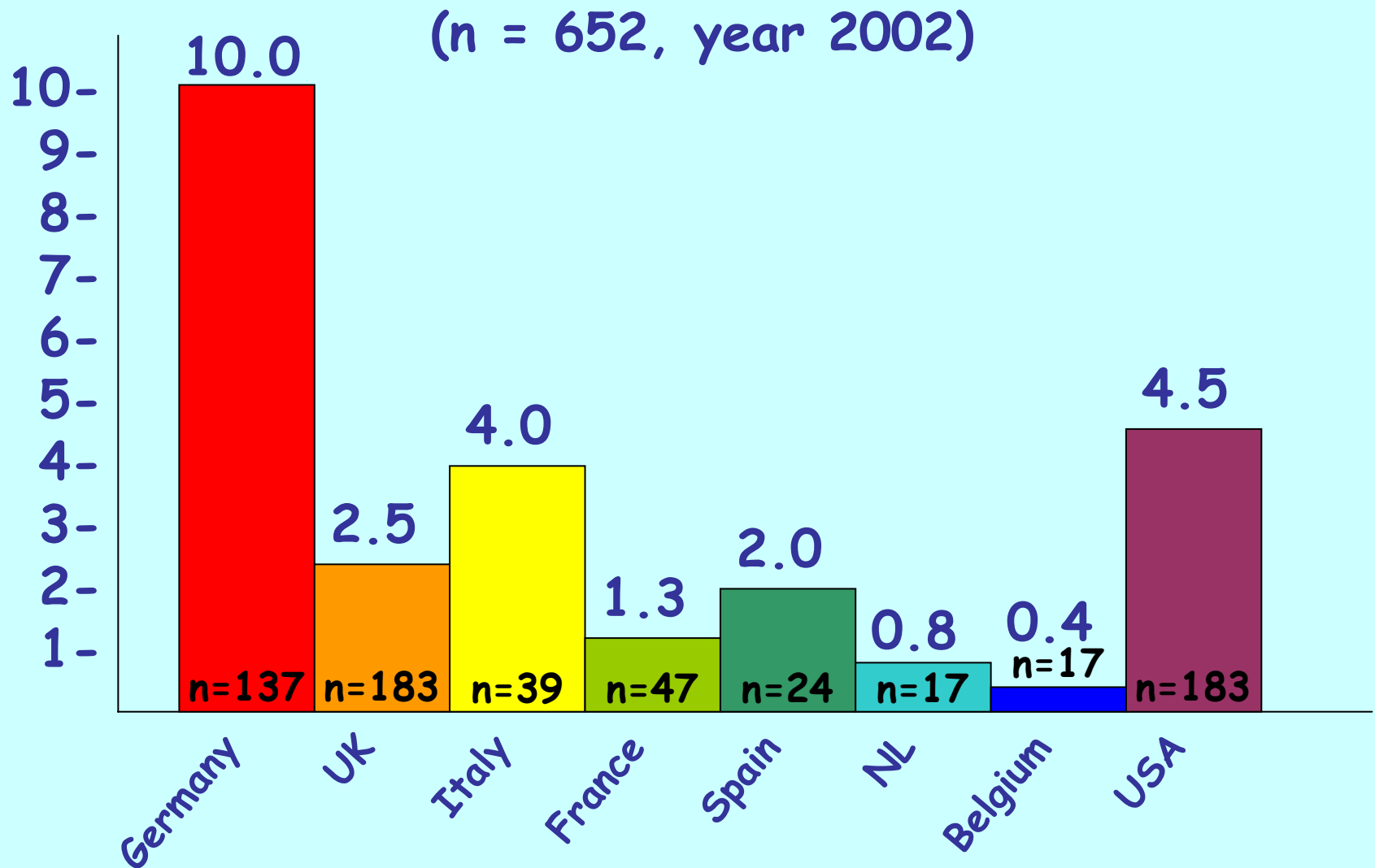


- Design:** systematic review
- Searches:** 6 electronic databases
- Inclusion:** RCTs assessing at least 1 coagulation parameter
- Results:**
- 8 RCTs were found (2 on interactions)
  - most were of good methodological quality
  - no significant changes were observed
- Conclusions:** "evidence does not demonstrate that extracts of ginkgo biloba causes significant changes in blood coagulation parameters"

# Obstacles



# CAM research: direction of conclusions

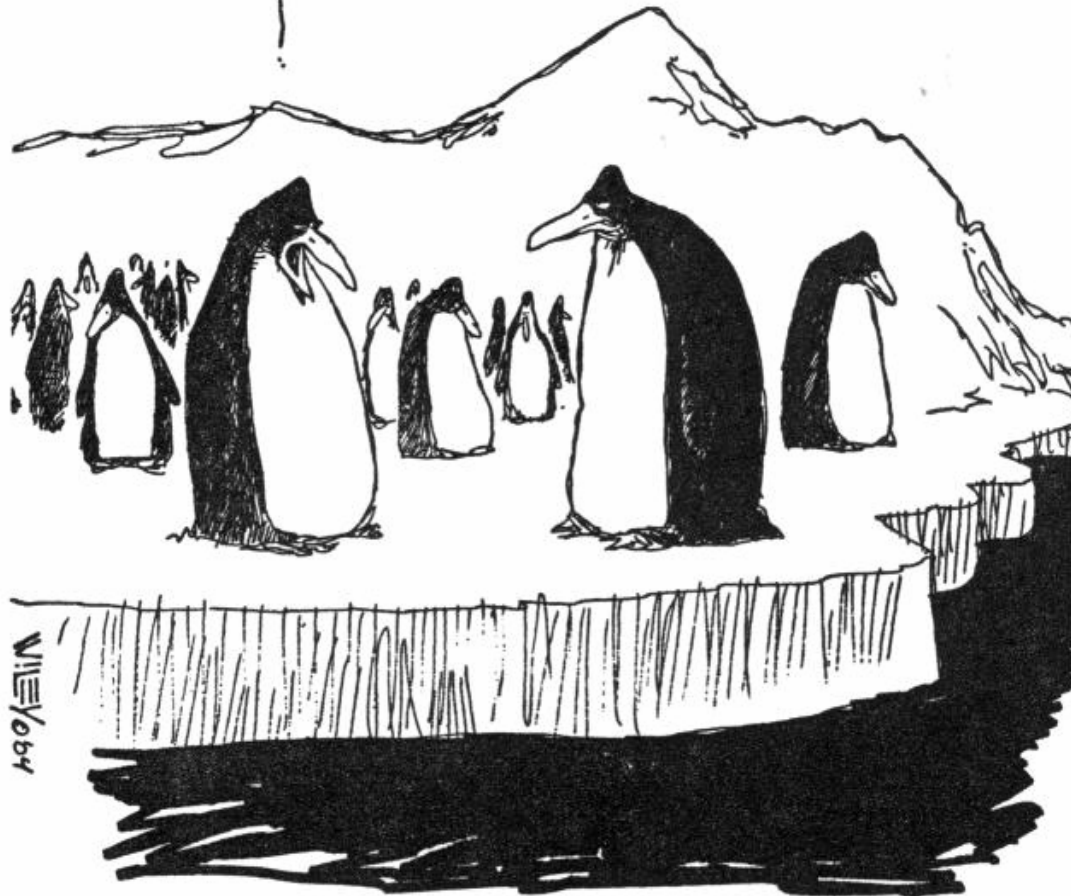


# CAM: the “black and white” view

Proponents: CAM is useful, regardless of evidence

Opponents: CAM is a waste of time, regardless of evidence

YES, AS A MATTER OF FACT, I DO HAVE TO TAKE EVERYTHING AS BLACK OR WHITE



# Homeopathic treatment for chronic disease

Design: Observational study

Sample: 6544 chronic out-patients

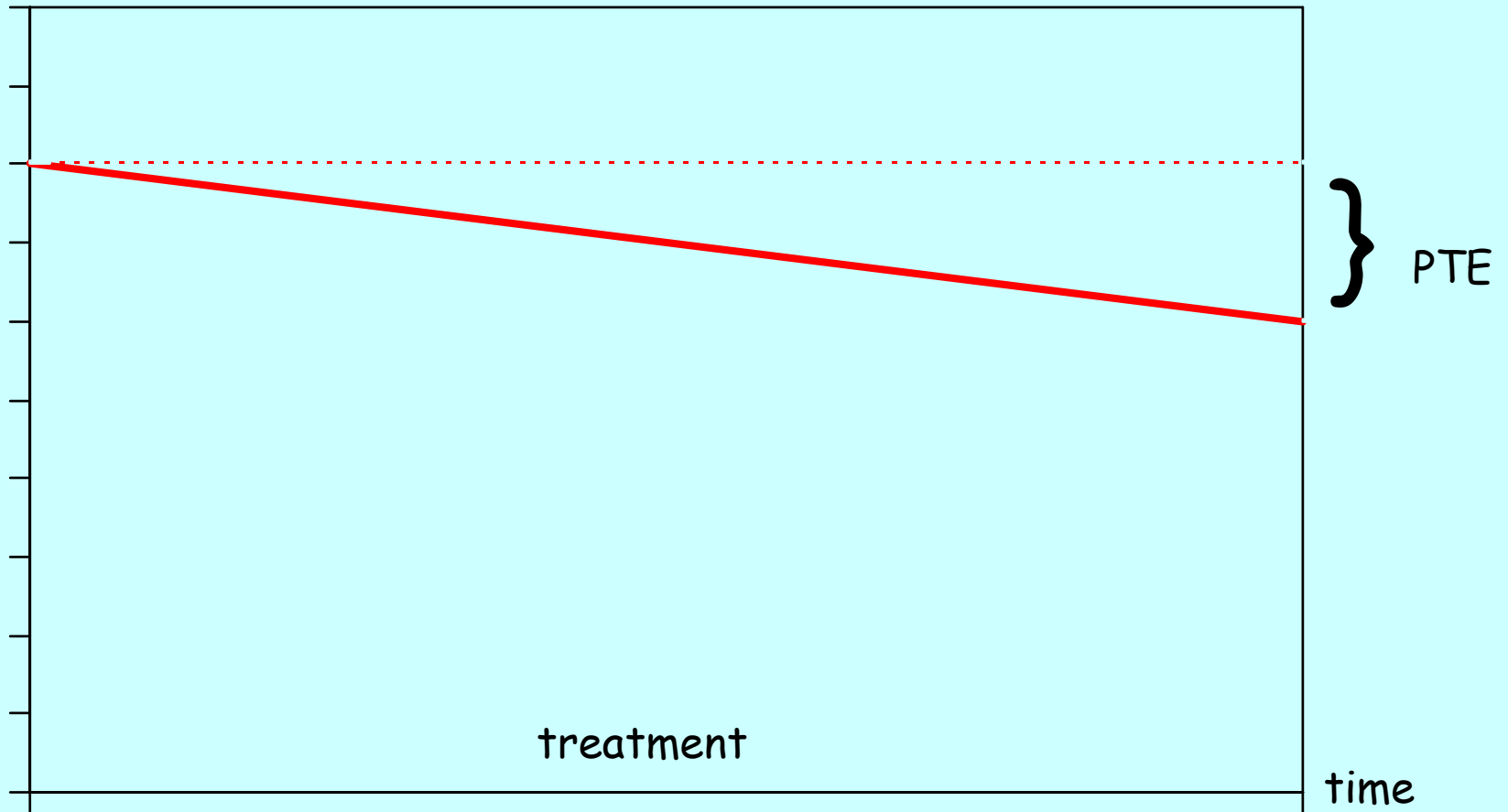
Endpoint: 7-point Likert scale

Results: 71% of all patients perceived positive changes

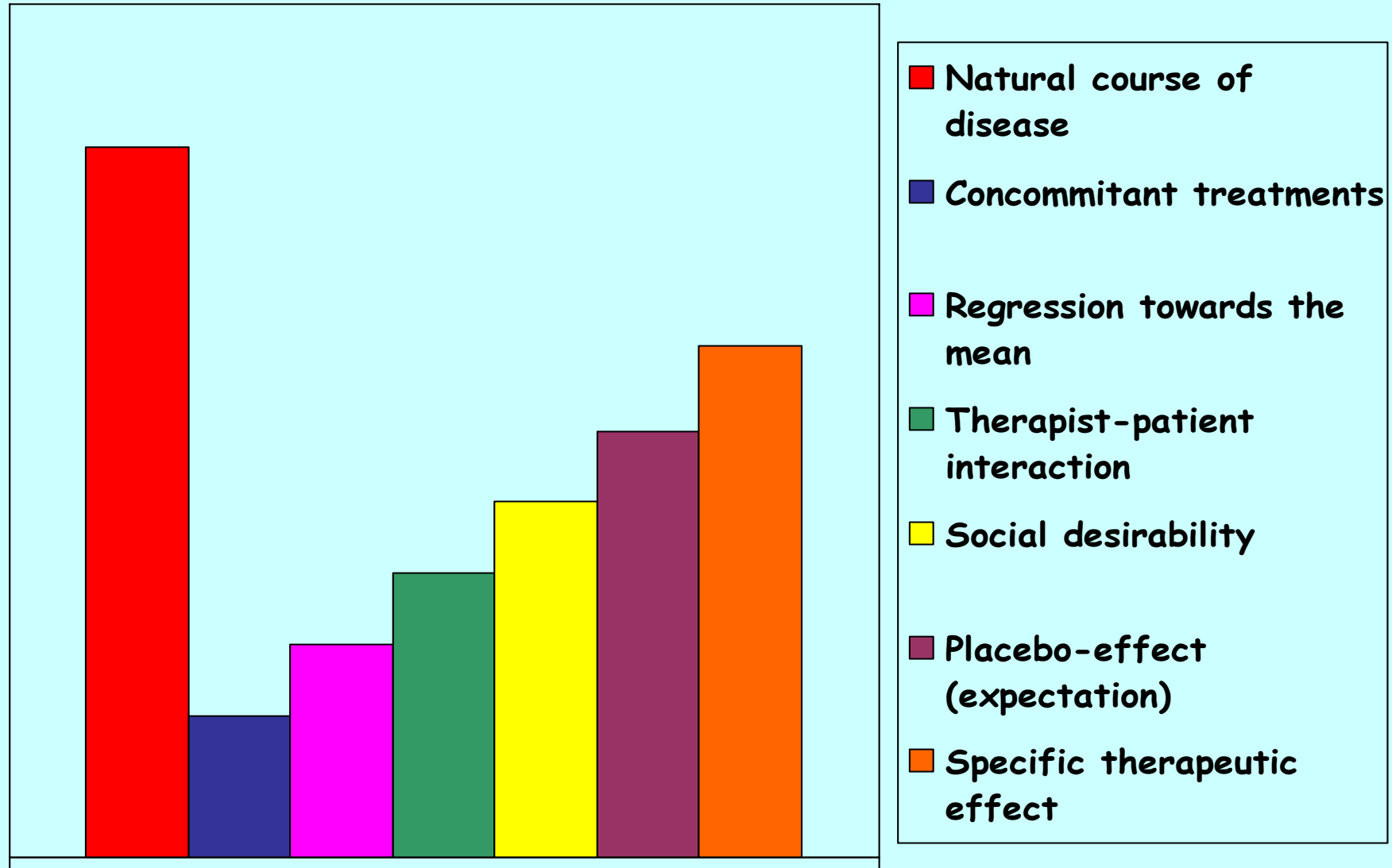
Conclusion: "The results show that homeopathic treatment is a valuable intervention"

# Perceived therapeutic effect (PTE)

symptom



# The "perceived therapeutic effect"



# The dilemma

A form of CAM is  
ineffective but  
nevertheless helps  
patients

# What counts is that it helps patients

Waxman J, oncologist at Imperial College London:  
"I'm all for healers. I've seen my patients look and feel better as a result. Who cares how it works as long as it does?"

Six counter-arguments:

1. therapy could also do harm
2. endorsement leads to use as an alternative
3. even effective therapies have a placebo-effect
4. doctors should not delegate empathy
5. therapy costs £100 per session
6. endorsement of mystical nonsense undermines rationality



# It follows:

- The use of an ineffective CAM is rarely justified.
- Prescribe a treatment with specific effects and maximize non-specific effects simultaneously.

# Conclusion

"CAM, like conventional medicines, should be subject to careful evaluation of their effectiveness and safety. It is important that treatments...are properly tested and that patients do not receive misleading information...NHS provision for CAM...should be confined to treatments that are supported by...evidence of both effectiveness and safety"



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