

GIMBE® *Workshop*
 Gruppo Italiano per la Medicina Basata sulle Evidenze
Evidence-based Medicine
 Le opportunità di un linguaggio comune 3ª ed.
 Evidence-Based Medicine Italian Group
 Como, 1-2 aprile 2006  Sezione di Como

Le medicine non convenzionali
 Tra prove di efficacia, rischi e stregoneria

Conduce: Nino Cartabellotta

Discussant: Gianni Garozzo, Maurizio Mancuso,
 Raffaele Pastore, Mara Ramploud

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CM
 Conventional
 Medicine

CAM
 Complementary and
 Alternative Medicine

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1. Differenze tra CAM e CM

Conventional	Unconventional
Mainstream	Alternative
Orthodox	Unorthodox
Regular	Irregular
● Scientific	● Unscientific
Evidence based	Not evidence based
Allopathic	Naturopathic
Western	
Modern	

The most compelling (and most "inflammatory") label is that conventional medicine is scientific and that unconventional is unscientific.

Dalen JE. Arch Intern Med. 1998
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1. Differenze tra CAM e CM

1. CAM is predominantly **private medicine**, not reimbursed within the healthcare system.
2. Providers of CAM often **lack medical training**, and often are not physicians.
3. The **effectiveness and safety** of many forms of CAM is **not proven**, according to the EBM standards.

Ernst E, et al. J Med Ethics 2004
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1. Differenze tra CAM e CM

4. The **research funds** for CAM are currently **scarce**, much more so than in CM.
5. CAM **lacks** a tradition or culture of modern, scientific research comparable to CM.
6. CAM is claimed to be holistic and its **benefits of CAM** are thought to be mental, psychological, spiritual, and social; thus they **can be less tangible or measurable than those of CM**.

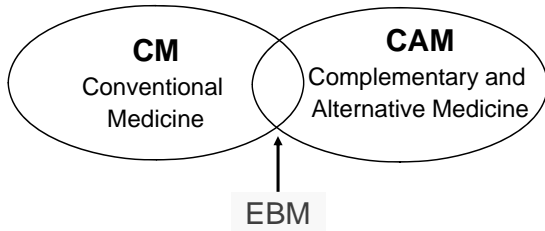
Ernst E, et al. J Med Ethics 2004
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Dalen JE

**"Conventional" and
 "Unconventional" Medicine
 Can they be integrated?**

Arch Intern Med 1998;158:2179-81
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CM & CAM: Can they be integrated?



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Tonelli MR, Callahan TC

Why alternative medicine cannot be evidence based

Acad Med 2001;76:1213-20

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1. Differenze tra CAM e MC
2. **Efficacia delle CAM**
3. Rischi delle CAM
4. CAM ed EBM

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La gerarchia delle prove di efficacia

1. Revisioni sistematiche di RCTs
2. Trials controllati e randomizzati
3. Trials controllati non randomizzati
4. Trials non controllati
5. Studi osservazionali analitici
6. Studi osservazionali descrittivi
7. Opinioni, fisiopatologia

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Mason S, Tovey P, Long AF

Evaluating complementary medicine: methodological challenges of randomised controlled trials

BMJ 2002;325:832-4

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- CAM should be evaluated as rigorously as conventional medicine to protect the public from charlatans and unsafe practices, but many practitioners of CAM are reticent about evaluation of their practice.

- In defence, many CAM practitioners argue that research methods dissect their practice in a reductionist manner and fail to take into account complementary medicine's holistic nature leading to invalid evaluation.

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Mason S, et al. BMJ, 2002

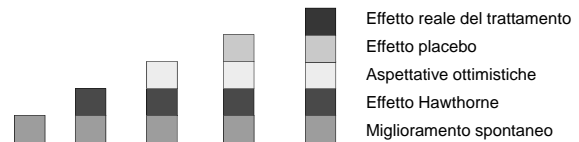
CAM: Where is the evidence?

- CAM cannot be evidence-based in the conventional sense of the word.
- Softer types of evidence need to be taken into consideration as well.
- Placebo effects must not be dismissed as nonbeneficial.
- The healing encounter includes significant factors that may never be quantifiable
- The scientific method cannot measure hope, divine intervention, or the power of belief.
- Research in CAM must consider social, cultural, political, and economic contexts.

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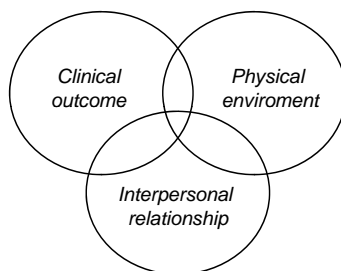
Ernst E. J Fam Pract, 2003

Quali fattori confondenti negli studi non controllati?



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Soddisfazione dei pazienti



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Trials non controllati e studi osservazionali

Nella CM il loro ruolo è limitato a:

1. Malattie rare
2. Studi di fase II
3. Quando sussistono tutte le condizioni seguenti:
 - malattia ad esito sfavorevole/fatale
 - drammatica efficacia del trattamento
 - effetti sfavorevoli accettabili
 - assenza di trattamenti alternativi
 - presupposti fisiopatologici convincenti

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Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials

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Smith GCS et al. BMJ, 2003

Trials non controllati e studi osservazionali

- Vitamina C (scorbuto)
- Insulina (coma diabetico)
- Antibiotici (polmonite pneumococcica, endocardite batterica)
- Vitamina B12 (anemia perniciosa)
- Appendicectomia (appendicite perforata)
- Trapianto di fegato (epatite acuta fulminante)
- Concentrati di fattore VIII e IX (emofilia)
- Inibitori della colinesterasi nella miastenia gravis
- Alcuni antidoti negli avvelenamenti
- Defibrillatore esterno nell'arresto cardiaco

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Problems in testing CAM

- The average size of the overall therapeutic effect associated with CAM is usually modest and the NNT are often high (statistically significant but of debatable clinical relevance)
- Even minor adverse effects would therefore critically disturb the delicate balance of risk and benefit.

Ernst E. J Fam Pract, 2003

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Table 1 Examples of techniques used in complementary and alternative medicine

Technique	Method	Indication (examples)	Serious risks (examples)	Benefits*	Risk/benefit analysis
Acupuncture ²	Therapeutic /diagnostic	Chronic pain	Local trauma, infections (rare)†	No convincing evidence	Uncertain
Herbalism ²	Therapeutic /diagnostic	Various	Local trauma, infections (rare)†	Continuing evidence	Positive
Yoga/therapy ²	Therapeutic	Various	Allergic reaction, carcinogenic potential in some oils	Good evidence for relaxing effects	Uncertain
Chelation therapy ²	Therapeutic	Intermittent claudication	Kidney damage, electrolyte imbalances†	No convincing evidence	Negative
Chiropractic ²	Therapeutic /diagnostic	Back pain	Vertebral or carotid artery dissection†	Promising but no convincing evidence for acute or chronic back pain	Uncertain
Herbalism ²	Therapeutic	(St John's wort for depression)†	Increased risk of bleeding interaction with numerous drugs	Clear evidence that it is superior to placebo	Positive
Herbalism ²	Therapeutic /diagnostic	(Sawage herbs for intermittent claudication)	Increased risk of bleeding interaction with anticoagulants	Clear evidence that it is superior to placebo	Positive
Herbalism ²	Therapeutic /diagnostic	Various	No serious direct risks of highly toxic remedies	No clear evidence for clinical effectiveness for any condition	Uncertain
Herbalism ²	Therapeutic /diagnostic	NA (diagnostic methods)	False positive or false negative diagnosis	No convincing evidence	Negative
Massage ²	Therapeutic /diagnostic	Back pain	No serious direct risks	No convincing evidence	Uncertain
Reflexology ²	Therapeutic /diagnostic	Various	No serious direct risks	No convincing evidence for clinical effectiveness for any condition	Uncertain
Herbalism ²	Therapeutic /diagnostic	Various	No serious direct risks	No convincing evidence for clinical effectiveness for any condition	Uncertain

Evidence based on recent systematic review or meta-analysis. †Adverse effects have occurred. ‡As examples of one specific herbal remedy. †Not applicable.

Ernst E, et al. J Med Ethics 2004

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Raschetti R, Menniti-Ippolito F, Forcella E, Bianchi C.

Complementary and alternative medicine in the scientific literature

J Altern Complement Med 2005;11:209-12

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RESULTS

- During the period 1996-2002, a total of 20,209 articles about CAM were published
- Approximately 50% of CAM articles appeared on journals with no IF.
- The proportion of clinical trials was 7.6% of total CAM articles.

Raschetti R, et al. J Altern Complement Med 2005

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CONCLUSIONS

- We believe there is an **urgent need to conduct rigorous research in the field of CAM** in order to support, for the need of the public, an **evidence-based approach** to these therapies.

Raschetti R, et al. J Altern Complement Med 2005

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1. Differenze tra CAM e MC
2. Efficacia delle CAM
3. **Rischi delle CAM**
4. CAM ed EBM
5. La posizione del **GIMBE®**

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3. Rischi delle CAM

1. Direct harm

- Harm results from a side effect of a CAM
 - Herb-drug interaction
 - Toxicity of herbs
 - Vertebral artery dissection or nerve damage after chiropractic manipulation
 - Needle penetrating the lung during acupuncture

Kotsirilos V. Aust Fam Physician, 2005

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3. Rischi delle CAM

2. Indirect harm

- Results from the delay of appropriate treatment for a medical condition due to misinformation about unrealistic treatment of a condition.
- Indirect harm is often seen with cancer treatments.

Kotsirilos V. Aust Fam Physician, 2005

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3. Rischi delle CAM

3. Economic harm

- Many CAMs are marketed directly to the public through advertising and testimonials in the press, the internet, television, and through multi-level marketing.

Kotsirilos V. Aust Fam Physician, 2005

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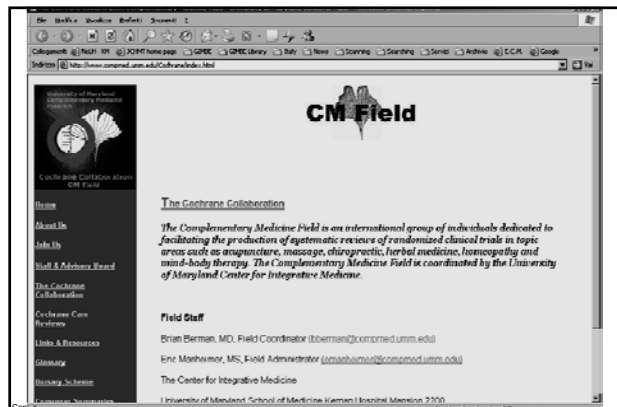
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Ezzo J, Berman BM, Vickers AJ, Linde K.

Complementary medicine and the Cochrane Collaboration

JAMA 1998;280:1628-30

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193 Cochrane Reviews related to CAM
(Issue 2, 2005)



Publicazioni secondarie

- ACP Journal Club
- Bandolier
- Evidence-Based Medicine
- Evidence-Based Cardiovascular Medicine
- Evidence-Based Mental Health
- Evidence-Based Nursing
- Evidence-Based Healthcare & Public Health
- Evidence-Based Dentistry
- Evidence-Based Obstetrics and Gynecology
- Evidence-Based Ophthalmology
- Evidence-Based Gastroenterology
- **Evidence-Based Complementary and Alternative Medicine**
- Journal of Evidence-based Dental Practice



Shekelle PG, Morton SC, Suttrop MJ, et al.

Challenges in systematic reviews of complementary and alternative medicine topics

Ann Intern Med 2005;142(12 Pt 2):1042-7

Vickers AJ

Message to complementary and alternative medicine: evidence is a better friend than power

BMC Complementary and Alternative Medicine 2001;1:1

- There are no good reasons to suggest that EBM is incompatible with CAM, or that it works to CAM's disadvantage.
- Were the CAM community to reject EBM, its future would be decided in the closed-off back rooms of power.
- By placing CAM on an equal footing with conventional medicine - what matters for both is evidence of effectiveness - EBM provides an opportunity for CAM to find an appropriate and just place in health care.

Vickers AJ.
BMC Complementary and Alternative Medicine, 2001

There is no alternative medicine.

There is only scientifically proven, evidence-based medicine supported by solid data or unproven medicine, for which scientific evidence is lacking.

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Fontanarosa PB, et al. JAMA, 1998



The Navajo have integrated “unconventional Western medicine” - provided by the Indian Health Service - into their centuriesold conventional health care, which is provided by native healers.

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Dalen JE. Arch Intern Med, 1998

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5. La posizione del GIMBE®

SI'

- Favorire l'integrazione tra CM e CAM
- Identificare le problematiche metodologiche - diverse nelle varie tipologie di CAM - che esistono per la valutazione dell'efficacia delle CAM.
- Diffondere la metodologia della ricerca nelle CAM.
- Finanziare la ricerca per valutare l'efficacia e la sicurezza delle CAM.
- Rimborsare le CAM di documentata efficacia.

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5. La posizione del GIMBE®

NO

- Diffusione indiscriminata delle CAM
- Pratica delle CAM da parte di professionisti non medici
- Legittimazione delle CAM solo per il fatto che è praticata dai medici.
- Spingere i pazienti ad abbandonare CM di provata efficacia in favore di CAM dall'incerto profilo beneficio-rischio.

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