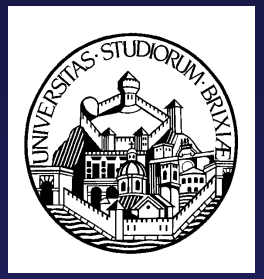

L'EVIDENCE-BASED MEDICINE PER LA VALUTAZIONE DI EFFICACIA DELLE MEDICINE COMPLEMENTARI

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Unità di Igiene, Epidemiologia e Sanità Pubblica
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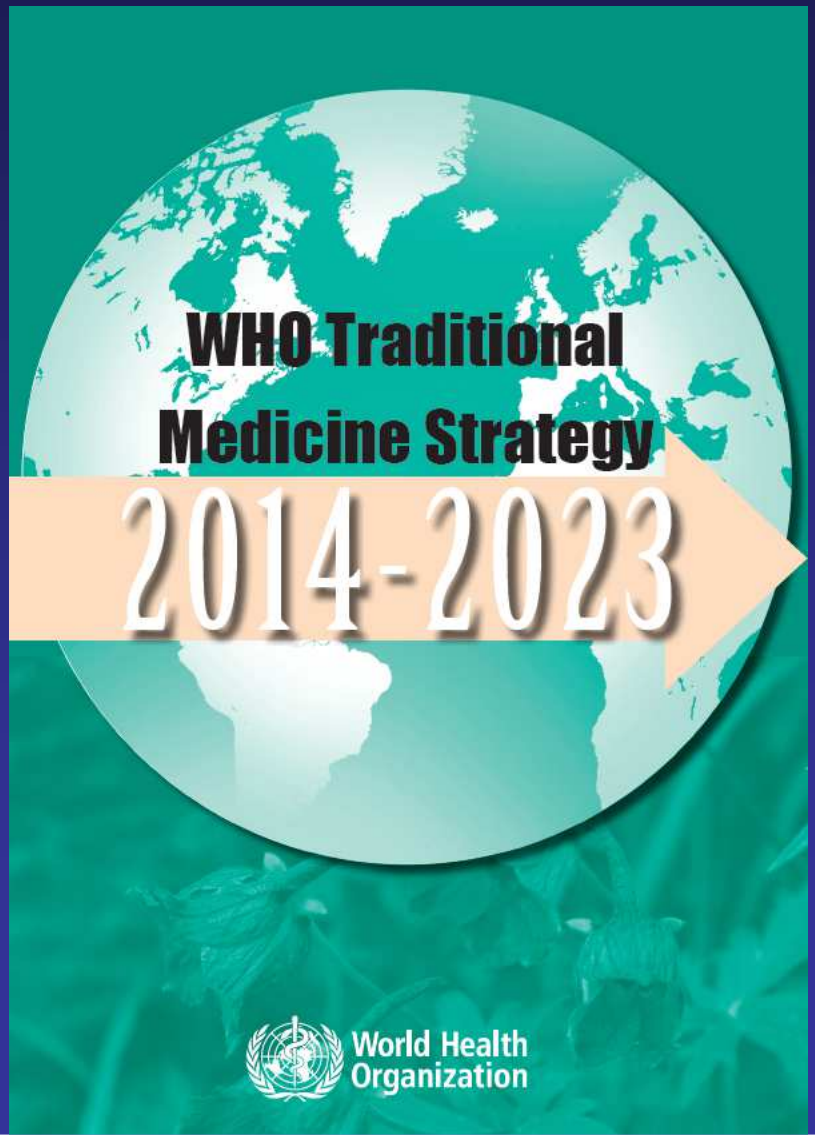
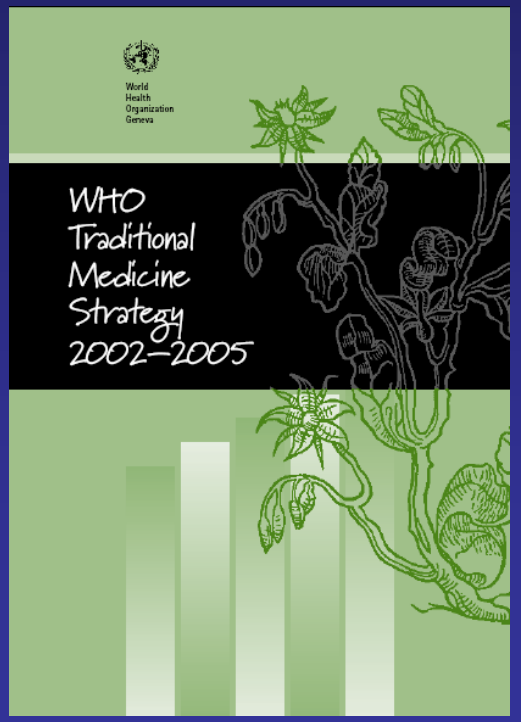
Indice della relazione

1. Tradizione, diffusione e regolamentazione delle medicine complementari (MC)
2. L'Evidence-Based Medicine
3. La sperimentazione clinica sulle MC
4. L'evidenza di efficacia e sicurezza dell'impiego di MC

1. Tradizione, diffusione e regolamentazione delle medicine complementari (MC)

Le medicine complementari/alternative usate tradizionalmente in alcuni paesi sono riconosciute dall'OMS





Medicina tradizionale/complementare

Across the world, traditional medicine (TM) is either the mainstay of health care delivery or serves as a complement to it. In some countries, traditional medicine or non-conventional medicine may be termed complementary medicine (CM).

T&CM is an important and often underestimated part of health care. T&CM is found in almost every country in the world and the demand for its services is increasing. TM, of proven quality, safety, and efficacy, contributes to the goal of ensuring that all people have access to care. Many countries now recognize

Dr Margaret Chan
Director-General

Table 1

Commonly used TM/CAM therapies and therapeutic techniques

	Chinese medicine	Ayurveda	Unani	Naturopathy	Osteopathy	Homeopathy	Chiropractic	Others
Herbal medicines	●	●	●	●	■	●		●[a]
Acupuncture/ acupressure	●				■			■[b]
Manual therapies	Tuina[c]	●	●	▣	●		●	Shiatsu[d]
Spiritual therapies	●	●	●	●				Hypnosis, healing, meditation
Exercises	Qigong[e]	Yoga		Relaxation				

Box 10: T&CM integration into the Swiss health-care system

In Switzerland, the average prevalence of T&CM use (persons who have used T&CM) was 49% (47) after 1990. In 1998, the Federal Department of Home Affairs (DHA) decided that, from 1999 to 2005, five complementary therapies – anthroposophical medicine, homeopathy, neural therapy, phytotherapy and TCM (more precisely, traditional Chinese herbal therapy) – would be covered by the compulsory health insurance program (KLV), if the service was provided by a physician certified in CAM. Meanwhile, the Swiss government also set up a comprehensive programme to evaluate CAM (PEK), which was playing an ever-increasing role in the Swiss medical system, in order to determine its role and effectiveness.

According to the PEK evaluation result, CAM practitioners can be distinguished from physicians providing conventional health care in respect of the nature, location and technical resources of their practice. In 2009, more than 67% of national voters opted for a new constitutional article on CAM, with the result that certain complementary therapies have been re-instated into the basic health insurance scheme available to all Swiss citizens (48). The constitutional article on CAM is also likely to speed up compulsory lessons for medical students, standardization of training and certification in complementary therapies for both doctors and non-medical practitioners, and the availability of CAM products in Switzerland (49).

"Obamacare" covers fifty-four million Americans for acupuncture as Essential Healthcare Benefit

Arthur Yin Fan
McLean Center for Complementary and Alternative Medicine, PLC, Vienna, VA 22182, USA

Medicine non convenzionali, le scelgono 10 mln di italiani. Occorre normativa

Le persone che in Italia si rivolgono alle cosiddette Medicine Non Convenzionali sono oltre 11 milioni, pari al 18,5% dell'intera popolazione (EURISPES, Rapporto Italia 2009) e circa 150 milioni in Europa.

SALUTE & PREVENZIONE 30 settembre, 2016 nessun commento

Dal simposio sulle "medicine tradizionali, complementari e non convenzionali, per l'uguaglianza dei diritti di salute oltre le esperienze regionalistiche" sono emersi dati che fotografano una realtà in evoluzione. In Europa non meno di 100 milioni ricorrono a prestazioni sanitarie inerenti le medicine non convenzionali, sia come terapie, sia come prevenzione. In Italia coloro che ricorrono, anche invia non esclusiva, a discipline come agopuntura, medicina tradizionale cinese, omeopatia, osteopatia, medicina antroposofica, chiropratica e altre sono circa 10 milioni. E sono circa 20 mila i medici e i veterinari che esercitano queste discipline in via esclusiva o come attività professionale prevalente. Si rende dunque necessario dare al settore una normativa di riferimento.

Box 3: Education system for TM practitioners in India

In India, all six traditional systems of medicine with official recognition (Ayurveda, Yoga, Naturopathy, Unani Medicine, Siddha and Homeopathy) have institutionalised education systems. India has 508 colleges with an annual admission capacity of 25 586 undergraduate students, 117 of these colleges also admitting 2493 postgraduate students. Colleges can only be established with the permission of central government and the prior approval of their infrastructure, syllabi and course curricula. Annual and surprise inspections ensure that educational and infrastructural standards are met. Central Government has the power to recognize or rescind any qualification and college[1].

Box 5: Described risks associated with T&CM products, practitioners and self-care:

- Use of poor quality, adulterated or counterfeit products;
- Unqualified practitioners;
- Misdiagnosis, delayed diagnosis, or failure to use effective conventional treatments;
- Exposure to misleading or unreliable information;
- Direct adverse events, side effects or unwanted treatment interactions.

Il concetto di malattia nella medicina occidentale e nelle medicine orientali

Medicina occidentale

Agente causale

↓

(individuo)

PATOGENESI

↓

Malattia

DIAGNOSI, CURA

↓

Complicanze, morte

Medicina orientale

EQUILIBRIO

Ambiente — Individuo

ROTTURA EQUILIBRIO

Malattia

APPROCCIO PREVENTIVO E CURATIVO: RIPRISTINARE E MANTENERE LO STATO DI SALUTE

Il trattamento delle malattie secondo le medicine orientali

I trattamenti sono individualizzati e prevedono più livelli di intervento:

- **Raccomandazioni per lo stile di vita e l'alimentazione**
- **Trattamenti con preparati, soprattutto erboristici (fitoterapia)**
- **Trattamenti fisici (massaggi, oleazioni, ginnastica ecc.)**
- **Trattamenti psichici: yoga, meditazione**

Medicina alternativa o complementare? La prevenzione del diabete

- La condizione di pre-diabete è rappresentata dalla ridotta tolleranza glucidica (IGT) e dall'alterata glicemia a digiuno (IFG): il 50% dei soggetti in questa condizione sviluppa il diabete nei 10 anni successivi
- La dieta e l'esercizio fisico si sono dimostrati in grado di evitare l'85% dei casi di diabete in soggetti obesi a rischio, con risultati pari o superiori al trattamento con farmaci anti-diabetici (metformina)

L'alimentazione e l'esercizio fisico sono "alternative" ai farmaci ?

Ministero della Salute

SCHEMA DI PIANO SANITARIO NAZIONALE 2011-2013

All'interno dello scenario sopra descritto il PSN pone come macro obiettivo del Servizio sanitario nazionale non solo quello della promozione "della salute dei cittadini", bensì quello della promozione del "*benessere e della salute dei cittadini e delle comunità*" nella consapevolezza che "*la vera ricchezza del sistema sanitario è la salute dei cittadini*". In questo

Le principali patologie croniche non trasmissibili, responsabili della maggior parte delle morti, delle sofferenze e dei costi sanitari hanno in comune pochi principali fattori di rischio. Elemento comune a questi fattori di rischio è che essi sono legati a comportamenti individuali non salutari (fumo, abuso di alcol, scorretta alimentazione, soprappeso e/o obesità, inattività fisica) fortemente condizionati, tuttavia, dal contesto economico, sociale ed ambientale in cui si vive e si lavora. Attuare strategie efficaci per ridurre questi fattori potrà quindi prevenire gran parte delle malattie.

2) Nutrizione e Dietetica

Numerose evidenze scientifiche documentano la correlazione tra abitudini alimentari non corrette e un cospicuo aumento dell'incidenza delle malattie croniche non trasmissibili (obesità, diabete, malattie cardiovascolari, alcuni tipi di tumore).

- attuare campagne mirate al controllo ed alla diminuzione del soprappeso e dell'obesità nelle giovani generazioni, tramite interventi che devono riguardare non solo la famiglia e la scuola ma anche i mass media e gli organismi di controllo;
- diffondere la cultura della sana alimentazione e corretti stili di vita, promuovendo il consumo di alimenti poveri di grassi animali, ricchi in vitamine, minerali e fibra, migliorando l'informazione nutrizionale nei fast food e nella distribuzione automatica e combattendo la pubblicità ingannevole nel settore alimentare;

E' ormai universalmente riconosciuto come l'80% circa delle malattie cardiovascolari e cerebrovascolari possano essere prevenute intervenendo sugli stili di vita e sui fattori di rischio.

La prevenzione del diabete secondo le medicina tradizionali orientali

1. Alimentazione corretta (alimenti a basso indice glicemico)
2. Evitare sovrappeso e obesità
3. Regolare esercizio fisico
4. Impiego di prodotti erboristici
5. Trattamenti fisici (massaggi, oleazioni, panchakarma, ecc.)

PHYTOTHERAPY RESEARCH
Phytother. Res. **24**: 1370–1376 (2010)
Published online 17 May 2010 in Wiley Online Library
(wileyonlinelibrary.com) **DOI**: 10.1002/ptr.3125

A Novel *Gymnema sy*
Insulin Secretion from
and *In Vitro*

La *Gymnema sylvestre* stimola la secrezione di insulina dalle cellule umane in vivo e in vitro

**A. Al-Romaiyan,[1]* B. Liu,[1] H. Asare-Anan
T. Biswas,[3] A. K. Chatterji,[4] G-C. Huang,[1]**

[1]Diabetes Research Group, King's College London, Londor
[2]Burdwan Medical College and J.B. Ayurveda College, Govt
[3]J.B. Ayurveda College, Govt. of West Bengal, India
[4]Ayurvedic-Life International LLC, 4650 West Spencer Street, Appleton, WI 54914, USA

Many plant-based products have been suggested as potential antidiabetic agents, but few have been shown to be effective in treating the symptoms of Type 2 diabetes mellitus (T2DM) in human studies, and little is known of their mechanisms of action. Extracts of *Gymnema sylvestre* (GS) have been used for the treatment of T2DM in India for centuries. The effects of a novel high molecular weight GS extract, Om Santal Adivasi, (OSA®) on plasma insulin, C-peptide and glucose in a small cohort of patients with T2DM are reported here. Oral administration of OSA® (1 g/day, 60 days) induced significant increases in circulating insulin and C-peptide, which were associated with significant reductions in fasting and post-prandial blood glucose. *In vitro* measurements using isolated human islets of Langerhans demonstrated direct stimulatory effects of OSA® on insulin secretion from human β-cells, consistent with an *in vivo* mode of action through enhancing insulin secretion. These *in vivo* and *in vitro* observations suggest that OSA® may provide a potential alternative therapy for the hyperglycemia associated with T2DM.

Cochrane Database Syst Rev. 2004: Chinese herbal medicines for type 2 diabetes mellitus.

(Liu JP et al, National Center for Research in Complementary and Alternative Medicine, University of Tromso, Norway.)

MAIN RESULTS: Sixty-six randomised trials, involving 8302 participants, met the inclusion criteria. Methodological quality was generally low. … Compared with hypoglycaemic drugs including glibenclamide, tolbutamide, or gliclazide, seven herbal medicines demonstrated a significant better metabolic control, including Bushen Jiangtang Tang, Composite Trichosanthis, Jiangtang Kang, Ketang Ling, Shenqi Jiangtang Yin, Xiaoke Tang, and Yishen Huoxue Tiaogan. In 29 trials that evaluated herbal medicines combined with hypoglycaemic drugs, 15 different herbal preparations showed additional better effects than hypoglycaemic drugs monotherapy. Two herbal therapies combined with diet and behaviour change showed better hypoglycaemic effects than diet and behaviour change alone. No serious adverse effects from the herbal medicines were reported.

REVIEWERS' CONCLUSIONS: Some herbal medicines show hypoglycaemic effects in type 2 diabetes. However, these findings should be carefully interpreted due to the low methodological quality, small sample size, and limited number of trials. In the light of some positive findings, some herbal medicines deserve further examination in high-quality trials.

Le medicine complementari/integrative

2. L’Evidence-Based Medicine

Evidence-Based Medicine

A New Approach to Teaching the Practice of Medicine

Evidence-Based Medicine Working Group

JAMA, November 4, 1992—Vol 268, No. 17

EBM = Medina basata sulle prove di efficacia

A NEW paradigm for medical practice is emerging. Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. Evidence-based medicine requires new skills of the physician, including efficient literature searching and the application of formal rules of evidence evaluating the clinical literature.

Evidence-Based Medicine (EBM) che cos' é

" L'Evidence-based medicine (EBM) è l'uso coscienzioso, esplicito e giudizioso della migliore evidenza scientifica disponibile per prendere decisioni sulla cura dei singoli pazienti. La pratica dell'EBM significa integrare l'esperienza clinica individuale con la migliore evidenza clinica esterna disponibile, prodotta da una ricerca sistematica. "

(Sackett et al: EBM: What it is and what it isn't. BMJ 1996;212:71-72.)

Evidence-based Medicine
What it is and what it isn't

Sackett et al. BMJ 1996

Livelli di certezza riguardo al beneficio (“netto”) di interventi sanitari secondo l’U.S. Preventive Services Task Force

Level of Certainty*	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: •The number, size, or quality of individual studies. •Inconsistency of findings across individual studies. •Limited generalizability of findings to routine primary care practice. •Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: •The limited number or size of studies. •Important flaws in study design or methods. •Inconsistency of findings across individual studies. •Gaps in the chain of evidence. •Findings not generalizable to routine primary care practice. •Lack of information on important health outcomes. More information may allow estimation of effects on health outcomes.

* The USPSTF defines *certainty* as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Livelli di evidenza della letteratura scientifica e raccomandazioni per la pratica clinica della U.S. Preventive Services Task Force

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.	Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Step 6: Link recommendation to net benefits:
USPSTF Grades of Recommendations

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

Figure 1. Screening for breast cancer: clinical summary.

Annals of Internal Medicine

U.S. Preventive Services TASK FORCE
www.USPreventiveServicesTaskForce.org

Primary Screening for Breast Cancer With Conventional Mammography

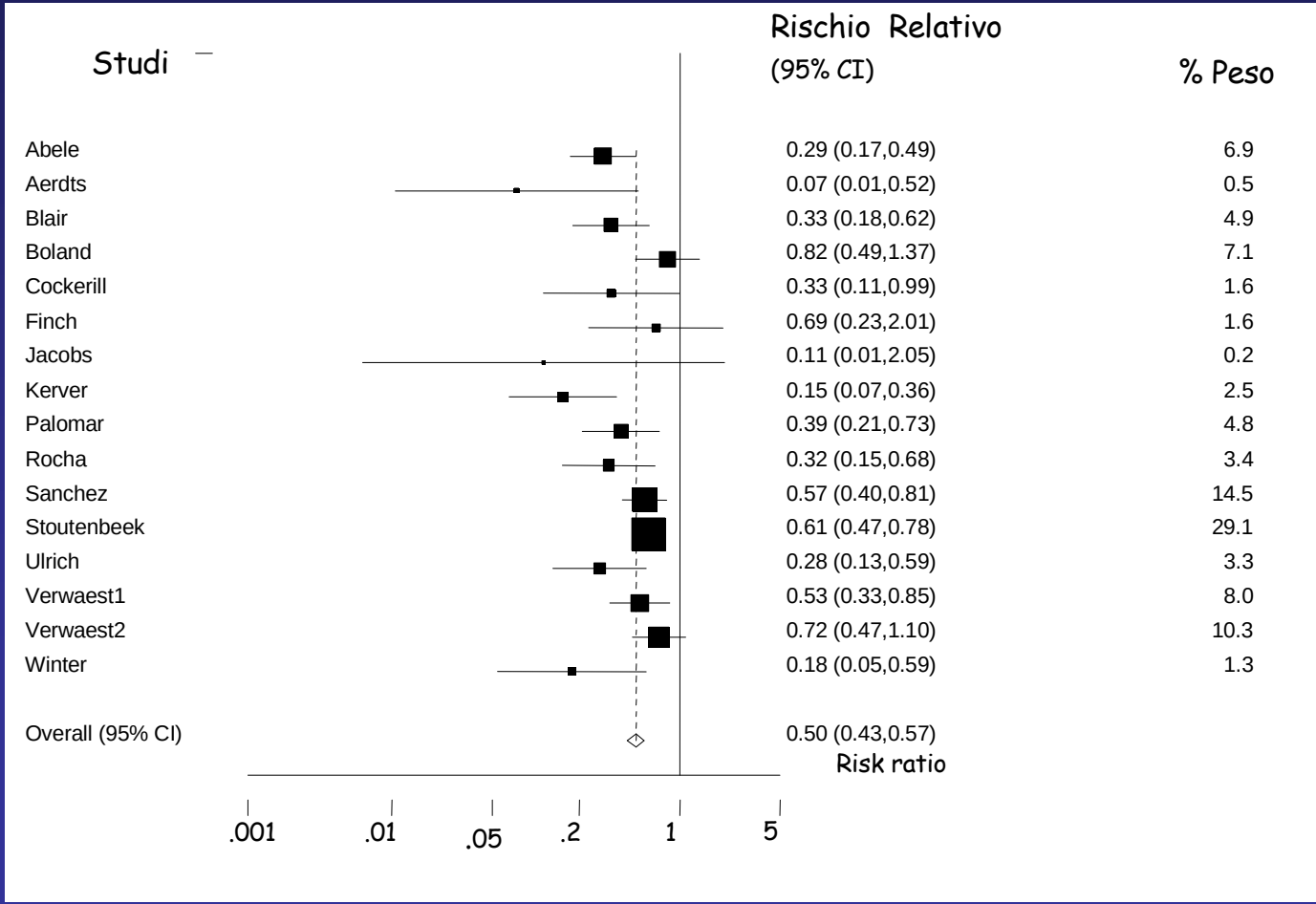
Population	Women aged 40 to 49 y	Women aged 50 to 74 y	Women aged ≥75 y
Recommendation	The decision to start screening should be an individual one. Grade: C	Screen every 2 years. Grade: B	No recommendation. Grade: I statement (insufficient evidence)

Risk Assessment	These recommendations apply to asymptomatic women aged ≥40 y who do not have preexisting breast cancer or a previously diagnosed high-risk breast lesion and who are not at high risk for breast cancer because of a known underlying genetic mutation (such as a *BRCA1* or *BRCA2* gene mutation or other familial breast cancer syndrome) or a history of chest radiation at a young age. Increasing age is the most important risk factor for most women.		
Screening Tests	Conventional digital mammography has essentially replaced film mammography as the primary method for breast cancer screening in the United States. Conventional digital screening mammography has about the same diagnostic accuracy as film overall, although digital screening seems to have comparatively higher sensitivity but the same or lower specificity in women age <50 y.		
Starting and Stopping Ages	For women who are at average risk for breast cancer, most of the benefit of mammography results from biennial screening during ages 50 to 74 y. While screening mammography in women aged 40 to 49 y may reduce the risk for breast cancer death, the number of deaths averted is smaller than that in older women and the number of false-positive results and unnecessary biopsies is larger. The balance of benefits and harms is likely to improve as women move from their early to late 40s.		
Screening Interval	For most women, biennial mammography screening provides the best overall balance of benefit and harms.		
Balance of Benefits and Harms	The net benefit of screening mammography in women aged 40 to 49 y, while positive, is small.	The net benefit of screening mammography in women aged 50 to 74 y is moderate.	Evidence on mammography screening in women aged ≥75 y is insufficient, and the balance of benefits and harms cannot be determined.
Other Relevant USPSTF Recommendations	The USPSTF has made recommendations about the use of medications to reduce women's risk for breast cancer, as well as risk assessment, genetic counseling, and genetic testing for *BRCA1*- or *BRCA2*-related cancer (including breast cancer). These recommendations are available on the USPSTF Web site (www.uspreventiveservicestaskforce.org).		

Revisione sistematica e meta-analisi

- definizione degli obiettivi
- ricerca sistematica delle fonti
- esaustività della ricerca di studi (studi non pubblicati)
- arco temporale ben definito
- definizione dei criteri di inclusione e di esclusione degli studi
- valutazione e scelta degli studi *(critical appraisal)*
- estrazione dei dati con un form prefissato
- valutazione della qualità metodologica degli studi
- sintesi qualitativa delle informazioni
- valutazione dell'eterogeneità tra gli studi
- sintesi quantitativa dei risultati (meta-analisi) se fattibile e appropriata
- *peer reviewing*

Risultati di 16 studi sull'efficacia della profilassi antibiotica nel ridurre il rischio di infezioni nosocomiali in pazienti in terapia intensiva: rappresentazione dei risultati e della loro stima combinata (D'Amico et al, 1998)



La qualità delle rassegne di letteratura

Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions

Deborah E. Barnes, MPH; Lisa A. Bero, PhD

JAMA, May 20, 1998—Vol 279, No. 19

Rassegna di 106 reviews sui rischi del fumo passivo

Table 3.—Relationship Between Article Conclusions and Author Affiliations

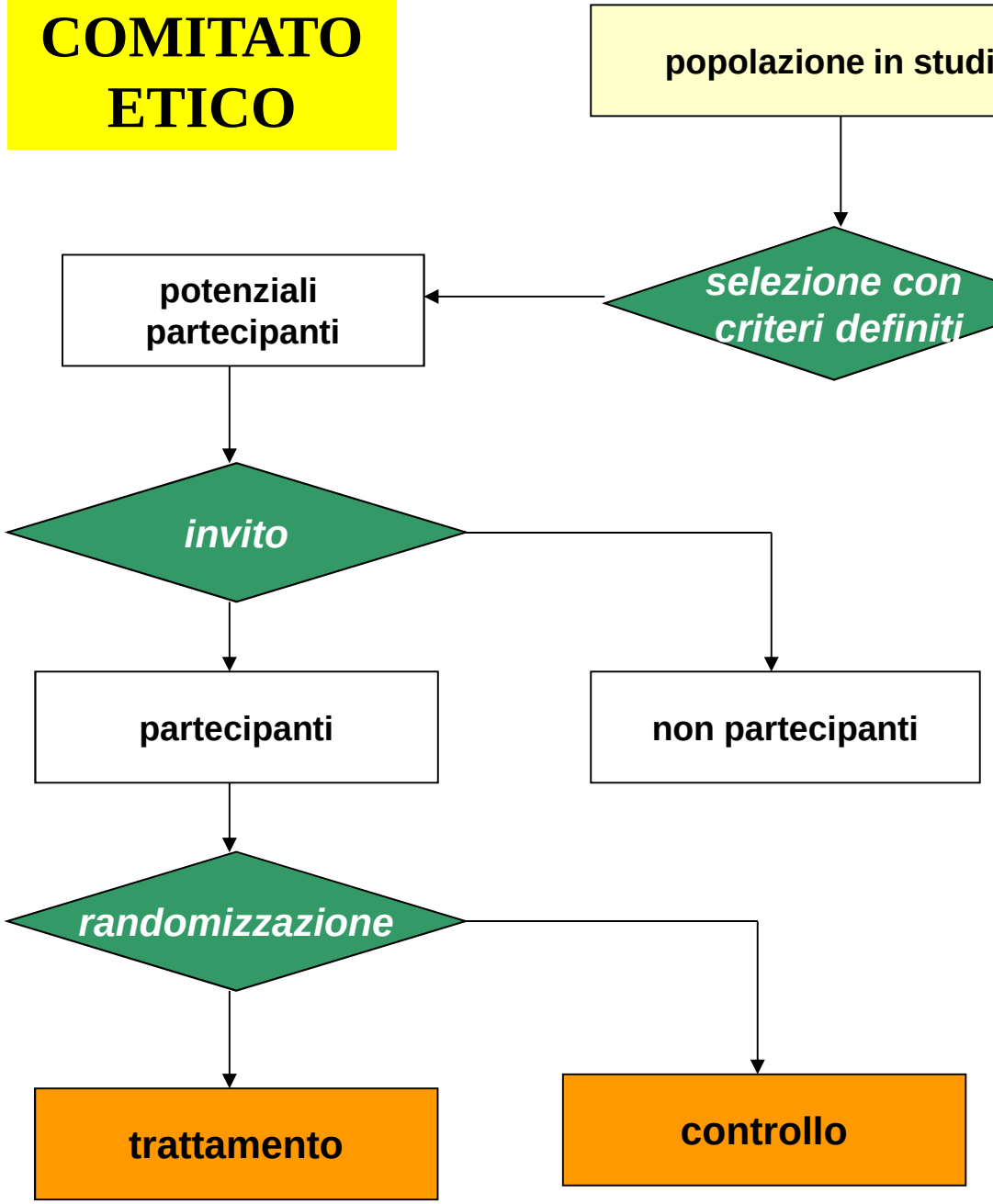
Article Conclusion	No. (%) of Reviews: Tobacco-Affiliated Authors (n = 31)	No. (%) of Reviews: Non–Tobacco-Affiliated Authors (n = 75)
Passive smoking harmful	2 (6)	65 (87)
Passive smoking not harmful	29 (94)	10 (13)
Significance	$\chi^2_1 = 60.69$; $P<.001$	

Odds ratio = 94

Le medicine complementari/integrative

3. La sperimentazione clinica sulle MC

COMITATO ETICO



Il disegno di un trial randomizzato controllato (RCT)

Limiti della ricerca scientifica sulle MC

Scarso interesse da parte delle aziende, poco supporto da enti pubblici	Trattamenti individualizzati, molto variabili, non standardizzati	Mancanza di interesse e/o opposizione da parte dell'accademia	Mancanza di interesse e/o opposizione da parte della medicina tradizionale
↓	↓	↓	↓
Mancanza di finanziamenti	Mancanza di riproducibilità	Mancanza di metodologia scientifica	Mancanza di pubblicazione su riviste influenti

Pochi trial, di bassa qualità e/o piccole dimensioni, poco conosciuti e poco citati

U.S. Department of Health and Human Services | National Institutes of Health

NIH National Center for Complementary and Integrative Health

NIH...Turning Discovery Into Health

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Health

All Health Topics from A-Z

Research-based info from acupuncture to zinc.

Complementary, Alternative, or Integrative Health

What do these terms mean?

Be Informed

Learn how to make wise health decisions.

Herbs at a Glance

Uses and side effects of herbs and botanicals.

How To Find a Practitioner

Information on seeking treatment.

Information for Health Care Providers

U.S. Department of Health & Human Services
National Institutes of Health

NIH National Center for Complementary and Integrative Health

Complementary, Alternative, or Integrative Health: What's In a Name?

We've all seen the words "complementary," "alternative," and "integrative," but what do they really mean?

This fact sheet looks into these terms to help you understand them better and gives you a brief picture of NCCIH's mission and role in this area of research.

Complementary Versus Alternative

Many Americans—more than 30 percent of adults and about 12 percent of children—use health care approaches developed outside of mainstream Western, or conventional, medicine. When describing these approaches, people often use "alternative" and "complementary" interchangeably, but the two terms refer to different concepts:

- If a non-mainstream practice is used **together with** conventional medicine, it's considered "complementary."
- If a non-mainstream practice is used **in place of** conventional medicine, it's considered "alternative."

True alternative medicine is uncommon. Most people who use non-mainstream approaches use them along with conventional treatments.

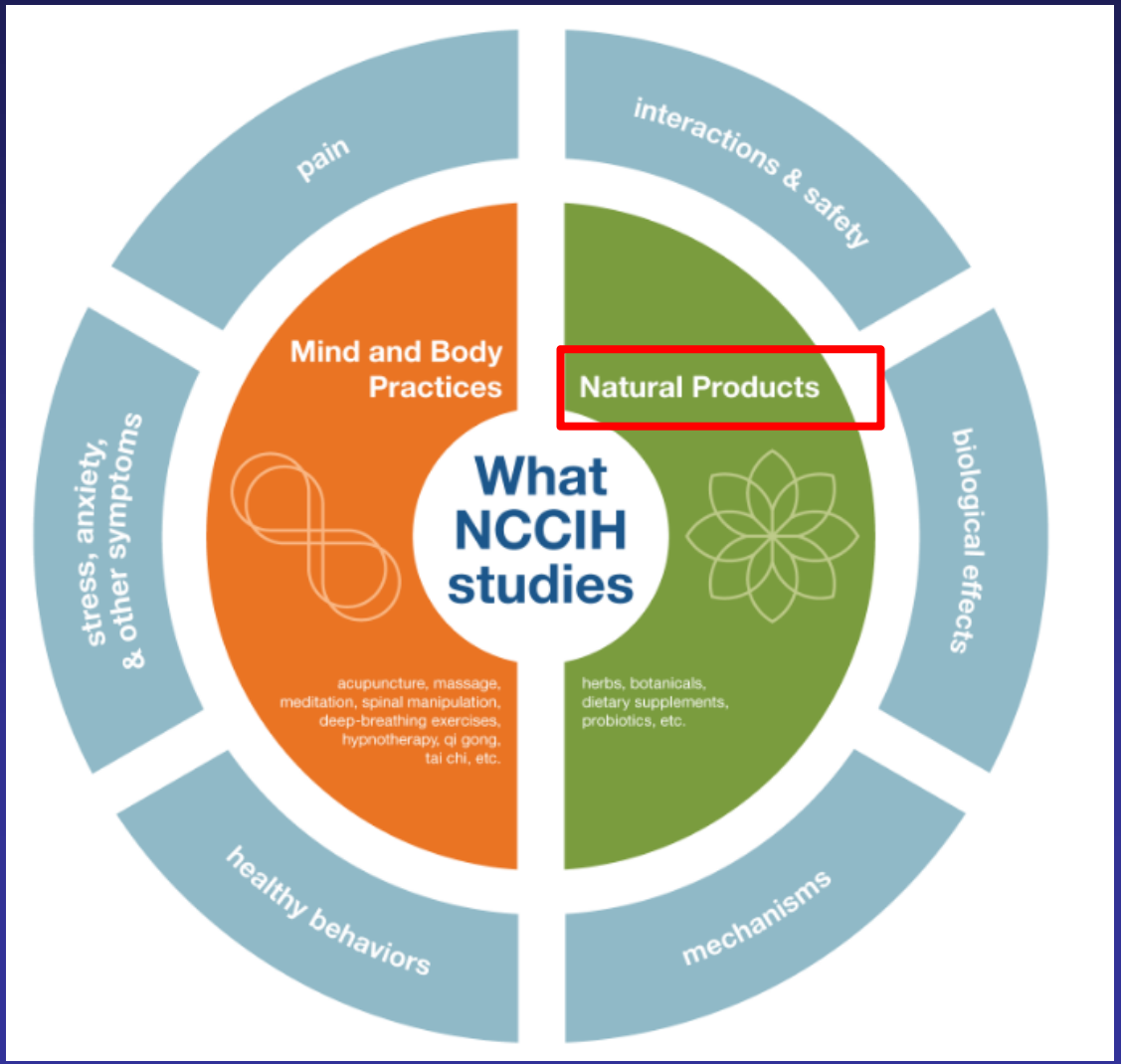
U.S. Department of Health & Human Services
National Institutes of Health

NIH National Center for Complementary and Integrative Health

2016 Strategic Plan

Exploring the Science of Complementary and Integrative Health

At the National Center for Complementary and Integrative Health (NCCIH), our mission is to build the scientific evidence base about the use of complementary and integrative health approaches in order to inform decisionmaking by the public, by health care professionals, and by health policymakers.



REVIEW ARTICLE

Acupuncture for Chronic Pain

Individual Patient Data Meta-analysis

Andrew J. Vickers, DPhil; Angel M. Cronin, MS; Alexandra C. Maschino, BS; George Lewith, MD; Hugh MacPherson, PhD; Nadine E. Foster, DPhil; Karen J. Sherman, PhD; Claudia M. Witt, MD; Klaus Linde, MD; for the Acupuncture Trialists' Collaboration

Background: Although acupuncture is widely used for chronic pain, there remains considerable controversy as to its value. We aimed to determine the effect size of acupuncture for 4 chronic pain conditions: back and neck pain, osteoarthritis, chronic headache, and shoulder pain.

Methods: We conducted a systematic review to identify randomized controlled trials (RCTs) of acupuncture for chronic pain in which allocation concealment was determined unambiguously to be adequate. Individual patient data meta-analyses were conducted using data from 29 of 31 eligible RCTs, with a total of 17 922 patients analyzed.

Results: In the primary analysis, including all eligible RCTs, acupuncture was superior to both sham and no-acupuncture control for each pain condition ($P < .001$ for all comparisons). After exclusion of an outlying set of RCTs that strongly favored acupuncture, the effect sizes were similar across pain conditions. Patients receiving acupuncture had less pain, with scores that were 0.23 (95% CI, 0.13-0.33), 0.16 (95% CI, 0.07-0.25), and 0.15 (95% CI, 0.07-0.24) SDs lower than sham controls for back and neck pain, osteoarthritis, and chronic headache, respectively; the effect sizes in comparison to no-acupuncture controls were 0.55 (95% CI, 0.51-0.58), 0.57 (95% CI, 0.50-0.64), and 0.42 (95% CI, 0.37-0.46) SDs. These results were robust to a variety of sensitivity analyses, including those related to publication bias.

Conclusions: Acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo. However, these differences are relatively modest, suggesting that factors in addition to the specific effects of needling are important contributors to the therapeutic effects of acupuncture.

Arch Intern Med. 2012;172(19):1444-1453.
Published online September 10, 2012.
doi:10.1001/archinternmed.2012.3654

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 9, Number 5, 2003, pp. 763–770

SHORT REPORT

The German Multicenter, Randomized, Partially Blinded, Prospective Trial of Acupuncture for Chronic Low-Back Pain: A Preliminary Report on the Rationale and Design of the Trial

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CARMEN SCHADE-BRITTINGER,[3] HELGE PRINZ, Ph.D.,[3]
HEINZ-DIETER BASLER, Prof.Ph.D., M.D.,[4] KONRAD STREITBERGER, M.D.,[5]
HELMUT SCHÄFER, Prof.Ph.D.,[2] and ALBRECHT MOLSBERGER, M.D.[6]

OBJECTIVES

The aim of this study is to show the superiority of traditional Chinese acupuncture (denoted as verum acupuncture) over sham acupuncture and over standard medical care with regard to subjective pain ratings and the improvement of disability in patients with chronic LBP.

Acupuncture was administered in 340 outpatient practices by physicians of various specializations who had at least 140 hours of acupuncture training: 55% had undergone basic training (mean, 213 hours) and 45% had advanced training (mean, 376 hours). The study physicians had practiced acupuncture for 2 to 36 years (median, 8.0 years). All took part in a 1-day training session with emphasis on acupuncture methods and study design. Each patient in the study practices was seen by the same physician-acupuncturist at each session. Independent telephone interviewers assessed outcome measures.

Blinding

Patients are blinded against verum and sham acupuncture. Clinical observers assessing the endpoints are blinded against verum acupuncture, sham acupuncture, and against standard therapy. Patients' blindness to the mode of acupuncture is assessed after the last follow-up by asking the patients to guess their group assignment. Additionally, patients will be asked directly after the intervention phase for the quantity of care they have received during the treatments.

BLINDING PROBLEM IN ACUPUNCTURE TRIALS

It is difficult to design an appropriate control group in acupuncture trials because it is a painful invasive physical modality (Vincent and Lewith, 1995). Sham acupuncture with superficial needling at nonappropriate sites is the most common control intervention, but may have nonspecific effects (Vincent and Lewith, 1995). Therefore, the difference between verum and sham acupuncture may be too small to detect significant results in smaller trials (Ernst and White, 1998).

The recently developed placebo acupuncture with a telescopic nonpenetrating placebo needle does not involve the nonspecific-effects of skin penetration (Streitberger and Kleinnenz, 1998). But the application of placebo needles needs a special device to keep the needles in place. The same device has to be applied in verum acupuncture, which makes the treatment different from its usual clinical setting. The risk that patients could unblind the treatment, may be higher than using sham acupuncture (Lao et al., 2001).

Because our trial including 1062 patients (354 patients in each group) is large, there is enough statistical power to detect even small differences. Thus we decided to use sham acupuncture as control group and to prove acupuncture also for specific effects by using acupuncture points.

Table 1. Eligibility Criteria

Inclusion Criteria
Signed written informed consent
Clinical diagnosis of chronic low back pain for 6 mo or longer
CPGS grade I and HFAQ less than 70%
Therapy-free interval 7 d or longer
Older than 18 y
Ability to speak, read, and write German
Exclusion criteria
Treatment with needle acupuncture for low back pain at any time in the past
Treatment with needle acupuncture for any other indication within the last year
History of spinal fracture (eg, osteoporosis or trauma) or disc or spinal surgery
Infections or tumors
Systemic bone or joi
Scoliosis or kyphosis
Sciatica or chronic p
Hemorrhagic disorde
Skin disease in the a
Abuse of drugs or pa
Pregnancy
Epilepsy
Patient included in ar

Abbreviations: CPGS, V
Functional Ability Question

OUTCOME MEASURES

Telephone interviews by trained employees of the study center were conducted at baseline and at 1½, 3, and 6 months. Our primary outcome was treatment response 6 months after randomization, defined as 33% improvement or better on 3 pain-related items on the Von Korff Chronic Pain Grade Scale[7] or 12% improvement or better on back-specific functional status measured by the Hanover Functional Ability Questionnaire.[8] Patients who had recourse to additional treatments other than rescue medication were classified as nonresponders, as were unblinded patients.

Secondary outcomes were responder rate at 1½ and 3 months after randomization, scores on the 12-item Short Form Health Survey,[12] and patient global assessment of therapy effectiveness on a scale of 1 (very good) to 6 (fail).[13] Physicians documented medication use, acupuncture treatment, and adverse events at each session and at the final examination after 6 months. Patient blinding was assessed at the 6-month interview by asking whether their physician had informed them of their allocation and, if not, by asking the method of acupuncture and how certain they were of their response.[14] All interview questions were given to the patients during the baseline visit.

RANDOMIZATION AND BLINDING

The 1:1:1 randomization was performed dynamically by a computer program balancing for 2 levels of chronification (<2 or ≥2 years), 2 levels of fear avoidance belief[15] (<4 or ≥4 average total points), 2 levels of activity (<60 or ≥60 minutes), patient expectations,[16] and trial center. The previous allocation scheme and a prespecified list of random numbers were used. After successful completion of the baseline interview and once the patient had come for the first treatment, the physician called a randomization hotline that registered the patient in the study and faxed the patient's assigned treatment group to the physician.

STATISTICAL ANALYSIS

The primary analysis included all randomized patients on the intent-to-treat basis. Patients in all groups who missed the 6-month-assessment were, therefore, classified as nonresponders. Response rates were tested for differences using the 2-sided Fisher exact test. The multiple testing problem caused by the comparison of 3 treatment methods was handled by a closed test procedure to guarantee the type I error level of 5% for all pairwise comparisons. Two tests comparing verum acupuncture with the 2 control groups at a level of 2.5% each were performed as a first step.[6] If this global test ruled out the null hypothesis of no difference among the 3 treatments, then all 3 pairwise comparisons were performed at a level of 5%. The study was powered to detect a change of 10% in response rates (verum acupuncture, 60%; conventional therapy, 50%; and sham acupuncture, 40%), with 95% power for the global test. Assuming a 30% dropout rate, this led to a required sample size of 354 patients per group. Exploratory analyses were performed for all secondary end points. Sensitivity analyses included comparisons with grouping by treatment, dropping patients who missed the 6-month assessment, and best and worst imputation of missing data at 6-month assessment in all pairwise comparisons.

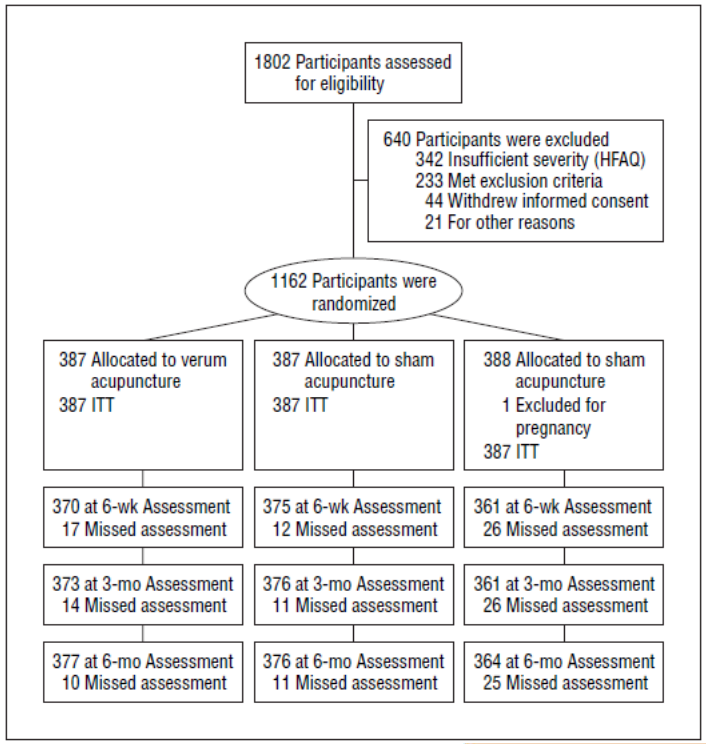

Figure 1. Participant flowsheet. HFAQ indicates Ha
Questionnaire; ITT, intention to treat.

Table 2. Baseline Characteristics in 1162 Patients Randomized and 640 Patients Screened-Only[a]

Baseline Characteristic	Verum Acupuncture (n = 387)	Sham Acupuncture (n = 387)	Standard Therapy (n = 388)	Screened Only (n = 640)
Sex, No.(%)				
Men	165 (42.6)	140 (36.2)	165 (42.5)	267 (41.7)
Women	222 (57.4)	247 (63.8)	223 (57.5)	373 (58.3)
Age, y	49.6 ± 14.6 (380)	49.2 ± 14.8 (382)	51.3 ± 14.5 (381)	48.5 ± 14.7 (619)
Body mass index[b]	26.9 ± 4.7 (381)	26.5 ± 4.8 (378)	26.3 ± 4.5 (378)	26.1 ± 4.4 (614)
Prognostic factors				
History of back pain, y	8.1 ± 7.7 (380)	7.7 ± 8.2 (382)	8.1 ± 8.3 (380)	7.6 ± 7.6 (617)
Patient expectations[c]	7.6 ± 1.7 (387)	7.7 ± 1.8 (387)	7.7 ± 1.8 (388)	7.4 ± 1.9 (512)
Fear avoidance beliefs[d]	3.3 ± 1.3 (387)	3.2 ± 1.3 (387)	3.3 ± 1.3 (388)	3.6 ± 1.2 (54)
Physical activity,[c] min/d	70.5 ± 121.5 (377)	67.1 ± 119.3 (347)	67.5 ± 117.4 (381)	48.8 ± 106.9 (54)
Pain, CPGS	67.7 ± 13.9	67.8 ± 13.2	67.8 ± 14.6	NA
Disability, HFAQ	46.3 ± 14.7	46.3 ± 15.3	46.7 ± 14.5	NA
Quality of life, SF-12				NA
Physical component summary	31.8 ± 6.8	31.5 ± 6.9	31.6 ± 6.8	
Mental component summary	46.6 ± 12.3	46.6 ± 11.5	47.1 ± 11.6	

Abbreviations: GCPS, Von Korff Chronic Pain Grade Scale (low values better); HFAQ, Hanover Functional Ability Questionnaire (high values better); NA, not available; SF-12, 12-item Short-Form Health Survey (high values better).
[a] Data are given as mean ± SD (number of patients) unless otherwise indicated.
[b] Calculated as weight in kilograms divided by height in meters squared.
[c] Not at all helpful, 0; extremely helpful, 10.
[d] Beliefs about back pain caused by physical activity: not at all, 0; absolutely true, 6.

Table 4. Primary Outcome: Pairwise Comparison of Treatment Response 6 Months After Randomization[a]

Treatment Response	Intergroup Difference	*P* Value[b]
Group 1 vs group 3 47.6 (42.4 to 52.6) vs 27.4 (23.0 to 32.1)	20.2 (13.4 to 26.7)	<.001
Group 2 vs group 3 44.2 (39.2 to 49.3) vs 27.4 (23.0 to 32.1)	16.8 (10.1 to 23.4)	<.001
Group 1 vs group 2 47.6 (42.4 to 52.6) vs 44.2 (39.2 to 49.3)	3.4 (–3.7 to 10.3)	.39

[a] Each group comprised 387 patients. Values are given as percentage of patients (95% confidence interval). Group 1, verum acupuncture; group 2, sham acupuncture; group 3, conventional therapy.
[b] Unadjusted; Fisher exact test (intention-to-treat analysis).

COMMENT

To our knowledge, the present study is the largest and most rigorous trial to investigate the efficacy of verum acupuncture for chronic low-back pain compared with sham acupuncture and guideline-based conventional therapy. The study yielded several surprising results. First, almost half of the patients in both acupuncture groups were responders. They experienced clinically relevant improvement in pain intensity or back-specific disability without having recourse to concomitant therapies. Second, only one-fourth of the patients receiving conventional therapy, consisting of a multimodal combination of pharmacologic and nonpharmacologic treatments, responded to treatment. Acupuncture, regardless of the technique, was significantly more effective than conventional therapy at all follow-up points. To our knowledge, this is the first time superiority of acupuncture over conventional treatment has been unequivocally demonstrated for the primary and secondary outcomes, including medication reduction, in contrast to studies with a usual-care group.[5,18] Third, there was essentially no difference between the results for verum and sham acupuncture.

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DECRETO N° 13751 Del 16/11/2007

Identificativo Atto n. 1202

DIREZIONE GENERALE SANITA'

Oggetto **APPROVAZIONE, CON RELATIVO FINANZIAMENTO, DEGLI STUDI, DELLE RICERCHE E DELLE SPERIMENTAZIONI CLINICHE DI MEDICINA COMPLEMENTARE PRESENTATI NELL'ANNO 2006 DA ENTI PUBBLICI E/O PRIVATI, DA PROFESSIONISITI SINGOLI ED ASSOCIATI E DA SOCIETA' SCIENTIFICHE.**

COD	TITOLO	RESPONSABILE	STRUTTURA SEDE DELLA SPERIMENTAZIONE	Metodo di cura	metodo sperim.	Durata in mesi	cofinanziamento struttura		Costo complessivo : 1.000	Finanz. Regione :1000
							Ris. Umane :1.000	Mat Invent. : 1.000		
46	Studio randomizzato controllato, in doppio cieco, per valutare l'efficacia e la tollerabilità di alcuni preparati erboristici della medicina ayurvedica (GUGGULU E TRIPHALA) verso Placebo nel tratamento di soggetti con Ipercolesterolemia e in sovrappeso.	Francesco Donato	ASL Brescia	AYU	randomizzato a gruppi paralleli aperto	12	8,40	0,00	25,40	7,60
48	Studio randomizzato, controllato in doppio cieco, per valutare l'efficacia e la tollerabilità di Phyllanthus Amaro verso placebo nel trattamento di pazienti affetti da epatite B cronica.	Massimo Puoti	AO Spedali Civili BS Clinica Malattie infettive e tropicali	AYU	randomizzato controllato in doppio cieco	24	n.i.	0,00	29,70	22,70

Journal of Viral Hepatitis, 2001, 8, 358–366

Genus *Phyllanthus* for chronic hepatitis B virus infection: a systematic review

J. Liu,[1] H. Lin[2] and H. McIntosh[3] [1]*The Cochrane Hepato-Biliary Group, The Copenhagen Trial Unit, Centre for Clinical Intervention Research, Copenhagen University Hospital, Copenhagen, Denmark,* [2]*Department of Epidemiology, Third Military Medical University, Chongqing, China and* [3]*NHS Centre for Reviews and Dissemination, University of York, York, UK*

SUMMARY. To evaluate the efficacy and safety of genus *Phyllanthus* for chronic hepatitis B virus (HBV) infection we performed a systematic review of randomized clinical trials. Randomized trials comparing genus *Phyllanthus* vs. placebo, no intervention, general nonspecific treatment, other herbal medicine, or interferon treatment for chronic HBV infection were identified by electronic and manual searches. Trials of *Phyllanthus* herb plus interferon (IFN) vs. IFN alone were also included. No blinding and language limitations were applied. The methodological quality of trials was assessed by the Jadad scale plus allocation concealment. Twenty-two randomized trials ($n = 1947$) were identified. The methodological quality was high in five double-blind trials and low in the 17 remaining trials. The combined results showed that *Phyllanthus* species had positive effect on clearance of serum HBsAg (relative risk 5.64, 95% CI 1.85–17.21) compared with placebo or no intervention. There was no significant difference on clearance of serum HBsAg, HBeAg and HBV DNA between *Phyllanthus* and IFN. *Phyllanthus* species were better than nonspecific treatment or other herbal medicines for the clearance of serum HBsAg, HBeAg, HBV DNA, and liver enzyme normalization. Analyses showed a better effect of the *Phyllanthus* plus IFN combination on clearance of serum HBeAg (1.56, 1.06–2.32) and HBV DNA (1.52, 1.05–2.21) than IFN alone. No serious adverse event was reported. Based on this review *Phyllanthus* species may have positive effect on antiviral activity and liver biochemistry in chronic HBV infection. However, the evidence is not strong due to the general low methodological quality and the variations of the herb. Further large trials are needed.

Keywords: chronic hepatitis B virus infection, genus *Phyllanthus*, medicinal herb, meta-analysis, randomized clinical trial, systematic review.

STUDIO RANDOMIZZATO CONTROLLATO, IN DOPPIO CIECO, PER VALUTARE L'EFFICACIA E LA TOLLERABILITÀ DI PHYLLANTHUS NIRURI VERSO PLACEBO NEL TRATTAMENTO DI PAZIENTI AFFETTI DA EPATITE B CRONICA: IL PROGETTO CORONA

OBIETTIVI DELLA RICERCA

L'obiettivo primario è dimostrare la superiorità della risposta virologica al mese 12 (al termine del trattamento), misurata in termini di non rilevabilità dell'HBV DNA – misurato attraverso il metodo Versant HBVDNA® (soglia di rilevabilità 2000 copie/mL) - della somministrazione di Phyllanthus amarus in confronto a placebo in pazienti adulti affetti da epatite B cronica non candidabili ad altre terapie.
Obiettivi secondari sono:

- Misurare la concentrazione dell'HBV DNA ai mesi 1, 3, 6, 9, 12 e 18 per valutare l'attività anti-virale del trattamento in esame.
- Confrontare, ai mesi 1, 3, 6, 9, 12 e 18 l'efficacia della terapia in termini di scomparsa della sieropositività per HBsAg e di HBeAg nei soli soggetti HBeAg positivi.
- Valutare la frequenza di normalizzazione dei valori di transaminasi nel corso dello studio
- Valutare la frequenza di persistenza della eventuale normalizzazione dei valori di transaminasi e di negativizzazione dell' HBVDNA a 6 mesi dalla fine dello studio

Complementary Therapies in Medicine (2005) 13, 279–290

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Guggul for hyperlipidemia: A review by the Natural Standard Research Collaboration

Catherine Ulbricht[a,*], Ethan Basch[b], Philippe Szapary[c], Paul Hammerness[d], Serguei Axentsev[e], Heather Boon[f], David Kroll[g], Levi Garraway[d], Mamta Vora[h], Jen Woods[h]

Natural Standard Research Collaboration[i]

[a] *Massachusetts General Hospital, USA*
[b] *Memorial Sloan Kettering Cancer Center, USA*
[c] *University of Pennsylvania, USA*
[d] *Harvard Medical School, USA*
[e] *Natural Standard Research Collaboration, USA*
[f] *University of Toronto, Canada*
[g] *Research Triangle Institute, USA*
[h] *Northeastern University, USA*

Available online 23 September 2005

KEYWORDS
Guggul;
Commifora mukul;
High-density lipoprotein

Summary
Objective: To evaluate the scientific evidence on guggul for hyperlipidemia including expert opinion, folkloric precedent, history, pharmacology, kinetics/dynamics, interactions, adverse effects, toxicology, and dosing.
Methods: Electronic searches were conducted in nine databases, 20 additional journals (not indexed in common databases), and bibliographies from 50 selected secondary references. No restrictions were placed on language or quality of publications. All literature collected pertained to efficacy in humans, dosing, precautions, adverse effects, use in pregnancy/lactation, interactions, alteration of laboratory assays, and mechanism of action. Standardized inclusion/exclusion criteria were utilized for selection.

Regione Lombardia

ASL Brescia

STUDIO RANDOMIZZATO CONTROLLATO, IN DOPPIO CIECO, PER VALUTARE L'EFFICACIA E LA TOLLERABILITÀ DI ALCUNI PREPARATI ERBORISTICI (GUGGULU E TRIPHALA) NEL TRATTAMENTO DI SOGGETTI CON IPERCOLESTEROLEMIA

Lo studio è stato promosso dall'ASL di Brescia, in collaborazione con la Sezione di Igiene, Epidemiologia e Sanità Pubblica e la Clinica Medica dell'Università degli Studi di Brescia, e supportata dalla Regione Lombardia.

Obiettivi

Riduzione della colesterolemia totale e riduzione del peso corporeo in soggetti in sovrappeso in pazienti con colesterolemia totale di 200-300 mg/dl e con rischio cardiovascolare inferiore al 20%.

Disegno dello studio

Sono stati utilizzati due prodotti erboristici, guggulu e triphala, integratori alimentari disponibili in farmacia. Il guggulu è un estratto dalla resina della Commiphora Mukul con attività ipocolesterolemica. Il triphala è un composto di tre piante (Terminalia chebula, Terminalia belerica e Phyllanthus emblica), che ha effetti positivi per il trattamento dell'obesità e la riduzione della colesterolemia.

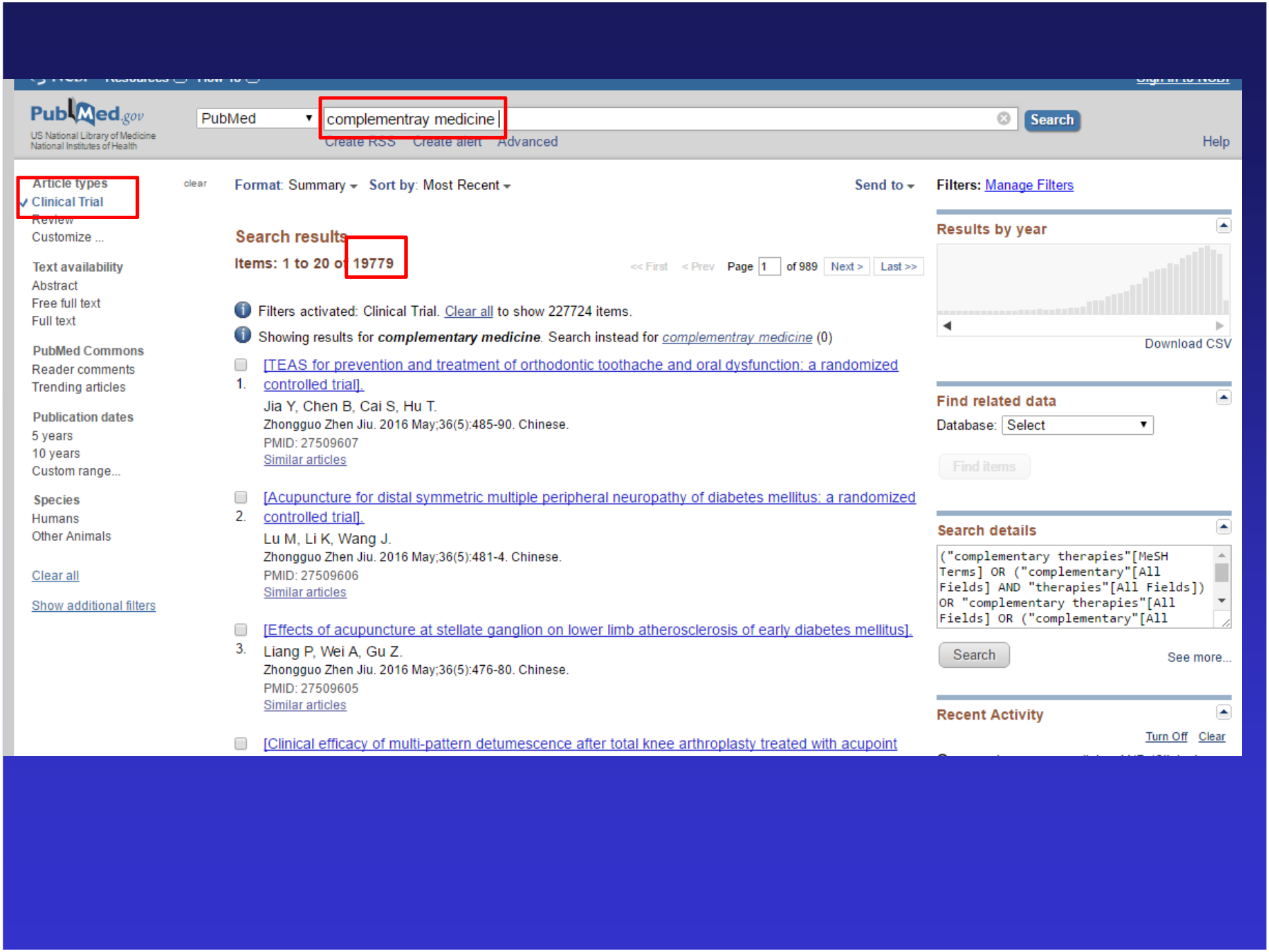
I pazienti eleggibili per la ricerca erano invitati dal loro medico di medicina generale a prendere parte allo studio e se aderivano venivano sottoposti al trattamento e seguiti per il periodo di follow-up dal loro medico curante.

I gruppi di trattamento erano i seguenti:

- Guggulu e Triphala per 3 mesi di terapia orale
- Placebo: 3 mesi di terapia orale

Le medicine complementari/integrative

4. L’evidenza di efficacia e sicurezza dell’impiego di MC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1. [TEAS for prevention and treatment of orthodontic toothache and oral dysfunction: a randomized controlled trial].
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L'omeopatia ha effetti clinici ? I risultati di due meta-analisi (M-A) di trial randomizzati controllati con placebo

1. **Linde et al.** (*The Lancet, 1997*):

Gli effetti clinici dell'omeopatia **non sono dovuti completamente ad effetto placebo**

2. **Shang et al.** (*The Lancet, 2005*):

La M-A ristretta ai "trial di maggiori dimensioni e di elevata qualità" mostra che gli effetti clinici dell'omeopatia **sono effetto placebo**
[Editoriale: «La fine dell'omepatia»]

3. **Ludtke and Rutten.** (*J Clin Epidemiol, 2008*):

I risultati della M-A di Shang's et al **cambiano** in relazione alla soglia definita per la dimensione campionaria. I risultati pertanto sono **meno conclusivi** di come sono stati presentati

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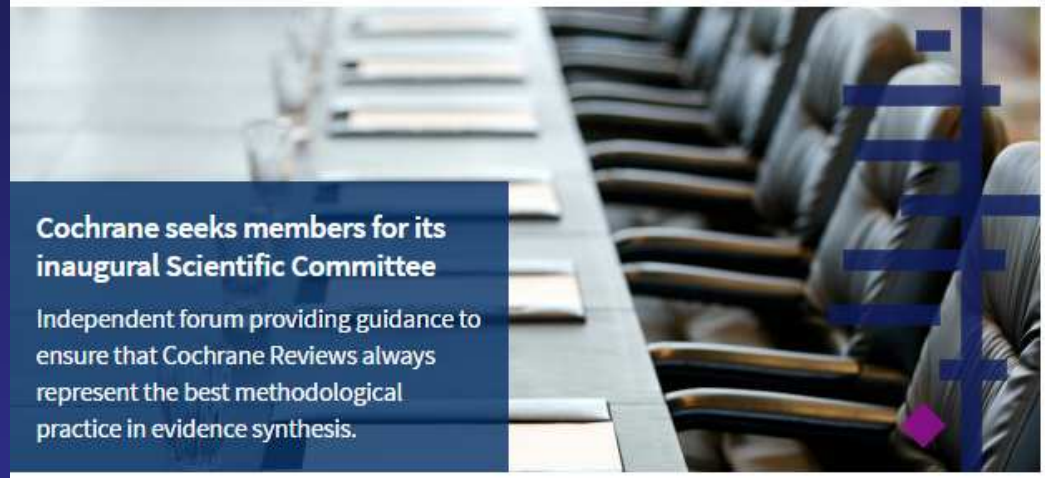

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- Vaccines to prevent influenza in healthy adults
- Amitriptyline for neuropathic pain in adults
- Vitamin E supplementation in pregnancy
- Corticosteroids for bacterial meningitis
- Intravenous infusion of lidocaine starting at the time of surgery for reduction of pain and improvement of recovery after surgery
- T-tube drainage versus no T-tube drainage after open common bile duct exploration
- Weaning from mechanical ventilation using pressure support or a T-tube for a spontaneous breathing trial
- Two different laparoscopic techniques for

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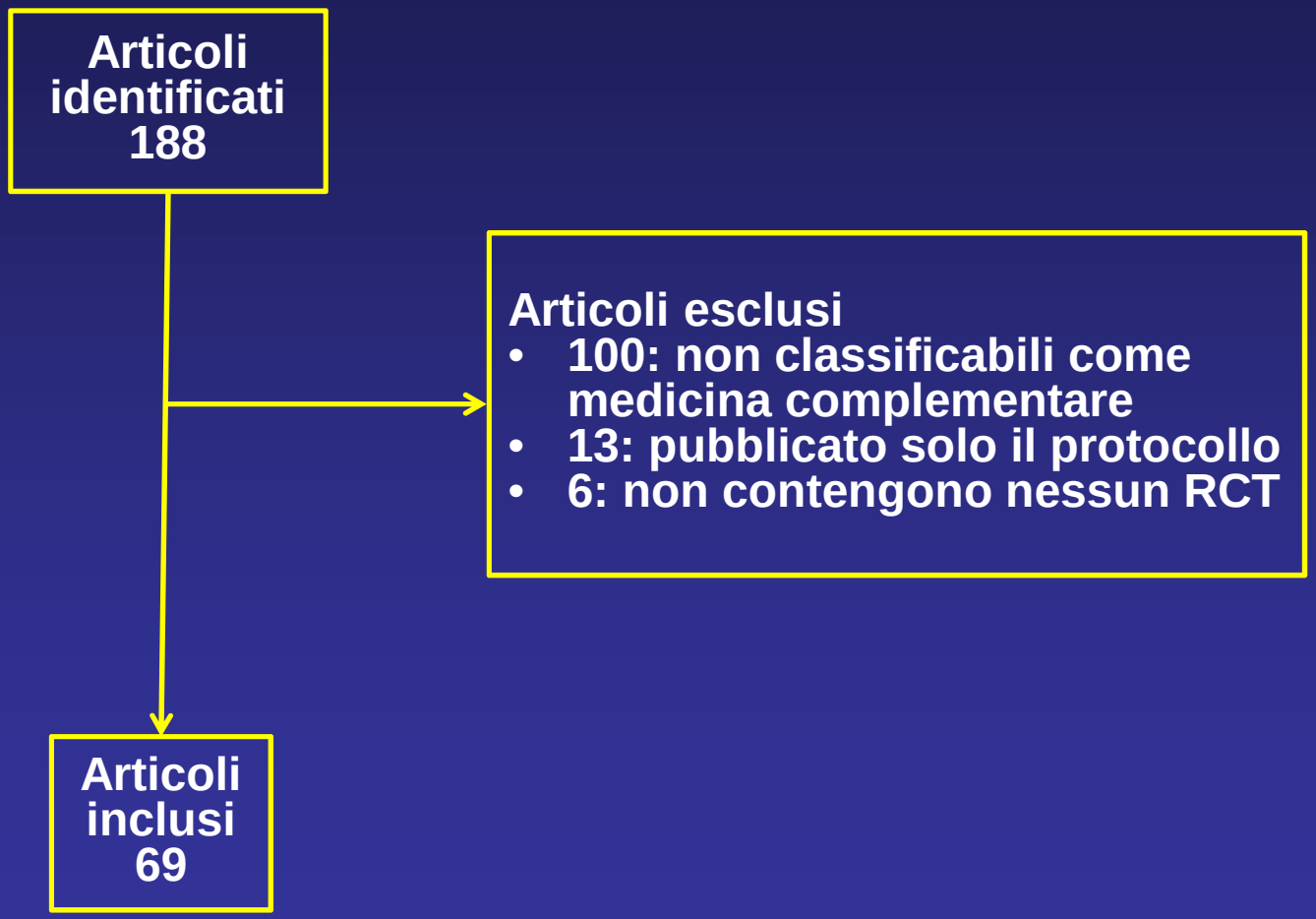
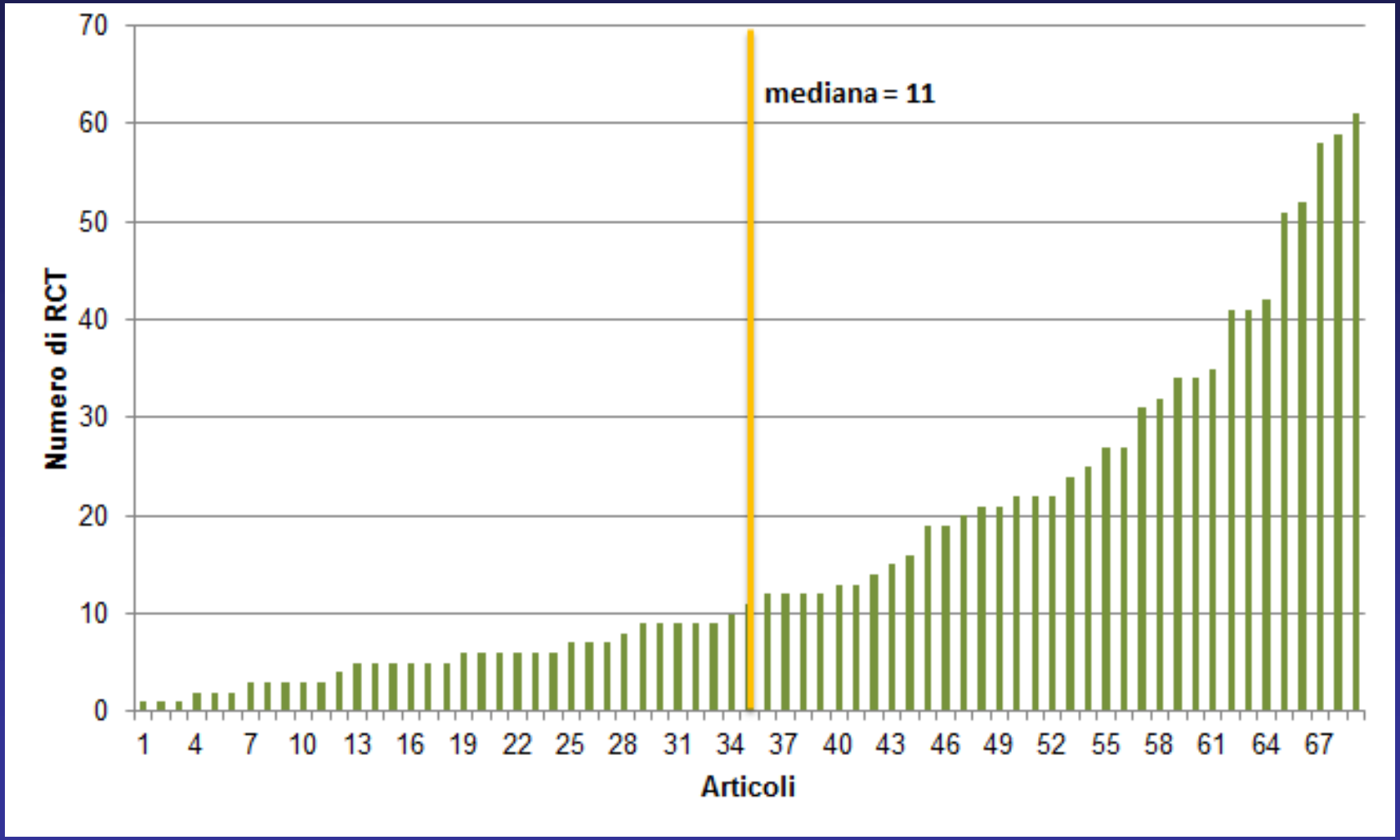
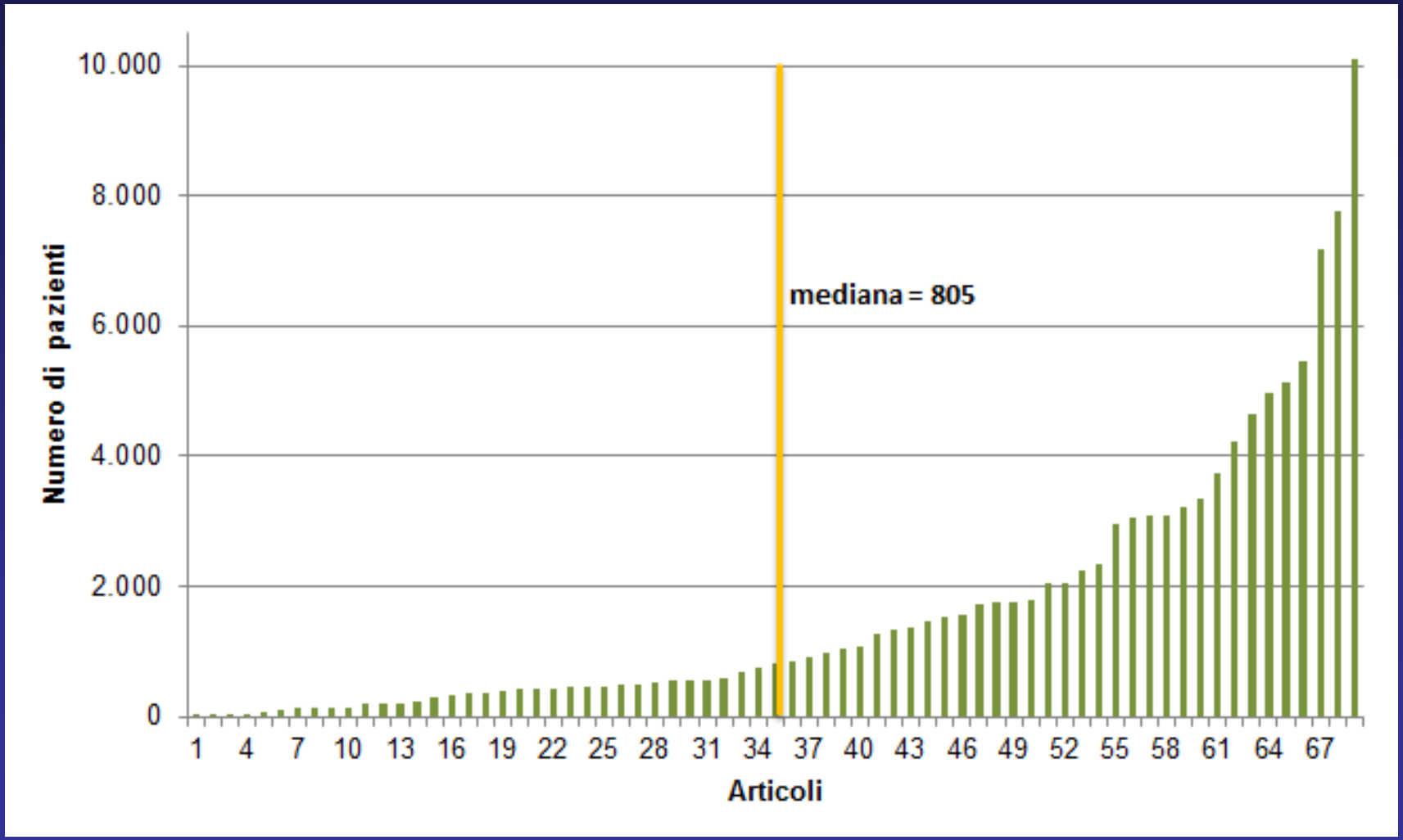


Distribuzione RCT

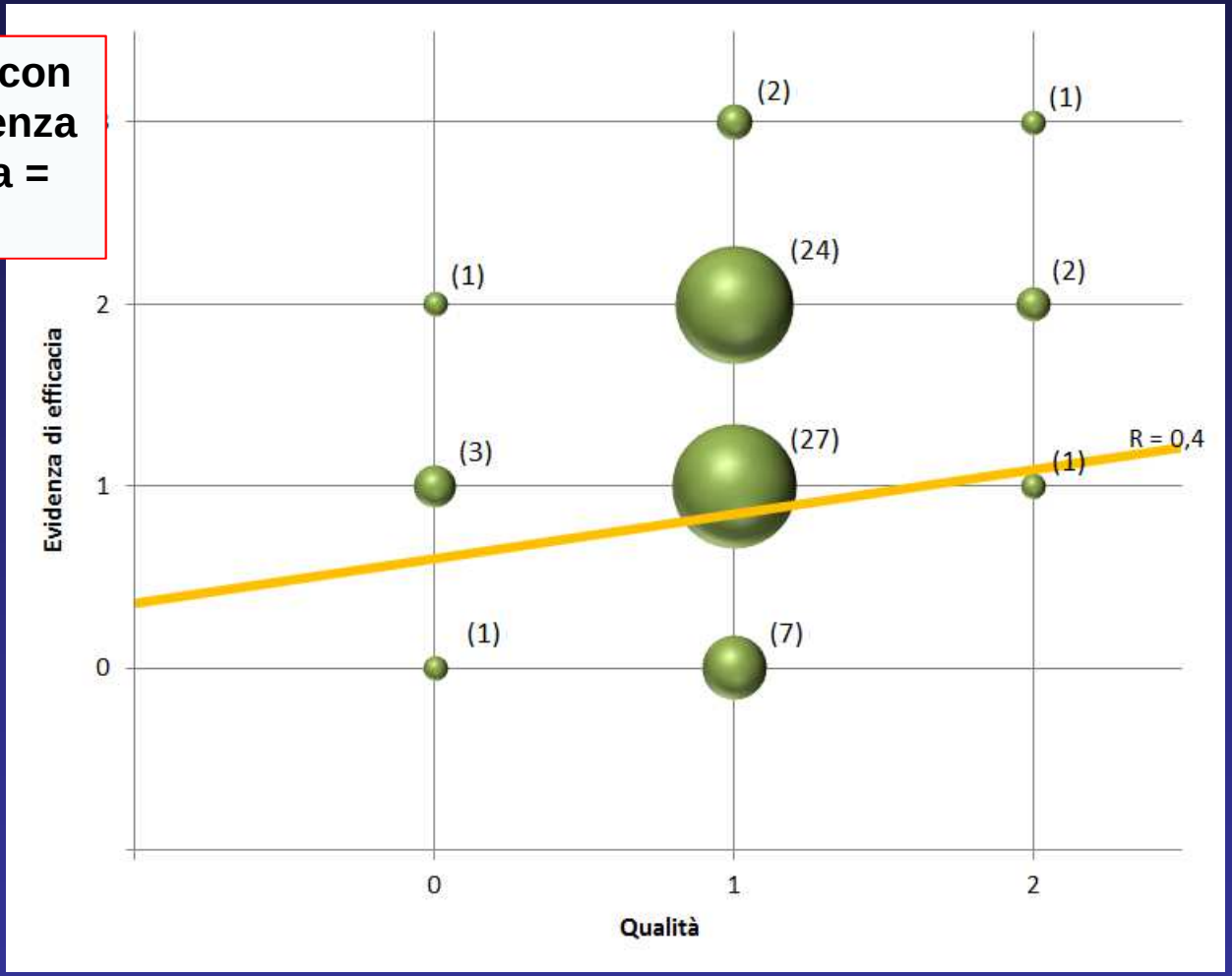


Distribuzione pazienti



Relazione efficacia-qualità

N° review con forte evidenza di efficacia = 3 (4%)

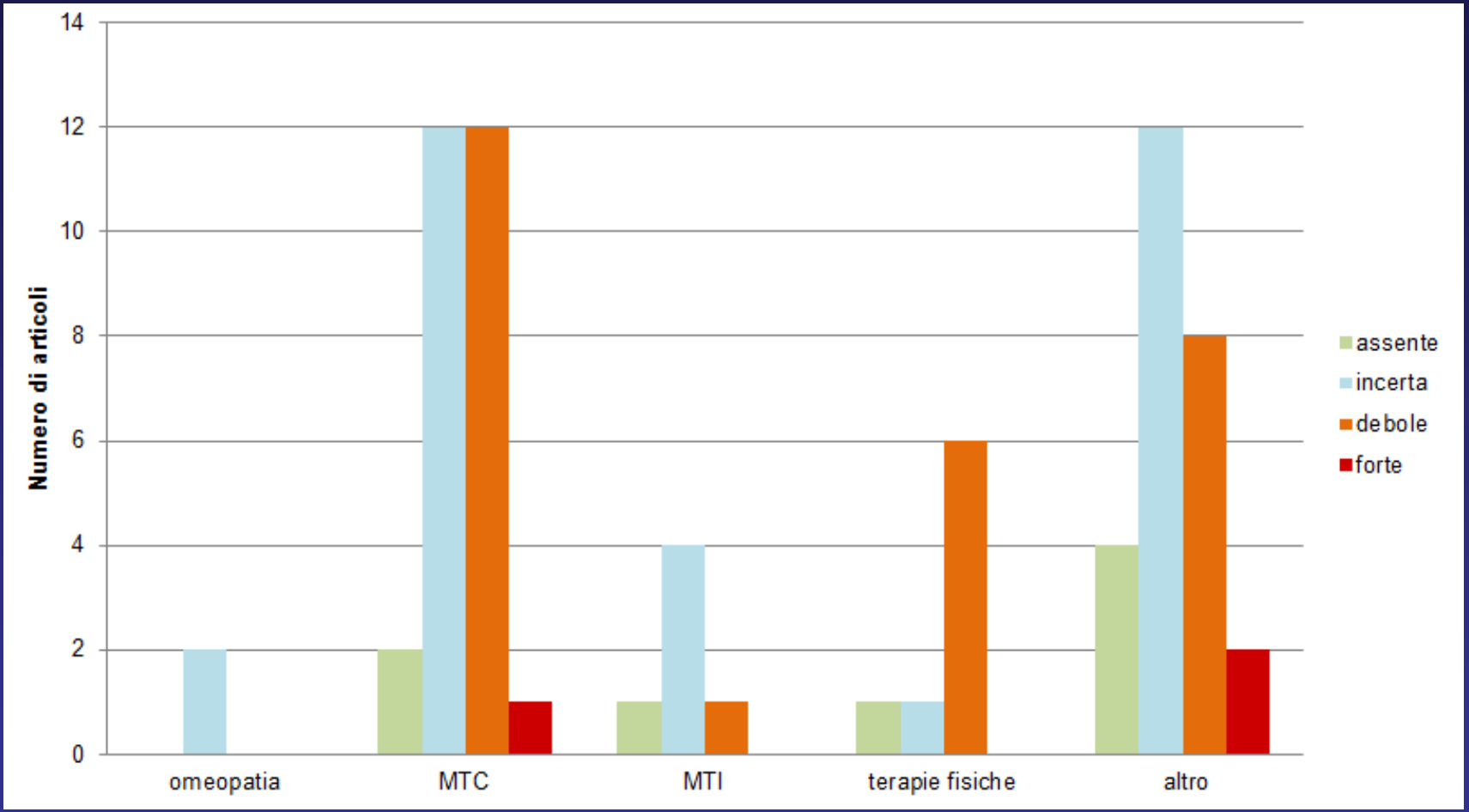


N° review con studi di medio /alta qualità = 4 (6%)

Efficacia
0 = assente
1 = incerta
2 = debole
3 = forte

Qualità
0 = nessuno studio di qualità medio/alta
1 = la maggior parte degli studi non è di qualità medio/alta
2 = la maggior parte degli studi è di qualità medio/alta

Evidenza di efficacia



MTC = medicina tradizionale cinese
MTI = medicina tradizionale indiana
Terapie fisiche = osteopatia, chiropratica, massaggi
Altro = musicoterapia, danza, canto, altri interventi non farmacologici

Efficacia MTC: sottogruppi

Sono stati inclusi 27 studi nella categoria MTC

	Numero studi	Evidenza di efficacia (debole/forte)
Agopuntura	9	4 (44%)
Prodotti erboristici	17	8 (47%)
Tai Chi Chuan	1	1 (100%)

Revisioni con studi di moderata/alta qualità - 1

Feverfew for preventing migraine

(partenio)

Barbara Wider[1,2], Max H Pittler[3], Edzard Ernst[4]

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Main results

We identified one new study for this update, resulting in six trials (561 patients) meeting the inclusion criteria. Five of the six trials reported on the main outcome, migraine frequency. Although five of the trials were generally of good methodological quality, all studies were either of unclear or high risk of bias with regards to sample size. Pooled analysis of the results was not possible due to the lack of common outcome measures and heterogeneity between studies in terms of participants, interventions and designs.

The most recent trial added to this version of the review is rigorous and larger (n = 218), using a stable feverfew extract at a dose determined by a previous dose-finding trial. It reports that feverfew reduced migraine frequency by 1.9 attacks from 4.8 to 2.9 and placebo by 1.3 from to 4.8 to 3.5 per month, resulting in a difference in effect between feverfew and placebo of 0.6 attacks per month. For the secondary outcome measures intensity and duration of migraine attacks, incidence and severity of nausea and vomiting, and global assessment no statistically significant differences were reported. Results of previous trials are not convincing: three trials reporting positive effects of feverfew are all of small sample size (17 to 60 participants), while two rigorous trials (n = 50, 147) did not find significant differences between feverfew and placebo. Only mild and transient adverse events, most commonly gastrointestinal complaints and mouth ulcers, were reported in the included trials.

Authors' conclusions

Since the last version of this review, one larger rigorous study has been included, reporting a difference in effect between feverfew and placebo of 0.6 attacks per month. This adds some positive evidence to the mixed and inconclusive findings of the previous review. However, this constitutes low quality evidence, which needs to be confirmed in larger rigorous trials with stable feverfew extracts and clearly defined migraine populations before firm conclusions can be drawn. It appears from the data reviewed that feverfew is not associated with any major safety concerns.

Revisioni con studi di moderata/alta qualità - 2

Acupuncture for the prevention of episodic migraine

Klaus Linde[1], Gianni Allais[2], Benno Brinkhaus[3], Yutong Fei[4], Michael Mehring[1], Emily A. Vertosick[5], Andrew Vickers[5], Adrian R White[6]

Comparison with sham acupuncture

Both after treatment (12 trials, 1646 participants) and at follow-up (10 trials, 1534 participants), acupuncture was associated with a small but statistically significant frequency reduction over sham (moderate quality evidence). The SMD was -0.18 (95% CI -0.28 to -0.08; I^2 = 47%) after treatment and -0.19 (95% CI -0.30 to -0.09; I^2 = 59%) at follow-up. After treatment headache frequency at least halved in 50% of participants receiving true acupuncture and 41% receiving sham acupuncture (pooled RR 1.23, 95% CI 1.11 to 1.36; I^2 = 48%; 14 trials, 1825 participants) and at follow-up in 53% and 42%, respectively (pooled RR 1.25, 95% CI 1.13 to 1.39; I^2 = 61%; 11 trials, 1683 participants; moderate quality evidence). The corresponding NNTBs are 11 (95% CI 7.00 to 20.00) and 10 (95% CI 6.00 to 18.00), respectively. The number of participants dropping out due to adverse effects (odds ratio (OR) 2.84; 95% CI 0.43 to 18.71; 7 trials, 931 participants; low quality evidence) and the number of participants reporting adverse effects (OR 1.15; 95% CI 0.85 to 1.56; 4 trials, 1414 participants; moderate quality evidence) did not differ significantly between acupuncture and sham groups.

Comparison with prophylactic drug treatment

Acupuncture reduced migraine frequency significantly more than drug prophylaxis after treatment (SMD -0.25; 95% CI -0.39 to -0.10; 3 trials, 739 participants), but the significance was not maintained at follow-up (SMD -0.13; 95% CI -0.28 to 0.01; 3 trials, 744 participants; moderate quality evidence). After three months headache frequency at least halved in 57% of participants receiving acupuncture and 46% receiving prophylactic drugs (pooled RR 1.24; 95% CI 1.08 to 1.44) and after six months in 59% and 54%, respectively (pooled RR 1.11; 95% CI 0.97 to 1.26; moderate quality evidence). Findings were consistent among trials with I^2 being 0% in all analyses. Trial participants receiving acupuncture were less likely to drop out due to adverse effects (OR 0.27; 95% CI 0.08 to 0.86; 4 trials, 451 participants) and to report adverse effects (OR 0.25; 95% CI 0.10 to 0.62; 5 trials 931 participants) than participants receiving prophylactic drugs (moderate quality evidence).

Authors' conclusions

The available evidence suggests that adding acupuncture to symptomatic treatment of attacks reduces the frequency of headaches. Contrary to the previous findings, the updated evidence also suggests that there is an effect over sham, but this effect is small. The available trials also suggest that acupuncture may be at least similarly effective as treatment with prophylactic drugs. Acupuncture can be considered a treatment option for patients willing to undergo this treatment. As for other migraine treatments, long-term studies, more than one year in duration, are lacking.

Revisioni con studi di moderata/alta qualità - 3

Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

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KMC versus conventional neonatal care: At discharge or 40 to 41 weeks' postmenstrual age, KMC was associated with a statistically significant reduction in the risk of mortality (risk ratio [RR] 0.60, 95% confidence interval [CI] 0.39 to 0.92; eight trials, 1736 infants), nosocomial infection/sepsis (RR 0.35, 95% CI 0.22 to 0.54; five trials, 1239 infants), and hypothermia (RR 0.28, 95% CI 0.16 to 0.49; nine trials, 989 infants; moderate-quality evidence). At latest follow-up, KMC was associated with a significantly decreased risk of mortality (RR 0.67, 95% CI 0.48 to 0.95; 12 trials, 2293 infants; moderate-quality evidence) and severe infection/sepsis (RR 0.50, 95% CI 0.36 to 0.69; eight trials, 1463 infants; moderate-quality evidence). Moreover, KMC was found to increase weight gain (mean difference [MD] 4.1 g/d, 95% CI 2.3 to 5.9; 11 trials, 1198 infants; moderate-quality evidence), length gain (MD 0.21 cm/week, 95% CI 0.03 to 0.38; three trials, 377 infants) and head circumference gain (MD 0.14 cm/week, 95% CI 0.06 to 0.22; four trials, 495 infants) at latest follow-up, exclusive breastfeeding at discharge or 40 to 41 weeks' postmenstrual age (RR 1.16, 95% CI 1.07 to 1.25; six studies, 1453 mothers) and at one to three months' follow-up (RR 1.20, 95% CI 1.01 to 1.43; five studies, 600 mothers), any (exclusive or partial) breastfeeding at discharge or at 40 to 41 weeks' postmenstrual age (RR 1.20, 95% CI 1.07 to 1.34; 10 studies, 1696 mothers; moderate-quality evidence) and at one to three months' follow-up (RR 1.17, 95% CI 1.05 to 1.31; nine studies, 1394 mothers; low-quality evidence), and some measures of mother-infant attachment and home environment. No statistically significant differences were found between KMC infants and controls in Griffith quotients for psychomotor development at 12 months' corrected age (low-quality evidence). Sensitivity analysis suggested that inclusion of studies with high risk of bias did not affect the general direction of findings nor the size of the treatment effect for main outcomes.

Authors' conclusions

Evidence from this updated review supports the use of KMC in LBW infants as an alternative to conventional neonatal care, mainly in resource-limited settings. Further information is required concerning the effectiveness and safety of early-onset continuous KMC in unstabilized or relatively stabilized LBW infants, as well as long-term neurodevelopmental outcomes and costs of care.

Revisioni con studi di moderata/alta qualità - 4

Music interventions for mechanically ventilated patients

Joke Bradt[1], Cheryl Dileo[2]

Main results

We identified six new trials for this update. In total, the evidence for this review rests on 14 trials (805 participants). Music listening was the main intervention used, and 13 of the studies did not include a trained music therapist. Results indicated that music listening may be beneficial for anxiety reduction in mechanically ventilated patients. Specifically, music listening resulted, on average, in an anxiety reduction that was 1.11 standard deviation units greater (95% CI -1.75 to -0.47, P = 0.0006) than in the standard care group. This is considered a large and clinically significant effect. Findings indicated that listening to music consistently reduced respiratory rate and systolic blood pressure, suggesting a relaxation response. Furthermore, one large-scale study reported greater reductions in sedative and analgesic intake in the music listening group compared to the control group, and two other studies reported trends for reduction in sedative and analgesic intake for the music group. One study found significantly higher sedation scores in the music listening group compared to the control group.

No strong evidence was found for reduction in diastolic blood pressure and mean arterial pressure. Furthermore, inconsistent results were found for reduction in heart rate with seven studies reporting greater heart rate reductions in the music listening group and one study a slightly greater reduction in the control group. Music listening did not improve oxygen saturation levels.

Four studies examined the effects of music listening on hormone levels but the results were mixed and no conclusions could be drawn.

No strong evidence was found for an effect of music listening on mortality rate but this evidence rested on only two trials.

Most trials were assessed to be at high risk of bias because of lack of blinding. Blinding of outcome assessors is often impossible in music therapy and music medicine studies that use subjective outcomes, unless the music intervention is compared to another treatment intervention. Because of the high risk of bias, these results need to be interpreted with caution.

No studies could be found that examined the effects of music interventions on quality of life, patient satisfaction, post-discharge outcomes, or cost-effectiveness. No adverse events were identified.

Authors' conclusions

This updated systematic review indicates that music listening may have a beneficial effect on anxiety in mechanically ventilated patients. These findings are consistent with the findings of three other Cochrane systematic reviews on the use of music interventions for anxiety reduction in medical patients. The review furthermore suggests that music listening consistently reduces respiratory rate and systolic blood pressure. Finally, results indicate a possible beneficial impact on the consumption of sedatives and analgesics. Therefore, we conclude that music interventions may provide a viable anxiety management option to mechanically ventilated patients.

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CLINICAL AND BIOLOGIC ACTIVITY OF AN ESTROGENIC HERBAL COMBINATION (PC-SPES) IN PROSTATE CANCER

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Adulterants in Asian Patent Medicines

To the Editor: Asian patent medicines are one component of what are called traditional Chinese medicines. Asian patent medicines comprise multiple products, including herbs, plants, animal parts, and minerals, which are formulated into tablets, pills, or liquids for ease of use. They are widely available in herbal stores and have gained acceptance by the American public as a form of alternative medicine. However, many patent medicines manufactured in Asian countries contain toxic ingredients, such as heavy metals, as well as prescription drugs or unapproved ingredients that may or may not be identified on the label.[1,2] Some have caused serious illness in unsuspecting consumers.[3,4]

The California Department of Health Services, Food and Drug Branch, initiated a study to screen imported Asian patent medicines for undeclared pharmaceuticals and heavy-metal contamination, using gas chromatography–mass spectrometry and atomic-absorption methods. Our objectives were to establish a computer data base for these products; educate the public, the herbal industry, and the medical community about the potential danger of Asian patent medicines; and provide objective information about toxicity.

Of 260 Asian patent medicines that have been collected from California retail herbal stores, 14 had labels that declared pharmaceutical ingredients, and 3 had insufficient sample amounts. Of the remaining 243 products, 17 (7 percent) contained undeclared pharmaceuticals. The most common undeclared ingredients were ephedrine, chlorpheniramine, methyltestosterone, and phenacetin. A total of 251 products were analyzed for lead, arsenic, and mercury; 9 other samples, including the 3 noted above, were insufficient for this analysis. Twenty-four products contained lead in a quantity of at least 10 parts per million (ppm) (range, 10 to 319; median, 29.8; mean, 54.9). Thirty-six products contained arsenic (range, 20.4 to 114,000 ppm; median, 180.5; mean, 14,553). Thirty-five products contained mercury (range, 22.4 to 5070 ppm; median, 329; mean, 1046); 2 of the 35 had labels that identified only pharmaceutical ingredients. The United States Pharmacopoeia limits heavy metals in most oral pharmaceuticals to 30 ppm, with lower limits for lead, arsenic, and mercury.

Of the 260 products we investigated, at least 83 (32 percent) contained undeclared pharmaceuticals or heavy metals, and 23 had more than one adulterant. The remaining products, which contained no detectable adulterants, cannot be assumed to be safe and free of toxic ingredients, in view of their batch-to-batch inconsistency, as well as limitations in our detection methods.

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Butyrolactone-Induced Central Nervous System Depression after Ingestion of RenewTrient, a "Dietary Supplement"

To the Editor: Ingestion of γ-hydroxybutyric acid, marketed as a "body-building supplement," may result in coma and apnea. Its sale has recently been banned by the Food and Drug Administration (FDA), but similar alternative products continue to be marketed. After the addition of water and sodium hydroxide, γ-butyrolactone, a solvent, is converted to γ-hydroxybutyric acid. Studies suggest that γ-butyrolactone poisoning can produce a clinical picture similar to that associated with γ-hydroxybutyric acid.[1]

RenewTrient, described on the label as a dietary supplement that "stimulates the body's own natural production of Growth Hormone," contains γ-butyrolactone. We report a case of central nervous system depression after the ingestion of RenewTrient.

A 36-year-old man was stopped by the police after he was seen to be driving erratically. The police found him to be lethargic, with diaphoresis and vomiting. In the emergency department, a physical examination was unremarkable except that the man appeared to be inebriated. His vital signs were normal. His mental status returned to normal within one hour after his arrival at the emergency department. He reported that he had ingested, for the first time, 2 oz (59 ml) of RenewTrient approximately 30 minutes before he was placed in police custody. He stated that he had not ingested any other substances at the time.

His medical history was unremarkable. The blood ethanol level was 0, and a urinary screening test for drugs of abuse with the use of an enzyme-multiplied immunoassay technique was negative. The results of comprehensive urinary drug screening with thin-layer chromatography and gas chromatography–mass spectrometry were also negative. The urine was positive for butyrolactone, as determined by gas chromatography and flame ionization detection. The patient was well when discharged after six hours of observation. The FDA was notified.

γ-Butyrolactone, a precursor in the synthesis of γ-hydroxybutyric acid, produced an intoxication similar to that caused by γ-hydroxybutyric acid. RenewTrient contains γ-butyrolactone and as of this writing was available for purchase in health-food stores.

The label on RenewTrient states:

> Higher doses will result in proportionally longer periods of deep sleep and sweating. Muscle spasms, vomiting, bedwetting, and diarrhea are typical reactions. Unless drugs or alcohol have been taken with RenewTrient™ the only treatment necessary is to SLEEP IT OFF! A call for help may result in uninformed emergency medical personnel using expensive, unnecessary and potentially dangerous methods of arousal.

Correspondence

Alternative Therapies for the Treatment of Childhood Cancer

To the Editor: Recently, we have been deeply disturbed by the decision of several families to use alternative therapies exclusively as front-line treatment for their children's cancer, or to use alternative rather than adjuvant therapy after radical surgery. We report here on two patients, in both of whom we documented tumor growth after the use of alternative therapies.

Patient 1, a 15-year-old boy, received a diagnosis of stage IIA nodular, sclerosing Hodgkin's disease in April 1998. Treatment with multiagent chemotherapy and low-dose irradiation to the involved field was recommended. Despite lengthy discussion, the patient, with the approval of his mother, instead elected to use Matol Biomune OSF Plus (Matol Botanical International). This compound contains the herb astragalus in combination with a special extract of dairy colostrum and whey, and it is alleged, according to the manufacturer's promotional literature, to "create a synergistic effect on the immune system, resulting in the elevation of natural killer (NK) cell activity." Case reports provided by Matol Botanical International indicate that the compound has beneficial effects on a wide range of disorders, including environmental illnesses, a variety of cancers, AIDS, hepatitis C, and the chronic fatigue syndrome.

When it was clear that the patient could not be persuaded to alter his decision, we urged him to keep visiting our outpatient clinic so that we could monitor his condition. Initially, no change in the tumor burden was noted, but in early August, both clinical and radiologic evidence of marked disease progression was seen. Two weeks later severe night sweats developed, and the patient requested the previously recommended conventional therapy. On restaging, we determined that the patient had stage IIB disease and therefore required more intensive therapy, including increased dosages of doxorubicin, etoposide, and bleomycin.

Patient 2, a nine-year-old girl, underwent a complete resection of a primitive neuroectodermal tumor of the right parietotemporal lobe in the brain. Since the three-year survival rate after adjuvant therapy for this tumor is more than 50 percent,[1] we recommended multiagent chemotherapy and radiotherapy after surgery. The parents, however, opted instead to treat their daughter with shark cartilage. Four months later, marked tumor progression was documented, and the patient subsequently died.

Conventional cancer treatments are recommended only after formal scientific study of their safety, tolerability, and efficacy. We refer to these therapies as "evidence-based." This approach has resulted in important improvements in the outcome of childhood cancer,[2,3] and we find it difficult to understand how conventional treatments for childhood cancer can be repudiated in favor of alternative approaches for which any evidence of efficacy is lacking.

In recent years, we physicians seem to have come to accept alternative therapies. We are even advised to seek better integration of conventional and alternative therapies because "it is what the patient wants."[4] To continue to have a laissez-faire attitude reinforces the public's notion that alternative therapies are devoid of potential harm. It is time to remember that each of us has taken an oath to uphold "the good of the sick to the utmost of my power, holding myself aloof from wrong." As a medical community, we have a responsibility to educate the public not only about the great benefits of evidence-based medicine but, in addition, about the risks of using therapies for which any evidence of efficacy or safety is lacking.

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Medicina convenzionale o alternativa ? Un’autorevole opinione

“ Non ci possono essere due tipi di medicina – convenzionale e alternativa. C’è solo una medicina, che è stata adeguatamente sperimentata e una medicina che non lo è stata. Una volta che un trattamento è stato sperimentato in modo corretto e se ne verifica efficacia e sicurezza esso sarà accettato nell’uso corrente”

(Angell e Kassirer, NEJM 1998)

Conclusioni

- Le medicine complementari (MC) potrebbero fornire un apporto significativo per la prevenzione e la cura delle malattie e la promozione della salute
- Le MC sono state largamente impiegate per molti anni e, nel caso delle medicine tradizionali (cinese, indiana, ecc.), sono regolamentate a livello nazionale, con un corpus di insegnamento universitario e un albo professionale
- La sperimentazione clinica sulle MC è difficile, a causa della mancanza di finanziamenti, personalizzazione del trattamento e variabilità dei trattamenti per scuole, operatori, e altro
- L'evidenza di efficacia e sicurezza dell'impiego di MC è complessivamente incerta: sono stati condotti pochi trial, con evidenze spesso deboli e contradditorie, e pochi trattamenti si sono dimostrati efficaci secondo le revisioni Cochrane

"Ci sono più cose in cielo e in terra di quelle immaginate dalla tua filosofia, Orazio"

Shakespeare, A*mleto*

Conflitti di interesse: nessuno.

Grazie per l'attenzione