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Perugia, 20-21 Novembre 2009

La valutazione di efficacia nel campo delle medicine non convenzionali: l'esperienza della Collaborazione Cochrane

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Regione Lazio 

Sommario

- Revisioni Cochrane su Medicine non Convenzionali: lo stato dell'arte
- La valutazione di efficacia: è possibile?
- Conclusioni (*ma soprattutto domande*)

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MnC: lo stato dell'arte

96 revisioni sull'efficacia delle medicine non convenzionali:

- agopuntura N. 26
- herbal N. 63
- altro N. 7

Altro=

Ayurvedic medicine: 1

Snoezelen (multi-sensory stimulation): 1

Yoga therapy: 1

Aroma therapy:1

Tai Chi Chuan (ancient Chinese martial art): 1

Meditation therapy: 1



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Intercessory prayer for the alleviation of ill health (Review)

Roberts L, Ahmed I, Hall S, Davison A



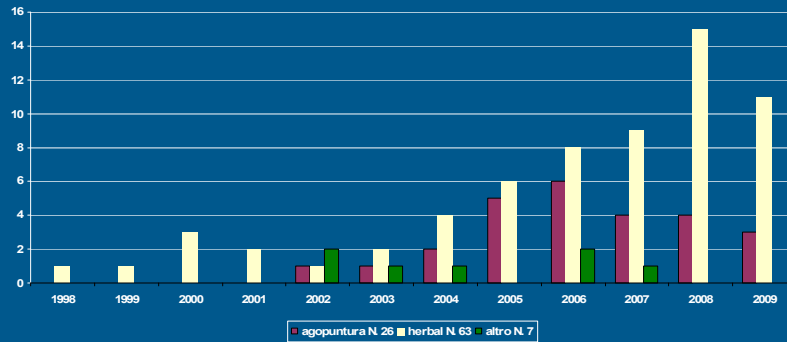
This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2009, Issue 2

<http://www.thecochranelibrary.com>

1	Acupuncture and assisted conception
2	Acupuncture and dry-needling for low back pain
3	Acupuncture and electroacupuncture for the treatment of rheumatoid arthritis
4	Acupuncture and related interventions for smoking cessation
5	Acupuncture for acute stroke
6	Acupuncture for Bell's palsy
7	Acupuncture for chronic asthma
8	Acupuncture for depression
9	Acupuncture for dysphagia in acute stroke
10	Acupuncture for epilepsy
11	Acupuncture for glaucoma
12	Acupuncture for induction of labour
13	Acupuncture for insomnia
14	Acupuncture for lateral elbow pain
15	Acupuncture for migraine prophylaxis
16	Acupuncture for neck disorders
17	Acupuncture for restless legs syndrome
18	Acupuncture for schizophrenia
19	Acupuncture for shoulder pain
20	Acupuncture for stroke rehabilitation
21	Acupuncture for tension-type headache
22	Acupuncture for treatment of irritable bowel syndrome
23	Acupuncture for vascular dementia
24	Acupuncture-point stimulation for chemotherapy-induced nausea or vomiting
25	Auricular acupuncture for cocaine dependence
26	Stimulation of the wrist acupuncture point P6 for preventing postoperative nausea and vomiting

1	Acanthopanax for acute ischaemic stroke	33	Herbal interventions for chronic asthma in adults and children
2	Aroma therapy for dementia	34	Herbal medicine for low back pain
3	Artichoke leaf extract for treating hypercholesterolaemia	35	Herbal medicines for treating HIV infection and AIDS
4	Cephalic version by moxibustion for breech presentation	36	Herbal medicines for treatment of irritable bowel syndrome
5	Chinese herbal medicine for atopic eczema	37	Herbal medicines for viral myocarditis
6	Chinese herbal medicine for endometriosis	38	Herbal preparations for uterine fibroids
7	Chinese herbal medicine for premenstrual syndrome	39	Herbal therapy for treating osteoarthritis
8	Chinese herbal medicine for primary dysmenorrhoea	40	Herbal therapy for treating rheumatoid arthritis
9	Chinese herbal medicine for schizophrenia	41	Horse chestnut seed extract for chronic venous insufficiency
10	Chinese herbal medicine for the treatment of pre-eclampsia	42	Kava extract versus placebo for treating anxiety
11	Chinese herbal medicine Huangqi type formulations for nephrotic syndrome	43	Medicinal herbs for esophageal cancer
12	Chinese herbal medicine suxiao jinxin wan for angina pectoris	44	Medicinal herbs for hepatitis C virus infection
13	Chinese herbal medicines for acute pancreatitis	45	Pelargonium sidoides extract for acute respiratory tract infections
14	Chinese herbal medicines for hyperthyroidism	46	Phytomedicines (medicines derived from plants) for sickle cell disease
15	Chinese herbal medicines for type 2 diabetes mellitus	47	Puerarin for acute ischaemic stroke
16	Chinese herbal medicines in the treatment of ectopic pregnancy	48	Puerarin injection for unstable angina pectoris
17	Chinese herbs combined with Western medicine for severe acute respiratory syndrome (SARS)	49	Pygeum africanum for benign prostatic hyperplasia
18	Chinese medicinal herbs for chemotherapy side effects in colorectal cancer patients	50	Sanchu for acute ischaemic stroke
19	Chinese medicinal herbs for acute bronchitis	51	Serenoa repens for benign prostatic hyperplasia
20	Chinese medicinal herbs for asymptomatic carriers of hepatitis B virus infection	52	Shengmai (a traditional Chinese herbal medicine) for heart failure
21	Chinese medicinal herbs for chronic hepatitis B	53	St John's wort for major depression
22	Chinese medicinal herbs for influenza	54	Tongxinluo capsule for acute stroke
23	Chinese medicinal herbs for measles	55	Traditional Chinese medicine for epilepsy
24	Chinese medicinal herbs for sore throat	56	Yizhi capsule for vascular dementia
25	Chinese medicinal herbs for the common cold	57	Zhiling decoction for vascular dementia
26	Chinese medicinal herbs to treat the side-effects of chemotherapy in breast cancer patients	58	Ginkgo biloba extract for age-related macular degeneration
27	Chuanxiong-type preparations for acute ischemic stroke	59	Ginkgo biloba for tinnitus
28	Dan Shen agents for acute ischaemic stroke	60	Ginkgo biloba for tinnitus
29	Danshen (Chinese medicinal herb) preparations for acute myocardial infarction	61	Ginkgo biloba for acute ischaemic stroke
30	Dengzhanhua preparations for acute cerebral infarction	62	Ginkgo biloba for cognitive impairment and dementia
31	Green tea (Camellia sinensis) for the prevention of cancer	63	Ginkgo biloba for intermittent claudication
32	Hawthorn extract for treating chronic heart failure		

Andamento temporale delle revisioni



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Di cosa parliamo

Just thought I'd share some info on the terminology for Traditional Chinese Medicine/Chinese medicinal herbs etc. We noticed that within our review group, we had several variants of TCM in titles. After enquiring with the Complimentary Medicine field group on which is the most appropriate term, we've been given the following guidance:

Traditional Chinese Medicine generally refers to a whole system of care, including acupuncture, herbs, diet, and movement therapies.

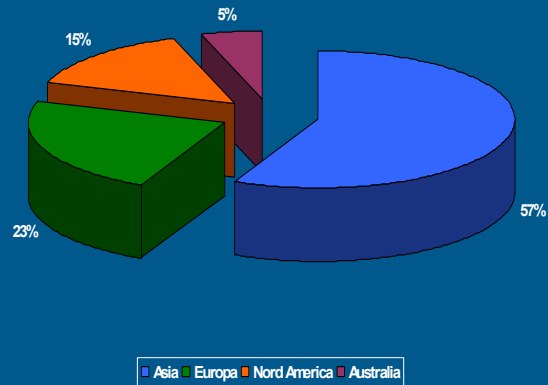
If it is herbal medicine, I would use the term "Chinese herbal medicines" as it is straight forward without getting into if it is traditional or modern and distinguishes from other countries' herbal approaches.

**Best wishes,
Karin (Karin Dearness, Review Group Coordinator, Cochrane Upper Gastrointestinal and Pancreatic Diseases Group Satellite Centre**

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Paese di origine degli autori (N= 414)

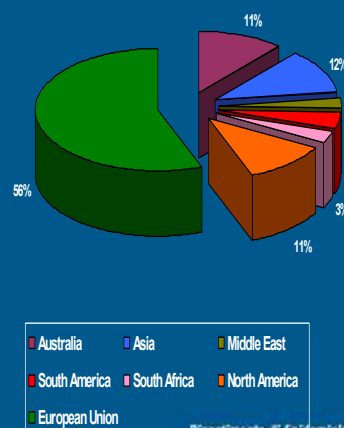
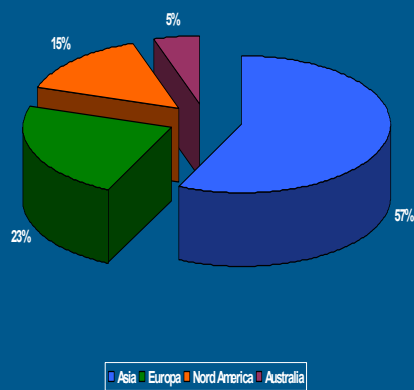


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Paese di origine degli autori (N= 414)

MnC N= 414

CDAG = 220



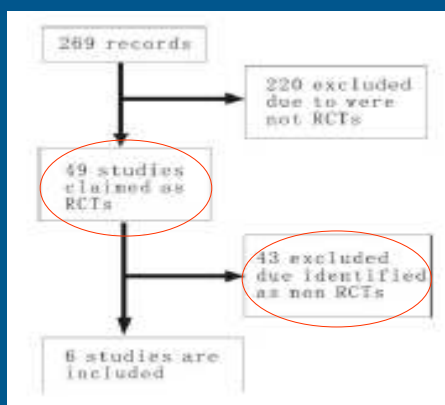
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% Studi Inclusi Nelle RS

RS Medicine non convenzionali				
N. Revisioni	N. Studi considerati	N Studi esclusi	N studi inclusi	% studi inclusi
94	12774	4635	8139	64%
RS CDAG				
N. Revisioni	N. Studi considerati	N Studi esclusi	N studi inclusi	% studi inclusi
49	1980	1314	669	34%



Danshen (Chinese Medicinal Herb) Preparations for Acute Myocardial Infarction



N. Partecipanti

Agopuntura (N=26)	31.243
Herbal (N=63)	1.679.546*
Other (N=7)	2.502
Total	1.713.291

* La RS Green tea (*Camellia sinensis*) for the prevention of cancer include 1.600.000 partecipanti , se si esclude queta RS I partecipanti sono **79.546**



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Study ID	Methods	Interventions	Notes	Allocation concealment
Chen 2004a	Country: China(Hengyang). Subjects of each group were treated for one month with Anjunning , Kanfuxin and placebo according to the principle of parallel - control and double blindness , and were	two Chinese herbal compounds : Anjunning and Kangfuxin on alleviating opioid protracted abstinence symptoms.	Tel:+86731-5550511-3269-2813>2674. First author said, first used random digits table, then patients into the study, and used double-blind.	<input type="radio"/> A - Adequate <input type="radio"/> B - Unclear <input type="radio"/> C - Inadequate <input type="radio"/> D - Not used
Guo 1995	Country: China(Lanzhou). Randomized, double blind clinical trail was adopted, the scale for withdrawal symptoms , the scale for side effect were evaluated to every patient .	Clonidine and Chinese materia medica Fukang pellet	Tel:+8610-62013330 This line always busy.	<input type="radio"/> A - Adequate <input type="radio"/> B - Unclear <input type="radio"/> C - Inadequate <input type="radio"/> D - Not used
Guo 2001	Country: China(Shanxi Guizhou Yunnan). Patients with heroin addiction were randomly assigned to double - blind groups of Zheng Tongning , clonidine hydrochloride and placebo. All of the subjects were t	Chinese materia medica Zhenqitongning ranula and Clonidine.	The same as "Guo 1995"	<input type="radio"/> A - Adequate <input type="radio"/> B - Unclear <input type="radio"/> C - Inadequate <input type="radio"/> D - Not used
Hu 1995	Country: China(Chengdu Chongqing). Randomized, double blind clinical trail was adopted, the scale for withdrawal symptoms , the scale for side effect were evaluated to every patient.	Clonidine and Chinese materia medica Fukang pellet	Ivisted this author doctor LI Jing of Mental Health Research Institute of West China Hospital, Sichuan University.	<input type="radio"/> A - Adequate <input type="radio"/> B - Unclear <input type="radio"/> C - Inadequate <input type="radio"/> D - Not used
Huang 2002	Country: China(Chengdu Changsha Yunnan). Multi - centered , randomized , double blind clinical trail was adopted , while the Scale for Withdrawal Symptoms , HAMA , the Scale for Side Effect were evaluated to every	Chinese materia medica Shenfutuodu capsule and Clonidine.	Ivisted this author doctor LI Jing of Mental Health Research Institute of West China Hospital, Sichuan University.	<input type="radio"/> A - Adequate <input type="radio"/> B - Unclear <input type="radio"/> C - Inadequate <input type="radio"/> D - Not used
Huang 2003	Country: China(Hubei Ensh). They were detoxified using Lofexidine Hydrochloride Tablet(LFX) for 12 d. While control group not any medicine, the treatment group A and B were treated with OL-ARH and Lofexidine.	(Oral Liquid of Agastachis for Restoring Health, OL-ARH) and (Tablet of Acanthopanax Senticosus Harms, T-ASH) and Lofexidine.	Author tel:+86 13886789019,+86718 8290198. I called this number on April 13th and April 14th , Doctor Huang DB said, used double-blind.	<input type="radio"/> A - Adequate <input type="radio"/> B - Unclear <input type="radio"/> C - Inadequate <input type="radio"/> D - Not used
Huang 2004a	Country: China(Hubei Ensh).All were detoxified with lofexidine hydrochloride (LFX) tablet for 12days. MBHD was given to the two treated groups, the medication started from the beginning of detoxification in the group B, and from the	Chinese materia medica Modified Banxia Houpu Decoction and lofexidine.	Author tel:+86 13886789019,+86718 8290198. I called this number on April 13th and April 14th, Doctor Huang DB said, used double-blind. Modified Banxia Houpu Decoction <Pinelliae tuber(Banxia)20g	<input type="radio"/> A - Adequate <input type="radio"/> B - Unclear <input type="radio"/> C - Inadequate <input type="radio"/> D - Not used
Huang 2004b	Country: China(Hubei Ensh).They were detoxified by using Lofexidine Hydrochloride Tablet(LFX) for 12d, and then, the control group took an imitate preparation, the treating group A took Huoxiangzhengqi Oral Liquid and Tablet of Radix et	Chinese materia medica Huoxiangzhengqi Oral Liquid and Tablet of Radix et Caulis Acanthopanaxis Senticosus and lofexidine.	Modified Banxia Houpu Decoction <Pinelliae tuber(Banxia)20g stir-baked CORTEX MAGNOLIAE OFFICINALIS with rhizoma zingiberis recens juice(Houpo)30g Tuckahoe(Fuling)20g purple common perilla(Zisu)10g zingiberis	<input type="radio"/> A - Adequate <input type="radio"/> B - Unclear <input type="radio"/> C - Inadequate <input type="radio"/> D - Not used
Kang 2002	Country: China(Chongqing).Take the same dose medicine 3 times every day. At the defined time, estimate the dependence symptoms, the adverse effects and the degree of anxiety with standard measuring scale. Examine	Chinese materia medica Kangfuxin, Fuakngpian, placebo and Clonidine.	Ivisted this author of Mental Health Research Institute of West China Hospital, Sichuan University.	<input type="radio"/> A - Adequate <input type="radio"/> B - Unclear <input type="radio"/> C - Inadequate <input type="radio"/> D - Not used
Li 1999a	Country: China.The efficacy and safety of Lingyi capsule has been compared with Clonidine and Placebo in 330 cases of heroin addicts through multi - center clinical trial (random controlled , double - blinded and open trial)	Chinese materia medica Lingyi capsule, placebo and Clonidine.	Ivisted this author of Mental Health Research Institute of West China Hospital, Sichuan University.	<input type="radio"/> A - Adequate <input type="radio"/> B - Unclear <input type="radio"/> C - Inadequate <input type="radio"/> D - Not used

Chinese medicinal herbs for the common cold

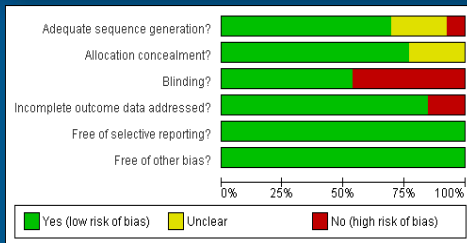
A total of 430 trials that claimed to be randomised were retrieved. We successfully contacted 365 trial authors by telephone. Of these trials, 302 were excluded, either because the trial authors misunderstood true random allocation or the trial reports were multiple versions of same study.”

traditional chinese medicine review

Your review can't be published in this form because of serious flaws:

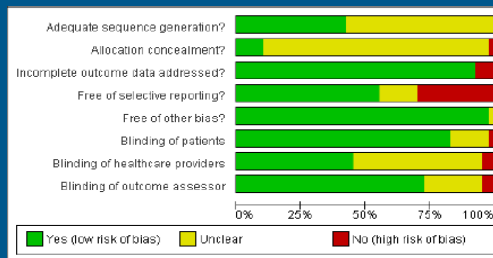
1. we have substantial doubt about the way you scored the methodological quality of included studies; for example: you scored as a high quality study Li 1999 which is a study where some of the patients were enrolled in a double blind study and some other in an open study and the results of the two groups of patients were considered altogether.
2. There are no correspondence between the score that you gave to the studies in the additional table 1 and what is described in the characteristics of included studies for blinding and for allocation concealment
3. From text and tables it is not clear how many studies have been included:
 - in the text it is reported that 24 studies have been included,
 - in the characteristics of included studies table 29 studies have been reported - in the additional table 2. 27 studies have been reported.
 - In the abstract you said that 5 studies have been included.
 - Then you report the results only for five studies (but they are 4 and not 5).

Risk of bias tables



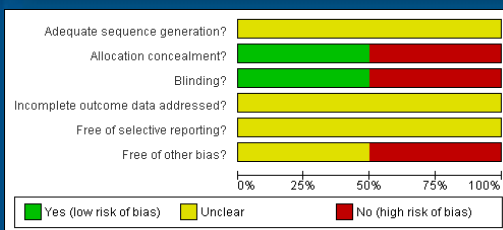
Acupuncture and assisted conception.

Stimulation of the wrist acupuncture point P6 for preventing postoperative nausea and vomiting



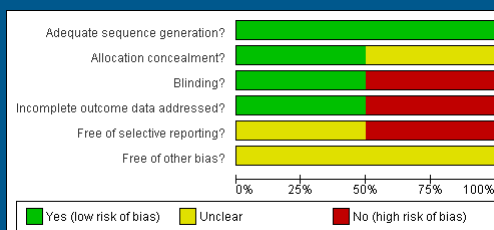
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Risk of bias tables



Chinese Herbal Medicine for Premenstrual Syndrome

Herbal Preparations for Uterine Fibroids



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. Acupuncture for neck disorders.

Methodological Quality (Jadad Scale)

Author	1a- randomized	1b- appropriate	1c- concealed	2a- double blind	2b- described	2c- appropriate	3- follow- up	Total Score
Birch 1998	1	0	0	0	0	0	1	2/5
Coan 1982	1	1	0	0	0	0	1	3/5
David 1998	1	1	0	0	0	0	1	3/5
Irnich 2001	1	0	0	0	0	0	1	2/5
Irnich 2002	1	1	0	1	1	0	1	5/5
Loy 1983	1	0	-1	0	0	0	0	0/5
Petrie 1983	1	0	0	0	0	0	1	2/5
Petrie 1986	1	0	0	0	0	0	1	2/5
White 2000	1	0	0	0	0	0	0	1/5
White 2004	1	0	0	1	0	0	1	3/5



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Lim Byungmook, Manheimer Eric, Lao Lixing, Ziea Eric, Wisniewski Julia, Liu Jianping, Berman Brian M. Acupuncture for treatment of irritable bowel syndrome

Linde Internal Validity Scale: score

Study ID	1.	2.	3.	4.	5.	6.	LIVS score
Fireman 2001	1	0	0	1	1		.5 3.5
Forbes 2005	1	.5	1	1	1		.5 5
Liao 2000	1	0	0	0	0	1	
Liu 1995	1	0	0	0	0	1	
Liu 1997	1	0	0	0	0	1	
Lowe 2000	1	0	.5	.5	.5	0	2.5



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Qualità metodologica: Conclusioni degli Autori

Acupuncture and dry-needling for low back pain

- no clear recommendations can be made because of small sample sizes and low methodological quality of the studies

Acupuncture and electroacupuncture for the treatment of rheumatoid arthritis

- The poor quality of the trial, including the small sample size preclude its recommendation

Acupuncture for Bell's palsy

the poor quality of the trials precludes firm conclusions.

Acupuncture for depression

Scientific study design was poor and the number of people studied was small.

Qualità metodologica: Conclusioni degli Autori

Questo concetto della bassa qualità metodologica degli studi viene ripetuto con queste percentuali nelle RS pubblicate:

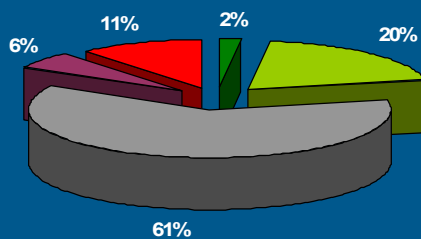
54% (14/26) RS relative all'agopuntura

67% (42/63) RS relative a Herbal medicine

100% (7/7) RS relative ad other

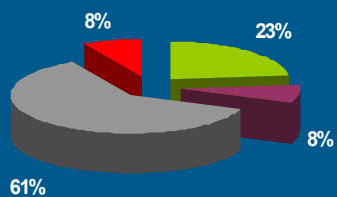
Il concetto base è quindi che è impossibile una valutazione dell'efficacia in assenza di trial ben disegnati e sufficientemente numerosi.

Valutazione efficacia Medicine N C



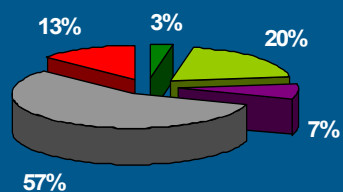
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Agopuntura

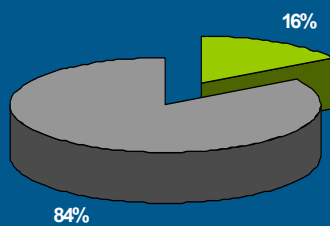


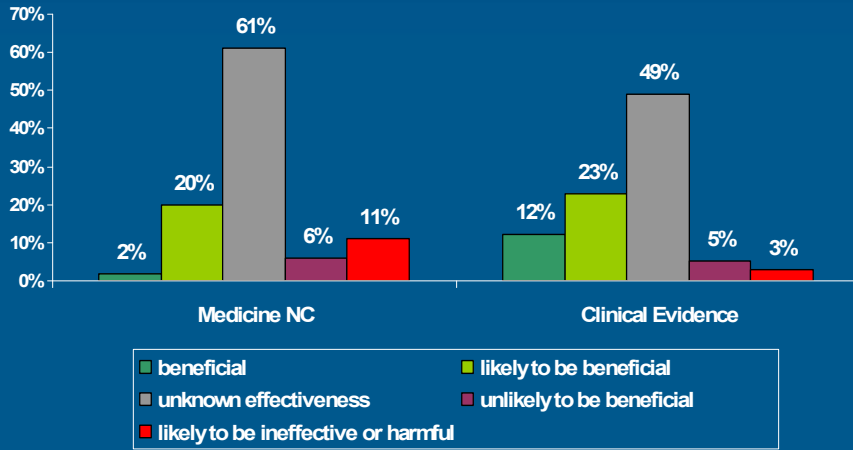
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Herbal



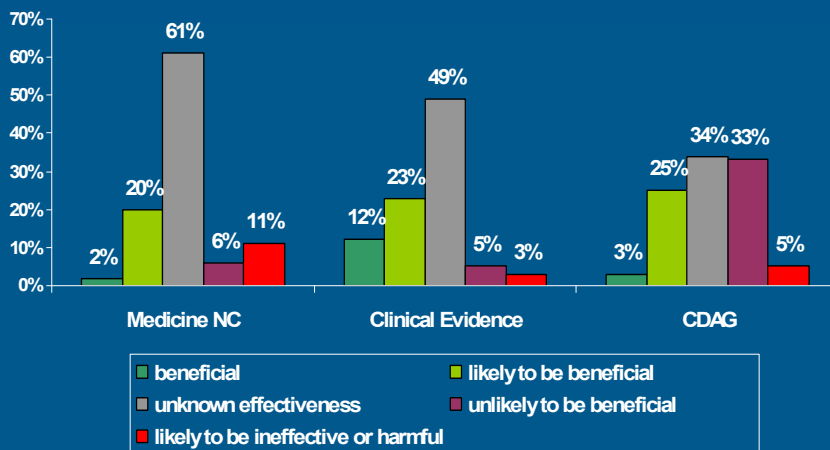
Other





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Conclusioni

La cattiva qualità degli studi inclusi rende di fatto impossibile valutare l'efficacia di questi interventi.

Infatti la % di interventi giudicati di unknown effectiveness (utilità non determinata) è molto alta 61%.

Questa percentuale appare più alta di quella di tutti gli interventi valutati da Clinical Evidence del luglio 2009 (49%) o da CDAG (34%)



Domande

**Bisogna fare uno sforzo per valutare l'efficacia?
(RCT di migliore qualità)**

Migliorare le competenze specifiche dei team di autori?

E' possibile farlo?

E' possibile valutare l'effectiveness?

Quali e quanti studi osservazionali ci sono e come è la loro qualità?

Senza mai dimenticare...

Conclusions

Responsible professionals in the health and social services need more than good intentions and plausible theories to guide their practice.

Their prescriptions and proscriptions for others should be informed by reliable research evidence showing that they are more likely to do good than harm.

Iain Chalmers



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- ***“All bad art is the result of good intentions”***
- ***“Tutte le opere cattive sono il risultato di buone intenzioni”***

Oscar Wilde

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GRAZIE per l'attenzione

