CHINESE MEDICINE & INSOMNIA
中藥 與 失眠

報告醫師： R2 胡心瀕

指導醫師： 陳星諭醫師

報告日期： 2012/08/13

OUTLINE

- Background information
- Introduction of EBM pyramid and appraisal
- Scenario
- ASK (PICO)
- AQUIRE
- APPRAISAL (VIP)
- APPLY

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INSOMNIA

- Definition
  - A complaint of difficulty initiating sleep, difficulty maintaining sleep, or waking up too early. Alternatively, sleep that is chronically nonrestorative or poor in quality.
  - The above sleep difficulty occurs despite adequate opportunity and circumstances for sleep.
  - The impaired sleep produces deficits in daytime function.

Overview of insomnia, UpToDate, 2012/04

INSOMNIA

- Types --- ICSD-2
  - Acute insomnia (short-term insomnia, stress-related insomnia)
  - Inadequate sleep hygiene
  - Psychophysiological insomnia (primary insomnia, chronic insomnia)
  - Idiopathic insomnia (childhood onset insomnia, life-long insomnia)
  - Paradoxical insomnia (sleep state misperception, subjective insomnia, pseudoinsomnia, and sleep hypochondriasis)
  - Insomnia associated with a medical condition, psychiatric disorder, neurologic disease, sleep disorder, medication, or drug use
  - Unspecified insomnia

Overview of insomnia, UpToDate, 2012/04

INSOMNIA

- Epidemiology
  - Chronic insomnia is prevalent in 10~15% of the adult population.
  - Primary insomnia is estimated to occur in 25% of all chronic insomnia patients.
  - The prevalence of insomnia increases with age.
  - 13~47% elders

The Epidemiology and Diagnosis of Insomnia, Karl Doghramji
The American Journal of Managed Care, 2006; 12:S214-S220

INSOMNIA

- Treatment
  - Cognitive behavioral therapy
    - Sleep hygiene --- improvement
    - Stimulus control relaxation
    - Sleep restriction therapy
  - Medications
    - BZD
    - Melatonin agent
    - Antidepressant and antipsychotics

Cognitive-behavioral therapy for sleep disturbance in patients undergoing peritoneal dialysis: a pilot randomized controlled trial.
Chen HY, Chiang CK, Am J Kidney Dis

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FIVE STEPS TO PRACTICE EBM (5 A)

1. **Formulate an answerable question. (Ask: PICO)PICO**
   由個案的臨床資料形成可回答的臨床問題
2. **Track down the best evidence. (Acquire)**
   尋找最佳的實證〔各種文獻及資料庫，包括發表及未發表的資料〕
3. **Critically appraise the evidence for validity, impact, and applicability. (Appraisal)** 評估各種醫學報告的可信度、臨床重要性，及可應用性
4. Integrate with our clinical expertise and patient values. **(Apply)**
   整合並應用於實際患者的治療決策〔臨床應用〕
5. Evaluate our effectiveness and efficacy. **(Audit)**
   [效果評估] 以病人可以聽懂的語言，告知各種處置之可能利益與風險？

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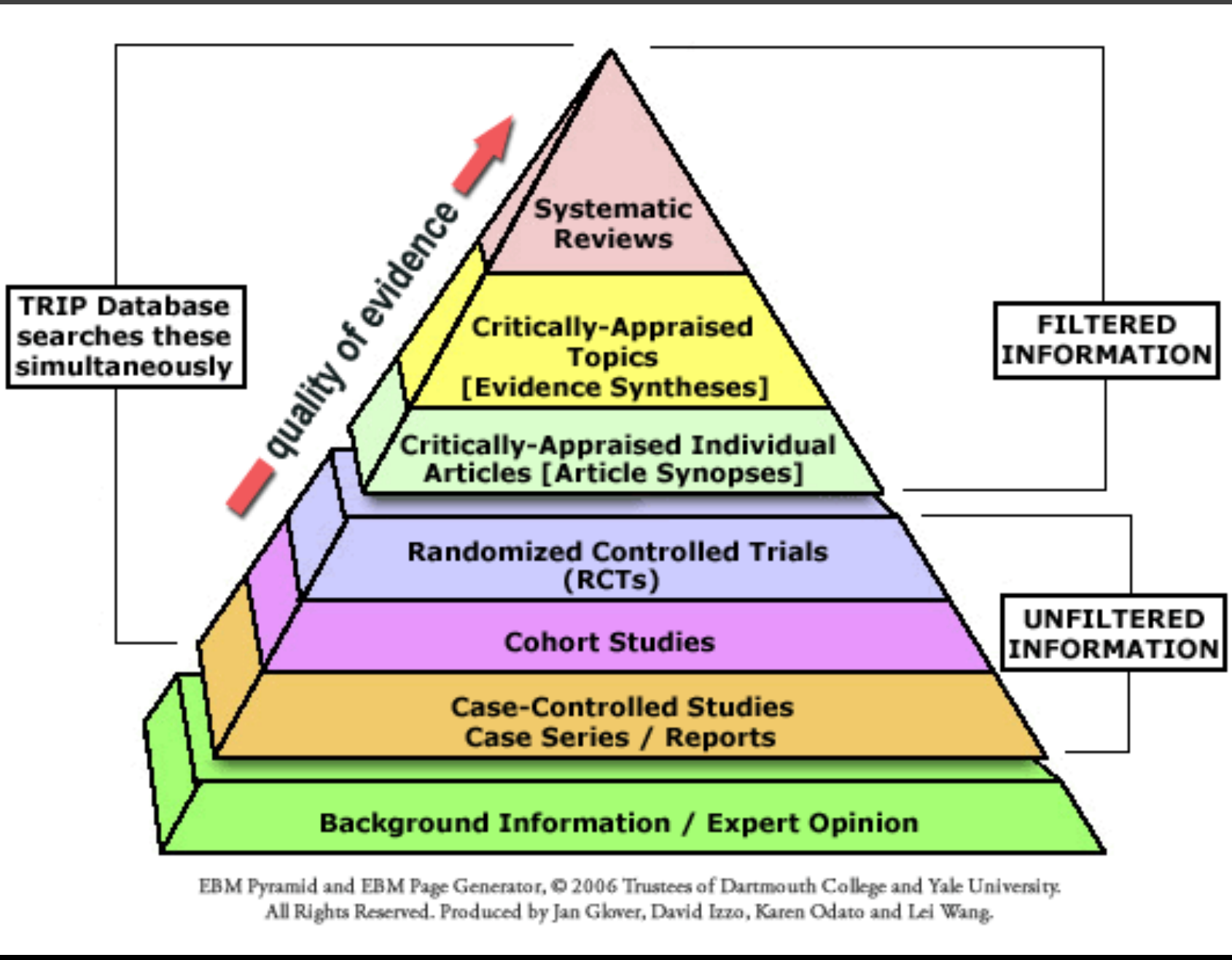

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APPRAISAL (VIP)

- Validity
  - CAT (clinical appraisal tool)
- Impact
  - Impact factor of journals
- Practicability (applicability) ---treatment effect
  - RRR (relative risk reduction)
  - NNT (number needed to treat)
  - NNH (number needed to harm)

VIP 原則證據力分級--- RCT

- Valid
  - Randomization
  - Blinding
  - Follow-up
- Impact
  - Size of effect
  - Precision of effect
  - Notes
- Pratical
  - Patient
  - Outcome - Benifit vs Harm

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SCENARIO

- 中藥對於失眠的療效如何？

ASK

- Patient
  - Human
- Intervention
  - Chinese medicine (formula, herbal medicine)
- Comparison
  - West medicine / placebo
- Outcome
  - Efficacy

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- APPLY

SYSTEMATIC REVIEW?

- EBM review
- Pubmed
  - Clinical queries

KEYWORDS

- Insomnia [title] AND
- *Traditional Chinese medicine [mesh]*
- *Herb*
- *Complimentary medicine [mesh]*

} OR

- Systematic/systemic review [title] AND

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2. Acupuncture for insomnia.

Cheuk, Daniel KL. Yeung, Jerry. Chung, KF. Wong, Virginia.

EBM Reviews - Cochrane Database of Systematic Reviews
Cochrane Depression, Anxiety and Neurosis Group Cochrane Database of Systematic Reviews. 1, 2009.
[Systematic Review]

AN: 00075320-100000000-04328

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- Find Citing Articles
- EBM Topic Review

3. Cognitive behavioural therapy for insomnia.

Aversa Lopes, Eliane. Silva, Ademir B. Macedo, Cristiane R. Soares, Bernardo. Saconato, Humberto. Atallah, Alvaro N.

EBM Reviews - Cochrane Database of Systematic Reviews
Cochrane Depression, Anxiety and Neurosis Group Cochrane Database of Systematic Reviews. 1, 2009.
[Protocol]

AN: 00075320-100000000-05444

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4. Chinese herbs for insomnia.

Xu, Lin. Li, Jing. Zhang, Mingming. Wang, Ling. Yuan, Wenming. Ai, Chang Lin. Wang, Gang. Zhang, Lan.

EBM Reviews - Cochrane Database of Systematic Reviews
Cochrane Depression, Anxiety and Neurosis Group Cochrane Database of Systematic Reviews. 1, 2009.
[Protocol]

Protocol

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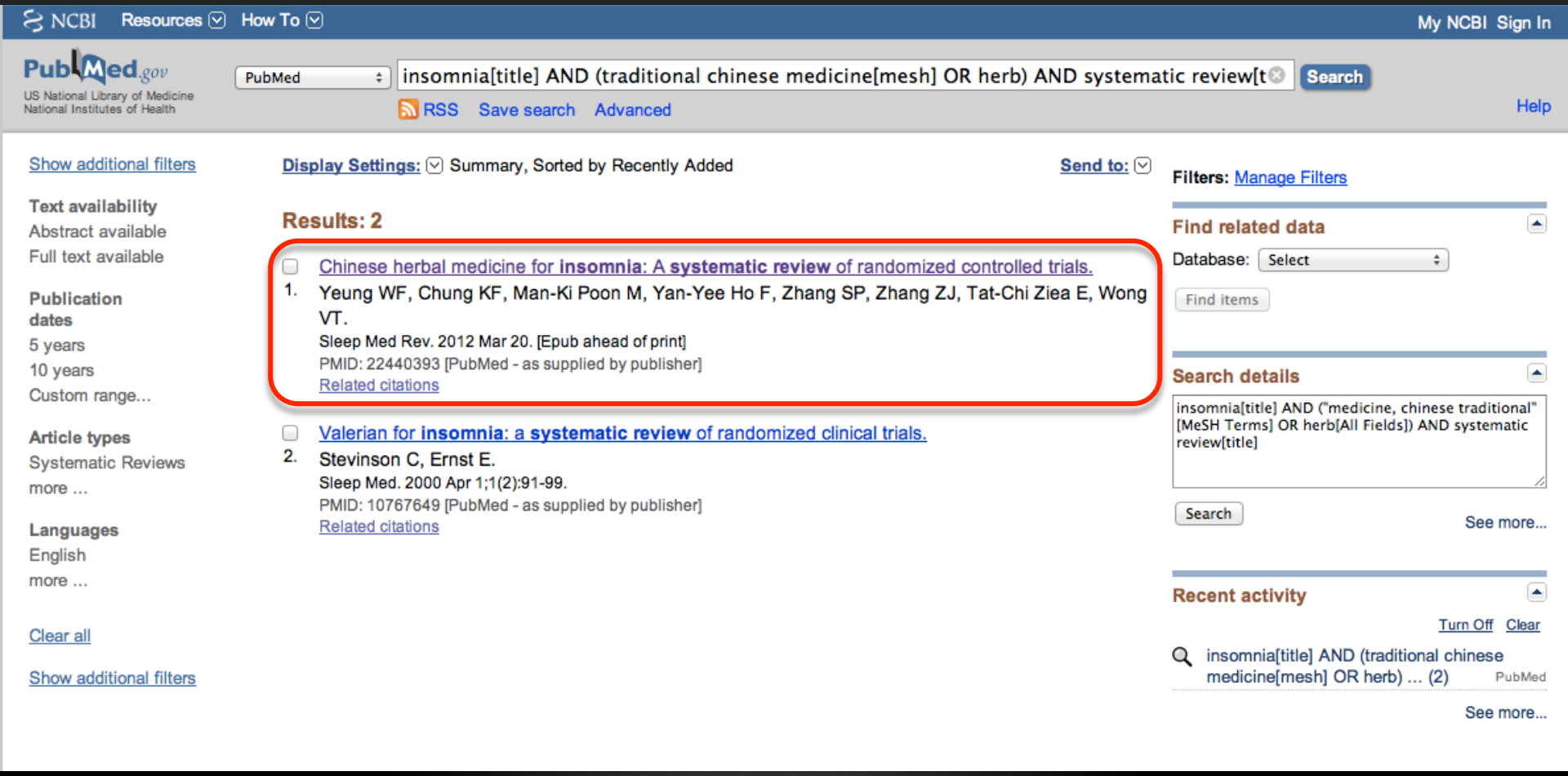
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insomnia[title] AND (traditional chinese medicine[mesh] OR herb) AND systematic review[t
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Chinese herbal medicine for insomnia: A systematic review of randomized controlled trials.
1. Yeung WF, Chung KF, Man-Ki Poon M, Yan-Yee Ho F, Zhang SP, Zhang ZJ, Tat-Chi Ziea E, Wong VT.
Sleep Med Rev. 2012 Mar 20. [Epub ahead of print]
PMID: 22440393 [PubMed - as supplied by publisher]
Related citations
Valerian for insomnia: a systematic review of randomized clinical trials.
2. Stevinson C, Ernst E.
Sleep Med. 2000 Apr 1;1(2):91-99.
PMID: 10767649 [PubMed - as supplied by publisher]
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insomnia[title] AND (traditional chinese medicine[mesh] OR herb) Search

Clinical Study Categories

Category: Therapy

Scope: Broad

Results: 5 of 18

Chinese herbal medicine for insomnia: A systematic review of randomized controlled trials.

Yeung WF, Chung KF, Man-Ki Poon M, Yan-Yee Ho F, Zhang SP, Zhang ZJ, Tat-Chi Ziea E, Wong VT.

Sleep Med Rev. 2012 Mar 20; . Epub 2012 Mar 20.

[Clinical study on intervention of spleen-restoring decoction integrating with dormancy hygiene education on subhealthy insomnia of deficiency of both heart and spleen pattern].

Ye R, Yuan Z, Dai C, Li W, Song X, Cheng Z, Hu W, Lin Y, Wang X, Sun S, et al.

Zhongguo Zhong Yao Za Zhi. 2011 Aug; 36(16):2285-9.

Patterns of herbal combination for the treatment of insomnia commonly employed by highly experienced Chinese medicine physicians.

Zhou XZ, Zhang RS, Shah J, Rajgor D, Wang YH, Pietrobon R, Liu BY, Chen J, Zhu JG, Gao RL.

Chin J Integr Med. 2011 Sep; 17(9):655-62. Epub 2011 Sep 11.

Systematic Reviews

Results: 4 of 4

Chinese herbal medicine for insomnia: A systematic review of randomized controlled trials.

Yeung WF, Chung KF, Man-Ki Poon M, Yan-Yee Ho F, Zhang SP, Zhang ZJ, Tat-Chi Ziea E, Wong VT.

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Chin J Integr Med. 2011 Sep; 17(9):655-62. Epub 2011 Sep 11.

Effects of acupuncture therapy on insomnia.

Sok SR, Erlen JA, Kim KB.

J Adv Nurs. 2003 Nov; 44(4):375-84.

Valerian for insomnia: a systematic review of randomized clinical trials.

Stevinson C, Ernst E.

Sleep Med. 2000 Apr 1; 1(2):91-99.

Medical Genetics

Topic: All

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IMPACT

- Impact factor

編號 No.	圖示 Icons	題名 Title	類型 Type	出版商 Publisher	收錄年代 Full Text Coverage	其他註記 Other Info.
51		Sexual and Reproductive Healthcare	Journal	Science Direct	2010-	北院區 南院區 聯合目錄
52		Sexual Development	Journal	Karger	2007-	JCR 北院區 南院區 聯合目錄
53		Sexually Transmitted Infections	Journal	ProQuest	1996/12-2003/12	JCR 北院區 南院區 聯合目錄
54		Shock	Journal	Ovid	2002-	JCR 北院區 南院區 聯合目錄
55		Skeletal Radiology	Journal	Springer	1997-2006	JCR 北院區 南院區 聯合目錄
56		Skin Pharmacology and Physiology	Journal	ProQuest	1998- (delayed 1 year)	北院區 南院區 聯合目錄
57		Skin Pharmacology and Physiology	Journal	Karger	1998-	北院區 南院區 聯合目錄
58		Sleep	Journal	American Academy Sleep Medicine	1978-	北院區 南院區 聯合目錄
59		Sleep Medicine	Journal	Science Direct	2000-	北院區 南院區 聯合目錄
60		Sleep Medicine Clinics of North America	Journal	MD Consult	2006-	南院區 聯合目錄
61		Sleep Medicine Reviews	Journal	Science Direct	1997-	JCR 北院區 南院區 聯合目錄
62		Small Ruminant Research	Journal	Science Direct	1995-	JCR 北院區 南院區 聯合目錄
63		Social Science and Medicine	Journal	Science Direct	1995-	北院區 南院區 聯合目錄
64		The Social Science Journal	Journal	Science Direct	1995-	北院區 南院區 聯合目錄
65		Social Science Research	Journal	Science Direct	1995-	北院區 南院區 聯合目錄
66		Social Work	Journal	ProQuest	1988-	北院區 南院區 聯合目錄
67		Soil and Tillage Research	Journal	Science Direct	1995-	JCR 北院區 南院區 聯合目錄
68		Soil Biology and Biochemistry	Journal	Science Direct	1995-	JCR 北院區 南院區 聯合目錄
69		Speech Communication	Journal	Science Direct	1995-	JCR 北院區 南院區 聯合目錄
70		Spinal Cord	Journal	Nature Publishing Group	1963-	JCR 北院區 南院區 聯合目錄
71		Spine	Journal	Ovid	1996-	JCR 北院區 南院區 聯合目錄
72		Spine Journal	Journal	Science Direct	2001-	JCR 北院區 南院區 聯合目錄
73		Sports Medicine	Journal	ProQuest	2008/6- (delayed 6 months)	JCR 北院區 南院區 聯合目錄
74		Springer Seminars in Immunopathology	Journal	ProQuest	2002/3- (delayed 1 year)	JCR 北院區 南院區 聯合目錄

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Full Journal Title: SLEEP MEDICINE REVIEWS
ISO Abbrev. Title: Sleep Med. Rev.
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VALIDITY

- Clinical appraisal tool (CAT)
  - CEBM for systemic review
  - Jadad score

SYSTEMATIC REVIEW: Are the results of the review valid?

What question (PICO) did the systematic review address?	
What is best?	Where do I find the information?
The main question being addressed should be clearly stated. The exposure, such as a therapy or diagnostic test, and the outcome(s) of interest will often be expressed in terms of a simple relationship.	The ***Title, Abstract*** *or final paragraph of the* ***Introduction*** should clearly state the question. If you still cannot ascertain what the focused question is after reading these sections, search for another paper!
This paper: Yes No ☐ Unclear ☐ Comment:	

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Sleep Medicine Reviews

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CLINICAL REVIEW

Chinese herbal medicine for insomnia: A systematic review of randomized controlled trials

Wing-Fai Yeung [a], Ka-Fai Chung [a,*], Maggie Man-Ki Poon [a], Fiona Yan-Yee Ho [a], Shi-Ping Zhang [b], Zhang-Jin Zhang [c], Eric Tat-Chi Ziea [d], Vivian Taam Wong [d]

[a] *Department of Psychiatry, University of Hong Kong, Pokfulam Road, Hong Kong SAR, China*
[b] *School of Chinese Medicine, Hong Kong Baptist University, Hong Kong SAR, China*
[c] *School of Chinese Medicine, University of Hong Kong, Hong Kong SAR, China*
[d] *The Chinese Medicine Section, Hospital Authority, Hong Kong SAR, China*

SUMMARY

Chinese herbal medicine (CHM), either in single herb or in herbal formula, has been used to treat insomnia for more than 2000 years. A systematic review including Chinese and English literature of randomized controlled trials was conducted to examine the efficacy, safety, and composition of CHM for insomnia. Among the 217 studies we have reviewed, only eight had a Jadad score ≥3, and seven out of these eight studies had at least one domain with high risks of bias. Meta-analyses of the studies with Jadad score ≥3 found that CHM was similar to Western medication (three studies) and placebo (three studies) in treating insomnia. Due to the poor methodological quality of the studies and the small number of trials included in meta-analyses, the current evidence is insufficient to support the efficacy of CHM for insomnia. The frequency of adverse events associated with CHM was similar to that of placebo, but lower than with Western medication. Gui Pi Tang was the most commonly used standardized formula, while Suan Zao Ren (*Ziziphus jujuba*) was the most frequently used single herb. Further studies with a double-blind placebo-controlled design are needed to accurately determine the benefits and risks of CHM for insomnia.

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F - Is it unlikely that important, relevant studies were missed?	
What is best?	Where do I find the information?
The starting point for comprehensive search for all relevant studies is the major bibliographic databases (e.g., Medline, Cochrane, EMBASE, etc) but should also include a search of reference lists from relevant studies, and contact with experts, particularly to inquire about unpublished studies. The search should not be limited to English language only. The search strategy should include both MESH terms and text words.	The ***Methods*** section should describe the search strategy, including the terms used, in some detail. The ***Results*** section will outline the number of titles and abstracts reviewed, the number of full-text studies retrieved, and the number of studies excluded together with the reasons for exclusion. This information may be presented in a figure or flow chart.
This paper: Yes ☐ No ☐ Unclear ☐ Comment:	

Methods

Our systematic review set out to examine all TCM treatment modalities for insomnia, including CHM, acupuncture, and variants of acupuncture. CHM is orally administered, while acupuncture and its variants are procedural intervention. The theories and mechanisms behind these TCM treatments may be different. Due to the different nature of the therapies, only the results on CHM were reported in this paper. We searched the MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Cumulative Index to Nursing and Allied Health Literature, and Allied and Complementary Medicine from inception to May 2010 using the grouped terms (insomnia* or wakeful* or sleepless* or sleep*) and ((acupuncture* or acupoints* or acupress* or meridian* or transcutaneous electrical nerve stimulation or TENS or moxibustion or tuina) or (herb* OR herbal medicine* or traditional Chinese medicine* or TCM)). The search also included China Journals Full-text Database, China Proceedings of Conference Full-text Database, Chinese Biomedical Literature Database, China Doctor Dissertations Full-text Database, China Master Theses Full-text Database, Chinese Science and Technology Documents Database, Chinese Dissertation Document Bibliography Database, Chinese Academic Papers Conference Database, Digital Periodical, and Taiwan Electronic Periodical Services. The reference lists of the retrieved papers were

A - Were the criteria used to select articles for inclusion appropriate?

What is best?	Where do I find the information?
The inclusion or exclusion of studies in a systematic review should be clearly defined a priori. The eligibility criteria used should specify the patients, interventions or exposures and outcomes of interest. In many cases the type of study design will also be a key component of the eligibility criteria.	The ***Methods*** section should describe in detail the inclusion and exclusion criteria. Normally, this will include the study design.

This paper: Yes ❤ No ☐ Unclear ☐

Comment:

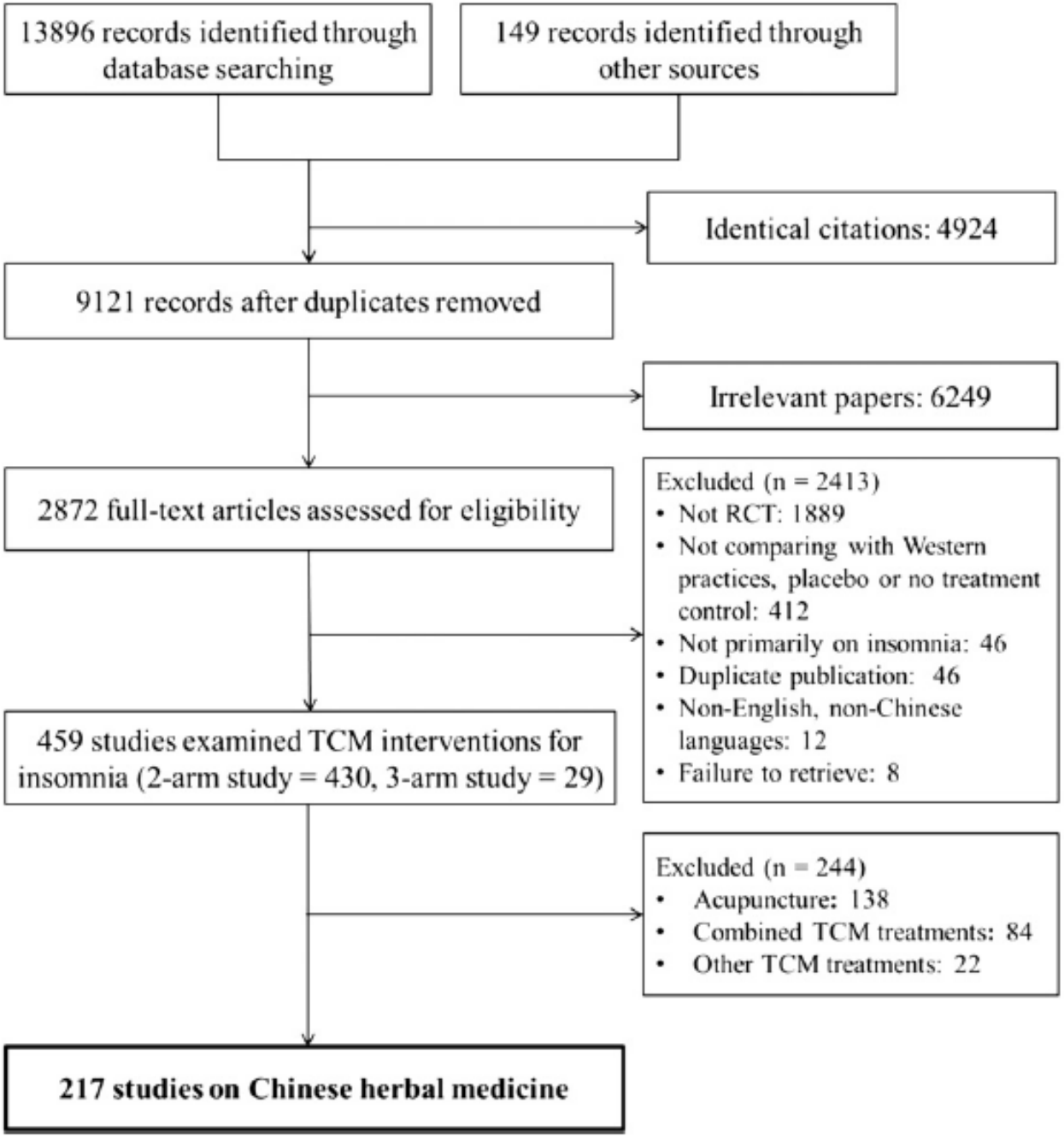


Fig. 1. Selection of trials for inclusion in the review.

A - Were the included studies sufficiently valid for the type of question asked?	
What is best?	Where do I find the information?
The article should describe how the quality of each study was assessed using predetermined quality criteria appropriate to the type of clinical question (e.g., randomization, blinding and completeness of follow-up)	The ***Methods*** section should describe the assessment of quality and the criteria used. The ***Results*** section should provide information on the quality of the individual studies.
This paper: Yes No ☐ Unclear ☐ Comment:	

T - Were the results similar from study to study?

What is best?	Where do I find the information?
Ideally, the results of the different studies should be similar or homogeneous. If heterogeneity exists the authors may estimate whether the differences are significant (chi-square test). Possible reasons for the heterogeneity should be explored.	The ***Results*** section should state whether the results are heterogeneous and discuss possible reasons. The forest plot should show the results of the chi-square test for heterogeneity and if discuss reasons for heterogeneity, if present.

This paper: Yes ☐ No ☐ Unclear ☐

Comment:

What were the results?

How are the results presented?

A systematic review provides a summary of the data from the results of a number of individual studies. If the results of the individual studies are similar, a statistical method (called meta-analysis) is used to combine the results from the individual studies and an overall summary estimate is calculated. The meta-analysis gives weighted values to each of the individual studies according to their size. The individual results of the studies need to be expressed in a standard way, such as relative risk, odds ratio or mean difference between the groups. Results are traditionally displayed in a figure, like the one below, called a **forest plot.**

Comparison: 03 Treatment versus Placebo
Outcome: 01 Effect of treatment on mortality

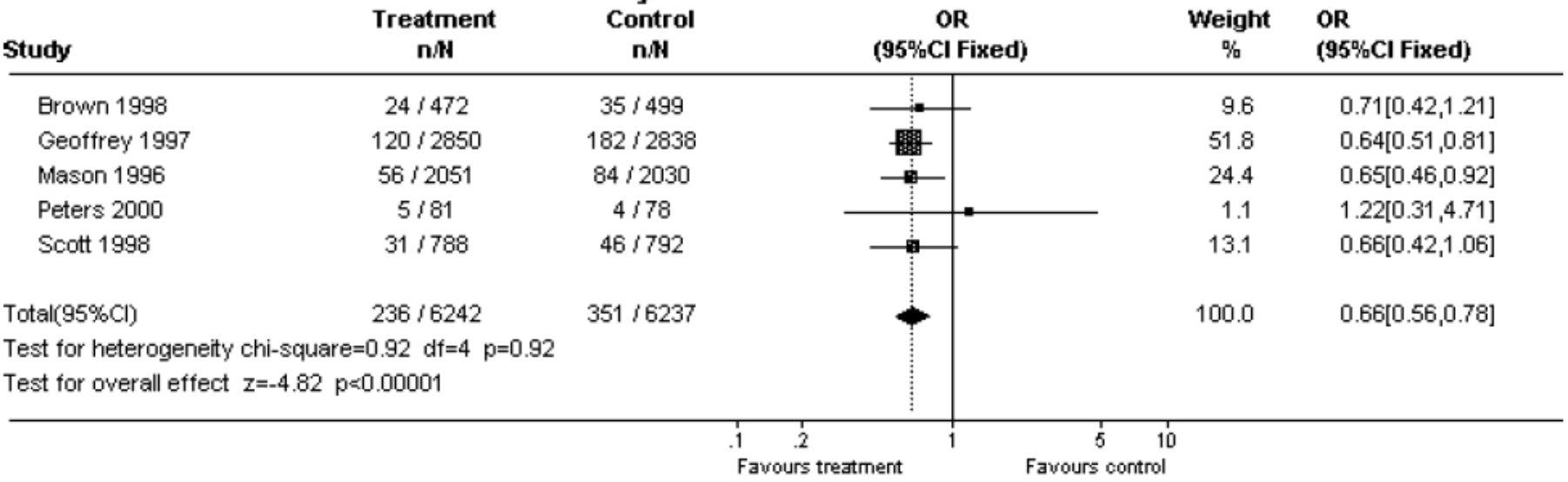


Table 2
Randomized controlled trials of Chinese herbal medicine for insomnia with Jadad score ≥3.

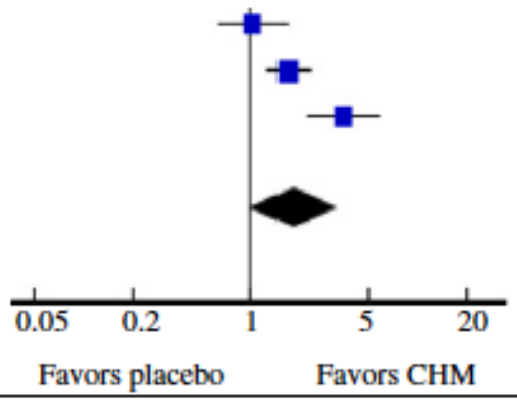
No.	1st author (year)	Country/type of case	Mean age, y (range)/ % female	Diagnostic system	TCM pattern diagnosis	Design	Follow-up	Sample size (CHM/control)	Treatment intervention (duration)	Control intervention	Outcome measure	Results reported
1	Cao (2005)[16]	China/inpatients with schizophrenia	28.0 (NR)/ 100%	ICD-10, CRG	No	2-parallel arms (CHM; benzo)	Nil	80 (50/30)	Shen An decoction (2 weeks)	Alprazolam 0.5 mg/day	Effective rate, PSQI	No significant differences between CHM and benzo
2	Hong (2004)[17]	China/patients with neurosis or neurasthenia	46.9 (18–65)/ 62.3%	ICD-10, CCMD	No	2-parallel arms (CHM; antidepressant)	Nil	55 (33/22)	Jie Yu Wan (6 weeks)	Trazodone 50–100 mg/day	Effective rate, SQ, SDS, SAS, CGI	No significant differences between CHM and antidepressant
3	Huang (1985)[18]	Taiwan/outpatients of TCM insomnia clinic	41.0 (NR)/ 43.3%	DSM-III, CIS	Hyperactivity of liver and gallbladder fire/ Hypoactivity of liver and gallbladder fire	2-parallel arms (CHM; placebo)	Nil	120 (60/60)	An Shen Bao (4 weeks)	Placebo	Effective rate	No significant differences between CHM and placebo
4	Li (2009a)[19]	China/NR	NR (18–65)/ NR	DSM-IV, CRG, TCM-text book	Liver depression and qi stagnation	2-parallel arms (CHM; benzo)	Nil	90 (45/45)	Dan Zhi Xiao Yao San (NR)	Estazolam 1–2 mg/day	Effective rate, TESS	No significant differences between CHM and benzo
5	Li (2009b)[20]	China/outpatients of sleep clinic	34.7 (NR)/ 75.8%	CRG, ICSD	No	4-parallel arms (CHM + benzo placebo; benzo + CHM placebo; CHM + benzo; CHM placebo + benzo placebo)	Nil	59 (9/5/9/10) 26 dropped out without report on group allocation	Modified Xiao Yao San (6 weeks)	CHM placebo + benzo placebo	PSQI, SRSS, PSG	No significant differences between the 4 groups
6	Ma (2008)[21]	China/inpatients and outpatients of sleep clinic	41.3 (25–61)/ 74.6%	CCMD	Internal harassment of phlegm-heat	2-parallel arms (CHM + benzo; benzo alone)	1 week	70 (36/34)	Qing Gan Ning Shen decoction (2 weeks)	Estazolam 2 mg/day	Effective rate, AIS, PSG	CHM + benzo significantly >benzo alone
7	Wang (2001)[22]	China/NR	NR (18–65)/ NR	SSQ ≥12	No	2-parallel arms (CHM; placebo)	1 week	148 (74/74)	Luo Hua Sheng Zhi Ye Zhi Ji (2 weeks)	Placebo	Effective rate, SSQ	CHM significantly >placebo
8	Zhu (2004)[23]	China/NR	34 (18–63)/ 60%	CRG	Yin deficiency and blood depletion	2-parallel arms (CHM; placebo)	Nil	80 (40/40)	Yang Xue An Shen Tang Jiang (2 weeks)	Placebo	Effective rate	CHM significantly >placebo

AIS, Athens insomnia scale; Benzo, benzodiazepine; CCMD, Chinese classification of mental disorder; CGI, clinical global impression; CHM, Chinese herbal medicine; CIS, clinical interview schedule; CRG, clinical research guidelines of new Chinese herbal medicine; DSM, diagnostic and statistical manual of mental disorders; ICD-10, international classification of diseases, 10th revision; ICSD, international classification of sleep disorders; NR, not reported; PSG, polysomnography; PSQI, Pittsburgh sleep quality index; SAS, self-rated anxiety scale; SDS, self-rated depression scale; SQ, sleep questionnaire; SRSS, self-rated scale on sleep; SSQ, Spiegel sleep questionnaire; TCM, traditional Chinese medicine; TESS, treatment emergent symptom scale.

CHM VS PLACEBO

No.[a]	1st Author (Year)	CHM N improved/ total N	Placebo N improved/ total N	RR 95% CI	Weight	RR	95% CI
3	Huang (1985)[18]	28/120	27/120		32.3%	1.04	0.65, 1.65
7	Wang (2001)[22]	53/72	32/74		36.5%	1.70	1.27, 2.29
8	Zhu (2004)[23]	39/40	11/40		31.2%	3.55	2.14, 5.88
	Total (95% CI)	120/232	70/234			1.82	1.00, 3.32

Test for heterogeneity: $Chi^2 = 12.41$, df = 2 (p = 0.002), $I^2 = 84\%$
Test for overall effect: Z = 1.96 (p = 0.05)



[a] Same as the study number in Table 1. CHM: Chinese herbal medicine; RR: risk ratio.

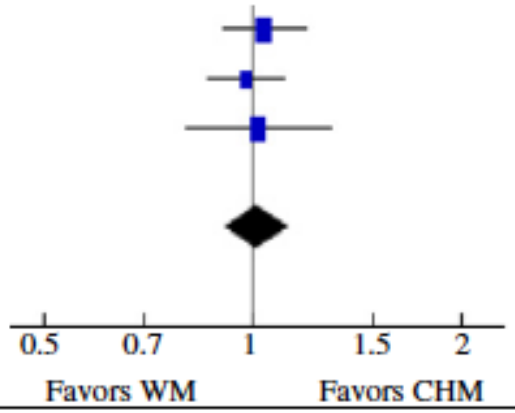
Fig. 2. Effective rates of Chinese herbal medicine and placebo for insomnia.

CHM VS WEST MEDICINE

No.[a]	1st Author (Year)	CHM N improved/ total N	WM N improved/ total N	RR 95% CI	Weight	RR	95% CI
1	Cao (2005)[16]	47/50	27/30		37.1%	1.04	0.91, 1.20
2	Hong (2004)[17]	29/31	21/22		27.0%	0.98	0.86, 1.12
4	Li (2009a)[19]	33/44	33/45		35.9%	1.02	0.80, 1.31
	Total (95% CI)	109/125	81/97			1.02	0.91, 1.14

Test for heterogeneity: $Chi^2 = 0.47$, df = 2 ($p = 0.79$), $I^2 = 0\%$

Test for overall effect: $Z = 0.35$ ($p = 0.73$)

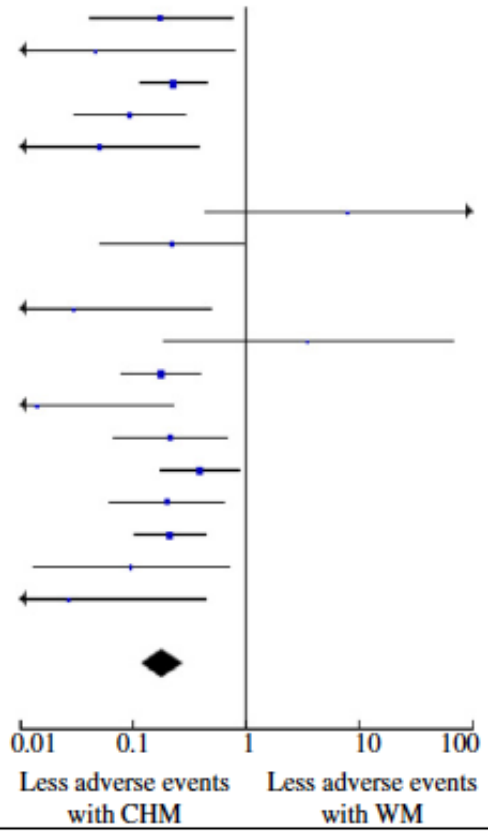


[a] Same as the study number in Table 1. CHM: Chinese herbal medicine; RR: risk ratio; WM: Western medication.

Fig. 3. Effective rates of Chinese herbal medicine and Western medication for insomnia.

ADVERSE EFFECT OF CHM

1st Author (Year)	CHM Total events/ Group total	WM Total events/ Group total	RR 95% CI	Weight	RR	95% CI
Bao (2007)[25]	2/41	11/40		5.8%	0.18	0.04, 0.75
Chen (2009)[26]	0/78	9/69		2.0%	0.05	0.00, 0.79
Ding (2008)[27]	10/120	22/60		12.3%	0.23	0.12, 0.45
Guo (2003)[28]	3/55	26/45		7.9%	0.09	0.03, 0.29
Hong (2004)[17]	1/55	11/31		3.6%	0.05	0.01, 0.38
Hong (2006)[29]	0/40	0/32			Not estimated	
Li (1995)[30]	4/71	0/63		1.9%	8.00	0.44, 145.72
Li (2009)[19]	2/45	9/45		5.7%	0.22	0.05, 0.97
Liu (2007)[31]	0/32	0/30			Not estimated	
Mai (2009)[32]	0/30	16/30		2.1%	0.03	0.00, 0.48
Ning (2004)[33]	3/100	0/50		1.9%	3.53	0.19, 67.13
Qin (2007)[34]	6/63	33/62		11.0%	0.18	0.08, 0.40
Wu (2006)[35]	0/70	34/70		2.1%	0.01	0.00, 0.23
Wu (2009)[36]	3/40	14/40		7.6%	0.21	0.07, 0.69
Xia (2007)[37]	7/60	18/60		11.0%	0.39	0.18, 0.86
Yao (2003)[38]	3/33	10/22		7.6%	0.20	0.06, 0.65
Yu (2004)[39]	7/46	32/45		12.0%	0.21	0.11, 0.43
Zhang (2007)[40]	1/33	10/32		3.6%	0.10	0.01, 0.71
Zhou (2002)[41]	0/58	19/62		2.1%	0.03	0.00, 0.44
Total (95% CI)	52/1070	274/888			0.18	0.12, 0.28



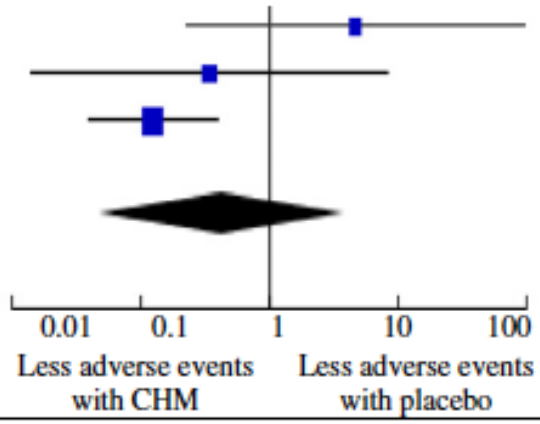
Test for heterogeneity: $Chi^2 = 26.46$, df = 16 ($p = 0.05$), $I^2 = 40\%$
Test for overall effect: $Z = 7.82$ ($p < 0.001$)

CHM: Chinese herbal medicine; RR: risk ratio; WM: Western medication.

Fig. 4. Likelihoods of adverse events of Chinese herbal medicine and Western medication.

ADVERSE EFFECT OF CHM

1st Author (Year)	CHM Total events/ Group total	Placebo Total events/ Group total	RR 95% CI	Weight	RR	95% CI
Quan (2008)[42]	2/98	0/92		26.9%	4.70	0.23, 96.55
Wang (2001)[22]	0/72	1/74		25.5%	0.34	0.01, 8.27
Wang (2008)[43]	3/65	18/48		47.6%	0.12	0.04, 0.39
Total (95% CI)	5/235	19/214			0.43	0.05, 3.81



Test for heterogeneity: $Chi^2 = 5.04$, $df = 2$ ($p = 0.08$), $I^2 = 60\%$
Test for overall effect: $Z = 0.76$ ($p = 0.44$)

CHM: Chinese herbal medicine; RR: risk ratio.

Fig. 5. Likelihoods of adverse events of Chinese herbal medicine and placebo.

ADVERSE EFFECT OF CHM

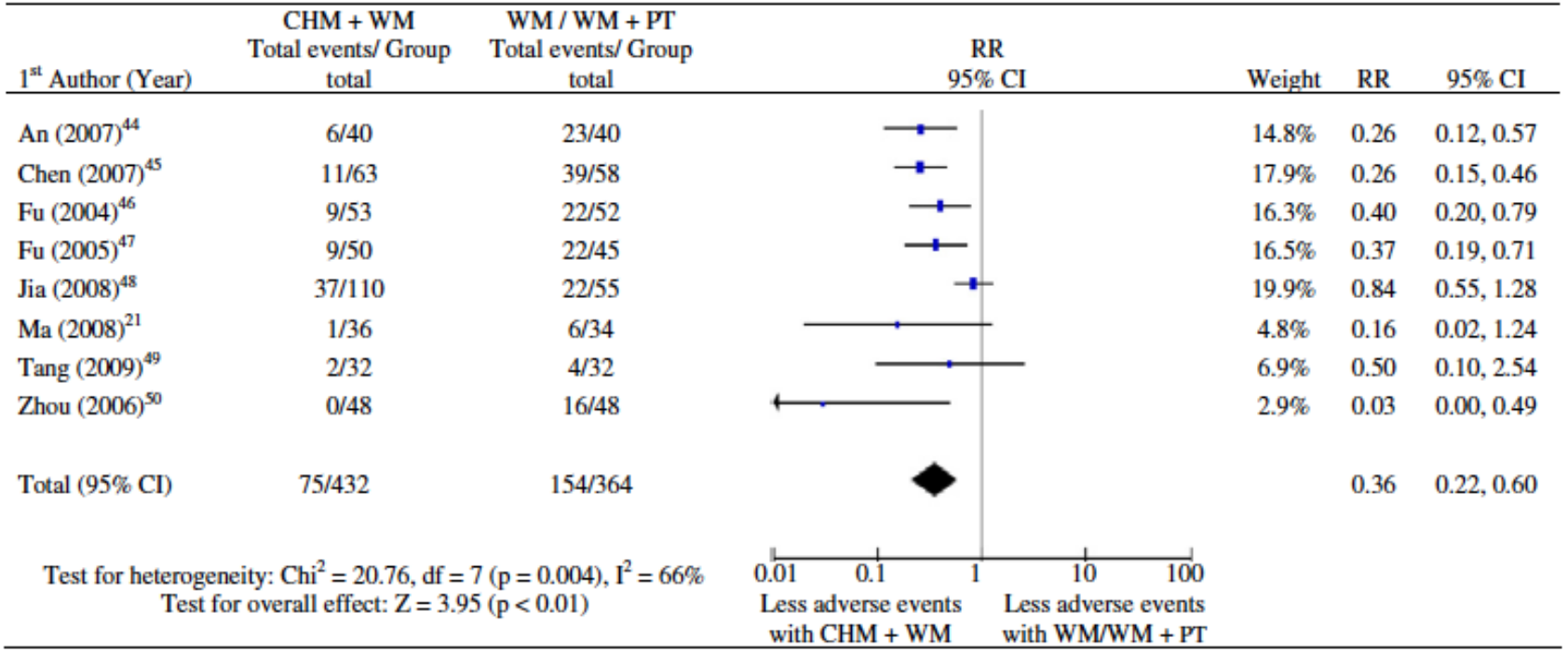


Fig. 6. Likelihoods of adverse events of Chinese herbal medicine plus Western medication and Western medication alone or Western medication plus psychotherapy.

PRACTICAL/ APPLICABILITY

- Relative risk change
- NNT ?
- NNH ?

DISCUSSION

- Meta-analysis of 8 studies with Jadad score of 3 or above found that CHM was equivalent to placebo and Western medicine in treating insomnia.

- Small number of trials included
- Heterogeneity in subject characteristics, herbal regimen, and outcome assessment across studies

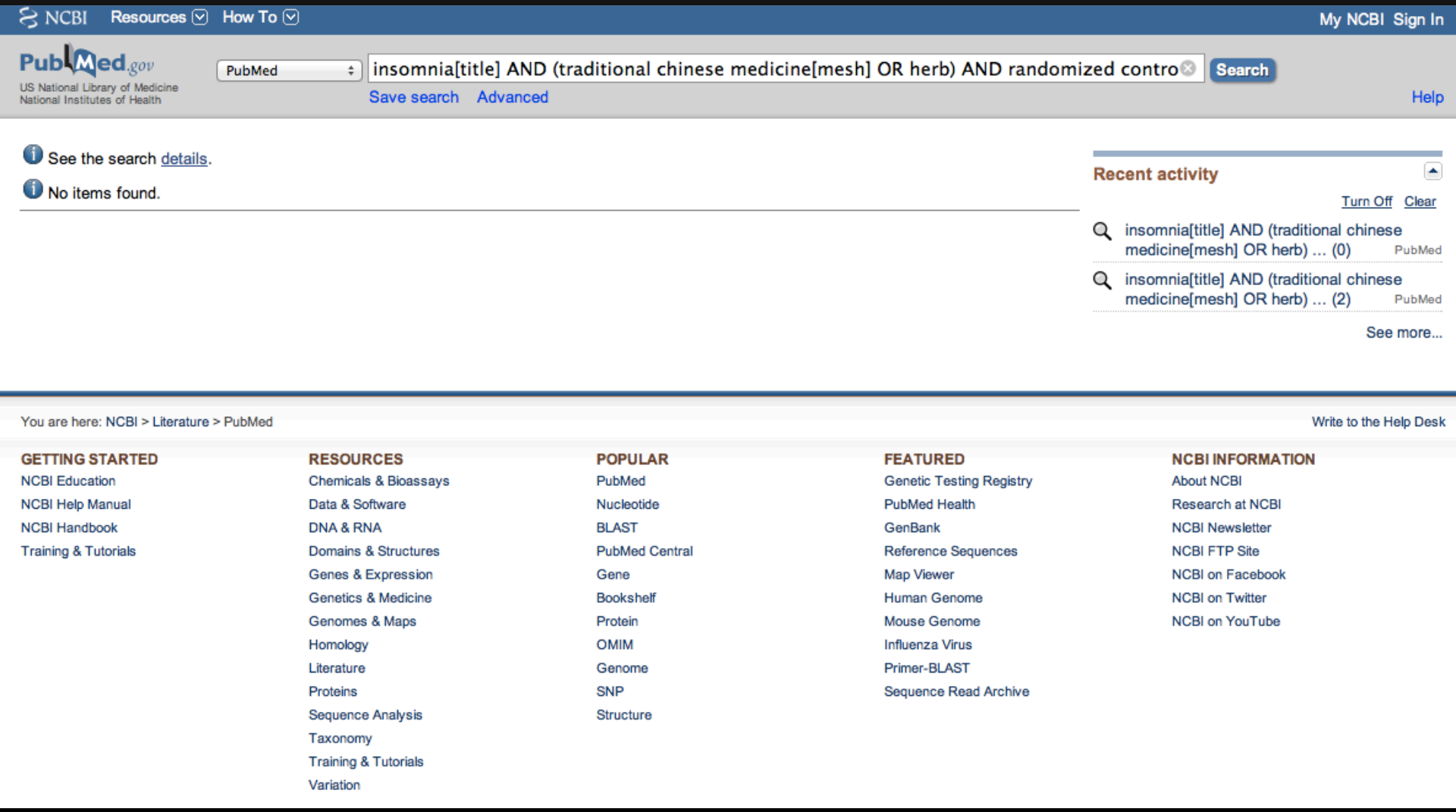
DISCUSSION

- The frequency of the adverse events associated with CHM was similar to that of placebo, but lower than with Western medication.

LEVEL OF EVIDENCE

	(Level 1*)	(Level 2*)	(Level 3*)	(Level 4*)	
How common is it? (E.g., Pre-test probabilities)	Most relevant local and current random sample survey (or censuses)	Systematic review of current surveys	Systematic review of local non-random sample	Systematic review of case-series	Opinion without explicit critical appraisal, based on limited/ undocumented experience, or based on mechanisms
Is this test accurate? (Diagnostic accuracy)	Systematic review of cross sectional studies	Systematic review of cross sectional studies With consistently applied reference standard and blinding	Systematic review of non-consecutive studies, or studies without consistently applied reference standards.	Systematic review of case-control study, or cross-sectional study with non-independent reference standard	Opinion without explicit critical appraisal, based on limited/ undocumented experience, or based on mechanisms
What will happen if we do nothing? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort or control arm of randomized trial	Systematic review of case-series	Opinion without explicit critical appraisal, based on limited/ undocumented experience, or based on mechanisms
Does this treatment help? (Treatment Benefits)	Systematic review of randomized trials or *n*-of-1 trial	Randomized trial or (exceptionally) observational studies with dramatic effect	Non-randomized controlled cohort/follow-up study	Systematic review of case-control studies, historically controlled studies	Opinion without explicit critical appraisal, based on limited/ undocumented experience, or based on mechanisms
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials or *n*-of-1 trial	Systematic review of nested case-control or dramatic effect	Non-randomized controlled cohort/follow-up study	Case-control studies, historically controlled studies	Opinion without explicit critical appraisal, based on limited/ undocumented experience, or based on mechanisms
What are the RARE harms? (Treatment Harms)	Systematic review of case-control studies, or studies revealing dramatic effects	Randomized trial or (exceptionally) observational study with dramatic effect			
Is early detection worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non-randomized controlled cohort/follow-up study	Case-control studies, historically controlled studies	Opinion without explicit critical appraisal, based on limited/ undocumented experience, or based on mechanisms

RANDOMIZED CONTROLLED TRIAL
AFTER 2010



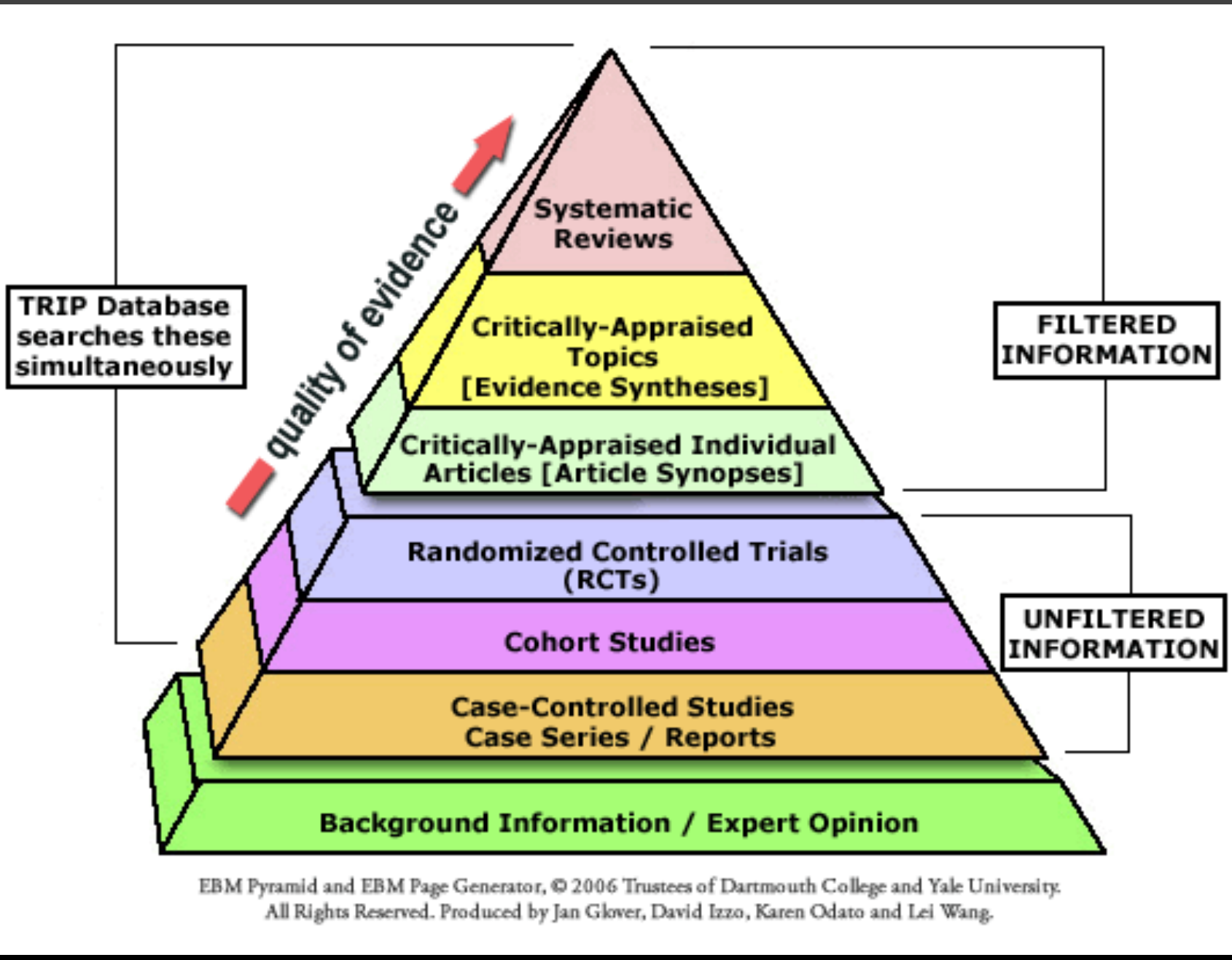
OUTLINE

- Background information
- Introduction of EBM pyramid and appraisal
- Scenario
- ASK (PICO)
- AQUIRE
- APPRAISAL (VIP)
- APPLY

- 中藥對失眠的療效有正面效果，但仍需更多同質性證據支持
- 與西藥比較，副作用較少

CONCLUSION

- The latest and upper level of evidence
- Chinese medicine in treating insomnia



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~~Thank you for attentions~~