

# COCHRANE COLLABORATION COMPLEMENTARY MEDICINE FIELD NEWSLETTER

Spring 2002, Number 9

## Message From The Field Coordinator

The scientific evaluation of complementary medicine (CM) is on the rise. This encouraging trend comes from increasing awareness of the use of complementary therapies amongst the general population of many countries and the need to better understand their effectiveness and safety. As the scientific spotlight has intensified, so has the debate on improving the quality of research. This debate has focused, among other things, on how to address the methodological challenges presented by complementary therapies and how to remain true to the actual practice of the therapy in a clinical setting when conducting a trial. As we take on the task of systematically reviewing this growing body of literature we need to consider some of these issues carefully. While numerous scales and checklists have been suggested to assess the quality of RCTs, most have not been validated, or their validity has been questioned<sup>1,2</sup> and they may not be appropriate for CM. For instance, the Jadad scale bases its assessment, in part, on the reporting and use of double blinding. Double blinding is often not possible in CM trials (e.g., how do you blind the participant for some mind-body interventions?), but does that necessarily mean they are low quality studies? We need scales that are relevant to CM and that are validated. As a Field we should take on this challenge if we are to continue to improve the quality and usefulness of our systematic reviews.

Other issues that confront us as a Field are productivity and sustainability, both of which, along with quality, are themes at the August 2002 Colloquium in Stavanger, Norway. The productivity of the Field continues on an upward curve as we now have 89 CAM reviews. However, in order to sustain this growth and to continue to improve the relevance and quality of our reviews, we need to broaden the base of those involved in reviews and, specifically, involve more practitioners and clinicians. It is important, however, that all reviewers be trained in the nuances of CM so that they are sensitive to the unique challenges presented by these therapies. The invaluable work of hand searching, as well as identifying relevant literature in languages other than English, also cries out for continued attention and more willing volunteers! Know of anybody who might be interested, or maybe eager to get involved yourself in either identifying or reviewing the literature? Please, let us know if you have any questions about how to participate or receive training!

On a final note, I would like to remind everyone of the great value of this work. Health care professionals, payers, policy makers and consumers all need high quality information to guide decisions about clinical care and future research. A White House Commission on CM that is soon to release its report and recommendations has focused a great deal of attention on the need for high quality information to guide the public, and looks to Cochrane for the top levels of evidence. For example, after publication of the review by Wilt et. al.<sup>3</sup>, the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health issued a request for applications for studies examining saw palmetto for benign prostatic hyperplasia.

I would like to thank the NCCAM for continued support of the Field and encourage other funding bodies to provide the support that is so essential to the continued efforts of all of those involved in producing high quality information on complementary medicine that informs the public and professional domains.

Brian Berman, Field Coordinator  
(*references on page 5*)

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## News From The Registry Coordinator

### Consumers, CAM and Quality Initiatives on the Internet

Recent surveys estimate that 86% of the estimated 168 million US Internet users now seek information on the Internet's over 100,000 health-related Websites<sup>1</sup>. With access to medical knowledge-bases that were once reserved for health professionals<sup>2</sup>, 70% percent of online health seekers now report that online health information has influenced their decisions about medical treatment<sup>3</sup>. However, the nearly unlimited amount of health and medical information available on the Internet makes searching the Internet a time consuming and frustrating experience. Furthermore, there remain many unresolved issues regarding the quality and relevance of the information available. This is particularly true of complementary and alternative medicine (CAM) products and services. In an unfortunate scenario that propelled profits rather than ethics, the broad reach and anonymous nature of the Internet has given rise to a multitude of CAM websites that promote fraudulent, dangerous and misleading therapies and devices to healthcare consumers.

Efforts to protect US consumers from this online fraud have been launched by the US Federal Trade Commission (FTC) and Food and Drug Administration (FDA). In one recent FTC, FDA enforcement action numerous CAM Websites were found to be encouraging patients with HIV or AIDS to use St. John's Wort as a safe and effective treatment, when in fact it is known to interfere with the effectiveness of the AIDS drug Indinivir.<sup>4</sup> In a similar enforcement action, the FDA filed suit against a multi-level marketing company that claimed that the FDA considered its products safe. However, the products contained Comfrey, which is known to pose significant risks to humans, including liver damage<sup>5</sup>.

These enforcement actions have provided some degree of protection, but at the present time, there exist no universally enforceable protections from harm caused by Websites offering health information on the Internet. In response, international efforts aimed at providing greater protection for Internet healthcare consumers have been launched. These initiatives (see Table on page 6) are focused on the development and implementation of quality measures, guidelines and seals of approval that provide guidelines for consumers seeking health and medical information on the Internet as well as codes of conduct for parties that provide Internet-based health and medical information.

*(continued on page 6)*

10<sup>TH</sup> INTERNATIONAL  
 COCHRANE COLLOQUIUM  
 31 JULY - 3 AUGUST 2002

#### Focus

*Quality, Productivity and  
 Sustainability*

#### Aims

*Help Review Groups achieve their  
 aims*

*Celebrate the 10th year of the  
 Collaboration*

Stavanger, Norway

<http://www.Cochrane.no/colloquium/>

#### Future Colloquia dates

25 October - 1 November 2003, Barcelona, Spain

2 October - 6 October 2004, Ottawa, Canada

#### For a copy of the registry, contact:

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## Consumer Update

### Ambiguity in Cochrane consumer synopses: Black, white, grey or taken as read?

Allen C, Smith A, Thornton N (c/o Cochrane Collaboration Secretariat, PO Box 726, Oxford, OX2 7UX, UK)

**Objective:** To explore how uncertainty and ambiguity are handled in consumer synopses of Cochrane reviews. In the authors' experience, most consumers want certainty when trying to assess information relating to their health condition<sup>1</sup>. This certainty can be positive ('this will help you') or negative ('this won't') but words such as 'might' and 'possibly' reminded us of the claims made in advertising copy, rather than an authoritative healthcare database, and may confuse, rather than impart knowledge to consumers.

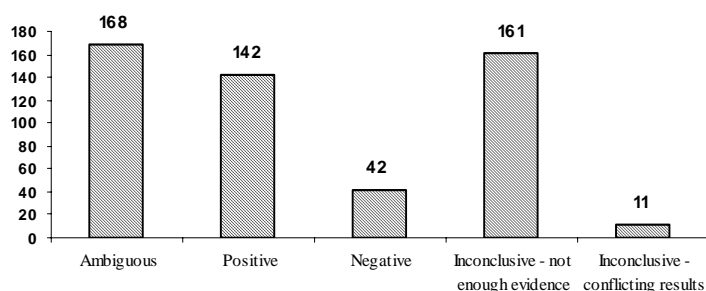
**Methods:** Building on previous work<sup>2</sup>, we searched Issue 1, 2001 of *The Cochrane Library* for reviews with consumer synopses. These were randomly allocated to the three authors. We analysed a random sub-sample of these synopses to determine:

- If the synopsis gave a definitive answer to the review's title.
- If not, what form of words was used to communicate the uncertainty.
- What other ways it was expressed.

**Results:** Of the 1832 reviews on *The Cochrane Library* Issue 1, 2001, 448 have consumer synopses (24%). Word counts varied from 18 to 418 (mean 113). The classification of synopses into conclusive (positive or negative) or inconclusive is shown in the bar chart. In some cases, authors of synopses had given specific reasons for negative findings.

#### Results in Cochrane reviews according to consumer synopsis

[Some synopses in more than one category]



We found the following words and phrases, which we consider unclear:

- May/ might/ can/ could
- Seems/ appears/ likely
- Perhaps/ doubtful/ possibly / sometimes
- Tended/ generally
- Relatively/ as good as/ implies/ suggests

Of the 448 synopses, 134 (29.9%) used potentially misleading words or phrases with some synopses using more than one. The frequency of the words used is shown in the table below.

|                      | Ambiguous | Positive | Negative | Inconclusive (not enough evidence) | Inconclusive (conflicting results) |
|----------------------|-----------|----------|----------|------------------------------------|------------------------------------|
| Appears              | 7         | 10       | 3        | 6                                  |                                    |
| As good as           |           |          |          | 1                                  |                                    |
| Can                  | 7         | 9        |          | 4                                  |                                    |
| Could                | 3         | 2        |          | 2                                  |                                    |
| Doubtful             |           |          |          |                                    | 1                                  |
| Generally            | 1         | 1        | 1        | 1                                  |                                    |
| Implies/implication  | 1         |          |          |                                    |                                    |
| In theory            |           |          | 1        |                                    |                                    |
| Likely               |           | 4        |          | 3                                  |                                    |
| May                  | 31        | 17       | 7        | 17                                 | 2                                  |
| Might                | 2         | 3        | 3        | 1                                  |                                    |
| Perhaps              |           | 1        |          |                                    |                                    |
| Possibly/possibility | 1         | 1        | 1        |                                    |                                    |
| Probably             | 1         | 1        |          |                                    |                                    |
| Relatively           |           | 1        |          |                                    |                                    |
| Seemed/seems         |           | 1        | 2        |                                    |                                    |
| Sometimes/some       | 3         | 2        |          | 2                                  |                                    |
| Suggests/suggestion  | 1         |          |          | 1                                  |                                    |
| Tended               | 1         |          |          |                                    |                                    |
| Uncertain            | 1         |          |          |                                    |                                    |

However, although such words imply ambiguity<sup>3</sup>, they were not necessarily restricted to synopses of inconclusive results. For instance, the word 'may' was used in 74 synopses, of which we considered 31 to be inconclusive, 26 to be definitely negative and 17 to be definitely positive.

**Discussion:** This analysis raises a number of issues. The first is how synopses are written. Writing concise, simple English for non-specialists is difficult. However, the Consumer Network will write synopses for reviewers if requested. The advice in the Cochrane Reviewers' Handbook<sup>4</sup> recommends that synopses be between 50 and 100 words, whereas our survey found that most were longer than this. It also suggests that synopses should 'simply present the evidence' and herein lies the problem. If the

(continued on page 4)

## Cochrane Collaboration Helping to Develop Policy

Research undertaken by the CM field has become the basis for an important UK government report on acupuncture. The "Centre for Reviews and Dissemination", based at York University, is given the task of producing reports on "Effective Health Care" for the UK National Health Service. These are intended to guide health managers, doctors and other health professionals in the commissioning and provision of medical care. Over 40 Effective Health Care bulletins have been published so far, covering issues as diverse as pregnancy prevention in teenagers, hip replacement, breast cancer treatment and pressure sores.

A bulletin on acupuncture was commissioned in November 2000 and was published early in 2002. A copy of the report is available at <http://www.york.ac.uk/inst/crd/ehc72.htm>. The report is largely based on a review of systematic reviews carried out by Klaus Linde and others in the CM field. This review, published on BioMedcentral Complementary and Alternative Medicine in 2001, is available at: (<http://www.biomedcentral.com/1472-6882/1/3>). This is another excellent example of how Cochrane reviews and other work associated with the Cochrane Collaboration are helping to develop evidence-based medicine and health policy throughout the world.

Andrew Vickers, Ph.D.

(continued from page 3) evidence is equivocal, then it could be argued that using ambiguous words such as 'may' or 'might' is entirely appropriate. We suggest, however, that if reviews really do have definitive conclusions, then they should not be used.

Related to this is the issue of who writes the synopses. We did not attempt to find out whether synopses were written by the reviewers themselves, or by the Consumer Network (or, in fact, a combination of both), which might have enabled comparison of synopses from the two sources.

Second, how far should consumers be exposed to the underlying difficulties that reviewers often face, in finding enough good evidence to answer their review question? In the authors' experience, consumers like definite answers, but if there are no clear-cut conclusions, how much should the underlying reasons be communicated to readers of synopses?

Third, granted that considerable uncertainty is often present, what alternatives are there to these words that can be all but meaningless without further qualification? The guidance on format<sup>4</sup> suggests avoiding the inclusion of full statistical results with confidence intervals, but might there be

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The Cochrane Library is published and distributed by Update Software. It is updated quarterly and is available in CD-ROM for Windows. Subscriptions are for one year and include current issue plus four quarterly updates.

Information about how to subscribe is available from:

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<http://www.cochrane.org>

some intermediate numerical format which would be easier to understand and be more precise?

**Conclusions and Recommendations:** We recognise that consumer synopses can be difficult to write unambiguously. There will inevitably be a trade-off between accessibility to consumers and scientific precision. However, we suggest that reviewers heed advice given in the Cochrane Reviewers' Handbook<sup>4</sup>, and also try to avoid the use of ambiguous words and phrases, especially in reviews with conclusive results.

### References

- 1) Vickers A, On breakfast and randomized trials. *BMJ* 2001;322:85
- 2) Smith AF, Middleton P, Wager E. Definitely maybe: how is uncertainty expressed in Cochrane reviews? Presented at 8<sup>th</sup> International Cochrane Colloquium, Cape Town, 2000.
- 3) Beyth-Marom R. How probable is probable? *Journal of Forecasting* 1982;1:257-69.
- 4) Appendix 2a. Guide to the format of a Cochrane review. From: The Cochrane Reviewers' Handbook, on *The Cochrane Library*, Issue 1, 2001.

## Colloquium Abstracts

Abstracts from the 9th Cochrane Colloquium are now available on BioMed Central. The address is: <http://www.biomedcentral.com/browse/abstracts/COCHRANE/1>.

## Workshop on Cochrane Editing

Copenhagen is the site for another workshop on Cochrane editing from September 12-14, 2002. The workshop is open to anyone involved in editing or writing Cochrane reviews, but preference will be given to editors and review group coordinators. If interested, please contact Kirsten Lone Jensen ([k.l.jensen@cochrane.dk](mailto:k.l.jensen@cochrane.dk)) as soon as possible since the 2001 workshop was fully attended. Checklists received from various review groups participating in the 2001 workshop can be found at <http://www.cochrane.dk/ncc/materials/index2.htm>.

## Comments and Criticisms

A summary of the current Cochrane process for dealing with comments and criticisms has been posted on the web at <http://www.cochrane.de/software/docs/comcrits.doc>

## Help with Hot Topics

Want to do more to spread knowledge from the Cochrane Collaboration? How about helping with Cochrane Consumer Network with its Hot Topics? They're available on-line at [www.cochraneconsumer.com](http://www.cochraneconsumer.com). In an effort to gear up to weekly production, individuals with any kind of interest or expertise are needed to help improve draft Hot Topics.

You can sign up for the Hot Topics support pool now. About once a month you'll receive an e-mail letting you know what's coming up and you can volunteer for as many or as few as you like. Just send an e-mail to [info@cochraneconsumer.com](mailto:info@cochraneconsumer.com) to sign up or for more information.

## 4th Oxford Symposium on Systematic Review Methodology

The symposium will focus on meta-analysis for policy decision, publication bias, heterogeneity models, and equating of medical outcome measures. In addition there will be other topics related to methodology. See the website for more information:

[http://zeta.msri.org/calendar/workshops/WorkshopInfo/198/show\\_workshop](http://zeta.msri.org/calendar/workshops/WorkshopInfo/198/show_workshop)

## Intro to Analysis Workshops

The UK Cochrane Centre will no longer be offering RevMan workshops. Although reviewers are much more able to use RevMan without the need for a workshop, there are requests for more on the analysis of reviews.

As a result, reviewers are encouraged to teach themselves to use RevMan using the exercise available on Cochrane websites. A new workshop "Introduction to Analysis" will replace the RevMan workshops. The workshop is suitable either for new reviews or those who are beginning the analysis in their review.

(From Cochrane News Issue 23, p. 10)

## Training and Workshops

For information about Cochrane workshops check the Collaboration website at <http://www.cochrane.org/cochrane/workshop.htm>

Other opportunities:

University Dental Hospital of Manchester, Manchester, UK. Workshops offered 15-17 April and 3-14 May 2002. Contact [lee.hooper@man.ac.uk](mailto:lee.hooper@man.ac.uk)

4th Annual Rocky Mountain Evidence Based Health Care Workshop, Keystone, Colorado, USA. Workshop 11-15 August 2002. Contact [jennifer.mcintyre@uchsc.edu](mailto:jennifer.mcintyre@uchsc.edu)

University of Texas Continuing Education Network, USA. See <http://www.sph.uth.tmc.edu/CEN>

## 4th Oxford Symposium on Systematic Review Methodology

The 4th Oxford Symposium is scheduled for 2-4 July, 2002, at St. Catherine's College, Oxford, UK. The symposium, which will focus on research relating to the methods and problems of doing and using systematic reviews, will bring together individuals from a wide variety of disciplines. Full details of the meeting and registration forms are available on the website:

<http://www.ihs.ox.ac.uk/csm/pushingtheboundaries/symp2002.html>

(continued from page 2)

**Table 1.** Leading Internet Quality Initiatives Designed for Healthcare Consumers

| Guide or Code                | URL   | Audience                      | Mechanism   | Philosophy   |
|------------------------------|---|-------------------------------|---|--|
| eHealth Code of Ethics       | <a href="http://www.ihealthcoalition.org/ethics/ethics.html">www.ihealthcoalition.org/ethics/ethics.html</a>        | Consumers                     | Guide   | Code of conduct  |
| HI-Ethics                    | <a href="http://www.ihealthcoalition.org/ethics/ethics.html">http://www.ihealthcoalition.org/ethics/ethics.html</a> | Consumers<br>Member companies | Quality seal  | Third-party certification or Voluntary compliance with code of conduct |
| MedCERTAIN                   | <a href="http://www.medcertain.org">www.medcertain.org</a>  | Consumers                     | Meta tags created by the site provider consumers evaluate content based on tags or rating or trust mark | Voluntary meta tags<br>Trust mark<br>Third-party certification         |
| Health on the Net (HON)      | <a href="http://www.hon.ch/">http://www.hon.ch/</a>   | Consumers                     | Quality seal  | Code of conduct  |
| OMNI                         | <a href="http://omni.ac.uk">omni.ac.uk</a>  | Research and Academic         | Manual filtering  | Third-party evaluation based on quality criteria                       |
| DISCERN                      | <a href="http://www.discern.org.uk">www.discern.org.uk</a>  | Consumers                     | Tool-based filtering  | Tool-based assessment  |
| American Medical Association | <a href="http://www.ama-assn.org/ama/pub/category/1905.html">www.ama-assn.org/ama/pub/category/1905.html</a>        | AMA sites<br>Consumers        | Self-regulation of own sites  | Code of conduct  |

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(continued from page 1)

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- Clark H, Wells G, Huet C, et al. Assessing the quality of randomized trials: Reliability of the Jadad scale. *Control Clin Trials* 1999;20:448-452
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**SUMMARY OF NEW COCHRANE REVIEWS****Horse chestnut seed extract for chronic venous insufficiency**

(M.H. Pittler, E. Ernst)

**Objective:** To assess efficacy and safety of oral horse chestnut seed extract (HCSE) against placebo or reference therapy

**Selection Criteria:** RCTs

**Main Results:** Six placebo-controlled trials reported significant reduction of leg pain in HCSE groups versus placebo. Met-analysis of four trials showed significant reduction in leg volume as compared with placebo.

**Authors' Conclusions:** HCSE is an efficacious and safe short-term treatment for CVI. More rigorous RCTs are needed to assess efficacy.

(Summaries continued on page 7)

## NEW COCHRANE REVIEWS/REGISTERED TITLES RELEVANT TO COMPLEMENTARY MEDICINE

### Reviews

- ◆ Deep transverse friction massage for treating tendinitis
- ◆ Homeopathy for induction of labor
- ◆ Horse chestnut seed extract for chronic venous insufficiency
- ◆ Kava for anxiety disorder
- ◆ Medicinal herbs for hepatitis C infection
- ◆ Pygeum Africanum for benign prostatic hyperplasia
- ◆ S-adenosyl-L-methionine for alcoholic liver diseases
- ◆ Spinal manipulation for primary and secondary dysmenorrhoea
- ◆ Transcutaneous electrical nerve stimulation and acupuncture for primary dysmenorrhoea
- ◆ Therapeutic ultrasound for treating Patellofemoral pain
- ◆ Thermotherapy for treating rheumatoid arthritis

### Registered Titles

- Acupuncture for opioid dependence
- Chinese herbal medicine for chronic renal failure
- Chinese medical herbs for burns
- Compound red sage root (radix salviae miltiorrhizae) versus nitrate for angina
- Fish oil for the prevention/treatment of pre-eclampsia
- Ginkgo biloba extract for acute ischaemic stroke
- Homeopathy for dementia

### Kava extract for treating anxiety

(M.H. Pittler & E. Ernst)

**Objective:** To review efficacy and safety of kava extract for treatment of anxiety

**Selection Criteria:** Randomized double-blind trials

**Main Results:** Seven trials were reviewed. Meta-analysis of three studies shows differential treatment effect of 9.7 on Hamilton Anxiety score.

**Authors' Conclusion:** Kava extract is superior to placebo and is relatively safe as a treatment for anxiety.

### Deep transverse friction massage (DTFM) for treating tendinitis

(L. Brosseau, L. Casimiro, S. Milne, V. Robinson, et al.)

**Objective:** To assess effectiveness of DTFM for pain due to iliotibial band friction syndrome

**Selection Criteria:** RCTs and CCTs of therapeutic ultrasound against placebo or active intervention

**Main Results:** One RCT with 17 patients showed no difference in pain relief despite 22% difference in pain while running.

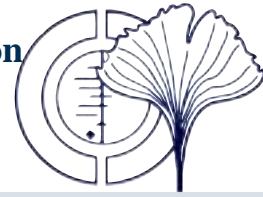
**Authors' Conclusion:** No conclusions can be drawn based on low methodological quality of one small sample trial.

## COCHRANE REVIEWS IN PROGRESS

- ◆ Acupoint P6 stimulation for preventing nausea and vomiting\*
- ◆ Acupuncture for acute stroke\*
- ◆ Acupuncture for bell's palsy
- ◆ Acupuncture for chemotherapy-induced nausea or vomiting among cancer patients
- ◆ Acupuncture for osteoarthritis
- ◆ Anti-oxidant foods or supplements for preventing cardiovascular disease
- ◆ Anti-oxidant treatment for amyotrophic lateral sclerosis/motor neuron disease
- ◆ Antioxidants for acute stroke
- ◆ Antioxidants for secondary prevention after stroke or transient ischaemic attack
- ◆ Aroma therapy for dementia
- ◆ Artichoke leaf extract for serum cholesterol reduction\*
- ◆ Behavioural interventions for primary and secondary dysmenorrhoea
- ◆ Chinese herbal medicine for atopic eczema
- ◆ Chinese medicinal herbs for asymptomatic carriers of hepatitis B
- ◆ Cognitive behaviour therapy for depressed carers of people with Alzheimer's disease and related disorders
- ◆ Complementary therapies for acne
- ◆ Enzyme therapy in oncology
- ◆ Evening primrose oil or other essential fatty acids for premenstrual syndrome
- ◆ Fish oil and other prostaglandin precursor supplementation during pregnancy for reducing preterm birth, pre-eclampsia, low birth weight and intrauterine growth restriction\*
- ◆ Folate for depressive disorders\*
- ◆ Fruits and vegetables for cardiovascular disease\*
- ◆ Ginkgo biloba in intermittent claudication
- ◆ Glutamine supplementation for critically ill adults
- ◆ Hydrotherapy for asthma
- ◆ Manual therapy for mechanical neck disorders
- ◆ Massage and aromatherapy for symptom relief in patients with cancer
- ◆ Medicinal herbs vs. medicinal herbs for chronic hepatitis b virus infection
- ◆ Mind/Body therapy for fibromyalgia
- ◆ Mistletoe therapy in oncology\*
- ◆ Noninvasive physical treatments for chronic headache
- ◆ Nutrition for preventing and treating pressure ulcers
- ◆ Omega-3 fatty acids for prevention of cardiovascular disease
- ◆ Omega-3 fatty acids for cystic fibrosis
- ◆ Padma 28 (a Tibetan herbal preparation) for intermittent claudication
- ◆ Phytoestrogens for menopausal symptoms
- ◆ Phytoestrogens in the treatment of postmenopausal osteoporosis\*
- ◆ Psychological interventions for non-ulcer dyspepsia
- ◆ Reflexology for symptom relief in patients with cancer
- ◆ Selenium supplementation to prevent short-term morbidity in preterm neonates\*
- ◆ Spinal manipulation for low back pain
- ◆ Stress management for coronary heart disease
- ◆ Therapeutic touch in wound healing
- ◆ Transcranial magnetic stimulation for treatment of depression\*
- ◆ Transcranial magnetic stimulation for the treatment of obsessive compulsive disorder\*
- ◆ Vitamin B6 and placebo in premenstrual syndrome

\*New

## Would You Like To Participate In The Cochrane Collaboration Complementary Medicine Field?



Name: \_\_\_\_\_ Country: \_\_\_\_\_

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- Prepare and maintain Cochrane  
Complementary Medicine reviews  
*List topics of interest below*
- Liaison between CM Field and a CRG
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Reviews
- Train and/or recruit reviewers
- Other

### How I Will Contribute to the Field

#### Identify Trials

- Hand search journals     Translate articles  
*Language (s)*                      *Language(s)*
- Other

#### Dissemination

- Promote The Cochrane Library
- Act as contact person from non-Cochrane  
Organization for CM Field
- Other

**Tell us about your interests.** \_\_\_\_\_  
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