The Italian National Health Service, the CISMO and Ayurveda Medicine

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Points of the lecture

1. **A look at the differences between Western and Ayurveda medicine: two separate worlds ?**
2. **Ayurveda medicine in Italy**
3. **The C.I.S.M.O.**
4. **The Local Health Authority of Brescia, Italy**
5. **The University of Brescia, Italy**
6. **The cooperation of the C.I.S.M.O. with Indian Authorities**
7. **Future projects**

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Two different views of medicine ?

"Western" medicine

"Eastern" medicine (Ayurveda)

PEACE OR WAR ?

The different views of Western medicine and Ayurveda

Western Medicine

- **healthy man = few interest**
- **sick man = specific therapy, mainly using medicine or surgery**

Ayurveda

- **NIDAN PARIVARJANA** = Removal of the causative factors
- **SAMSODHANA** = Purificatory measures
- **SAMSHAMANA** = Pacificatory measures

The limits and faults of the Western medicine

- A man is a sum of organs: take care of the diseased organ and forget the man as a whole
- Many more resources are devoted to diagnosis and therapy than to prevention of diseases
- The technology progress in diagnosis and treatment of diseases is fascinating but it increases the costs of the health care system enormously
- It is easier to take medicines than to change one subject's lifestyle

Alternative Medicine — The Risks of Untested and Unregulated Remedies

(Angell and Kassirer, NEJM, 1998)

It is time for the scientific community to stop giving alternative medicine a free ride.

There cannot be two kinds of medicine — conventional and alternative.

There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work.

Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted. But assertions, speculation, and testimonials do not substitute for evidence. Alternative treatments should be subjected to scientific testing no less rigorous than that required for conventional treatments.

The New England
Journal of Medicine

VOLUME 339 SEPTEMBER 17, 1998 NUMBER 12

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

ROBERT S. DIPAOLA, M.D., HUAYAN ZHANG, M.D., GEORGE H. LAMBERT, M.D., ROBERT MEEKER, B.S., EDWARD LICITRA, PH.D., MOHAMED M. RAFI, PH.D., BAO TING ZHU, PH.D., HEIDI SPAULDING, R.N., SUSAN GOODIN, PHARM.D., MICHEL B. TOLEDANO, M.D., WILLIAM N. HAIT, M.D., PH.D., AND MICHAEL A. GALLO, PH.D.

Background Herbal mixtures are popular alternatives to demonstrated therapies. PC-SPES, a commercially available combination of eight herbs, is used as a nonestrogenic treatment for cancer of the prostate. Since other herbal medicines have estrogenic effects in vitro, we tested the estrogenic activity of PC-SPES in yeast and mice and in men with prostate cancer.

creased uterine weights substantially. In six of six men with prostate cancer, PC-SPES decreased serum testosterone concentrations ($P<0.05$), and in eight of eight patients it decreased serum concentrations of prostate-specific antigen. All eight patients had breast tenderness and loss of libido, and one had venous thrombosis. High-performance liquid chromatography, gas chromatography, and mass spectrometry showed that PC-SPES contains estrogenic organic compounds that are distinct from diethylstilbestrol, estrone, and estradiol.

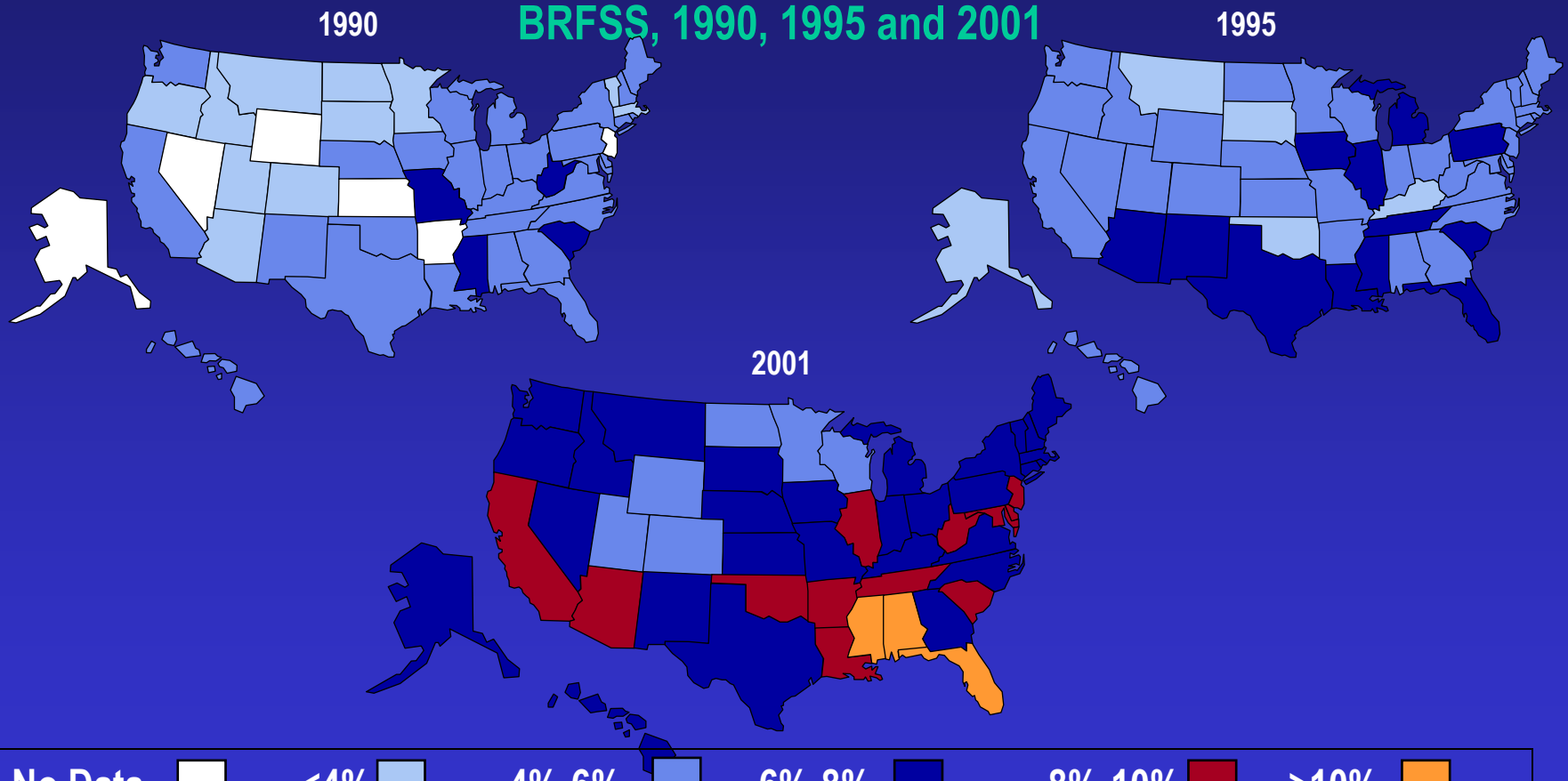
Conclusions PC-SPES has potent estrogenic activity. The use of this unregulated mixture of herbs may confound the results of standard or experimental therapies and may produce clinically significant adverse effects. (N Engl J Med 1998;339:785-91.)

An example of modern preventive medicine: the prevention of diabetes mellitus

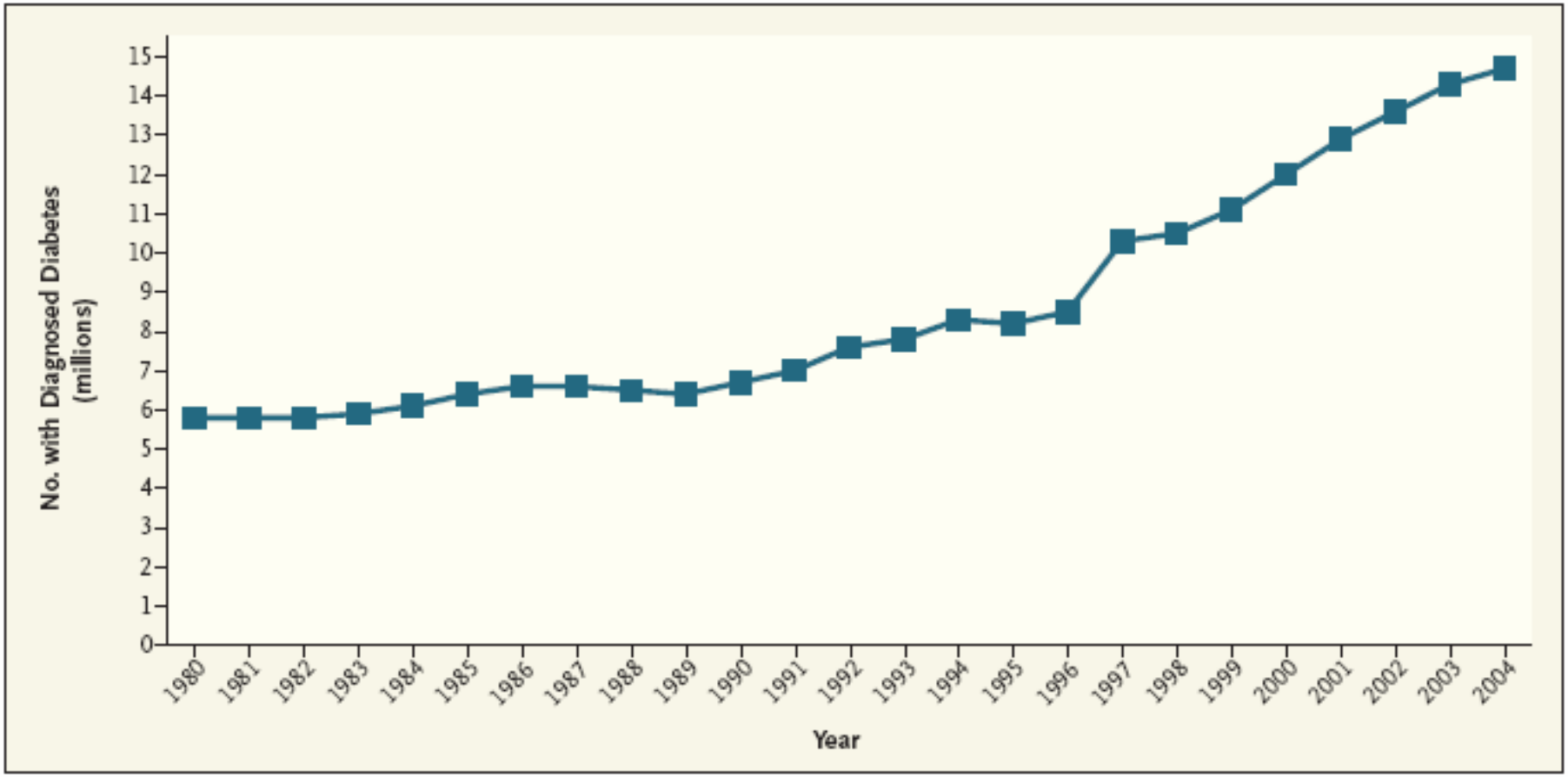
Diabetes Trends* Among Adults in the U.S.,

(Includes Gestational Diabetes)

BRFSS, 1990, 1995 and 2001

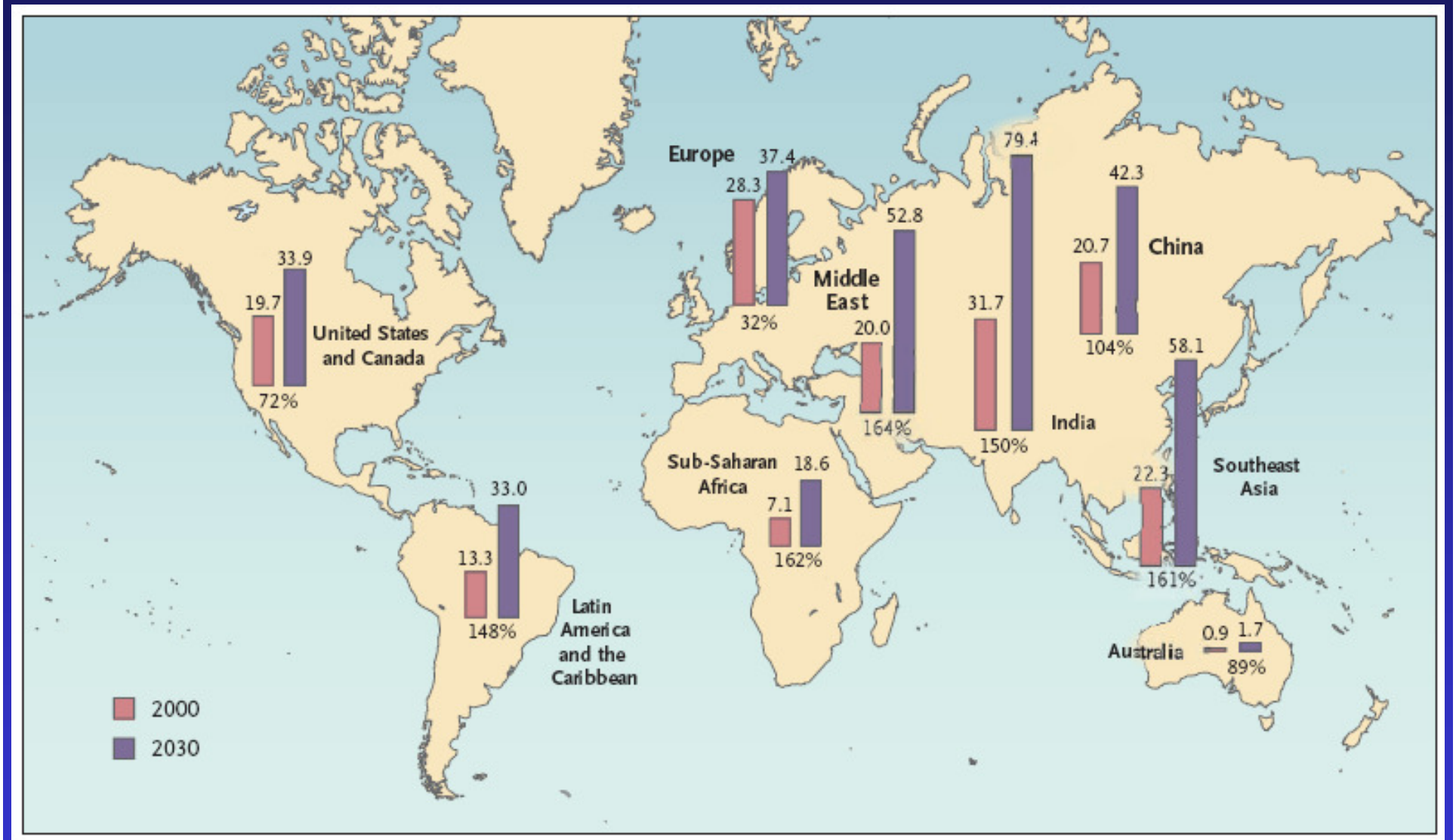


Source: Mokdad et al., *Diabetes Care* 2000;23:1278-83; *J Am Med Assoc* 2001;286:10.



Number of Persons with Diagnosed Diabetes in the United States, 1980–2004.

Data are from the Centers for Disease Control and Prevention. The increase in the number of cases between 1996 and 1997 reflects a redesign of the National Health Interview Survey.



Millions of Cases of Diabetes in 2000 and Projections for 2030, with Projected Percent Changes.

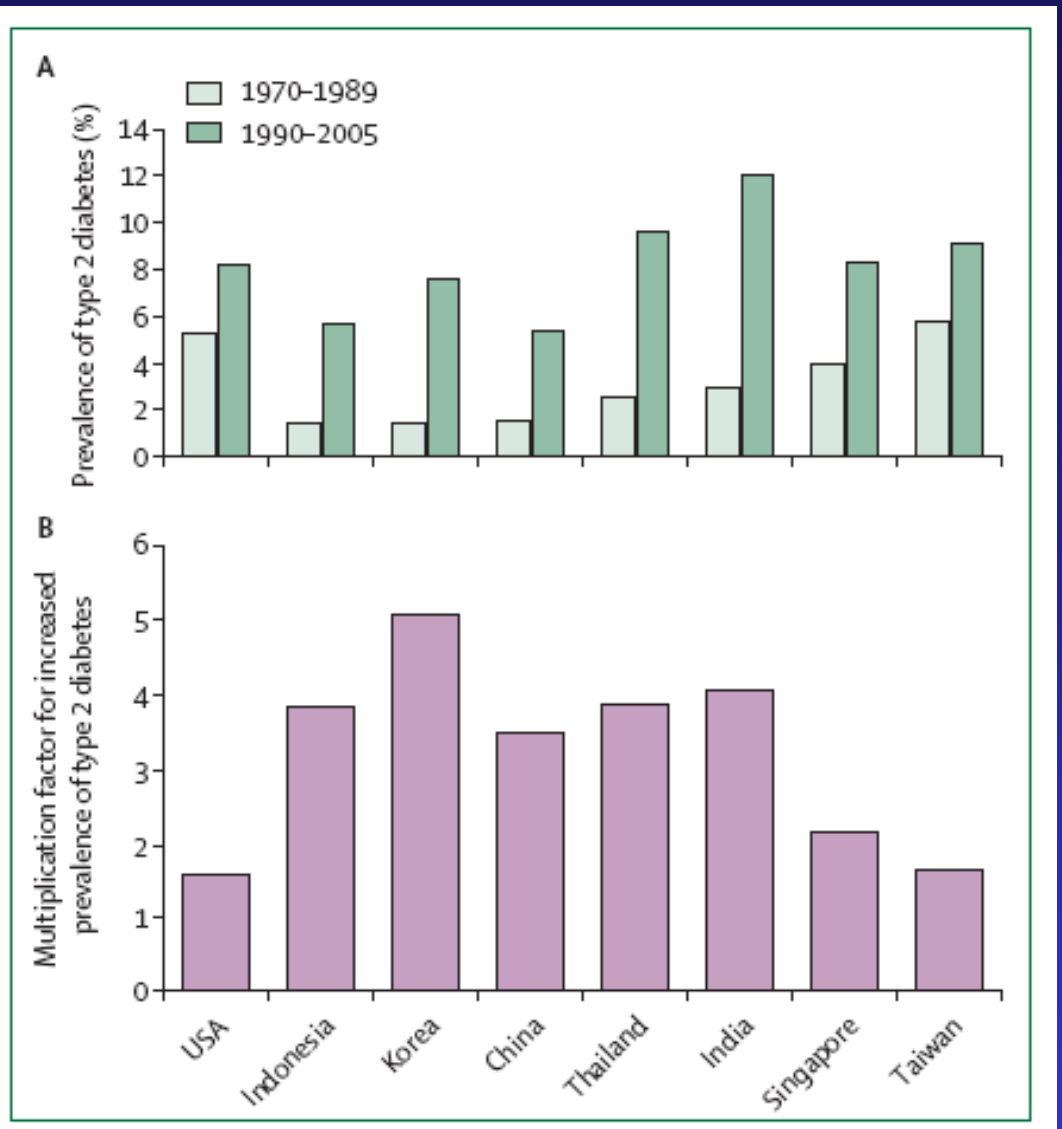
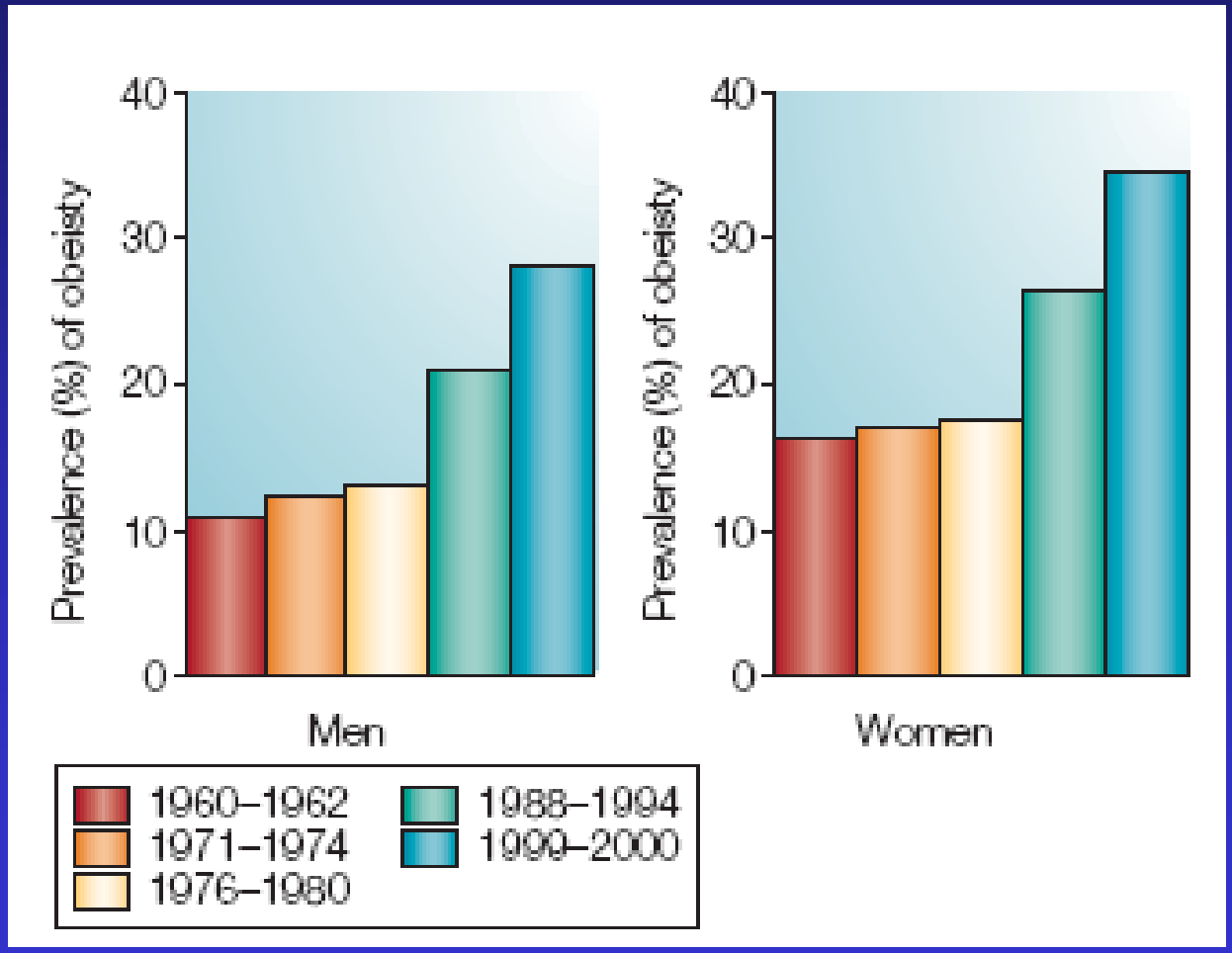


***Figure 1*: Comparison of prevalence rates of diabetes in selected countries between 1970–1989 and 1990–2005**

(A) Prevalence of diabetes in selected nations. (B) Multiplication factor for change in prevalence of diabetes in selected nations between 1970–1989 and 1990–2005.

Prevalence of obesity (BMI 30+ kg/m^2) in USA adult population from 1960 to 2000



Prevalence of overweight and obesity in various areas of the world in 45-59 year old people

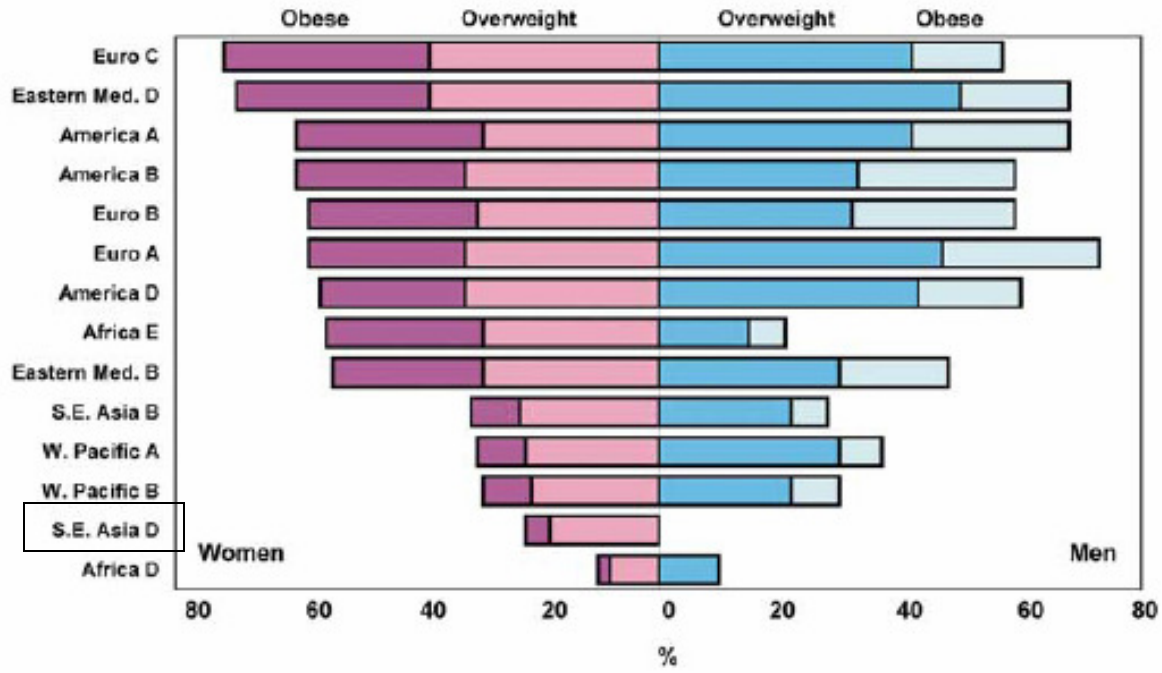


Figure 2 Prevalence of overweight and obesity in 45–59 year olds in different parts of the world. The three countries with the biggest populations in each subregion is defined as follows – Afr D: Nigeria, Algeria, Ghana; Afr E: Ethiopia, Congo, South Africa; Amr A: United States, Canada, Cuba; Amr B: Brazil, Mexico, Colombia; Amr D: Peru, Ecuador, Guatemala; Emr B: Iran, United Arab Emirates, Saudia Arabia; Emr D: Pakistan, Egypt, Sudan; Eur A: Germany, France, United Kingdom; Eur B: Turkey, Poland, Uzbekistan; Eur C: Russian Federation, Ukraine, Kazakhstan; Sear B: Indonesia, Thailand, Sri Lanka; Sear D: India, Bangladesh, Myanmar; Wpr A: Japan, Australia, Singapore; Wpr B: China, Vietnam, Philippines. Source: James PT *et al*. *Obes Res* 2001; 9: 228S–233S

Metabolic syndrome: NCEP definition

At least 3 of the following 5:

- **Fasting blood glucose ≥110 mg/dL**
- **Abdominal obesity : waist circumference :**

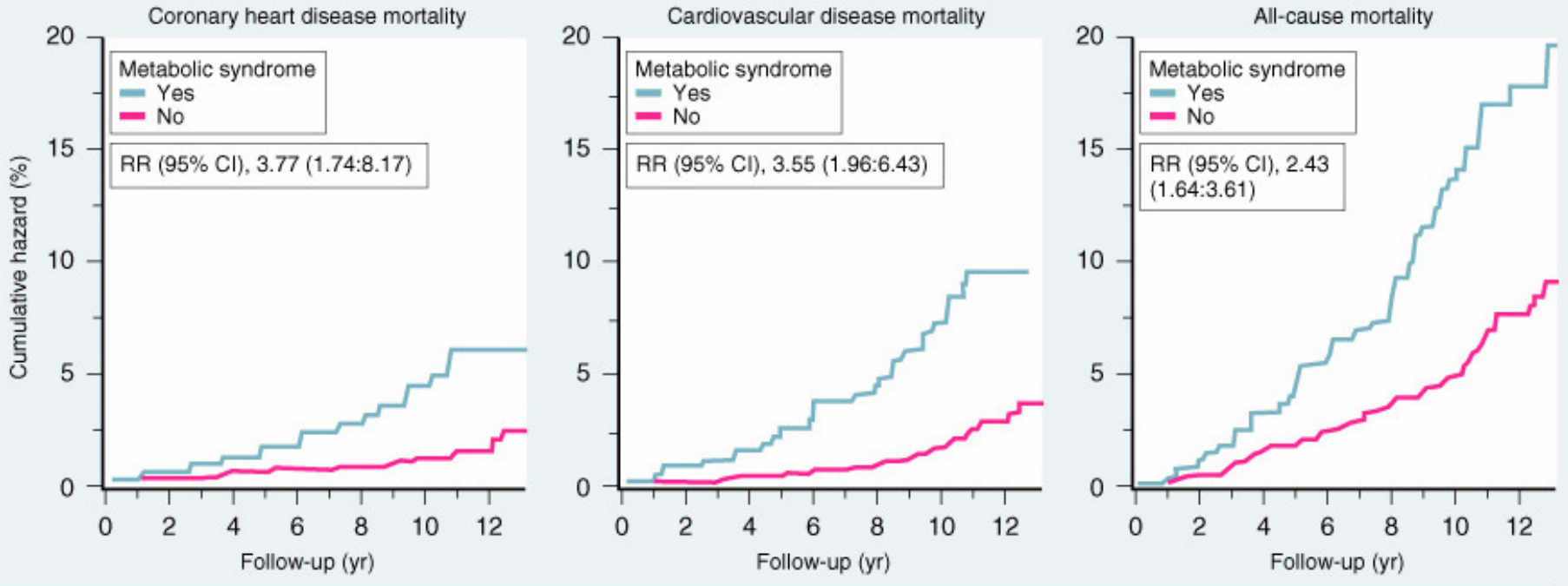
  man: > 102 cm; woman: > 88 cm
- **Triglycerides ≥ 150 mg/dL**
- **HDL-C**

  man < 40 mg/dL

  Woman < 50 mg/dL
- **Blood pressure ≥ 130/85 mm/ Hg or therapy for hypertension**

78% among women and 84% among men with type 2 diabetes

Mortality for metabolic syndrome



POTENTIALLY PREVENTABLE PROPORTION OF SOME COMMON DISEASES DUE TO LIFE STYLE CHANGES ONLY

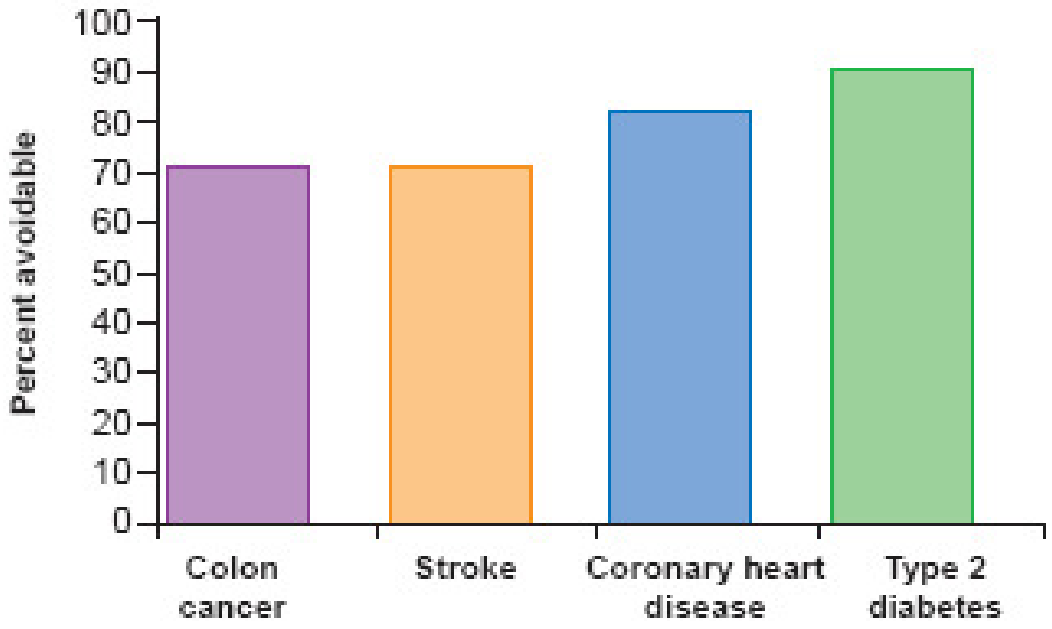


Fig. 1. Percentage of colon cancer, stroke, coronary heart disease, and type 2 diabetes that is potentially preventable by life-style modifications. For colon cancer (*7*), the low-risk definition includes body mass index <25 kg/m^2, physical activity equivalent to >30 min per day of brisk walking, folic acid supplement of 100 μg per day or more, less than three alcoholic drinks per day, lifetime nonsmoking, and fewer than three servings of red meat per week. For stroke (unpublished data) and coronary heart disease (*6*), the low-risk definition includes nonsmoking, a good diet (incorporating low intake of saturated and trans fat and glycemic load and adequate intake of polyunsaturated fat, N-3 fatty acids, cereal fiber, and folic acid), body mass index <25 kg/m^2, physical activity equivalent to > 30 min per day of brisk walking, and moderate alcohol consumption. For diabetes (*8*), the low-risk definition was similar to that for coronary heart disease except that the dietary score did not include folic acid or N-3 fatty acids.

Global cardiovascular disease prevention: time to get serious

Robert Beaglehole

Lancet 2001; **358:** 661–63

The proximal causes of the cardiovascular disease epidemics are well known. The major risk factors—inappropriate diet and physical inactivity (as expressed through unfavourable lipid concentrations, high body-mass index, and raised blood pressure), together with tobacco use—explain at least 75% of new cases of cardiovascular disease.[4] In the absence of these risk

After more than half a century of productive public-health science, there is an urgent need to take the prevention of cardiovascular disease more seriously. The only sensible strategy is the population approach to primary prevention. The bulk of available resources should be directed towards this strategy, and policies and guidelines should be realistic with respect to resource and context.

Present scientific evidence: are lifestyle changes effective in prevention of diabetes and metabolic diseases ?

- Diet, reduction in BMI and exercise are effective in reducing the risk of diabetes and related diseases, particularly cardiovascular diseases
- Prevention trials demonstrate that up to 80% of diabetes can be prevented with lifestyle changes
- lifestyle changes are more healthy and safe than oral anti-diabetic drugs.

Landmarks for the prevention of diabetes and metabolic syndrome and related diseases (Western medicine)

1. Healthy dietary habits (food with a low glycemic index and reducing LDL cholesterol serum levels)
2. Avoiding overweight/obesity
3. Regular exercise
4. Avoid tobacco smoking
5. Control of the blood pressure
6. Drugs

Ayurveda suggestions for the prevention of diabetes and metabolic syndrome and related diseases

1. Healthy dietary habits (food with a low glycemic index and reducing LDL cholesterol serum levels)
2. Avoiding overweight/obesity
3. Regular exercise
4. Avoid tobacco smoking
5. Herbs
6. Panchkarma

How to prevent diabetes ?

Western medicine

- Diet
- Avoid overweight
- Exercise

Ayurveda

- Diet
- Avoid overweight
- Exercise

Where is the difference ?

Do Ayurveda medicine treatments meet the Western parametres of 'Evidence-Based Medicine' ?

1. Randomized controlled, double blind, trials (RCTs) carried out in humans are actually the best study designs to test efficacy and safety of treatments, especially herbs.
2. Though all the scientific journals are theoretically valid, there are some parameters, mostly based on the journal diffusion (impact factor), which are very important for relevance given to study results.
3. Most Ayurvedic treatments still lack a strong scientific evidence according to Western rules.

The promotion of research on complementary medicine in the USA: the activity of NIH

- Many Americans use one or more health promotion, illness prevention or healing practices that are considered as complementary and alternative medicine (CAM).
- In recognition of this, the United States Congress legislated in 1991 to establish the Office of Alternative Medicine to "investigate and evaluate promising unconventional medical practices".
- In 1998, Congress expanded this mandate by enacting legislation that created the National Center for Complementary and Alternative Medicine (NCCAM), endowing it with the resources and authority to fund research, train researchers, and disseminate information to the public and healthcare professionals.

The promotion of research on complementary medicine in the USA: the activity of NIH

- The US$117.7 million allocated to NCCAM in 2004, while generous by most standards, permits only a limited sampling of possible CAM approaches.
- The resulting first strategic plan stressed investment in basic and clinical research, training, dissemination of findings, and integration of safe and effective practices.
- NCCAM made a commitment to aspire to the same rigorous standards that characterise National Institutes of Health (NIH) research in general, while its research priorities would focus on the most promising scientific opportunities.
- As NCCAM celebrates its fifth anniversary, it is possible to list its not inconsiderable achievements to date (see Box 1), and to reflect on some of the lessons learned for current and future directions.

The promotion of research on complementary medicine in the USA: the activity of NIH

1 Activities of the National Center for Complementary and Alternative Medicine in its first 5 years:

- It built a centre responsive to its mission and integrated into the other institutes at the United States National Institutes of Health
- It funded over 780 projects at 123 institutions, resulting in over 700 scientific publications
- It awarded more than 100 individual doctoral and postdoctoral training and career awards
- It enrolled nearly 40 000 participants in clinical protocols
- It received over 1.5 million visitors to the website <www.nccam.nih.gov> each year who search for information about CAM, clinical trials, and research opportunities
- It developed a database known as "CAM on PubMED" that lists nearly 400 000 articles on CAM-related subjects published in 45 languages from 70 countries
- It informed public policy, patient choice, and clinical practice through outreach activities, including public town meetings, public media, and scientific and professional conferences

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2 Status of National Center for Complementary and Alternative Medicine Phase III Clinical Trials

Complementary and alternative medicine modality	Target disease	Sample size	Status
Acupuncture	Osteoarthritis	*570*	Trial complete; analysis underway
Glucosamine/chondroitin	Osteoarthritis	*1588*	Enrolment complete; ongoing
Ginkgo biloba	Dementia	*3073*	Enrolment complete; ongoing
Shark cartilage	Lung cancer	*756*	Patients enrolling; ongoing
Vitamin E	Prostate cancer	*32400*	Enrolment complete; ongoing
St John′s wort	Minor depression	*300*	Patients enrolling; ongoing
Saw palmetto	Benign prostatic hyperplasia	*2860*	Final protocol under development

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

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

BACKGROUND: Traditional Chinese herbal medicines have been used for a long time to treat diabetes, and many controlled trials have been done to investigate their efficacy.

OBJECTIVES: To assess the effects of Chinese herbal medicines in patients with type 2 diabetes mellitus. **SEARCH STRATEGY:** We searched the following electronic databases: The Cochrane Library (CENTRAL), the Chinese BioMedical Database, MEDLINE, EMBASE, and LILACS, combined with hand searches on Chinese journals and conference proceedings. Date of last search was April 2004. No language restriction was used.

SELECTION CRITERIA: Randomised trials of herbal medicines (with at least two months treatment duration) compared with placebo, pharmacological or non-pharmacological interventions were included.

DATA COLLECTION AND ANALYSIS: Data were extracted independently by two reviewers. The methodological quality of trials was evaluated using the parameters of randomisation, allocation concealment, double blinding, and drop-out rates

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

(Liu JP, 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. ....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.

Seminars in
Arthritis and
Rheumatism

Ayurvedic Medicine for Rheumatoid Arthritis: A Systematic Review

Jongbae Park, KMD, PhD,*,† and Edzard Ernst, MD, PhD, FRCP*

OBJECTIVE To systematically review all randomized controlled trials (RCTs) on the effectiveness of Ayurvedic medicine for rheumatoid arthritis (RA).

METHODS Computerized literature searches for all RCTs of Ayurvedic medicine for RA in the following databases: Medline (March 1969 to March 2003), Embase (February 1985 to February 2003), AMED (March 1980 to March 2003), Cochrane Controlled Trial Register (October 1997 to March 2003), and the abstract service of Central Council for Research in Ayurveda and Siddha (CCRAS; 1976 to March 2003). Hand searches were performed in 1 Sri Lankan and 3 Indian journals and the authors' personal files. Key data of included studies were extracted and reviewed. The methodological quality of all studies was evaluated with the Jadad scale.

RESULTS Seven studies met our inclusion criteria. Trials tested either Ayurvedic medicine against placebo or other Ayurvedic medicines. In general, patient and physician global assessments on the severity of pain, and morning stiffness were used as endpoints. Of 3 placebo-controlled RCTs, 1 high-quality trial did not show benefit of the active treatment against placebo, while another incompletely reported study indicated beneficial effects of an Ayurvedic medicine. A further incompletely reported study showed no significant difference. The remaining 4 trials were difficult to interpret because they tested an Ayurvedic medicine against other Ayurvedic medicines whose effects were not proven.

CONCLUSION There is a paucity of RCTs of Ayurvedic medicines for RA. The existing RCTs fail to show convincingly that such treatments are effective therapeutic options for RA.

Semin Arthritis Rheum 34:705-713

Ayurvedic Medicine: It Is "Time" for Scientifically Sound Studies

Dinesh Khanna, MD, MS

Ayurveda translates into *knowledge* (Veda) of *life* (Ayur) (1) and is one of the oldest and still widely practiced medical systems in the Indian subcontinent (2). The concept of Ayurvedic medicine is to promote health, rather than to fight disease, and Ayurveda in daily life aims at maintaining harmony between nature and the "individual" to ensure optimal health (1). Appropriate food, sleep, and sexual activity are three pillars of good health, with emphasis on personal hygiene, massage, and exercise. The disruption of this harmony leads to disease, and reversal of the steps that produce disease is the main therapeutic approach. Individualized treatment regimens include fasting, massages, and/or Ayurvedic medicines (both herbs and mineral compounds) to restore the harmony with nature (1).

approach in a 1-year RCT conducted in the US (8). In another RCT in African Americans, stress reduction obtained through Transcendental Meditation, an integral part of Maharishi Vedic Medicine, was compared against a nonpharmacological, cardiovascular disease risk factor prevention education program (13). After an average intervention period of 6.8 ± 1.3 months, the meditation group had a statistically significant decrease in their carotid intima-media thickness compared with the control population.

However, claims of effectiveness of herbs are limited to anecdotal reports and personal experiences. These claims do little justice when the "science" of the herb is unknown, and herb use can result in potential toxicity and drug–herb interactions. Appropriate skepticism, hesitancy, and fear regard-

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The current publication by Amarasinghe and coworkers in the *Seminars* reviews the RCTs on the efficacy of Ayurvedic medicine in rheumatoid arthritis (RA). Their meta-analysis is limited to the herbal medicinal aspect of Ayurveda and omits the other aspects of Ayurveda. Their extensive literature search for RA trials evaluating either Ayurvedic medications against placebo or other Ayurvedic medicines yielded 7 RCTs. Of the 7 trials, 3 were placebo controlled, and 4 compared one Ayurvedic medicine against another. Only 1 article (22) was considered of high quality as assessed by the Jaded score and the rest of the 6 were of poor quality. A study by Chopra and coworkers (22) compared a standardized formulation of an Ayurvedic medicine (RA-1) against placebo in double-blind RCT. The primary end points were the proportion of patients achieving American College of Rheumatology (ACR) 20 and 50% improvement response for individual core set variables, and an ACR 20% composite response. At the end of 16 weeks (primary endpoint), the responses for individual core set variables and ACR 20% response were numerically but not statistically higher in the Ayurvedic treatment group. The other 6 studies had flawed study design, analysis, and reporting of the results.

In conclusion, herbs must undergo the same strict guidelines for drug standardization reserved for conventional medications. Well-designed safety and toxicity studies must be conducted in animal models for arthritis, especially for multicomponent herbs. Well-designed RCT assessing the concept of the Ayurveda including herbal preparations, meditation, and Yoga (an integral part of Ayurveda) (1), not just the herbal aspect, should be conducted. Two recent RCTs have shown a beneficial effect of these modalities over conventional treatment on the carotid intima-media thickness (8,13).

In addition to standardization of the herbal formulations, the trials should be conducted in a scientific and ethical manner. For example, all trials in RA should have an anti-rheumatic agent as the background therapy and poor responders can be randomized to either medication or placebo. Radiographs should be a part of these studies to evaluate for any disease-modifying effects of these herbs. Better, trials assessing the "complete" Ayurveda against conventional allopathic treatment for RA should be conducted. As stated by the authors, international collaboration could be one of the avenues to design future methodologically sound clinical trials. Such

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Ayurveda medicine in Italy -1

- In Italy, the only official medicine provided by NHS is the typical Western medicine. The Italian State does not recognise complementary and alternative medicine (CAM) officially, and it has never provided definite statements on the subject so far.
- According to Italian law, only doctors in Western medicine can practice in Italy
- Any physician can claim to be an ‘expert’ in some CAM
- Any physician can prescribe his/her patients CAM remedies
- Only a few Ayurveda herbal products (ashwaganda, neem, phyllanthus, spirulina, boswellic acid, triphala, isabgol …) are available in pharmacies and herboristic shops (no medical prescription is required to buy them)

Ayurveda medicine in Italy - 2

- Some Regions (e.g. Tuscany) have made laws to control the practice of some CAMs.
- Other regions, like Lombardy, promoted research activities in CAM and provided grants for carrying out them as such as cultural initiatives (meetings, and so on) and have contacts with WHO centre for Traditional Medicine.
- The Italian Medical Association declared to recognize some CAM practices, including Ayurveda medicine, as medical activities
- Some Local Health Authorities have promoted initiatives like clinics where some practices of CAM are provided at low cost by 'expert physicians'.

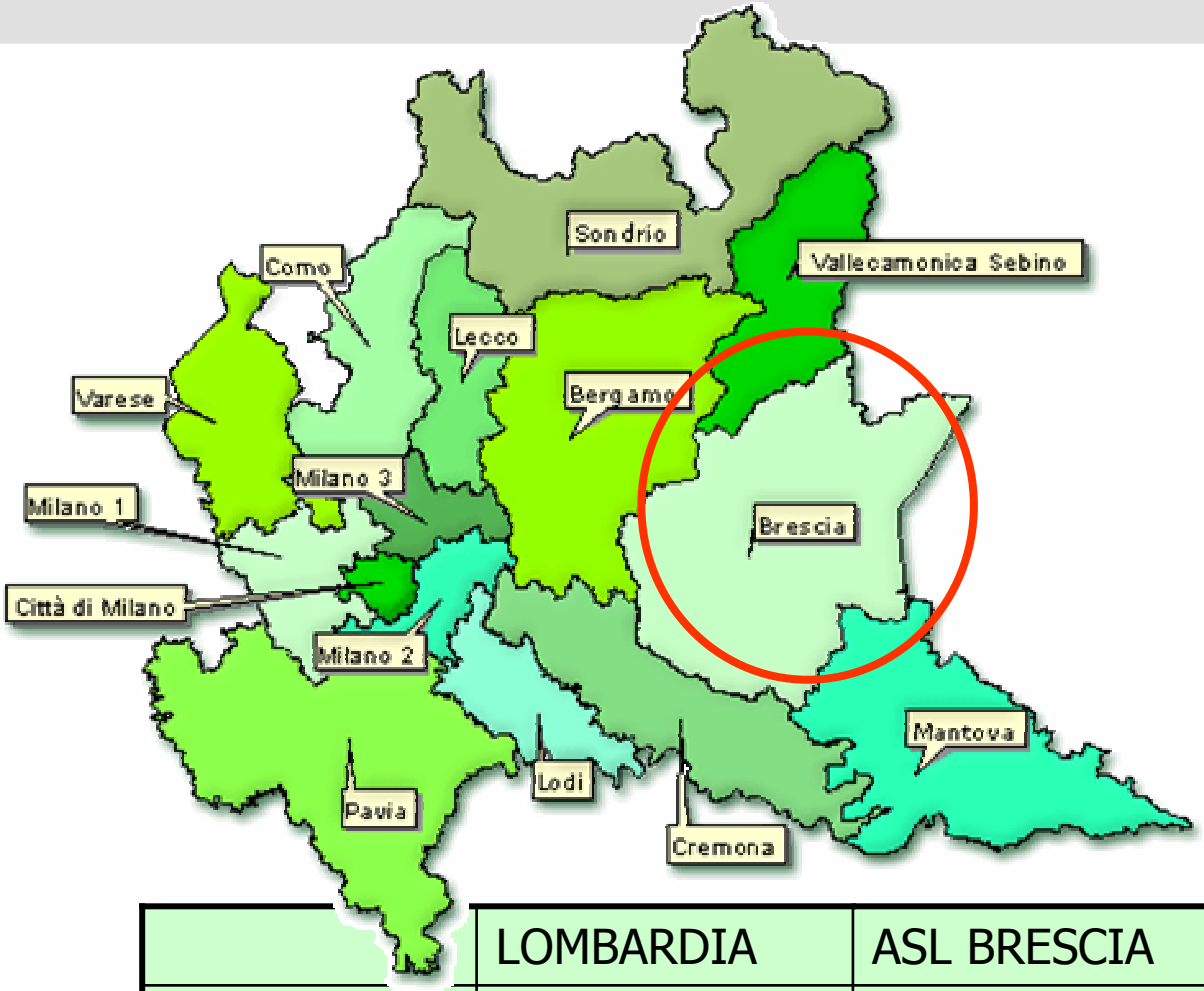
Complementary and alternative medicine in Italy

- Some practices are widely used in the country and CAM drugs can be bought freely.
- About 8 million Italians have tried CAM at least once in their lives, and 70% were satisfied of the results.
- About 10 000 Italian physicians recommend CAM, at least sometimes.
- Homeopathy is the most practiced CAM, followed by acupuncture and phytotherapy, and many others, including Chinese and Indian traditional medicines (Ayurveda).

• The Lombardy Region included Complementary Medicine among the projects in its 2002-2004 regional Health Plan, and under a resolution passed in 2003 entered into an agreement with the World Health Organisation to regulate information on the use of such medical practices for the benefit of consumers and to promote basic operator training on the application of complementary medicine.

• In 2005-06 and 2006-07, as part of its Training Scheme, the Brescia Health Authority promoted two introductory courses on Ayurvedic medicine for doctors and pharmacists. Both courses were held by Dr Deepika Gunawant and Dr. Nilesh Wakde, who were born and trained in India, and have practised Ayurvedic medicine at hospitals and clinics. Furthermore, a one-day short course on foot massage (padabhyanga) was held by Dr. Avinash Lele, one of the most famous ayurvedic experts in the world

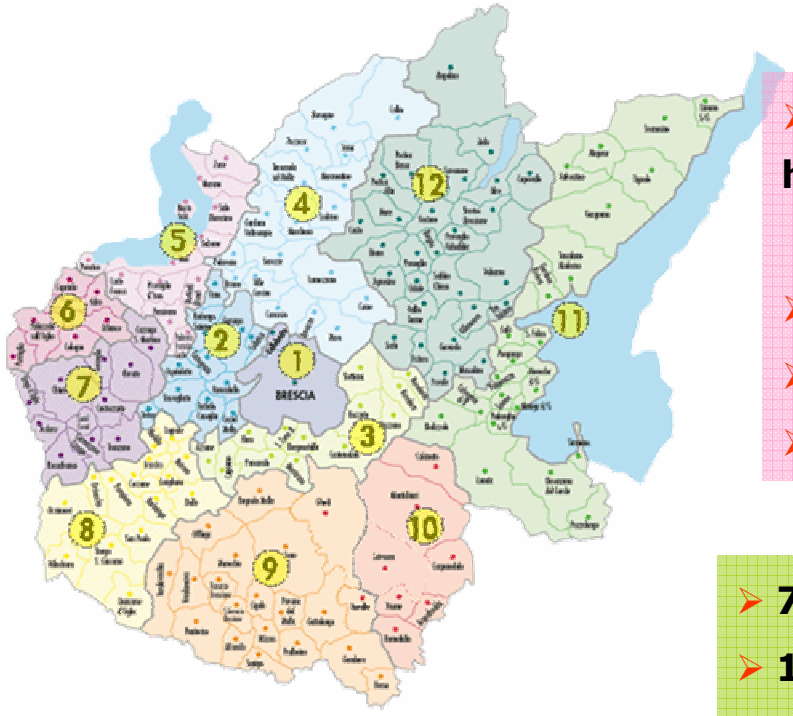
Regione Lombardia and ASL Brescia



	LOMBARDIA	ASL BRESCIA
Population	9.393.092	1.071.035 (data at 31/12/2005)
Area	23.900 km^2	3.434 km^2

MAIN FIGURES

Data 31/12/2006



- 6 Managerial districts - 12 social and health districts – 6 veterinary districts
- NORTH: mountains and valleys
- CITY: high urbanization
- SOUTH: plains

- 1.679 ASL employees
- 2007 budget 1.458.607.000 €

- 700 General practitioners
- 118 Pediatricians
- 276 Pharmacies
- 6086 Ordinary hospital beds (data 30/06/2007)
- 5989 Residential nursing home beds
- 11779 Home care patients

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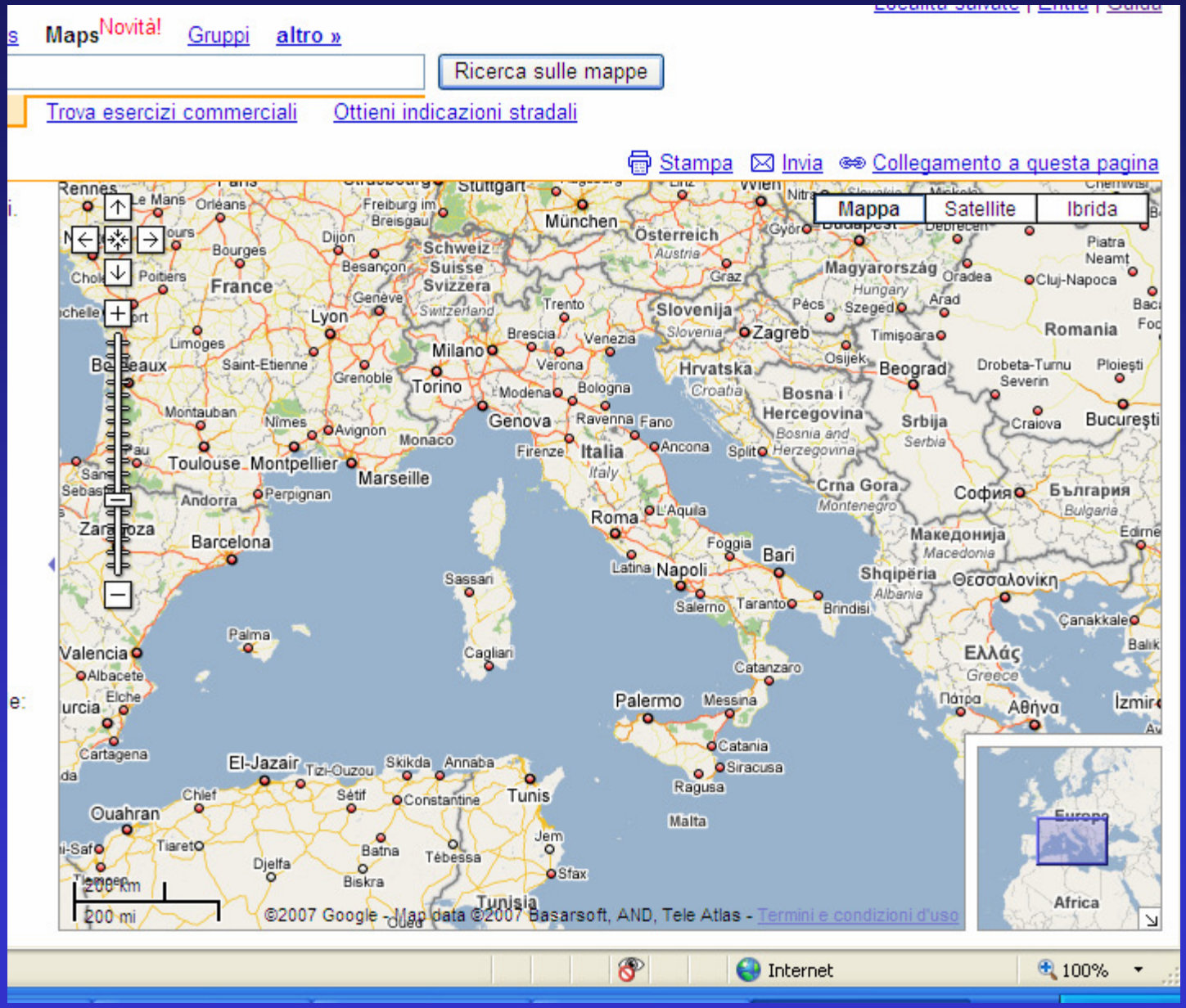
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Venezia
Verona
Modena
Bologna
Genova
Ravenna
Fano
Ancona
Firenze
Italia
Monaco
Montauban
Nîmes
Avignon
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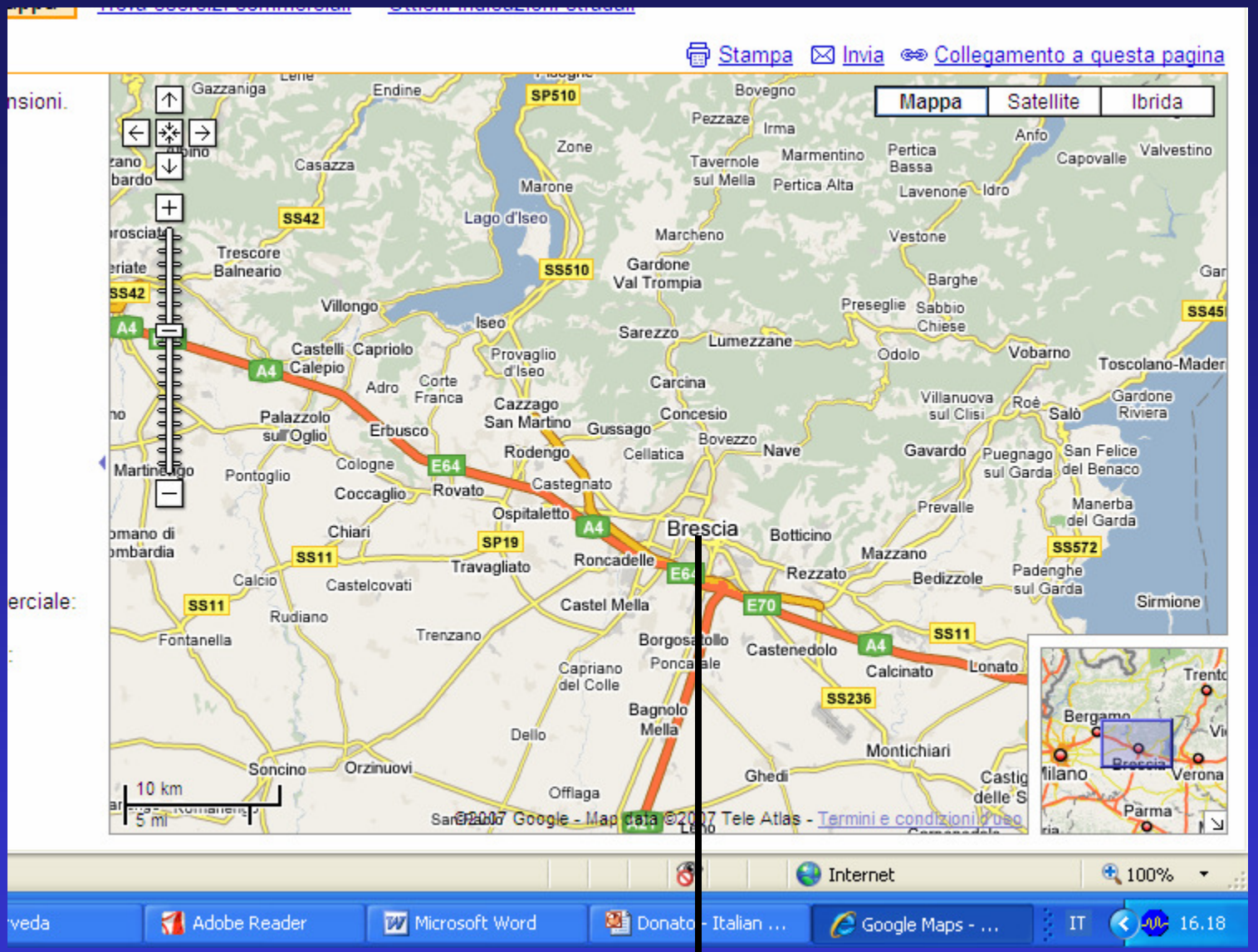
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BRESCIA

"CENTRO ITALIANO STUDI MEDICINE ORIENTALI"
(ITALIAN CENTRE FOR THE STUDY OF ORIENTAL MEDICINES)

A non-profit association of public utility

C.I.S.M.O.

Centro Italiano Studi Medicine Orientali

C.I.S.M.O.

- **Established in May 2005**

- **Article 3. PURPOSES OF THE ASSOCIATION.**

  The mission of the C.I.S.M.O. is to promote mental and physical wellbeing through initiatives to prevent and treat diseases according to the principles and techniques of oriental medicine, in order to integrate western medical practice.

  The main aims of the **C.I.S.M.O.** are to:

  - promote knowledge of the Ayurveda in all its aspects - cultural, philosophical and technical;
  - promote the integration of Ayurvedic and Western medicine in order to enrich the latter;
  - promote Ayurvedic teachings and practice among health professionals;
  - encourage a free choice of medical treatment according to the individual's ethnic group, culture and religion;
  - set up a clinic in Brescia devoted to promoting health and disease prevention by applying the principles and practices of Ayurvedic medicine;
  - set up a reference group for public and private institutions, at a local, regional or national level, in order to promote the knowledge and application of oriental medicine;
  - promote health education among the general population and specific high-risk groups, and encourage healthy lifestyles according to Ayurvedic principles;
  - produce publications and use the mass media to spread the knowledge of Ayurveda and other oriental medicines in order to promote the integration of foreign populations which traditionally engage in such medical practices according to their cultural environment.

LIST OF THE INTELLECTUAL ASSETS AND INSTITUTIONS COOPERATING WITH THE C.I.S.M.O" (ITALIAN CENTRE FOR THE STUDY OF ORIENTAL MEDICINES)

The C.I.S.M.O. is supported by physicians and other health personnel who work at the local National Health Services institutions: general practitioners and operators at Local Hospitals and Clinics. Some University professors working at the local Brescia University, Faculty of Medicine and Faculty of Economics, also promote and support the initiatives of the C.I.S.M.O.

A Scientific Committee is setting up with the intent to give a scientific rationale to any initiative of the Association regarding the organization of courses, seminars, meetings and other initiatives to diffuse the knowledge and practice of Ayurveda in Italy, on the basis of the best scientific evidence of efficacy and safety of these practices and in accordance with the recommendations of the World Health Organization and of the Italian Institutions (National Government and Lombardy Region).

The following institutions are cooperating with the C.I.S.M.O. at present:

- The General Director of the Local Health Authority of Brescia Promotes CISMO initiatives.
- The main General Hospital of Brescia, ("Spedali Civili" Hospital), where some physicians who are founder members work
- The University of Brescia, some professors of which are going to be members of the Scientific Committee
- The College of Physicians of the Province of Brescia, that gives its support to the cultural initiatives of the C.I.S.M.O.
- The College of Pharmacists of the Province of Brescia, that gives its support to the cultural initiatives of the C.I.S.M.O.

Points of the lecture

1. A look at the differences between Western and Ayurveda medicine: two separate worlds ?
2. Ayurveda medicine in Italy
3. The C.I.S.M.O.
4. **The Local Health Authority of Brescia, Italy**
5. The University of Brescia, Italy
6. The cooperation of the C.I.S.M.O. with Indian Authorities
7. Future projects

Azienda Sanitaria Locale (ASL) di Brescia

Local Health Authority of Brescia, North Italy

The Italian National Health Service

NATIONAL LEVEL

The State determines the essential levels of health services guaranteed all over the Country

REGIONAL LEVEL

Regions organize health services regarding health promotion, disease prevention and care

LOCAL LEVEL

Local Health Authorities (ASL) are bodies with public juridical status and operate autonomously with regard to organization, administration, management

LOMBARDIA REGION

Differentiation between ASL and hospitals regarding to their mission

ASL: responsible for population health status

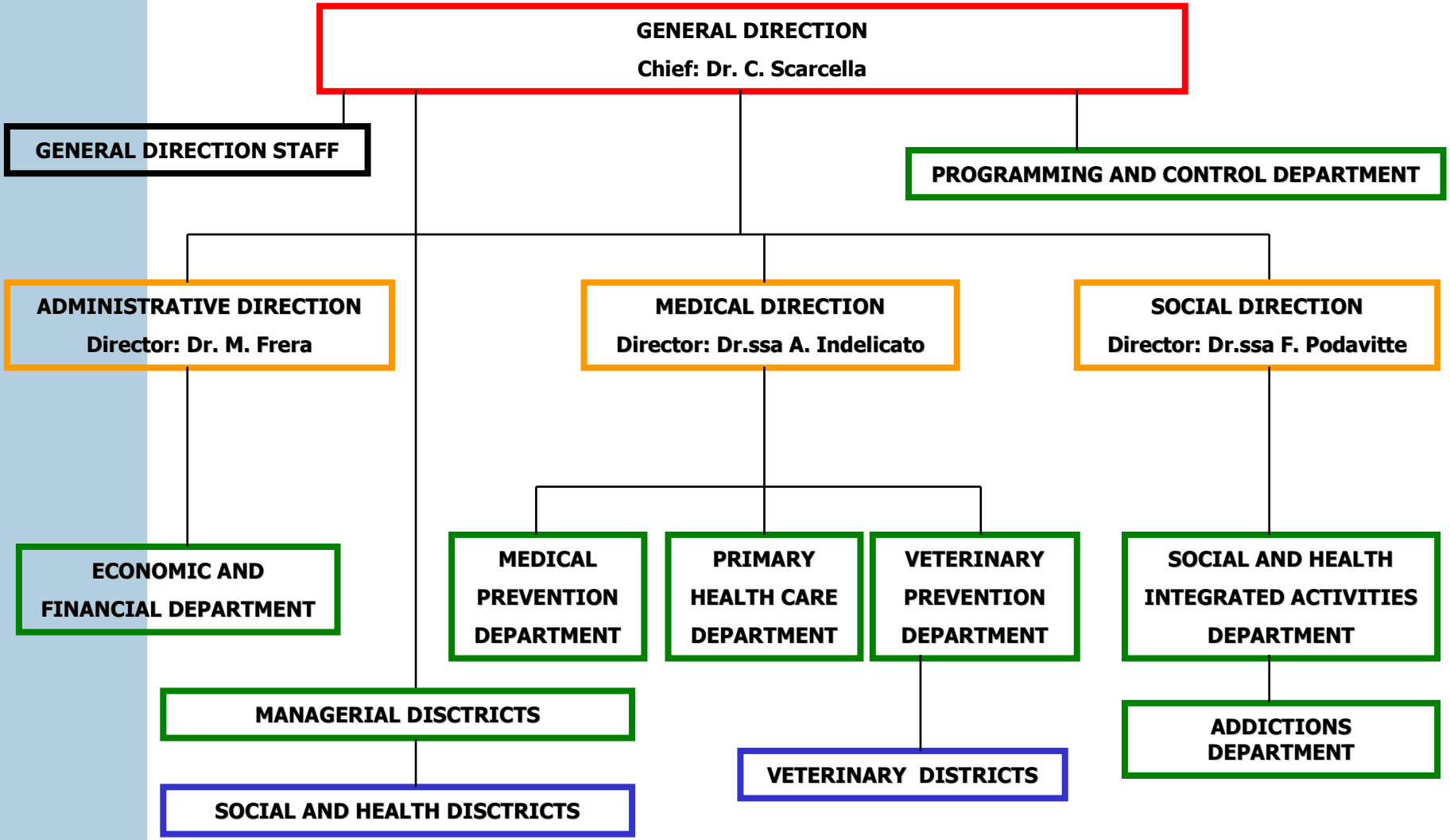
HOSPITALS: clinical care

ASL MISSION AND STRATEGIC TARGETS

ASL IS RESPONSIBLE FOR THE HEALTH STATUS OF THE POPULATION LIVING IN THE AREA

- **To investigate the population's health needs**
- **To assess the weight of the most common risk factors for acute and chronic diseases in the area**
- **To plan the health services required to respond to the population's health demands**
- **To pay the hospitals and other local authorities for the services they provide**
- **To evaluate the effectiveness, safety and cost-benefit ratio of the health services provided according to standards of quality**

Organizational Chart



EXPERIENCES IN CRISIS MANAGEMENT

- **Bovine spongiform encephalopathy (BSE)**
- **Avian Influenza**
- **Earthquake**
- **Anthrax**
- **Polychlorinated Biphenyl pollution (PCB)**

- **Health Continuity Plan**
- **N.O.G.E.R. Operative unit for the management of important events**

- **Pilot study about development of an Integrated Decision Support System (DSS) for crisis management**

- **Training courses about crisis management in Public Health:**
  - ✓ 1 Top managers course (40 hours – 15 participants)
  - ✓ 2 Crisis managers courses (120 hours – 25 participants)
  - ✓ 5 Health professionals courses, 1 for veterinarians only (40 hours – 60 participants)

- **Publication in April 2007 of a manual on "Crisis management in Public Health"**

Relatori e Moderatori

Dr. Deepika Gunawant
Laurea in Medicina Ayurvedica a Calcutta
Associate Lecturer alla Thames Valley University di Londra
Chief Physician al Charitable Hospital in Gran Bretagna.

Dr. Daniela Cecchi
Responsabile Servizio Assistenza Specialistica
dipartimento cure primarie ASL di Brescia

Dr. Graziella Cristini
Dipartimento delle Malattie Infettive e Tropicali
Spedali Civili Brescia

Prof. Francesco Donato
Cattedra di Igiene
Università degli Studi di Brescia

Dr. Giampiero Di Giovanni
Centro Ricerche Bioclimatologia e Medicine Naturali
Università di Milano

Dr. Issa El-hamad
Dipartimento delle Malattie Infettive e Tropicali
Spedali Civili Brescia

Dr. Mario Franzini
Servizio di Psichiatria
AO "Mellino Melini", Chiari

Prof. Rosella Levaggi
Cattedra di Economia sanitaria
Università degli Studi di Brescia

Dr. Gustavo Marfurt
Farmacista

Dr. Cristina Mancini
Consulente in Economia Sanitaria

Dr. Carmelo Scarcella
Direttore Generale ASL di Brescia

C.I.S.M.O.

Centro Italiano Studi Medicine Orientali

Nel mese di maggio 2005 è stato istituito il Centro Italiano di Studio delle Medicine Orientali (C.I.S.M.O.) con sede a Brescia in Via Cuzzetti 20.

Il Centro si propone di concorrere al benessere psicofisico dei cittadini mediante l'utilizzo di tecniche mediche orientali integrative alla medicina convenzionale con particolare attenzione alla medicina ayurvedica, cinese e tibetana.

L'associazione è apolitica, aconfessionale e senza fini di lucro. Possono essere soci del C.I.S.M.O. tutti coloro che ne condividono gli scopi.

I soci sono tenuti al versamento della quota associativa di 30 euro annuale.

Chiunque aderisca all'associazione può notificare in qualunque momento la sua volontà di recedere dall'Associazione. Per partecipare al corso "*Medicina Ayurvedica: le sue applicazioni complementari nella professione medica*" è necessario essere socio del C.I.S.M.O.

Segreteria organizzativa

Dr. Rita Martinelli
Rag. Maria Celotti

Per iscrizioni e informazioni:

Tel.: 339/7692079
Fax: 030/51068649
E-mail: cismo.bs@libero.it

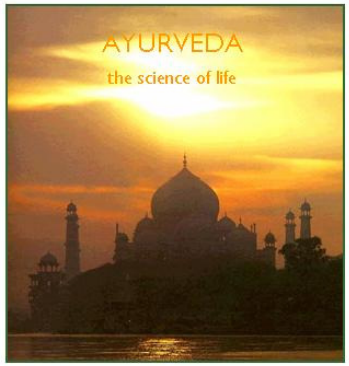
Su richiesta è possibile ricevere
il programma dettagliato del corso

Anno accademico 2005-2006

C.I.S.M.O.
Centro Italiano Studi Medicine Orientali

Corso di introduzione alla Medicina Ayurvedica

"Medicina Ayurvedica: le sue applicazioni complementari alla professione medica"



Periodo del corso:
Ottobre 2005 - Giugno 2006

Sede del corso:
Sala Formazione ASL
Via Duca degli Abruzzi, 15 - Brescia

Con il patrocinio di:

ASL azienda sanitaria locale BRESCIA

ORDINE MEDICI CHIRURGHI E ODONTOIATRI DELLA PROVINCIA DI BRESCIA

Crediti E.C.M. richiesti

Relatori e Moderatori

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Laurea in Medicina Ayurvedica a Calcutta
Associate Lecturer alla Thames Valley University di Londra
Chief Physician al Charitable Hospital in Gran Bretagna.

Dr. Daniela Cecchi
Responsabile Servizio Assistenza Specialistica
Dipartimento Cure Primarie ASL di Brescia

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Dr. Gustavo Marfurt
Farmacista

Dr. Cristina Mancini
Consulente in Economia Sanitaria

Dr. Carmelo Scarcella
Direttore Generale ASL di Brescia

Presentazione del corso

In materia di Medicina Complementare la Regione Lombardia, a seguito della promozione di studi osservazionali e della sottoscrizione di un programma di cooperazione con l' Organizzazione Mondiale della Sanità, favorisce un approfondimento delle conoscenze relative alla Medicina Complementare, finalizzate ad offrire criteri di sicurezza e di efficacia per la tutela della salute dei cittadini, la tutela dei consumatori e dei fornitori di servizi.
L' ASL di Brescia, in collaborazione con il CISMO (Centro Italiano Studi Medicine Orientali), promuove ed organizza un Corso per le figure professionali dei Medici e dei Farmacisti

Per iscrizioni e informazioni:

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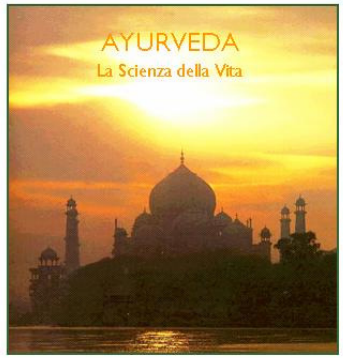
C.I.S.M.O.

CORSO
PER MEDICI E FARMACISTI

Ayurveda- Scienza della Vita
Medicina Complementare nella prevenzione e cura delle malattie



Ottobre 2006 - Giugno 2007

Sede del corso:
ASL di Brescia - Sala di Rappresentanza
Viale Duca degli Abruzzi, 15 - Brescia

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ORDINE MEDICI CHIRURGHI E ODONTOIATRI DELLA PROVINCIA DI BRESCIA

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azienda sanitaria locale
B R E S C I A

Azienda Sanitaria Locale della Provincia di Brescia

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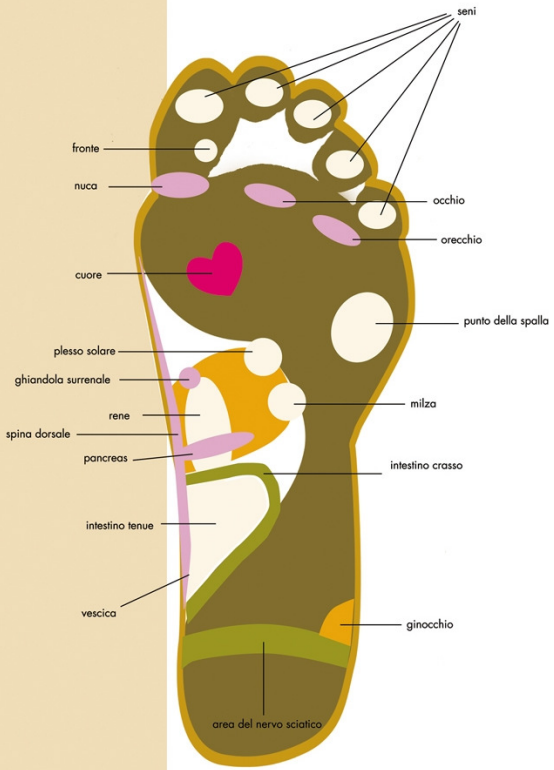
CORSO DI RIFLESSOLOGIA PLANTARE

DOTT. AVINASH LELE
INTERNATIONAL ACADEMY OF AYURVEDA

26-27 MAGGIO 2007



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Relatori

Dr. Morandi

Dr.Brincivalli

Dr.Lisciani

Dr.Sartori

Dr.Narah

Centro Italiano Studi Medicine Orientali

In materia di Medicina Complementare la Regione Lombardia, a seguito della promozione di studi osservazionali e della sottoscrizione di un programma di cooperazione con l'Organizzazione Mondiale della Sanità, favorisce un approfondimento delle conoscenze su questa materia, finalizzate ad offrire garanzie di sicurezza e di efficacia dei trattamenti, per la tutela della salute dei consumatori.

L'ASL di Brescia, in collaborazione con il CISMO(Centro Italiano Studi Medicine Orientali), promuove ed organizza un Corso per le figure dei Medici e dei Farmacisti.

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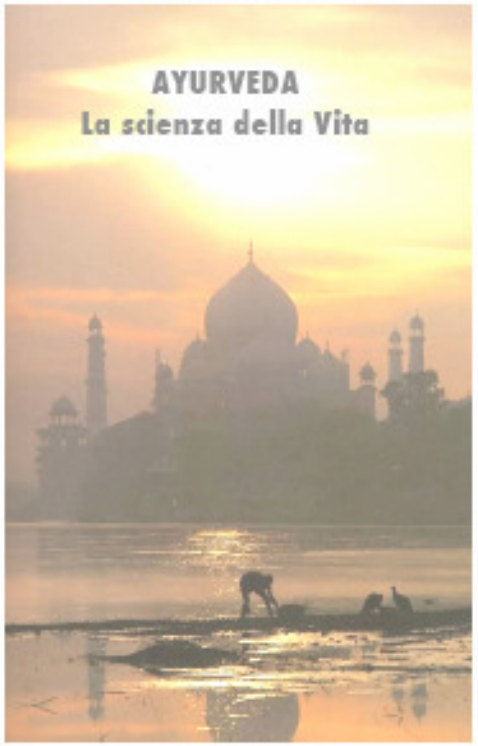
C.I.S.M.O.

Corso per Medici e Farmacisti

Impiego della medicina Ayurvedica a integrazione della medicina tradizionale occidentale

Corso 2007-2008



Sede del corso : ASL di Brescia -Via Duca degli Abruzzi, 15

Relatori

Dr.ssa Huang

Ha frequentato la scuola di MTC presso l'Università di Shanghai dove ha conseguito la laurea in farmacologia. Dopo aver lavorato alcuni anni presso l'Ospedale Beizhan di Shanghai si è trasferita in Italia continuando l'aggiornamento in MTC durante i soggiorni di lavoro e studio in Cina.

Dr.Perini

Laureatosi in Medicina e Chirurgia ha poi conseguito il diploma in Agopuntura frequentando numerosi stage di aggiornamento. Docente del corso di perfezionamento in Agopuntura presso diverse Università, è autore di numerose pubblicazioni.

Presidente dell'UMAB dal 1990

Dr. Favalli

Laureatosi in Medicina e Chirurgia ha poi conseguito il diploma in MTC ed in far macologia cinese. E' stato relatore in numerosi convegni ed è docente ai corsi universitari di perfezionamento in Agopuntura.

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Centro Italiano Studi Medicine Orientali

In materia di Medicina Complementare la Regione Lombardia, a seguito della promozione di studi osservazionali e della sottoscrizione di un programma di cooperazione con l'Organizzazione Mondiale della Sanità, favorisce un approfondimento delle conoscenze relative alla Medicina Complementare, finalizzate ad offrire criteri di sicurezza e di efficacia per la tutela della salute dei cittadini, la tutela dei consumatori e dei fornitori di servizi.

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C.I.S.M.O.

Corso Per Medici e Farmaci

Medicine Complementari nella prevenzione e cura delle malattie:

Medicina Tradizionale Cinese "La porta della Vita"

!5 Dicembre 2007

7 Giugno 2008

Sede del corso

ASL di Brescia

Via Duca degli Abruzzi 15

Points of the lecture

1. A look at the differences between Western and Ayurveda medicine: two separate worlds ?
2. Ayurveda medicine in Italy
3. The C.I.S.M.O.
4. The Local Health Authority of Brescia, Italy
5. **The University of Brescia, Italy**
6. The cooperation of the C.I.S.M.O. with Indian Authorities
7. Future projects

Initiatives by the University of Brescia – Faculty of Medicine

1. An independent Scientific Committee including University professors was established in order to carry out research on oriental medicine, according to the C.I.S.M.O. charter
2. Two experimental studies (randomized controlled trials) using Ayuveda herbs conducted by university professors and physicians are going to start with financial support by the Lombardy Region.
3. A course on complementary medicine (including Ayurveda) for Medical students was held by expert doctors and University professors
4. An article on pros and cons of complementary medicine was written by various University professors and the Dean of the Faculty of Medicine

Two randomised controlled trials with Ayurveda herbal remedies

- **PLACEBO-CONTROLLED, DOUBLE-BLIND, RANDOMIZED CLINICAL TRIAL TO INVESTIGATE EFFICACY AND SAFETY OF PHYLLANTUS AMARUS FOR THE TREATMENT OF CHRONIC HEPATITIS B**

- **A PLACEBO-CONTOLLED, DOUBLE-BLIND, RANDOMIZED TRIAL TO INVESTIGATE EFFICACY AND SAFETY OF GUGGUL AND TRIPHALA FOR THE TREATMENT OF HYPERCHOLESTEROLEMIA AND OVERWEIGHT IN SUBJECTS NOT SUITABLE FOR THERAPY WITH STATINS**

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.

Study ID	*Phyllanthus*	Control	Effect (RR)	95% CI
01 *Phyllanthus* vs. placebo/no intervention				
Leelarasamee 1990	1/49(2.0%)	1/42(2.4%)	0.86	0.06, 13.29
Peng 1993	2/15(13%)	1/13(7.7%)	1.73	0.18, 16.99
Thamlikitkul 1991	2/34(5.9%)	0/31	4.57	0.23, 91.67
Thyagarajan 1988	22/37(59%)	1/23(4.3%)	13.68	1.97, 94.72
Total	27/275(9.8%)	3/197(1.5%)	5.64	1.85, 17.21
02 *Phyllanthus* vs. nonspecific treatment				
Huang 1993	6/62(9.7%)	2/60(3.3%)	2.90	0.61, 13.82
Huang 1999	8/38(21%)	1/32(3.1%)	6.74	0.89, 51.04
Total	14/100(14%)	3/92(3.3%)	4.24	1.25, 14.42
03 *Phyllanthus* vs. other herbal medicine				
Ma 1993	7/30(23%)	3/30(10%)	2.33	0.67, 8.18
Wang 1999b	2/112(1.8%)	0/101	4.51	0.22, 92.91
Zhang 1992	25/100(25%)	5/30(16%)	1.50	0.63, 3.58
Zhang 1996	8/69(11%)	1/37(2.7%)	4.29	0.56, 33.0
Zhang 1997	7/59(12%)	1/37(2.7%)	4.39	0.56, 34.26
Total	49/370(13%)	10/235(4.3%	2.32	1.25, 4.32
04 *Phyllanthus* vs. interferon				
Li 1998	2/30(6.7%)	2/25(8%)	0.83	0.13, 5.50
05 *Phyllanthus* plus interferon vs. interferon				
Wang 1999a	5/40(12%)	2/30(6.7%)	1.88	0.39, 9.01
06 *Phyllanthus* plus thymosin vs. thymosin				
Li 1999b	5/30(16%)	3/30(10%)	1.67	0.44, 6.36
Ouyang 1999	6/42(14%)	1/21(4.8%)	3.0	0.39, 23.33
Total	11/72(15%)	4/51(7.8%)	2.08	0.67, 6.40
07 *Phyllanthus* vs. Poly I:C				
Zhu 1992	2/47(4.2%)	1/28(3.6%)	1.19	0.11, 12.55

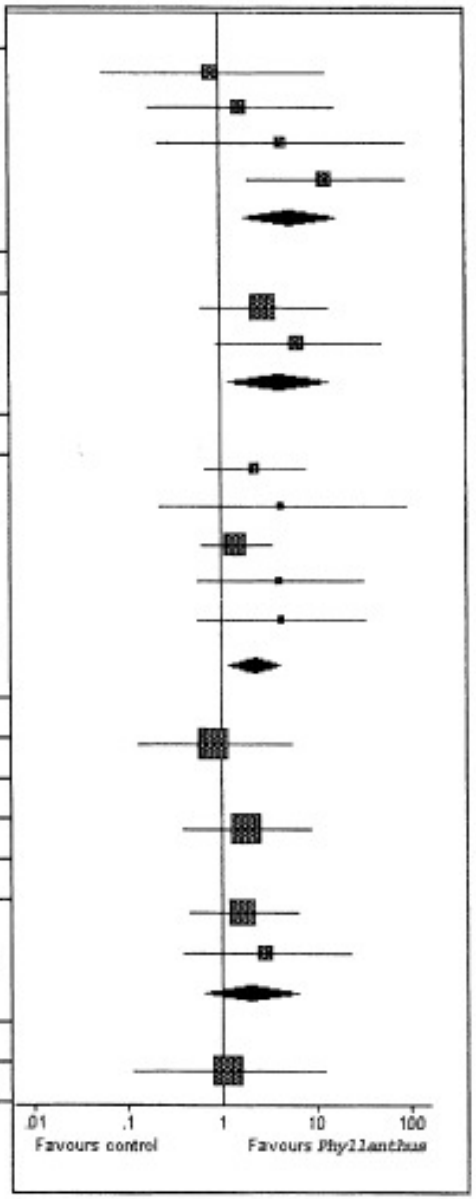

Fig. 1 Loss of HBsAg in RCTs of *Phyllanthus* for chronic HBV infection.

Quality of study

Jadad Score Calculation

Item	Score
Was the study described as randomized (this includes words such as randomly, random, and randomization)?	0/1
Was the method used to generate the sequence of randomization described and appropriate (table of random numbers, computer-generated, etc.)?	0/1
Was the study described as double blind?	0/1
Was the method of double blinding described and appropriate (identical placebo, active placebo, dummy, etc.)?	0/1
Was there a description of withdrawals and dropouts?	0/1
Deduct one point if the method used to generate the sequence of randomization was described and it was inappropriate (patients were allocated alternately, or according to date of birth, hospital number, etc.).	0/−1
Deduct one point if the study was described as double blind but the method of blinding was inappropriate (e.g., comparison of tablet vs. injection with no double dummy).	0/−1

Table 1 Randomized trials of genus *Phyllanthus* in chronic hepatitis B virus infection

Study ID	Year	*n*	Mean age (years)	Sex (% male)	Jadad score	*Phyllanthus*	Control	Length (days)	Follow-up (months)	Reference
Berk	1991	10	36	80	3	Single herb	Placebo	28	No	22
Cao	1998	52	NA*	NA	1	Single herb	Other herbs	90	12	33
Huang	1993	122	NA	NA	2	Single herb	Nonspecific drugs	30	6	29
Huang	1999	70	18–48	80	1	Single herb	Nonspecific drugs	90	No	30
Leelarasamee	1990	116	NA	NA	3	Single herb	Placebo	30	6	23
Li	1998	55	31	78	1	Compound	IFN	90	No	31
Li	1999	90	38	68	1	Compound + thymosin	Thymosin	180	No	39
Ma	1993	60	NA	NA	1	Compound	Mieaoling	150–180	6	34
Milne	1994	105	30	100	3	Single herb	Placebo	60	No	24
Ouyang	1999	89	37	71	1	Single + thymosin	Thymosin	90	No	40
Peng	1993	30	21–58	77	2	Single herb	Placebo	60	1	25
Thamlikitkul	1991	65	25	54	3	Single herb	Placebo	30	No	26
Thyagarajan	1988	60	21	67	4	Single herb	Placebo	30	3	27
Wang	1995	123	34	80	2	Single herb	No intervention	90	No	28
Wang a	1999	70	31	71	1	Compound + IFN	IFN	90	No	42
Wang b	1999	213	12–58	62	2	Compound	Yiganning	90	No	35
Zhang	1992	130	15–65	71	1	Single herb	Other herb	90	No	36
Zhang	1996	106	15–61	72	1	Compound	Mieaoling	90	No	37
Zhang	1997	96	15–61	69	1	Compound	Mieaoling	90	No	38
Zheng	1999	120	13–60	82	1	Compound	IFN	90	3	32
Zhou	1999	90	36	64	1	Compound + IFN	IFN	180	No	43
Zhu	1992	75	14–73	80	1	Single herb	Poly I:C	90	No	41

*NA, no data available. IFN, interferon; Mieaoling, compound of herbs; Poly I:C, poly inosinic and cytidylic acid.

The methodological quality of clinical trials of treatment with *Phyllanthus* herbs for chronic hepatitis B needs to be improved. Rigorously designed, larger randomized, double-blind, placebo-controlled trials are required to evaluate efficacy of *Phyllanthus* herbs in chronic HBV infection. The outcome measures should include virological changes, liver pathology, and end-point events. Long-term adverse events should also be monitored by standardized, effective report system.

Institute of Hygiene, Epidemiology and Public Health
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PLACEBO-CONTROLLED, DOUBLE-BLIND, RANDOMIZED CLINICAL TRIAL TO INVESTIGATE EFFICACY AND SAFETY OF PHYLLANTUS AMARUS FOR THE TREATMENT OF CHRONIC HEPATITIS B

AIMS OF THE RESEARCH

Primary

- to investigate effectiveness of a twelve months treatment with Phyllanthus amarus on the clearance of serum HBVDNA in patients with HBV chronic hepatitis not suitable for standard therapies.

Secondary

- HBVDNA serum levels at months 1, 3, 6, 9 ,12, and 18 to evaluate how study treatment may affect viral kinetics;
- HBsAg and HBeAg (in patients HBeAg+) seroconversion rate
- serum liver enzymes normalization rate during treatment;

STUDY DESIGN

We will perform a placebo-controlled, double-blind, RCT to investigate effectiveness and safety of Phyllanthus amarus in adult patients with CHB.

The two treatment arms are the following:

- Arm A: Phyllanthus amarus: 1 tablet (mg 250) by mouth, twice daily for 12 months;
- Arm B: Placebo: 1 tablet by mouth, twice daily for 12 months.

STUDY DURATION

- **Duration of the RCT: 2 years, including 2 months for study projecting, 3 months for active patients enrolment, 1 year of treatment and 6 months of follow-up after the end of treatment.**

SAMPLE SIZE AND STATISTICAL ANALYSIS

- **Number of patients to include: 140 patients, 70 for each group. We suppose a rate of premature withdrawals of 20/70. The study will allow to observe a proportion of patients with serum HBVDNA clearance of 30% in the treated group vs 2% in the placebo group (relative risk of about 15), with 90% power, 2-sided tests at 0.05 alpha level.**
- **The statistical analysis will be performed by comparing the rate of serum HBVDNA clearance at the end of the Phyllanthus or placebo treatment, according to the intention to treat principle.**

SETTING

- Patients will be enrolled among those affected by CHB regularly followed and treated by the personnel at the Hepatitis Unit, Department of Infectious Diseases, Spedali Civili Hospital in Brescia (Chief: Prof. Massimo Puoti).
- Randomization will be centrally controlled by an epidemiologist working at the Institute of Hygiene, Epidemiology and Public Health of the University of Brescia.

ESTIMATED COSTS

- Costs for additional laboratory tests have a total of about 162.49 euro per patient with a total of 162.49*140=22728.6 euro. Other 7000 euro should be provided for one physician who will see all patients included in the study during therapy and follow-up. No costs for insurance and Ethics Committee examination of the protocol are necessary as the project has no sponsorship and it has no commercial aim.

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

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www.elsevierhealth.com/journals/ctim

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

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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.

Conclusion

Prior to 2003, the majority of scientific evidence suggested that guggulipid elicits significant reductions in serum total cholesterol, low-density lipoprotein, and triglycerides, as well as elevations in high-density lipoprotein.[1–11] However, most published studies were small and methodologically flawed. In August 2003, a well-designed trial reported small significant *increases* in serum LDL levels associated with the use of guggul compared to placebo.[12] No significant changes in total cholesterol, high-density lipoprotein, or triglycerides were measured. These results are consistent with two prior published case reports.[13] Although this evidence provides preliminary evidence against the efficacy of guggul for hypercholesterolemia, due to the precedent of prior research and historical use, further study is necessary before a definitive conclusion can be reached. There is no reliable research comparing guggul preparations with HMG-CoA reductase inhibitors (''statins''), or evaluating long-term effects of guggul on cardiac morbidity or mortality outcomes. Safety concerns exist as outlined above.

Guggulipid for the Treatment of Hypercholesterolemia

A Randomized Controlled Trial

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Context Herbal extracts from *Commiphora mukul* (guggul) have been widely used in Asia as cholesterol-lowering agents, and their popularity is increasing in the United States. Recently, guggulsterones, the purported bioactive compounds of guggul, have been shown to be potent antagonists of 2 nuclear hormone receptors involved in cholesterol metabolism, establishing a plausible mechanism of action for the hypolipidemic effects of these extracts. However, there are currently no published safety or efficacy data on the use of guggul extracts in Western populations.

Objective To study the short-term safety and efficacy of 2 doses of a standardized guggul extract (guggulipid, containing 2.5% guggulsterones) in healthy adults with hyperlipidemia eating a typical Western diet.

Design Double-blind, randomized, placebo-controlled trial using a parallel design, conducted March 2000-August 2001.

Participants and Setting A total of 103 ambulatory, community-dwelling, healthy adults with hypercholesterolemia in the Philadelphia, Pa, metropolitan area.

Intervention Oral, 3 times daily doses of standard-dose guggulipid (1000 mg), high-dose guggulipid (2000 mg), or matching placebo.

Main Outcome Measures Percentage change in levels of directly measured low-density lipoprotein cholesterol (LDL-C) after 8 weeks of therapy. Secondary outcome measures included levels of total cholesterol, high-density lipoprotein cholesterol (HDL-C), triglycerides, and directly measured very low-density lipoprotein cholesterol (VLDL-C), as well as adverse events reports and laboratory safety measures including electrolyte levels and hepatic and renal function.

Results Compared with participants randomized to placebo (n=36), in whom levels of LDL-C decreased by 5%, both standard-dose guggulipid (n=33) and high-dose guggulipid (n=34) raised levels of LDL-C by 4% (P=.01 vs placebo) and 5% (P=.006 vs placebo), respectively, at 8 weeks, for a net positive change of 9% to 10%. There were no significant changes in levels of total cholesterol, HDL-C, triglycerides, or VLDL-C in response to treatment with guggulipid in the intention-to-treat analysis. While guggulipid was generally well tolerated, 6 participants treated with guggulipid developed a hypersensitivity rash compared with none in the placebo group.

Conclusions Despite plausible mechanisms of action, guggulipid did not appear to improve levels of serum cholesterol over the short term in this population of adults with hypercholesterolemia, and might in fact raise levels of LDL-C. Guggulipid also appeared to cause a dermatologic hypersensitivity reaction in some patients.

JAMA. 2003;290:765-772 www.jama.com

GUGGUL IS AN EXTRACT FROM the resin of the mukul myrrh tree (*Commiphora mukul*). The medicinal use of guggul dates back to 600 BC, when it was used for obesity, atherosclerosis, and various inflammatory conditions.[1,2] The plant sterols E- and Z-guggulsterone are believed to be the bioactive compounds.[2,3] Recent research indicates that guggulsterones are antagonists of the farnesoid X receptor (FXR)[4,5] and the bile acid receptor (BAR),[6] 2 nuclear hormone receptors involved in bile acid regulation and cholesterol metabolism.

To date, there have been 9 published human clinical trials evaluating the hypolipidemic effect of guggul extracts.[7-15] However, only 5 studies used a standardized guggul extract (guggulipid),[7-11] only 2 of these were randomized,[9,10] and only 1 was placebo-controlled.[10] In the randomized studies, guggulipid reduced levels of total cholesterol by 11%, of low-density lipoprotein cholesterol (LDL-C) by 12%, and of triglycerides by 15%.[9,10] Guggulipid received regulatory approval in India in 1987 for use as a lipid-lowering drug, and it is available in the United

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A PLACEBO-CONTOLLED, DOUBLE-BLIND, RANDOMIZED TRIAL TO INVESTIGATE EFFICACY AND SAFETY OF GUGGUL AND TRIPHALA FOR THE TREATMENT OF HYPERCHOLESTEROLEMIA AND OVERWEIGHT IN SUBJECTS NOT SUITABLE FOR THERAPY WITH STATINS

AIMS OF THE RESEARCH

Primary

- to investigate the efficacy and safety of three months' treatment with a combination of Guggul and Triphala on the blood levels of cholesterol in subjects with both hypercholesterolemia (200-300 mg/dl) and overweight (BMI: >25 and <35), who are not suitable for therapy with statins, due to their relatively low global cardiovascular risk (< 20% of events expected in the next 10 years).

Secondary

- To reduce LDL and triglyceride blood levels
- To reduce body weight
- To reduce cardiovascular risk
- To assess safety of treatment

STUDY DESIGN

- **We will perform a placebo-controlled, double-blind RTC to investigate the efficacy and safety of Guggul and Triphala in adults with both hypercholesterolemia (200-300 mg/dl) and overweight (BMI: >25 and <35) who are not suitable for therapy with statins, because of their relatively low global cardiovascular risk. The two treatment arms are the following:**
- **Arm A: GUGGUL + TRIPHALA combination:**
- **GUGGUL (*Commiphora mukul Hook, one* 200mg tablet): one tablet by mouth three times a day for 3 months**
- **TRIPHALA (*Mirobolano chebula - Terminalia chebula Retz*., - 150 mg powder, *Mirabolano belerico - Terminalia belerica Roxb*., - 150 mg powder and *Mirabolano emblico - Phyllanthus emblical*, - 150 mg powder): two 200 mg tablets three times a day.**
- **Arm B: placebo, 2 tablets by mouth, three times a day for 3 months**

STUDY DURATION

- The total duration of the study is 12 months: 2 months for organizing the study, 3 months for active patient enrolment, 3 months for treatment, 3 months of follow-up after the end of treatment, and 1 month for statistical analysis and reporting.

SAMPLE SIZE AND STATISTICAL ANALYSIS

- The study design includes the enrolment of 120 subjects, 60 for each arm. The study will allow researchers to observe a decrease in blood cholesterol of at least 10% in the treatment vs the placebo group. Assuming a mean total blood cholesterol of 250 mg/dl in enrolled subjects, with a standard deviation (SD) of 25, decrease to 225 mg/dl is expected at the end of the three-month treatment. Supposing a rate of premature withdrawals of 10/60, we would have a global reduction of blood cholesterol to 229 mg/dl (8%) contrasted with no substantial change in the control group. Enrolling 60 subjects for each group will allow us to show a statistically significant difference with a 95% power, in a 2-sided test, assuming a 0.05 alpha level.
- The statistical analyses will be performed by comparing the mean of the total cholesterol levels at the end of the treatment between the two groups, according to the intention-to-treat principle.

SETTING

- **Subjects will be enrolled by their General Practitioners (GPs). We expect 20 GPs to take part in the research, with a minimum of 6 patients each.**
- **Subjects will undergo the following examinations:**
- **GP's visit (anamnesis and measurement of weight, height, blood pressure, waist circumference, etc.) to evaluate global cardiovascular risk at the start;**
- **blood levels of cholesterol (LDL and HDL) and other common blood parameters to evaluate possible side effects of the treatment (blood biochemical common exams + LDH and CPK and serum creatinine);**
- **evaluation of side effects using a questionnaire (myalgia, myasthenia, myopathy, etc.)**
- **Randomization will be performed centrally by an epidemiologist working at the Institute of Hygiene, Epidemiology and Public Health of the University of Brescia.**

ESTIMATED COSTS

Total estimated costs are € 25.410, as detailed below:

- **€ 70 will be provided to the GPs for each subject enrolled, giving a total cost of € 8,400;**
- **a coordinating doctor will receive € 4,000;**
- **blood biochemical exams: € 9410;**
- **experimental medicines: € 3,600.**
- **The study has no sponsor and no conflict of interest. An application form requesting financial support for the study was sent to the Lombardy Region on 26th February 2007.**

Points of the lecture

1. A look at the differences between Western and Ayurveda medicine: two separate worlds ?
2. Ayurveda medicine in Italy
3. The C.I.S.M.O.
4. The Local Health Authority of Brescia, Italy
5. The University of Brescia, Italy
6. **The cooperation of the C.I.S.M.O. with Indian Authorities**
7. Future projects

Agreement with Sh. Dhanwantry Educational Society

- A memorandum of understanding was signed between Shri Dhanwantry Educational Society (Chandigarh) and the C.I.S.M.O. on 11th October 2006 in Chandigarh.
- “The cooperation between the C.I.S.M.O. and Dabur-Dhanwantry Hospital can contribute to induce the Italian Health Organization to recognize the practice of Ayurveda Medicine in Italy.”

Agreement with the Central Council for Research in Ayurveda and Siddha (CCRAS), Department of Ayush, Gov. of India

- An agreement of cooperation was signed between the CCRAS and the C.I.S.M.O. on 13th October 2006 in Delhi.

OBJECTIVES AND SCOPE

- To promote cooperation in the field of Ayurveda and Siddha and interelated sciences to furher advance, propagate research in Ayurveda and Siddha systme of medicines and its validation scientifically and cooperate each other through collaborative research programme.
- Both parties will share their research activities especially in reference to use of drugs and other therapies for prevention and treatment of chronic diseases.
- ….
- In addition to joint monitoring ther will be seminars/workshops in both the countries related to the specific disease condition.

Points of the lecture

1. A look at the differences between Western and Ayurveda medicine: two separate worlds ?
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5. The University of Brescia, Italy
6. The cooperation of the C.I.S.M.O. with Indian Authorities
7. **Future projects**

What's on in the next future?

1. **Brescia Local Health Authority:**
   - An oriental medicine (Indian and Chinese) clinic for wellbeing, health promotion and preventive medicine
   - New courses for Western physicians and pharmacists
   - A one day course on back massage

2. **Brescia University:**
   - Other experimental studies (randomized controlled trials) using Ayuveda herbs conducted by university professors
   - A course on complementary medicine (including Ayurveda) (2nd edition)

Two different views of medicine : a bridge between two cultures