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Non-conventional medicine

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Agenzia sanitaria regionale
viale Aldo Moro 21 - 40127 Bologna - Italy
fsarti@asr.regione.emilia-romagna.it

The booklet can be downloaded from
www.regione.emilia-romagna.it/agenziasan

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Why should the NHS include non-conventional medicine?

The Italian National Health Service (NHS) is committed to providing health care to the public in effective and appropriate ways. It is therefore engaged in a continuous scientific evaluation of the quality of medical assistance procedures usually adopted.

People often refer to other medical practices, such as acupuncture, herbal medicines, homeopathy, etc., not offered by the NHS and claim that these are also effective. The perception that these practices imply less risk may partly explain their growing popularity, but this is also a controversial aspect of such practices that requires further study.

The diffusion of non-conventional medicine (NCM; see section “What is non-conventional medicine?”) involves many physicians and other health professionals whose attitude towards NCM is changing. The National Federation of Medical and Dentists’ Associations (FNOMCeO)¹ is requesting the formation of a National Agency with a role in research, education and information, and for a specific NCM legislation. The FNOMCeO considers most of the procedures connected with NCM as medical acts. Therefore they should be:

- practised only by physicians;
- offered to those patients that could derive some benefits, only after obtaining adequate and complete information and having patient’s consensus;
- included as educational courses in Continuing Medical Education programs.

Many experts have stressed the importance of maintaining a strictly scientific, evidence-based approach when dealing with NCM. It follows that there are no ‘alternative’ medicines: there are medicines that are have been proved effective based on scientific data, and there are medicines for which there is insufficient evidence of efficacy. It is necessary to prevent the risk of an improper demand for NCM, which is based not only on the desire to solve health problems, but often also conditioned by irrational attitudes or particular interests.

Is it advisable for the NHS to consider NCM? The NHS has to commit to the evaluation of data and knowledge on NCM, as it is of interest to

Editor

Marco Biocca, Agenzia sanitaria regionale dell’Emilia-Romagna

In collaboration with:

Xiaorui Zhang, Team Coordinator, Traditional Medicine, Department of Essential Drugs and Medicines Policy, WHO, Geneva

Elisabetta Minelli, Intern, Traditional Medicine, Department of Essential Drugs and Medicines Policy, WHO, Geneva

Erus Sangiorgi, Centro di metodologie naturali delle Terme di Riolo (Ravenna)

Umberto Solimene, Centro di ricerche in bioclimatologia medica, biotecnologie e medicine naturali, Università di Milano

The editor is grateful to the following experts for their collaboration and contributions:

Luigi Bertani, Ordine dei medici chirurghi e odontoiatri di Modena

Giorgio Cocconi, Ordine dei medici chirurghi e odontoiatri di Parma

Francesca Menniti-Ippolito, Istituto superiore di sanità, Roma

Giuseppe Traversa, Istituto superiore di sanità, Roma

many people. Furthermore, it is important to recognize what is useful and to alert people against what can be useless or even dangerous.

In Italy, there is currently no national policy or regulation on NCM. Article 9 of Decree 229/1999 on NHS integrative funds does not include NCM among essential and uniform levels of health care (LEA) but lists them among additional services. During the previous legislature, a number of proposals were presented in this regard to the Italian Parliament for it to officially recognise NCM; an integrated version of these proposals is now being discussed.

There are three sets of obstacles that can be addressed through the following questions:

1. What is the therapeutic effectiveness of NCM? What are the possible risks? How can these aspects be studied and controlled?
2. What are the professional competence and skills necessary to practise NCM? What criteria can be adopted to officially recognize those who can practice NCM and where they can practise it?
3. What guidelines should be followed to identify adequate schools and educational systems ?

One of the main reasons for the increasing focus on NCM is the search for “soft” therapeutic methods, and improved relations between patients and physicians which were impoverished in the last years by the development of health organization and the parcelling of medical knowledge.² Moreover, longer life expectancy has brought with it increased risks of developing chronic, debilitating illnesses such as heart disease, cancer and mental disorders. For many patients, the healthcare available for the treatment of these illnesses is not sufficiently efficacious.

The focus on NCM should not be confused with the necessity to reinforce communication and collaboration between the public and health services. These are fundamental elements and have to be considered as priorities for innovation and improvement in the NHS.

This booklet provides essential and useful information on important aspects of NCM. It is not exhaustive in itself, but should be considered as a step in the process of gaining a better understanding of NCM, with the awareness that any choice about healthcare should be based on stakeholders’ full consciousness.

It is mainly addressed to general practitioners and health professionals, but also to anyone interested in forming a more conscious opinion.

What is non-conventional medicine?

The World Health Organization has launched a global traditional medicine strategy³ that includes “diverse health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness”.

The Cochrane Collaboration uses the following definition for NCM: “a wide range of therapeutic resources that involves all health systems, procedures and practices, and their supporting theories and beliefs, and that is different from those of the health systems dominant in a society or culture at a specific moment”.

In the Report by a White House Commission⁴ *complementary* medicine (treatments adopted as integrations to others) and *alternative* medicine (medical and surgical treatments instead of others) are defined by their differences in relationship with traditional medicine.

The European Parliament (Resolution May 29, 1997) and the European Council (Resolution 1206/1999)⁵ deal with *non-conventional* medicine therapies, considering them as a set of health systems and therapeutic disciplines that share a particular aspect (their validity is not or is only partially recognized), and ask for a coordinated approach for all countries.

In this booklet we have used the expression “non-conventional medicine” (NCM). It is not completely satisfactory, but it seems to the authors the most complete and common and the least affected by prejudice.

NCM therapies have diverse origins and there are significant differences between them. In addition, there is no shared classification system. For this reason they are usually only listed. To describe and to get to know NCM better, it would be useful to classify them in a more articulate way.^{3 6 7}

In general, it is possible to distinguish between two large categories of NCM according to the kind of therapy:³

- those that use medicines (of plant, animal or mineral origin)
- and those that do not.

Some NCM therapies are autonomous medical systems, with their own theories, procedures and scientific literature. They often have their own institutions, schools and professional associations. The most popularly used are: Chinese traditional medicine including acupuncture, Ayurvedic Indian Medicine, Homeopathy and Chiropractic in all its branches.

Phytotherapy and Diets have historically been very important. These therapies have their own theories, but they are based on biological principles similar to those in food science and pharmacology.

Manual treatments constitute a group with specific characteristics: they are manipulation methods similar to physiotherapy principles. Chiropractic and Osteopathy are the most popularly used. This section includes various massage techniques, e.g., foot reflexology and Shiatzu.

Exercise-therapy belongs to physical activities, that include also Ti ji, Qigong, Yoga and others.

Other interventions also exist, but they are much less popular in Italy and they will not be considered in this text.

Which non-conventional medicine therapies are most commonly used and by whom?

NCMs are widely used⁸ world wide, but data on their use are not many and often not comparable. In the European Union, on the average 1 person out of 4 turns to an NCM therapy at least once a year.³

According to the last survey on health⁹ conducted by ISTAT (Italian National Institute of Statistics) at the end of 1999 in collaboration with the National Health Service, about 9 million Italians have referred to NCM practises at least once in the 1997-1999 period. This is 15.6% of the population and twice the number in 1991. In Emilia-Romagna, the percentage is even higher: about 840.000 people, or 21.3% of the population. In more than 1 family out of 3, one person has turned to NCM practises in the 1997-1999 period.

According to ISTAT data collected over a three-year period, the NCM therapies most often used are homeopathy, followed by manual treatments, phytotherapy, acupuncture, and finally the others (see Table 1).

Table 1. Percentage of people who turned to at least one NCM therapy in the 1997-1999 period (data from ISTAT survey, 2001)

Therapy	Emilia-Romagna	North-western Italy	North-eastern Italy	Central Italy	Southern Italy	Italy
Homeopathy	11.8	11.8	12.8	8.3	2.5	8.2
Manual treatments	9.1	9.5	10.8	7.4	2.9	7.0
Phytotherapy	6.8	6.2	8.5	4.4	1.9	4.8
Acupuncture	4.9	3.8	4.0	2.9	1.5	2.9
Other	1.7	1.8	2.0	1.5	0.5	1.3
All	21.3	20.7	24.1	16.3	6.5	15.6

In recent years, interest has grown particularly in Homeopathy: on a national level its use has tripled between 1991 and 1999; the use of the others has also increased. Women (about 5.5 million in Italy, 18,2%) are more involved than men (about 3.5 millions in Italy, 12.9%). In Emilia-Romagna, the variation between genders is even higher: about 550.000 women (26.8%) and 297.000 men (15.5%).

Adults between 35 and 44 years are most likely to turn to NCM. At least 1 woman out of 4 and 1 man out of 5 in this age range have used NCM. Elderly people prefer acupuncture, probably as a remedy for painful syndromes.

On the whole, NCM is administered to children less often: 9.2% in Italy and 15.4% in Emilia-Romagna under 14 years of age; 10.4% in Italy and 19.0% in Emilia-Romagna between 3 and 5 years. Children are mostly treated with homeopathy and, obviously, treatment of children is related to their parents' preferences.

The inclination to use NCM increases in proportion to educational qualification: in Emilia-Romagna only 15.4% of people that have at most a primary school certificate turn to NCM, whereas for people with a degree the figure is 32.8%. This is true in particular for homeopathy, and less for acupuncture and the other therapies. Homeopathy is frequently used by families that have declared a better earning power which is, at least partially, linked with the level of education.

Nearly 70% of people that have tried some NCM therapy say that they benefited from the treatment; 17.7% say that they benefited partially, and only 3.3% declared no or negative effects. The most satisfied people seem to be those that have turned to manual treatments (77.6%).

Family doctors are usually informed of the intention to try some NCMs (about 60%), in particular if children or elderly people are concerned (respectively 79% and 68.6%).

In Emilia-Romagna these values are even higher; in fact, in 37.6% of cases the use of NCM is suggested directly by the physician. The percentage increases up to 65% among elderly people.

A survey recently conducted by the Medical Association in Parma among its members reveals that as a whole 8.3% of them directly practise an NCM therapy. Physicians employed in public structures (hospitals or universities) are less likely to practise NCM therapy (4.2%). This figure is higher for self-employed doctors (11.1%), those practising in the NHS (12.7%), paediatricians (12.2%), specialists in anaesthesiology/reanimation (13.8%) and specialists in practices connected with locomotive apparatus (24.7%). As a result of the ISTAT survey, the problem of NCM is emerging from a mysterious limbo: "mysterious were the attitudes both of sceptics and detractors, who were scandalized by the idea to deal with these practises even only by talking of them, and

of experts and practitioners, made cautious by the lack of official, legal and normative references for the practises".¹⁰

Nearly 80% of physicians in Parma say that they receive requests for NCM services, but from a minority of their patients. 53% believe that NCMs have "some" efficacy. This question was formulated to allow prudent answers, but it still seems a significant percentage, higher among women doctors. Among NCM practitioners, 82% say they use NCM for locomotive pathologies, 32% for neuropsychic problems and somatizations, and 28% for headaches and migraines. Homeopathy is the most commonly used, but many other therapies are often integrated with conventional procedures.

The Ministerial Decree of July 22, 1996 on "Outpatient specialist assistance services that can be supplied by the NHS, and their prices" includes acupuncture services.

Is there any evidence of the therapeutic efficacy of NCM? Can it be dangerous?

The wider use of NCM, the increasing access to information on health and, more generally, the growing concern as regards negative effects of medical treatments have given rise to a pressing demand for evidence of therapeutic efficacy and safety of NCM, and of product quality.

The experimental clinical method - i.e., randomised and controlled clinical trials based on comparative observations of people affected by similar pathologies but treated in different ways - is the main instrument used at the moment to evaluate the effective therapeutic potential of a treatment.

However, some doubts have arisen on the possibility to apply the same methods to NCM, as many of these therapies are based on “holistic” principles. It follows that treatment should take into account not only a person’s physical condition, but also the psychological and social conditions . Many research studies on NCM efficacy are based on the analysis of single cases or groups of patients, without any comparison with control groups. Moreover, this position also highlights some contradictions in conventional medicine.¹¹

The difficulty of finding scientific evidence, which is implicit in NCM, cannot be a sufficient justification to accept only subjectivity and to refuse any commitment to evaluation research. Attention should be focused not on action mechanisms but on the effects on health since resources are limited. In such a way a comparison among interpretations is possible, and can promote integration strategies among different procedures.

In the following sections, some background information is provided on the NCM therapies identified as those most commonly used, along with a synthesis of the main scientific evidence collected by qualified independent sources. Specific bibliographic references are quoted in footnotes; more general ones are listed in the section “Where can further information be obtained”.

Some instructions to avoid negative effects of the treatment are also signalled. The “natural” approach or the long history that many NCM researchers stress should not be confused with an intrinsic harmlessness and efficacy.

It should, however, be noted that - in addition to possible specific risks in the adoption of a particular therapy - there can also be adverse consequences of not using or interrupting more efficacious conventional treatments.

Finally, scientific training of the health professionals providing NCM should be considered, in a context that has no precise rules and relies only on individual responsibility.

Acupuncture

What is acupuncture?

Acupuncture is part of Chinese ancient medicine. It is the stimulation of specific points of the body, usually by insertion of fine needles. Selection of points to be treated depends on the knowledge and skills of the practitioner.

“Traditional” acupuncture theory sees illness in terms of excess or deficiencies in various exogenous and endogenous factors, and treatment is aimed at restoring balance. Needles are inserted at specific points which lie under the skin along invisible channels. The channels carry energy and are called “meridians”.

Orthodox medical trained doctors also practice acupuncture and they could adopt Western style diagnostic approaches to associate with acupuncture treatment.

Which patients or conditions would benefit most from treatment?^{12 13 14 15}

Acupuncture is often successfully used:

- for **chronic pain**;
- in the treatment of **headache**, dysmenorrhoea, nausea and vomiting after surgical operations or chemotherapy, and for pain relief after surgical operations;
- in the treatment of neck and facial pain and in general of any chronic muscular and skeletal pain;
- for cessation of smoking.

Although it cannot be assessed with certainty that acupuncture is in fact efficacious, this does not mean that it has not brought positive effects in many cases.

Attention to¹⁶

- Infections due to inadequately sterilised needles.
- Interventions on patients with coagulation problems.
- Interventions in emergency cases, which should not be treated by acupuncturists who do not have enough western medical knowledge.
- Electrostimulation in patients with pacemaker or suffering from arrhythmia or convulsions which should not be treated by acupuncturists who has not enough western medical knowledge.

Homeopathy

What is homeopathy?

Homeopathy is a diagnostic and therapeutic system developed in the 19th century in Central Europe. It uses very low dose preparations which are selected according to the principle that a substance that produces symptoms very similar to the disease in a healthy person, may also cure it (*similia similibus curantur*). Symptoms are considered the method of the organism to fight the disease; therefore, medicine should help the organism in its fight rather than act directly on the disease.

Selected plants, minerals or animal substances are treated with particular chemical procedures to get a hydro-alcoholic solution called tincture. It is gradually diluted and made more powerful through strong shakes of the container (succussion). Lactose is added to the final dilution, which has a very low concentration of substance but high energy level, to prepare homeopathic pellets.

The homeopath provides general medical advice followed by specific homeopathic information to evaluate symptoms and find their origin. There are different therapeutic approaches that use medicines prepared according to the homeopathic pharmacopoeia: the “single” approach uses one single remedy; the “plural” or “complex” approach uses more remedies at the same time.

The definition “homeopathy” includes anthroposophic medicine and homotoxicology.

Which patients or conditions would benefit most from treatment?^{17 18 19 20}

Homeopathy is used to treat a wide range of acute and chronic physical and emotional illness (allergies, pathologies of vascular and gastrointestinal systems, coagulation problems, influenza, etc.). However, there is neither evidence of effectiveness of homeopathy in particular conditions, nor against its use.

Some results are registered in the following cases:

- when there is no known diagnosis, and test are normal but the patient feels unwell;
 - where drug treatments are poorly tolerated or contra-indicated;
 - in patients who suffer from repeated episodes of acute functional illnesses.
- Specific conditions for which homeopathy seems to be more useful are those where there is an allergic component, for example asthma, rhinitis, hay fever or urticaria.

Attention to

- Risk deriving from not using or interrupting more efficacious conventional treatments.
- Scientific training of the health professionals.

Phytotherapy

What is phytotherapy?

Phytotherapy uses medicines mainly of **plant origin**. The use of phytotherapy is widespread in many places of the world since ancient times. It is registered also in Western medicine tradition, through the transcriptions of ancient books by Middle Ages monks and phytogeographic naturalist physicians.

Pharmacology has studied active ingredients of plants, some times it has used extracts, some others use combination or mixture medicinal plants. Phytotherapeutic prescriptions should be based not only on symptoms, but also on the theory and diagnosis of traditional medicinal systems such as Chinese medicine and Indian medicine.

Extracts from plants are marketed as tablets (dried extracts), hydro-alcoholic dyeing, glyceric extracts, oils, herbal teas. Many compounds are prepared with different elements. The appropriate dose and treating period are needed.

Which patients or conditions would benefit most from treatment?

The possible application of phytotherapy is too wide to be treated. The World Health Organization has published a number of documents on the subject.²¹

Attention to

The phytotherapeutic medicines have their indications and contraindications, appropriate dosage as well as precautions. Patients should either follow the indications or consult with phytotherapy providers. WHO is developing consumer guidelines for proper use of traditional medicine which will help the patients and consumers in the safe use of phytotherapy.

The Istituto superiore di sanità (Italian National Institute of Health) has promoted a surveillance pilot study on adverse reactions to medicinal herbal products.²²

WHO has its Drug Monitoring Programme. There are 60 countries participated this system including Italy. This system will expand to monitor herbal medicines. WHO guidelines for herbal medicine safety monitoring is in preparation. The guidelines will provide technical guidance to facilitate expansion of existing systems to monitor and report adverse drug reaction to herbal medicines or establish national safety monitoring systems where these do not already exist and to support countries in strengthening the post marketing surveillance system for herbal medicines.

Manual treatments (chiropractic and osteopathy)

What are chiropractic and osteopathy?

Chiropractic was first developed at the end of the 19th century in the United States. It aims at diagnosing and treating mechanical disorders of spinal joints, muscles and ligaments by manual adjustment. Laboratory tests and x-rays are sometimes used as an aid to diagnosis. Chiropractic is based on the premise that dysfunction of the spine, pelvis and extremity articulations may disturb associated nerve function. This in turn may lead to painful syndromes or specific pathologies. If a patient is deemed suitable for chiropractic care, treatment will consist mostly of specific manipulation adjustments. An emerging treatment, especially for back and neck pain, is “active rehabilitation”, based around fitness and endurance regimens which are tailored to the patient’s abilities. This approach is also used by osteopaths.

Osteopathy is a system of manual medicine which is concerned with the interrelationship between the structure of the body and the way in which the body functions. Osteopaths are trained in orthodox medical assessment and diagnostic procedures. They treat by manipulating the musculo-skeletal system, convinced that illness occurs when body mechanics are not sound. Emphasis is placed on identifying factors which may be maintaining the problem. A variety of techniques are used to correct the underlying cause of pain. These include massage to relax stiff muscles; stretching to help joint mobility; and manipulation and high-velocity thrust techniques. As in chiropractic, “active rehabilitation” is also used.

In manual treatments, usually no medicines of any kind are used.

Which patients or conditions would benefit most from treatment?^{23 24}

In general, disorders of bones, muscles, tendons and fleshy tissues are treated by chiropractic, osteopathy and also other manipulative techniques, to reduce the pain and re-establish organism’s normal activities. Among these problems, the main are:

- **acute low back pain and simple backache.** Manipulation provides better short-term improvement in pain and activity levels and higher patient satisfaction than other treatments to which it has been compared;
- **low back pain** associated with dysmenorrhoea and headaches;
- **neck pain.** Mobilisation produces at least short-term benefits; manipulation is probably slightly more effective than mobilisation or physical therapy for patients with sub-acute or chronic neck pain;
- **disorder and pain of muscle, joints, tendons and bones on limbs.**

Attention to

Manual treatments cannot be practiced in case of fractures, serious lesions or osteoporosis. Manual treatments should be carefully used on elderly people and patients with fragile bone. It is very important that professionals practising these treatments have received an adequate training.

Where can further information be obtained

HYPERLINK

World Health Organization (WHO)

WHO has developed a Traditional Medicine Strategy for 2002-2005, to create a reference framework for national policies to promote the most appropriate use of these therapies. WHO has published many documents, in particular on evaluative methods and on existing legislations, and some monographs on medicinal plants and acupuncture:

- WHO, *Legal status of traditional medicine and complementary/ alternative medicine. A worldwide review* (in press)
- WHO, *Traditional medicine strategy 2002-2005*, Geneva, 2002
- WHO, *Acupuncture: review and analysis of controlled clinical studies*, Geneva, 2002
- WHO, *Monograph on selected medicinal plants*, vol. 1, Geneva, 1999; vol. 2, Geneva, 2002
- WHO, *General guidelines for methodologies on research and evaluation of traditional medicine*, Geneva, 2000
- WHO, *Guidelines on basic training and safety in acupuncture*, Geneva, 1999

More details can be found in the WHO website (www.who.int/medicines/organization/trm/orgtrmmain1.shtml) or www.who.int/medicines/library/trm/trmmaterial.shtml).

EMA - European Agency for the Evaluation of Medicinal Products

In 1997 EMA promoted a Herbal medicinal products working party. The Group mainly works for information and research exchange, to orient quality and safety evaluation of herbal medicinal products.

More details can be found in the EMA website (www.emea.eu.int).

IN THE USA

Beyond the Report by the White House Commission already quoted,⁴ a National Center for Complementary and Alternative Medicine (NCCAM) has been constituted at the National Institutes of Health (NIH). Interesting information can be found in its website (nccam.nih.gov).

The *Journal of American Medical Association (JAMA)* has published a monograph on "Alternative Medicine" (280: 1549-1640, 1998).

More recently, also the *American Journal of Public Health* dedicated a monographic issue to this subject (92, 1561-1672, 2002).

IN GREAT BRITAIN

The House of Lords has prepared and published an important Report on "Complementary and alternative medicine", *HL Paper 123*, Stationery Office, London, 2000 (www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/123/12301.htm)

The Department of Health has published an interesting document for the diffusion of information to health professionals which has been largely used also in this booklet: Bonnet J., *Complementary medicine: information pack for primary care groups*, UK Department of Health, June 2002.

On the *British Medical Journal* great attention is given to NCM (bmj.com/cgi/collection/complementary_medicine). Many articles published in 1999 were collected in a volume: Zollman C. and Vickers A.J. (eds.), *ABC of complementary medicine*, BMJ Books, London, 2000.

EVIDENCE BASED MEDICINE

Evaluative studies on NCM therapeutic effectiveness can be looked for in many web sites, for example:

Bandolier (www.jr2.ox.ac.uk/bandolier/booth/booths/altmed.html)

The Cochrane Library (www.cochrane.org)

IN ITALY

Istituto superiore di sanità - ISS (Italian National Institute of Health)

The Istituto superiore di sanità has promoted a surveillance project on adverse reactions to medical herbal products (see Phytotherapy) and co-ordinates a project on *Non-conventional therapies* to collect systematic information, to study the possible risks for health and to evaluate the evidence of efficacy, safety and quality of these practises. First results are published in Raschetti R., Menniti-Ippolito F., Forcella E. et al., "Le terapie non convenzionali in Italia: i primi dati", *Notiziario ISS*, 14 (7/8): 11-14, 2001.

Roberto Raschetti and Giorgio Bignami have edited a "Multidisciplinary evaluation of non-conventional therapies" and published a collection of papers, referred to also in these pages ("Riflessione multidisciplinare sul fenomeno delle terapie non convenzionali", *Annali dell'Istituto superiore di sanità*, 35 (4): 477-552. 1999).

More details can be found in the ISS website (www.iss.it).

Medico-legal aspects

Norelli G.A., Monelli A., Magliona B., Papp L. e Giannelli A., of the University of Florence, have published a complete article: "Aspetti medico-legali dei trattamenti non convenzionali", *Rivista italiana di medicina legale*, 24: 305-332, 2002.

Other references in Italian

Many organisations deal with NCM in Italy and there are many websites with interesting information. Among the many scientific and popular publications, some are listed here; the list is however not complete, and there was no qualitative evaluation on the information presented.

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Omeopatia: gli studi scientifici che ne provano l'efficacia, Guna editore, Milano, 2002.

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Linee guida di agopuntura e medicina tradizionale, Red Edizioni, Milano, 2001 (www.naturmed.unimi.it/index.html).

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Federazione italiana delle società di agopuntura FISA
(www.agopuntura-fisa.it/index.asp)

Agopuntura. Evidenze cliniche e sperimentali, aspetti legislativi e diffusione in Italia, Casa editrice ambrosiana, 2000.

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