

# Integration of homeopathy and complementary medicine in the public health system in Italy: national regulation and regional experiences

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Received: 11 June 2014 / Accepted: 16 September 2014 / Published online: 19 November 2014  
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**Abstract** Complementary medicine (CM) is being increasingly used by citizens across Europe as a means to maintain their health and to treat illness and disease. In Italy the reform of Title V of the Italian Constitution allows each Region to decide how to put into practice and organize the Public Healthcare System. The agreement among the Italian National Government, the Regions, and the Provinces of Trento and Bolzano on the terms and requirements for the quality certification of training and practice of acupuncture, herbal medicine, and homeopathy by medical doctors and dentists, signed on February 2013, sets up rules for education and training in acupuncture, herbal medicine, homeopathy, homotoxicology, and anthroposophic medicine. Some regions, including Tuscany, have decided to include Complementary Medicine in their Essential Levels of Assistance, by creating some structures that integrate the health services into the public structures. The Homeopathic Clinic in Lucca, funded by the Tuscany Region, was established in 1998 as part of a pilot project aimed at assessing the feasibility of integrating complementary medicine into the public health care system. To date, over 4,000 patients have been consecutively visited at the Homeopathic Clinic in Lucca. Concomitantly, research into homeopathy effectiveness has been conducted on the whole sample and on specific groups of children, women or patients' parents as well. Studies were also performed on symptom reduction or resolution of atopic diseases,

respiratory diseases, side effects of anticancer therapies in women. Other researches concerned cost/effectiveness of therapies, sociodemographic characteristics and compliance of patients, and risk management. The results demonstrate that homeopathy can effectively integrate or, in some cases, substitute allopathic medicine and that the Tuscan example can be useful to the development of national or European rules on CM utilization.

**Keywords** Complementary medicine · Homeopathy · Public healthcare · National rules · Regional experience · Public homeopathic clinic · Outcome data

## Introduction

According to the European Information Centre for Complementary and Alternative Medicine (EICCAM) the use of complementary medicine (CM) has grown considerably in Europe in the past 20 years. More than 100 million EU citizens are regular users of CM, mainly for chronic conditions [1] and largely in addition to conventional care. It is, however, difficult to have a clear picture of CM use across the whole EU owing to various reasons, which include evidence drawn from only a few EU member states, heterogeneity of studies, and poor quality of reporting [2].

The results of the 2005 multipurpose survey on “Non-Conventional Therapies in Italy”, performed and published by the Italian National Institute for Statistics (ISTAT), show that 13.6 % of the Italian population (around 8 million) had used complementary medicine (CM) in the previous 3 years [3].

Quite different are the data reported by the most recent ISTAT survey “Protection of Health and access to

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healthcare” (2013), which show a decrease in the use of complementary therapies in Italy compared to the previous survey conducted in 2005. According to the latter survey, in fact, about 4.9 million (8.2 %) people have chosen at least one non-conventional therapy; homeopathy is still the most common (4.1 %), followed by osteopathy and chiropractic (3.6 %), herbal medicine (1.9 %), and acupuncture (1 %). Going into details of the study, it can be, however, assumed that the last economic crisis has impacted significantly on these results [4].

The typical Italian CM users are adults aged 35–44 years, with post-high school qualifications. Two-thirds are women and the most commonly used CMs are homeopathy, chiropractic/osteopathy, acupuncture, and herbal remedies.

It is not easy to calculate the number of qualified homeopathic practitioners in Europe. According to the data relative to the European Coalition on Homeopathic and Anthroposophic Medicinal Products (ECHAMP), there are at least 60,000 prescribers of homeopathic medicines in the EU, namely 11.4 homeopathic prescribers per 100,000 inhabitants. It has been calculated that the same percentage of Italian practitioners (physicians, dentists, veterinarians) prescribe homeopathic remedies, including homotoxicological and anthroposophic remedies. Italy is the third largest market in Europe (preceded by France and Germany) for the use of homeopathic and anthroposophic medicines [5]. Homeopathic medicines are generally found in pharmacies. At present, we can assume that around 90 % of the Italian pharmacies offer homeopathic and herbal products.

The aim of this article was to describe the experiences and the results of the Homeopathic Clinic situated in Lucca, Tuscany, in 15 years of activity, taking into consideration both the clinical results and the regulatory environment. It starts with the description of the Italian National regulation, the health programs of the Tuscany Region (including the rules for the training of CM specialists), and follows with the descriptions of some of the main projects realized in the Hospital “Campo di Marte” in Lucca.

### **Complementary medicine in the Italian public health system and the Tuscan experience**

#### **National regulation of CM in Italy**

The Italian Government and Parliament have been urged to pass a national law regulating the practice of CM, but no such national law has yet been passed. Since 1986 more than 100 draft bills on CM regulation have been tabled without results.

On 18 May 2002 the National Council of the Italian National Federation of Medical Doctors and Dentists Associations (FNOMCeO) issued the “Guidelines of the FNOMCeO on non-conventional Medicines and Practices” [Resolution of Terni] that recognized nine disciplines: acupuncture, traditional Chinese medicine, ayurvedic medicine, homeopathy, anthroposophic medicine, homotoxicology, herbal medicine, chiropractic, and osteopathy. These practices are considered to be exclusively under the professional responsibility of medical doctors and dentists.

The “Guidelines for non-conventional Medicine and Practices Education” were published by FNOMCeO in 2010 [6], and consisted in recommendations for an agreement to be reached during the State-Regions and Provinces Conference on the criteria for CM education and training (amount of hours for a basic course, number of years, educational program, professional qualification of teachers, etc.). The FNOMCeO guidelines followed the proposals put forward by the Interregional Group on Complementary Medicine of the Health Commission of the Permanent State-Regions and Provinces Conference in 2008.

In Italy, complementary medicine courses are generally continued medical education (CME)-accredited. At present, there are, or at least were until last year 2013, many postgraduate courses: “High specialization courses”, or “Masters”, or “Elective courses” included in the basic teaching programs of the Universities, of Turin, Milan Statale and Milan Bicocca, Brescia, Bologna, Florence, Siena, Pisa, Rome La Sapienza and Rome Tor Vergata, Chieti, Naples Federico II, Cosenza, Messina, Palermo, Sassari, Viterbo [7].

#### **Italian national and regional (federal) healthcare system**

The Constitutional Law no. 3 (October 18, 2001) has reformed most of Title V of the Italian Constitution (concerning regions, provinces, municipalities), forming a so-called “federal system of state”. The rule of the State (Government, Ministry, etc.) is to set the “fundamental principles” on different subjects including healthcare while that of the Regions is to decide on how to implement and organize the public healthcare system according to the political and social perspective of each region [8].

The “essential level of assistance” is guaranteed for all Italian citizens; this means that every person has the right to have a minimum (essential) level of healthcare, in any hospital of the country.

In the Regional Healthcare Plans (*PSR*) of Lombardy, Emilia Romagna, Tuscany, Umbria, Campania, Valle d’Aosta and Lazio, there are chapters about or references to CM. A number of regions (including Campania, Emilia Romagna, Lombardy, Tuscany, Lazio, Friuli Venezia Giulia and the Bolzano Province) have set up Regional

Commissions and/or Scientific Committees and/or Regional Observatories and/or Regional Structures of Reference for CM. Valle d'Aosta, Lombardy, Emilia Romagna, Tuscany, Umbria, and Campania have allocated funds to support research on the efficacy and effectiveness of CM. Information campaigns on CM or informative material have been published by the Autonomous Province of Bolzano and by the Regions Emilia Romagna, Lombardy, Tuscany, and Campania. Moreover, the Province of Bolzano has supported associations and schools of CM. Post-graduate courses on CM for medical doctors and paramedical staff have been provided by the Province of Bolzano, by the Region Friuli Venezia Giulia, Lombardy, Tuscany, Campania, and Umbria. A survey on public clinics providing CM service in Italy was conducted by Bolzano, Emilia Romagna, Umbria, and Tuscany [9]. Some regions, such as Tuscany, Umbria, Valle d'Aosta, partially Campania and, for specific projects, Emilia Romagna, have included CM in their regional LEA. According to a survey carried out by some CM Associations, until March 2006 there were at least 150 public complementary medicine clinics for out-patients in the Italian regions [9].

#### National regulation for the education in complementary medicine

The Healthcare Board of the Conference State—Regions and Provinces of Trento and Bolzano set up an Interregional Technical Group on Complementary Medicine on February 22, 2007. The basis was a proposal submitted by the representatives of a group of regions agreed upon in 2006. The group has been re-confirmed in the present legislature and coordination has been re-assigned to the Tuscany Region. The principal aim of the working group was to define the national criteria for education and training in Complementary Medicine, and to reach an agreement between the Italian government and all the Regions, and applicable throughout the national territory.

A document based on the work of the Technical Group defined the criteria of professional training in CM and was approved, in order, by the Health Committee (formed by the regional Ministers of Health), the Conference of the Presidents of Regions, and finally by the Ministry of Health. The Agreement among the Italian National Government, the Regions and the Provinces of Trento and Bolzano on the terms and requirements for the quality certification of training and practice of acupuncture, herbal medicine, and homeopathy by medical doctors, dentists, medical veterinaries, and pharmacists, signed on February 2013, sets up rules for education and training in acupuncture, herbal medicine, homeopathy, homotoxicology, and anthroposophic medicine. At the moment it

defines the criteria for medical doctors and dentists, but will later be extended to pharmacists and medical veterinaries. The agreement also defines the accreditation of complementary medicine professionals and educational institutions and provides for the establishment—within the provincial Associations of medical doctors and dentists—of lists of CM experts in acupuncture, herbal medicine, homeopathy, homotoxicology, and anthroposophic medicine (Art. 3).

Those wishing to register must have a certificate issued by accredited public and private training centers (also universities) and have completed a course of no less than 500 training hours, including 100 h of clinical practice, after having passed a theoretical and practical exam and discussed a thesis. Courses for medical doctors should last 3 years (Art. 4). Transitional provisions were also set up for professionals who initiated the practice of CM before passing of the law (Art. 10). In addition to the basic principles and clinical application of complementary medical techniques, courses must ensure the teaching of medical criteria based on evidence, the capacity to conduct clinical research, and the knowledge of legislation on rights to information and informed consent (Art. 5).

The public or private institutions accredited must meet specific requirements, for example the director of studies must be a professional in the discipline, officially listed in the professional register of medical doctors and dentists, with at least 10 years of documented clinical experience and 7 years of specific teaching experience in the disciplines: moreover, the tenured teachers must be at least 5 professionals in the disciplines in question, officially listed in the professional registers (Art. 8) [10].

On July 27th, 2014, the Italian Ministry of Health has issued a “Note of clarification” which explains in details how to apply the Agreement, to ensure a proper and homogenous application of its criteria all over the country. This document aims also at facilitating the interpretation of those regulatory issues included in the Agreement that were too general and required specific definitions.

Very important steps have been made in the field of Complementary Medicine regulation. The Italian regulation on education in CM could be a point of reference in the process aimed at defining rules in the European Union.

#### Healthcare programs of the Tuscany region for CM

Since 1996 the healthcare programs of the Tuscany region have contained references to various types of non-conventional medicine, and all recent Regional Health Plans have included a chapter on these medicines. The aim is to guarantee definite integration into the Regional Health Service of the types of non-conventional medicine that on

the basis of scientific evidence can be acknowledged as forms of complementary medicine (acupuncture, herbal medicine, homeopathy, and manual medicine).

The Regional Health Plan of 2005–2007 integrated CM in the regional health service and acupuncture, herbal medicine, homeopathy, and manual medicine were introduced in regional essential levels of assistance (LEA), with official price lists [11].

Moreover, the Regional Law N. 40/2005 concerning the Rules of the Regional Healthcare System provides for the presence of a representative complementary medicine in the Regional Healthcare Council, in all Tuscan Hospital Healthcare Councils (2 per hospital) and in the Regional Bioethics Committee [12].

With Resolution N. 655 (20 June, 2005) complementary medicines were included in the official regional price lists, making it possible for residents to receive specialist treatment in acupuncture, homeopathy, herbal medicine, and manual therapy for a €24.00 fee. Access to treatment is direct (no referral from the family doctor is needed) [13].

In September 2006 the Tuscany Region signed an Integrative Agreement on specialist care for out-patients that includes complementary medicine, thus filling a gap in national legislation. The agreement provides for the treatment of out-patients also by doctors specializing in complementary medicine.

Specialists must have a certificate issued by the provincial medical association proving successful completion of theoretical and practical training in complementary disciplines (acupuncture, herbal medicine, and homeopathy). This was the first attempt, in Italy, to establish a procedure for health services wishing to offer complementary medicine to their patients [14].

#### University courses in CM in Tuscany

The process of incorporating complementary medicines in the regional health system was developed in cooperation with the medical Association and the Tuscan Universities (Florence, Siena, Pisa), which organized a number of activities in this field.

The Faculty of Pharmacy of the University of Florence set up a course in advanced Chinese Herbal Medicine (2006–2007), the Faculty of Medicine a level-II Master's degree in "Acupuncture and Traditional Chinese Medicine" and a level-II Master course in "Clinical Herbalism", in collaboration with the University Centre of Empoli (2007–2008). In 2008, the Faculty of Pharmacy of the University of Pisa introduced a level-I Master degree course in "Medicinal and aromatic plants: raw materials for the food, cosmetics, pharmaceutical and health industry". A master's degree course in Natural Medicine (herbal medicine; acupuncture and Traditional Chinese Medicine)

has been set up in the Faculty of Medicine of Florence since 2011.

Finally, since 2009 the Faculty of Medicine of the University of Siena has set up a two-year Master degree course in "Integrative Medicine" which includes homeopathy, acupuncture, and herbal medicine.

#### Tuscany regional reference centers and network of integrative medicine

Since 1996, a total of 108 public services for Complementary Medicine have been opened in Tuscany. There are 54 services of acupuncture and TCM, 25 of homeopathy, 11 of herbal medicine and 18 of other non-conventional therapies (manual medicine, etc.) [15].

The "regional reference structure for complementary medicine" is made up of three regional reference centers: the Acupuncture and Traditional Chinese Medicine Clinic "Fior di Prugna" of Florence, which is also the Coordinating Center For Complementary Medicine in the region; the Herbal Medicine Clinic of S. Giuseppe Hospital, Empoli, which has now been transferred to the Careggi Hospital in Florence, and the Homeopathic Clinic of Lucca, Campo di Marte Hospital [16].

The "Tuscan Network of Integrative Medicine" (RTMI), composed by the public CM clinics, was established in 2007. This organizational model aimed at ensuring a unitary system, integration, quality of services, safety for patients, with the objectives of prevention, therapy, and rehabilitation. In 2009 it was recognized as a "regional structure of clinical government" [17].

Finally, in the Hospital of Integrated Medicine "Petrucchioli" at Pitigliano (Grosseto), since February 2011, integrated services are available to "in-patients" and to citizens in an "out-patients clinic", according to a health project promoting the therapeutic combination of conventional and complementary medicine [18].

#### Regional law regulating bio-natural disciplines

The regional law 2/2005 regulates the practice of "Bio-natural Disciplines" (BND), therapies, and practices such as naturopathy, shiatsu, reflexology, tuina, and prana practice, aimed at improving the well-being and quality of life with a holistic approach. BNDs do not interfere in the relationship between medical doctors and patients and do not use any kind of medicinal product [19].

#### Regional law on complementary medicine

The Regional Law of Tuscany no. 9/2007 regulates the practice and training of complementary medicine by medical doctors, pharmacists, and veterinarians and

stipulates that the corresponding professional associations are to draw up lists of professional experts in complementary medicine based on the requirements defined by the Regional Committee for training in complementary medicine, and to issue a specific certification [20].

The Regional Committee, established by the General Directorate of the Health Department, is composed of representatives of professional and CM associations, Tuscan universities, directors of the regional CM centers, and experts appointed by the Regional Health Council. Public or private non-university training centers can be accredited according to the Bill no. 993/2009.

The following regional agreement (April 8, 2008) between the Tuscany Region and the Regional Federation of the Association of Medical Doctors and Dentists, the Regional Committee of Pharmacists and the Regional Federation of Medical Veterinarians [21] defines the training and accreditation for complementary medicine professionals and training institutions and provides lists of CM professionals who practice acupuncture, herbal medicine, and homeopathy. Those who wish to register must have a certificate issued by accredited public or private training centers and must have completed a course of no less than 450 training hours and 100 h of clinical practice, after having passed a theoretical and practical examination, and presented a dissertation. Courses for medical doctors and veterinarians cannot last less than 3 years. Training courses for pharmacists are annual and require at least 100 h of theory and practice. So far, six private training Institutes (5 of homeopathy and 1 of acupuncture) were accredited by the Tuscany region.

### **Homeopathy in the public health system: the experience of the clinic in Lucca**

The Homeopathic Clinic in Lucca, funded by the Tuscany region, was established in 1998 as part of a pilot project aimed at assessing the feasibility of integrating complementary medicine into the public health care system. Since then, doctors and researchers have always carried out research aimed at evaluating the efficacy of homeopathic remedies and at familiarizing with the patients' characteristics.

#### **Setting and treatment**

The homeopathic doctors working at the clinic are professional specialists who have attended a school of homeopathy for at least 3 years, have over 30 years' experience in the field, and are registered with the Medical Association as experts in homeopathy, according to the Tuscan law n. 9/2007 and the relative Agreement

Protocol of 2008. The duration of a homeopathic visit is about half an hour.

The patients who wish to be treated by homeopathy—either self-referred or sent by their general practitioner or other specialists—can book an appointment at the Homeopathic Clinic of Lucca. Average waiting times are between 3 and 5 months, owing to the high number of requests. No specific admission criteria are required. All the patients were asked to sign a privacy disclaimer and an informed consent form for therapy and use of their data for future analysis. An individual identification number was assigned to all patients so that data were anonymized and could be collected and stored in a database. All the patients are treated with individualized homeopathic treatment (single remedy), without excluding other conventional drugs or concomitant treatments when necessary.

During more than 13 years of activity of the Homeopathic Clinic in Lucca (ASL 2 Tuscany Region, Italy), over 180 diseases have been examined. The most frequent diseases included respiratory (29.4 %); dermatological (14.7 %); digestive (17 %); psychological (14 %), and gynecological (6.6 %). A significant difference was observed in the distribution of diseases by age. In children, two-thirds of the patients came to the Homeopathic Clinic for respiratory diseases, compared to 25 % of patients aged 15–39 and 15 % of patients aged 40 or more. The most frequently observed respiratory diseases were: asthma (12.5 %) and allergic rhinoconjunctivitis (7.6 %); many cases, especially in children, were of acute recurrent respiratory infections (6.7 %) and upper respiratory tract infections (6.1 %).

Specific data for female ailments were obtained from the Women's Homeopathic Clinic, opened in November 2003, where a total of 1,392 female patients (mean age 41 years) were visited until 31 March 2013. The most frequently observed problems were those associated with menopause (53.9 %) and psychological disorders (12.8 %).

The patients of the Homeopathic Clinic of the Hospital in Lucca include essentially clerks, but also students, teachers, housewives, freelancers; many patients are unemployed, pensioners, or healthcare professionals. [22].

#### **Pediatric patients at the homeopathic clinic of Lucca**

An observational longitudinal study was carried out on a total of 551 pediatric patients,  $\leq 14$  years, in 2011. 67 % of children had used conventional medicine for the treatment of the ailments for which they came to the clinic. Respiratory infection was the most frequently observed disease with 337 cases (61 %), followed by dermatological (88 cases; 16 %), psychological (45; 8 %), and digestive problems (40; 7 %). The most frequent dermatological disorder was atopic dermatitis (76 cases). The diseases

were significantly associated with patients' age. In fact, the majority of children between 0 and 6 years of age presented with recurrent upper respiratory tract infections (72 %); those between 7 and 14 (36 %) displayed allergic manifestations; 33 % had lower respiratory tract, and 31 % upper respiratory tract infections.

The probability of important improvement or resolution of the problem is significantly higher among patients with upper respiratory tract infections who present success rates of 77 %, followed by patients with allergic rhinoconjunctivitis (63 %), and finally by those with diseases of the lower respiratory tract (54 %). The likelihood of success is considerably higher in patients with follow-up of at least 1-year.

No negative effects resulted from the use of homeopathic treatment in pediatric patients: 0 patients presented slight worsening. Only 3 % of the children did not benefit from the use of homeopathic treatment.

A specific observational longitudinal study was carried out on 213 patients (38.6 %) with atopic diseases; at follow-up re-evaluation the sample showed a significant ( $p < 0.01$ ) improvement of symptoms: 74.1 % presented a complete remission. The results of this study seem to confirm a positive therapeutic effect of homeopathy in children presenting with atopic diseases [23].

Another observational longitudinal study has explored the socio-demographic features of the pediatric population homeopathically treated for respiratory complaints (89 pediatric patients aged 0–14 examined between 1998 and 31 December 2005). To date, 74 children were traced, 26 patients with allergic rhinitis showing a significant ( $p < 0.01$ ) improvement of symptoms, and 48 with allergic or bronchial asthma presenting a significant ( $p < 0.01$ ) improvement of symptoms.

These results seem to confirm that homeopathic medicine produces mainly a positive therapeutic response in children with respiratory complaints [24].

### Qualitative research

The homeopathic clinic in Lucca promoted a qualitative survey to investigate parents' opinions, experiences, and decisional criteria in choosing homeopathic treatment for their children. The sample was formed by the parents of 20 pediatric patients consecutively attending the Clinic from March 1, 2012. The sample was selected to cover a wide range of ages and disease.

The aim of the research was to collect information to improve the level of the homeopathic service, provide more attention to the needs of the "homeopathic families", and suggest new options for the clinic itself.

In our sample, parents seem willing to manage their own and their children's health, avoiding any passive attitude

towards the healthcare system and appear to be strongly influenced by the context. Approval of friends and grandparents, when present, is considered very important and encourages parents to use homeopathy for their children both for prevention and for treatment, mainly of respiratory diseases.

Parents commonly decide to use allopathic traditional medicine in case of severe diseases, but this does not seem to depend on the diseases themselves, but on the difficulty of access to homeopathy [25].

### Adverse effects of homeopathic therapy

To assess the possible harm arising from the use of homeopathic medicine, a prospective study [26] was conducted on adverse reactions related to homeopathic medicines between June 1st 2003 and June 30 2004 during follow-up visits consecutively carried out at the Homeopathic Clinic. In this research a homeopathic (not the prescribing) doctor examined the effects following the administration of a homeopathic medicine, prescribed according to the classical homeopathic method and the relationship with the dose and frequency of administration, time relationship between drug use and adverse events, challenge, de-challenge, possible concomitant factors, causality (improbable, unlikely, possible, probable, certain).

Out of 335 homeopathic consecutive follow-up visits, nine adverse reactions were reported (2.68 %), including one case of allergy to lactose, excipient of the granules.

### Clinical risk management

A training course for the health professionals of Tuscan public centres of CM was conducted to develop a plan for the management of clinical a systematic approach aimed at identifying and preventing risks, also through the reporting and management of ADRs. CM were analyzed and the criteria were outlined to evaluate risk and to monitor diagnostic and the therapeutic paths to be undertaken. The relationship between medical doctors and patients, and the communication among healthcare centres were a specific focus. These issues, in fact, were identified as the most critical aspects in the risk management of complementary medicine. In the end, an operational program was set up to perform regular control measurements in public centers for the safety of patients and to decrease the risk of clinical practice. To this aim, the audit about significant events and the failure modes and effects analysis were used, after adapting them to CM, for pro-active evaluation of the risks [27]. Finally, a questionnaire was filled in by the participants to identify the reasons of commitment in the prevention and management of clinical risk in daily practice [28].

### Effectiveness of homeopathic treatment

In order to assess the outcomes of homeopathic therapy, a total of 1,129 patients' records were examined from the 2,592 patients (43.5 %) returning for at least one check-up visit after the initial consultation. Of these, 395 patients (34.9 %) were men, and 734 (65.1 %) women.

A total of 20 % of patients reported that the complaint had been resolved, 27 % had experienced a significant improvement, 22 % reported a good improvement, and 21 % a slight improvement. Only 0.5 % of patients experienced a slight worsening, and 10 % reported no change. 528 patients reported a significant improvement or resolution of the symptoms in relation to the duration of the therapy. The overall success rate (GHHOS +3 or +4) was 47 % and percentages increased with the duration of the therapy: after 2 months the percentage was 25 %, rising to 78 % after 24 months or more of follow-up. The most successful outcomes were obtained for respiratory diseases (68 % upper and 66 % lower respiratory tract), and the least successful were for anxiety and depressive disorders (37 %).

As the age of patients rose, the proportion of subjects reporting a significant improvement or resolution of the complaint was reduced. Diseases with a more positive outcome score were respiratory complaints (with 31 % reporting a significant improvement and 27 % reporting a resolution). Psychological complaints appeared to be more difficult to treat (27 % showed significant improvement but only 7 % were resolved) despite a good and significant improvement for 54 % of the subjects treated. The length of time from the beginning of therapy and the follow-up visit had a great influence. The longer the patient's duration of the therapy, the better the outcome score. After 2 years of treatment, 45 % of patients reported a resolution of the complaint, compared to only 7 % of patients after 2 months [22].

### Homeopathic treatment in women complaints

An observational longitudinal study was carried out on 1067 women consecutively examined from 2002 to 2011 at the Women's Homeopathy Clinic at Campo di Marte Hospital.

The mean age of the patients was 41 years, 747 (70.0 %) coming from the Province of Lucca, mainly clerks (290) and students (115). 35.3 % had already used conventional therapy and 15.3 % homeopathic treatment. Gynecological complaints in 620 (58.1 %) patients; 249 cases (23.3 %), with menopausal disorders and 128 with menstrual irregularities (12 %) were the most frequently observed diseases. The homeopathic prescription was followed by a herbal therapy in 105 (42.2 %) % of the

patients with menopausal disturbances. Due mainly to the long waiting list (up to more than 12 months), the follow-up was done only on 348 women (32.6 %). 91 of them (26.1 %) were followed up after 2 months, 166 (47.7 %) after 6 months, and 91 (26.1 %) after 12 months.

Patients with a major improvement or resolution were 152 (43.6 %), and those with menopausal complaints were 35 (43.1 %). Four patients (1.1 %) had slight worsening; 45 (12.9 %) had no improvement; 60 (17.2 %) had slight improvement; 87 (25 %) had moderate improvement; 93 (26.7 %) had major improvement; and 59 (16.9 %) had resolution of symptoms [29].

### Compliance of the patient to homeopathic therapy

In order to ascertain the reasons for patients not returning for follow-up consultations ("drop-outs"), a telephone survey was carried out on 104 patients who had been seen during the period from 1 June 2002 to 31 May 2003, but who did not return for a follow-up visit.

Seventy-three eligible patients were contacted: 36 patients (49 %) completed treatment, 29 (81 %) said that treatment had been effective and for that reason had not returned for a follow-up visit; 3 patients (12 %) considered the treatment ineffective.

Twenty-six patients (28 %) did not take treatment completely, interrupting it due to lack of improvement (five patients), or because of an improvement in their symptoms (eight patients), for various other reasons (13 patients).

Eleven patients did not take the homeopathic treatment prescribed, 2 patients reported a negative impression about homeopathy, and in 2 cases the symptoms disappeared before the medicine was taken. The remaining seven patients gave various other reasons: fear of side-effects (1), self-prescribing of homeopathic remedies (2), reasons independent of treatment (3), resorting to pharmacological treatment (1) [30].

### Homeopathy and cancer patients

The Homeopathic Clinic of Lucca established also an out-patient Clinic of integrative medicine applied to oncology in October 2010. The aim is to provide citizens with qualified and evidence-based information on the use of Complementary Medicine and on a correct diet for cancer patients, and to evaluate the effects of homeopathic treatment in decreasing the adverse reactions of chemotherapy, radiation therapy, and anticancer drugs in cancer patients, to improve their quality of life.

From October 2010 to April 2012 and from January to February 2014, 123 patients were consecutively visited (18 males and 105 females); the mean age was 56 (35–88) years. Nearly all patients were referred by their medical

oncologists. Cancer type or localization was as follows: 81 patients with breast cancer, 6 with gynecologic cancer, 12 with gastro-intestinal cancer, 2 with head and neck cancer, 4 with prostate cancer, 1 with brain cancer, 4 with NSCLC, 4 with hematologic cancer, and 3 with other kinds of cancer; 28.5 % already had metastasis. 40 % of patients asked for information about CM in oncology. 10 % of patients were using CM for other purposes before cancer diagnosis: the majority was women with a high level of education. 17 % of patients were often using “alternative therapy” instead of anticancer treatment. By comparing the clinical conditions before and after treatment, we observed significant amelioration of the following symptoms of the cancer or of the adverse effects of the anticancer therapies: nausea ( $p = 0.039$ ); insomnia ( $p = 0.008$ ); depression ( $p = 0.004$ ); anxiety ( $p = 0.007$ ); asthenia ( $p = 0.007$ ); hot flushes ( $p = 0.008$ ). The most commonly used remedies were *Nux vomica* (symptoms from chemotherapy), *Radium bromatum* and *Belladonna* (symptoms from radiation therapy), *Lachesis* and *Sepia* in the artificial menopausal syndrome [31].

#### Cost-effectiveness evaluation

Patients affected by respiratory diseases and seen regularly between October 1998 and May 2003 were recruited for the study. These patients were identified by specific individual codes generated by the Pharmaceutical Operating Unit of Local Health Authority 2 in Lucca, and used for this particular study. On the basis of these codes, conventional drug consumption was monitored using the Pharmaceutical Prescription Archive of the Local Health Authority 2, recorded by the ARGO–CINECA Center of Casalecchio del Reno (Bologna), for at least one year before the start of homeopathic therapy, for at least 1-year after starting homeopathic treatment, and up to 2 years when possible.

In order to check that the trends in pharmacological consumption were not due to a normal evolution of the pathology towards improvement or to spontaneous recovery, we performed a case control study. 105 patients (60 females: 57.14 %; 45 males: 42.86 %) were recruited for the study.

At the time of their first appointment 87 % of the patients recruited were undergoing conventional therapy. The majority of cases concerned allergic pathologies (asthma and allergic rhinoconjunctivitis) and pathologies of a recurrent chronic nature.

Expense variations were determined taking into account the different diagnoses, and the complete set of respiratory pathologies with regard both to the general consumption of drugs granted by the NHS, and the specific drug categories for each pathology.

From the cost data obtained for patients affected by bronchial and allergic asthma, a considerable cost reduction was observed in the homeopathy compared to the control group: in the homeopathy group the costs for the specific chemical/therapeutic subgroup were reduced by  $-71.07$  % in the first year, and  $-54.44$  % in the second year, while an increase of  $+10.99$  % and of  $+31.14$  % was observed in the latter. Patients treated with homeopathy reduced their overall pharmacological costs by  $-63.57$  % in the first year and  $-49.87$  % in the second year, while the control group increased its monitorable general pharmacological costs by  $+3.84$  % and  $+15.61$  % in the first and second years, respectively.

The use of homeopathy in children under 10 years for recurrent acute respiratory infections was associated with a reduction in conventional pharmacological expenses of 50 %.

The data show that for both the group of patients affected by asthma and for those affected by recurrent acute infections in childhood, the cost of conventional therapy in the control group is higher than the sum of the cost of conventional therapy and homeopathic therapy in the homeopathic patients [32].

#### Discussion

Homeopathy can be a useful and sustainable resource in chronic diseases, life-styles, natural childbirth, allergies, tumors, pre- and post-operative rehabilitation, epidemics, pediatrics, third age, dentistry, and veterinary medicine. Its inclusion/integration in the public health system should go hand in hand with an adequate process of scientific validation to control the efficacy, safety, and quality of the health services and products by means of case/control observational studies, as well as randomized and double-blind clinical trials (evidence based medicine). Unfortunately, despite the considerable increase of scientific publications showing the effectiveness and efficacy of homeopathy, their quality level and methodology are not considered to be sufficient. Furthermore, despite the many scientific works, *in vivo* and *in vitro*, showing that the remedy in dilution has a biological activity even exceeding the number of Avogadro (ultramolecular doses), homeopathic medicine is generally badly accepted by the international scientific community.

For these reasons, the experience of inclusion of homeopathy—alongside acupuncture and herbal medicine—within the Regional Public Healthcare System in Tuscany is an element of great novelty in Italy and Europe, increasing the opportunity of therapeutic choice for both patients and healthcare professionals, and more equal access to treatment to all citizens. It is important to stress



that homeopathy was able to find a place in Tuscany's public health system thanks to the Italian public health federalist system, which has developed a regional regulatory system of CM education and practice.

The major gap that needed to be filled was the absence of a national law that defines training for specialists in complementary medicine: in fact the absence of an official recognition to the title of "Complementary Medicine expert" does not allow the local health authorities to establish public calls for such physicians and, consequently, the full integration of CM in the Public Health System. As the National public health federalist system permitted the inclusion of homeopathy in the Tuscan Public Healthcare System, this experience has allowed signing the National Agreement which in 2013 introduced the first form of national regulation of complementary medicine in Italy and can be considered a good start for a European regulatory system in the future. Meanwhile, the Tuscan health regulations have made possible experiences like the Homeopathy Clinic in Lucca, whose results allow us to consider homeopathy a convenient complementary therapy for a wide range of diseases, a useful alternative when allopathic medicines are poorly tolerated or ineffective and represent the treatment of choice for some kinds of diseases such as atopic or dermatological diseases.

Homeopathic remedies also ensure reduced cost treatment (about 50 % for respiratory diseases) [37], with no or very few side-effects

Homeopathy clinics can be well integrated within the public health system in the same way as homeopathic remedies can be integrated into allopathic medicines. At present, there are more than 100 Complementary Medicine Clinics in Tuscany, of which 27 are homeopathic. Homeopathy is also practiced in the Hospital of Lucca for the treatment of side-effects of chemo- and radiotherapy, and particularly to reduce the side-effects of hormone therapy in women operated for breast cancer.

In this way Tuscan citizens have been provided with an efficient and durable service of homeopathy with affordable costs. These encouraging results need to be confirmed with observational studies on larger samples of patients, preferably using randomized controlled trials and simultaneously experiencing the best forms of integration with the allopathic medicines and the Public healthcare system. This needs to be the aim of future research.

## Conclusions

Tuscany is not an isolated case in Italy, even though the same levels of integration have not been achieved in other regions.

Concrete actions are being implemented to encourage the inclusion of complementary and integrative medicine, in particular homeopathy, in the Public healthcare systems. These actions include the introduction of CM in regional and national healthcare planning and in the programs of public health clinics. For that specific regional and/or national regulations were passed. Finally, special attention should be given to the programs for the education and training of healthcare staff and to inform citizens, which are issues of primary importance for the development and success of the integration of homeopathy and CM as a whole.

**Acknowledgments** We thank Dr Laura Cignoni for the English translation.

**Conflict of interest** No conflict of interest. All the costs for this study were supported by the Public Health System of the Tuscany Region.

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