Regione Toscana

CRMI
Centro Regionale per la Medicina Integrata

SST Servizio Sanitario della Toscana

Complementary medicines in the Tuscan regional healthcare system

Regional Centre for Integrative Medicine
December 2023

Index

1. Introduction

In the Region of Tuscany, non-conventional/complementary/integrative medicines have a long story that started in 1996, when the Regional Healthcare Plan introduced rules to valorise these type of medicines for the first time.
After a process of timely systemisation and integration of CMs in the regional healthcare facilities, today acupuncture, herbal medicine and homeopathy are fully included in the Tuscan public healthcare service with 84 complementary medicine outpatient's clinics and 30 intramoenia activities (total 114).
The clinics are located in all the local health authorities in both hospital and outpatient settings and provide Tuscan citizens with treatments of acupuncture and traditional Chinese medicine (53), homeopathy (16), herbal medicine (9) and other complementary therapies (6).
The integration of complementary medicine (CM) in Tuscany represents a peculiar and innovative experience not only at a national level, but also in Europe.
This document summarises the most relevant steps and the main regulatory acts of this integration.

2. Complementary medicines in Tuscany: epidemiological data

2.1. National and international data

In the United States, approximately 38% of adults and 12% of paediatric patients use a modality of complementary and/or integrative medicine (National Centre for Complementary and Integrative Health -NCCIH). In Europe, at least 100 million citizens use complementary medicines and techniques. A European multicentre study reported for instance that 32.2% of the population use complementary therapies, with percentages ranging from 5% to 74.8%.
Also in Italy, the use of complementary therapies is widespread and consolidated, as reported by a number of surveys (Istat 2005, Eurispes 2012, Eurispes 2017). The percentages of use of acupuncture, homeopathy and herbal medicine range between 15 and 20% of the population, depending on the type of CM and the user's financial availability.
Noteworthy, a study by the Italian Society of Paediatrics (ISP) reported that 23% of Italian paediatricians use CMs. In 2011, a survey by Health Monitor Compugroup Medical - Sole 24 ore Sanità stated that 52% of Italian general practitioners (GPs) recommended homeopathic medicines to their patients.
CMs are also widely used among cancer patients (see later in the text).

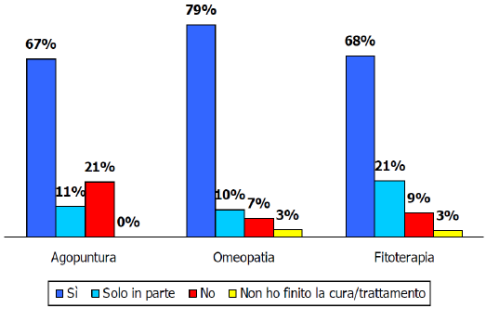
2.2 The survey of the Regional Health Agency (RHA)

The survey covered 1,523 randomly selected Tuscan adults, <40 years old, stratified by local health authority, sex, and age.
- One in 5 Tuscans are familiar with CMs, especially homeopathy (18%) and acupuncture (14%)
- 13.4% have used at least one of these medicines (3.6% acupuncture, 1.8% herbal medicine, 7.9% homeopathy)
- Homeopathy is widely used in the paediatric age and almost a quarter of respondents use it to treat their children
- Satisfaction with the care received is high for all users of CMs: 79% for homeopathy, 68% for herbal medicine and 67% for acupuncture
- Tuscan citizens decide to turn to complementary therapies because they are natural (74%), effective (43%) and have fewer side effects (32%)
- About half of the users turn to public facilities and 57% inform their doctor.

Complementary medicines in Tuscany: knowledge and use in the population (2010)

	Conoscenza %	Uso negli ultimi 3 anni %	La prima volta negli ultimi 12 mesi %
Medicina Tradizionale Cinese			
Agopuntura	**14,1**	**3,6**	**1,8**
Moxibustione	0,5	0,2	0,1
Farmaco-terapia cinese	0,5	0,3	-
Coppettazione	0,2	-	-
Fior di Prugna/martelletto	0,03	-	-
Omeoterapie			
Omoepatia	**17,6**	**7,9**	**2,0**
Antroposofia	0,4	0,04	-
Omotossicologia	0,04	-	-
Piante medicinali			
Fitoterapia	**4,0**	**1,8**	**0,4**
Erboristeria	34,3	21,9	6,1
Floriterapia §	4,6	2,5	0,8
Aromaterapia	2,5	1,0	0,2

Beneficial effects perceived by users of Complementary Medicines



2.3. Opinion of Tuscan GPs and paediatricians: RHA survey

The survey involved 2,228 Tuscan GPs and paediatricians (response rate 82%)
- 15.2% practise CMs
- 57.8% recommend them to their patients
- 11% have a specific training
- 65.7% are in favour of teaching these therapies at universities
- 23.7% used non-conventional medicines to treat their own disorders.

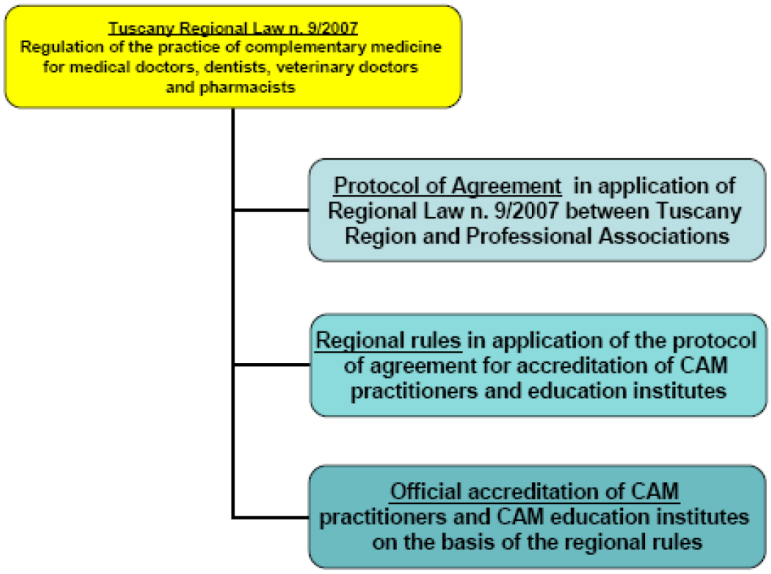
2.4. Regional survey on lifestyles and complementary medicine

According to international literature, usually the users of CMs have healthier lifestyles and follow habits that improve the health by facilitating the prevention of numerous diseases.
In order to assess this trend also in our territory, in 2014 we distributed a questionnaire on lifestyles and CMs to the patients of Tuscan public complementary medicine clinics and according to the data of the survey citizens who used CMs had less sedentary lifestyle habits and ate healthier food compared to the national population.

3. Integration of CMs in the Tuscan Health Service (1997 - 2023)

3.1. The Regional Law 40/2005

The Regional Law 40/2005 regulates the integrative health and social planning, the organisation of the Tuscan Health Service and the organisational solutions to guarantee the integrated taking charge of health and social needs and the continuity of the diagnostic, therapeutic and care pathway.
The Article 4 stated that, "The territorial health services of the area-district and those of hospital services in the network are organised with the aim of guaranteeing the patients in the use of appropriate care pathways, corresponding to the ascertained need, according to the principles of the qualification of the services provided and compatibility with the available resources. These services also provide *complementary and integrative medicine*, on the basis of their evidence and in compliance with the regional planning activities", in order to guarantee the access to CMs to a wide range of citizens, in accordance with the principles of clinical appropriateness, quality and safety.
Furthermore, it established that the Regional Centre for Integrative Medicine, an evolution of the Tuscan Network of Integrative Medicine, was included in the Regional Clinical Governance Structure (Article 43).



3.2 Complementary medicines in the RHPs and PSSIRs

Since 1996, all the Regional Health Plans (RHPs) have recognised the role of non-conventional/ complementary medicines in the therapeutic offer to Tuscan citizens.
Noteworthy, the regional health plan (1996) contained for the first time regulations aimed at the valorisation of non-conventional medicine. The last RHP (2018-2020) confirmed the use of CM treatments in gender medicine, and particularly in the menopause, pain control, oncology and old age.

3.3 The Regional Law 9/2007 and the Agreement between the Region of Tuscany and Professional Associations

The Regional Law 9/2007 regulates the practice of complementary medicine (acupuncture, herbal medicine and homeopathy) by medical doctors and dentists, veterinarians and pharmacists, providing for a training course of at least 3 years and the possibility of being registered in the lists of physicians practising CMs. A specific agreement between the Region of Tuscany and the Professional Associations of medical doctors and dentists, veterinarians and pharmacists defined accreditation criteria in April 2008.

This document defined the general accreditation criteria, the transitional provisions for registration on the lists of the experts in CM and the accreditation criteria for public and private training schools.

The Regional Resolution n. 993/2009 set up the procedure for requesting the accreditation of CM training schools in detail; the subsequent Decree n. 1332/2010 approved the model for submitting applications. Later, the regional Resolution n. 106/2018 updated the criteria and the Decree no. 5426/2018 defined the new application forms.

At the Article 4 the Law also established the training/education Commission, dealing with all aspects relating to the accreditation of training schools and promoted research and regional CME (Continuous medical education) projects in specific areas and in the areas of integration with conventional medicine.

The Region of Tuscany and the Associations of medical doctors and dentists, veterinarians and pharmacists signed a new Memorandum of Understanding after the approval of the agreement at the State-Regions Conference in 2013 (see later in the text).

The regional Resolution n. 106/2018 incorporated the Regional Law 9/2007, as regards to medical doctors, and dentists, implemented the State-Regions Agreement. Therefore, it entrusted the professional Associations of MDs with the activation and management of the lists of experts in acupuncture, herbal medicine and homeopathy, the latter divided into three sublists of homeopathy, homotoxicology and anthroposophy.

Here the criteria for the training in CMs

- 500 hours, including 100 hours of clinical practice and 100 hours of individual study and guided training
- three year training courses
- Accreditation of two-year university master's degrees provided they meet the protocol requirements.

3.4 The Regional Referral Centres

The regional Resolution n. 1384/2002 established the Regional Referral Structure for TCM, herbal medicine, and homeopathy; the Regional Referral Structure for integrative medicine in hospital was established later (2016).

- Regional referral centre for TCM 'Fior di Prugna'

The ‘Fior di Prugna’ Centre started its activities in Campi Bisenzio (1995) and is presently located in Florence. The Centre coordinates 24 outpatient clinics of acupuncture, homeopathy and herbal medicine. In September 2019, it expanded activities opening two outpatient clinics in Pistoia and Pescia.

The healthcare staff consists of five medical doctors and four non-medical healthcare workers.

Regional activities: coordination of regional activities in acupuncture an TCM; definition of guidelines; training and refreshing courses of practitioners, university masters' practical training, accreditation of TCM events, training activities in TCM and CM for Tuscan health personnel, meetings on therapeutic protocols in complementary treatments.

Prevalent pathologies: side effects of radio-chemotherapy in cancer patients, Long Covid, osteo-musculo-skeletal, gynaecological, respiratory, urinary, gastrointestinal, skin, neurological pathologies, anxiety and minor depression, headache.

Research projects: dysphagia related to head and neck cancer; treatment of pain in women taking aromatase inhibitors with auriculotherapy; treatment of musculoskeletal pain with auriculotherapy.

The centre has also a library specialised in CMs and natural techniques, which is connected to the Health Education Centre of the Florentine area.

- Regional referral centre for herbal medicine – University hospital of Careggi, Florence

The referral structure for herbal medicine started its activities in Empoli (1995); it is presently located at the University Hospital of Florence. The health team consists of two medical doctors and two biologists.

Regional activities: coordination of regional activities in herbal medicine and phytovigilance in collaboration with the National Health Institute, the Ministry of Health, the Tuscan Network of Pharmacovigilance and the University of Florence; consultancy for patients and health professionals on herb-drug interactions; drafting of guidelines and treatment protocols in herbal medicine.

Training activities (University of Florence): education in herbal medicine and phytovigilance in the Master degree course in clinical phytotherapy (post-graduate).
Research activities: preclinical and clinical studies on the efficacy of medicinal plants and on their biological, pharmacological and toxicological activity, herbs/drugs interactions in collaboration with regional and national Universities and other national research centres.

- Regional referral centre for homeopathy - Cittadella della Salute Campo di Marte, Lucca

The referral centre for homeopathy started its activities in 1998 at the Campo di Marte Hospital, today the Citadel of Health. It includes the Homeopathy Outpatient Clinic; the Homeopathy for Women Outpatient Clinic; the Complementary Medicine and Nutrition in Oncology Outpatient Clinic, plus an Acupuncture Outpatient Clinic for cancer patients.
The health professionals are one homeopathic doctor and one oncologist specialised in CM, one acupuncturist, two psychologists for the CHEMOCIM research project.
Regional activities: evaluation of CM user characteristics; quality standards and therapeutic protocols in homeopathy; training of health staff, training of university masters; information courses for healthcare personnel, GPs and paediatricians, pharmacists; accreditation of events; international health cooperation programmes in CM; printing and dissemination of MC Toscana; telephone information service on homeopathic medicines and pharmacovigilance; organisation of national and international congresses; coordination of the activities of regional public homeopathy outpatient clinics.
Publications and research projects: research activity on adverse effects of homeopathic treatment; treatment compliance; outcome data of homeopathy; CM and oncology; clinical research on efficacy and cost/benefit evaluation of homeopathy; short and long term outcomes of homeopathic treatment of atopic diseases in children and adults; international cooperation activities in support of CMs; qualitative research on the motivations and problems of families choosing homeopathy; outcomes of homeopathic treatments of female disorders; clinical risk and patient safety in complementary medicine; international perspectives of integrative oncology. Chemocim project with regional funds "Clinical, controlled, randomised, open-label, multicentre, non-profit study to evaluate the superiority of a complementary treatment with homeopathic medicines and additional acupuncture/auriculotherapy compared to an active control group with only cognitive rehabilitation and nutritional advice".
Prevalent pathologies: respiratory; gastrointestinal; gynaecological; psychosomatic and psychic; adverse effects of cancer treatments and cancer-related symptoms; Long Covid.

- Regional referral centre for integrated medicine activities in the hospital pathway - Pitigliano

The Centre for Integrated Medicine in Pitigliano was identified as the regional referral centre for integrative medicine in hospital pathways in 2016.
The health staff consists of four medical doctors (three acupuncturists and one homeopath).
Regional activities: the centre participates in the Regional Commission for Complementary Medicines and collaborates in the implementation of regional clinical research protocols.
Training activities: tutoring activities for compulsory training in the qualifying courses in acupuncture, homeopathy; collaboration and organization of training/information courses for health care and non-health care personnel on CMs (homeopathy and lifestyles, acupuncture).
Activities for research projects: the Centre promotes and collaborates in regional research projects. It is currently developing a study on the effects of radiotherapy in breast-operated women with the Department of Oncology; study on the quality of life in cancer patients; study on fibromyalgia with the Rheumatology Outpatient Clinic of Hospital in Grosseto. The FAIRAC project, which aims at assessing the effectiveness of acupuncture in cancer-related fatigue, is ongoing.
The Centre participates in national and international conferences and courses and publishes scientific articles related to research and care activities.
Prevalent pathologies: neurological and orthopaedic rehabilitation and palliative care; chronic pain control, gender medicine, physiological pregnancy in low-risk pregnancies, integrative therapy and prevention of chronic diseases.




3.5 CMs in the Regional Tariff Nomenclature

The regional resolution n. 655/2005, updated in 2011, established the branch "Complementary Medicines" and included CMs in the Regional Essential Levels of Care. CMs were therefore included in the official regional price lists.

3.5.1. Resolution n. 652/2011

visit of acupuncture	24,00 €
visit of herbal medicine	24,00 €
visit of homeopathy	24,00 €
visit of manual medicine	24,00 €

Subsequent treatments of manual medicine

manual medicine manipulations two or more districts	36,00 €

Subsequent acupuncture treatment

Acupuncture + different techniques; acup. with electrostimulation	24,00 €
acupuncture	18,00 €
Auricular therapy, craniopuncture, 'plum blossom', cupping, moxibustion	18,00 €
acupuncture with moxibustion	24,00 €
tuina massage for children	24,00 €
acupuncture for anaesthesia (listed in the National Tariff Nomenclature)	9,70 €

3.6 The Tuscan Network of Integrative Medicine

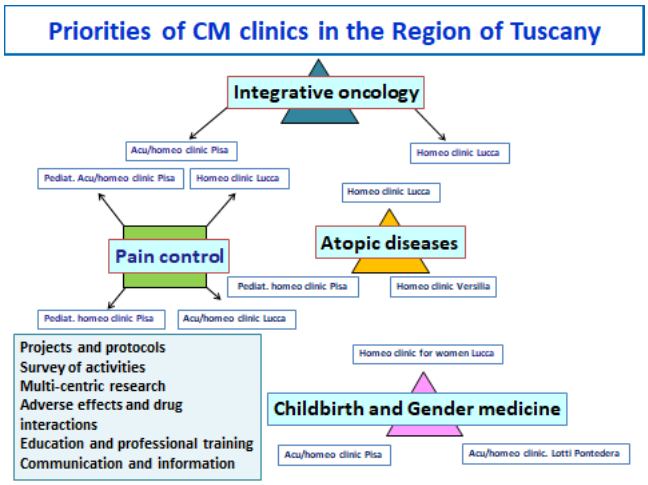
The regional resolution n. 623/2007 established the Tuscan Network of Integrative Medicine (TNIM), strengthening in this way the integration of CMs in the Tuscan Healthcare Service.
For its activities, the TNIM used an operational Coordination", an organizational secretariat and a scientific technical committee, identified in the Regional Commission for complementary medicines.
Furthermore, the resolution provided that a "Natural Point" for CM services would be identified in each local health authority, to provide preventive, therapeutic and rehabilitative programs, and guaranteeing the implementation of clinical governance in this area.
The TNIM was a regional clinical governance body according to the regional law n. 40/2005 and later changed its name to "Regional Centre for Integrative Medicine".

3.7 The regional Resolutions 1224/2016 and 642/2019

The regional Resolution 1224/2016 reorganized the complementary medicine area as follows:
- established the regional referral centre for integrative medicine in the hospital path in Pitigliano Centre
- identified the priority sectors of intervention: cancer care, pain control, promotion of physiological birth in low-risk pregnancies, gender medicine and prevention and treatment of respiratory and atopic diseases in childhood and adulthood
- approved the "Guidelines for Tuscan local health authorities and university hospitals for the reorganization of integrative complementary medicine activities"
- provided for the financing of projects to improve the efficiency of the system and reduce waiting lists
- approved the program of activities for the three-year period (2016-2018) of the regional referral centres in CMs.

The subsequent regional resolution n. 642/2019 confirmed the location of the Regional Centre for Integrative Medicine at the Health Directorate, to ensure the best integration between the policies on CMs and the clinical governance functions attributed to the Regional Centre for Integrative Medicine.
The Annex A of the resolution described the technical aspects and redefined the organization of the system.
The Tuscan System for Integrative Medicine is a network organizational model and responds to the objectives of guaranteeing quality and safety of healthcare services, the collaboration between the different facilities sharing information, knowledge and skills and promoting governance activities. It includes the Regional Centre for Integrative Medicine (Director; Secretariat; Coordination Office) and the regional referral centres for CMs; it is supported by the Regional Commission for education in

complementary medicines and by the Regional Committee for natural disciplines (Regional Law 2/200)5.
The resolution confirmed the priority sectors of intervention of CMs, i.e. cancer care, pain control, promotion of physiological birth in low-risk pregnancies, gender medicine, prevention and treatment of respiratory and atopic diseases in childhood and adulthood.



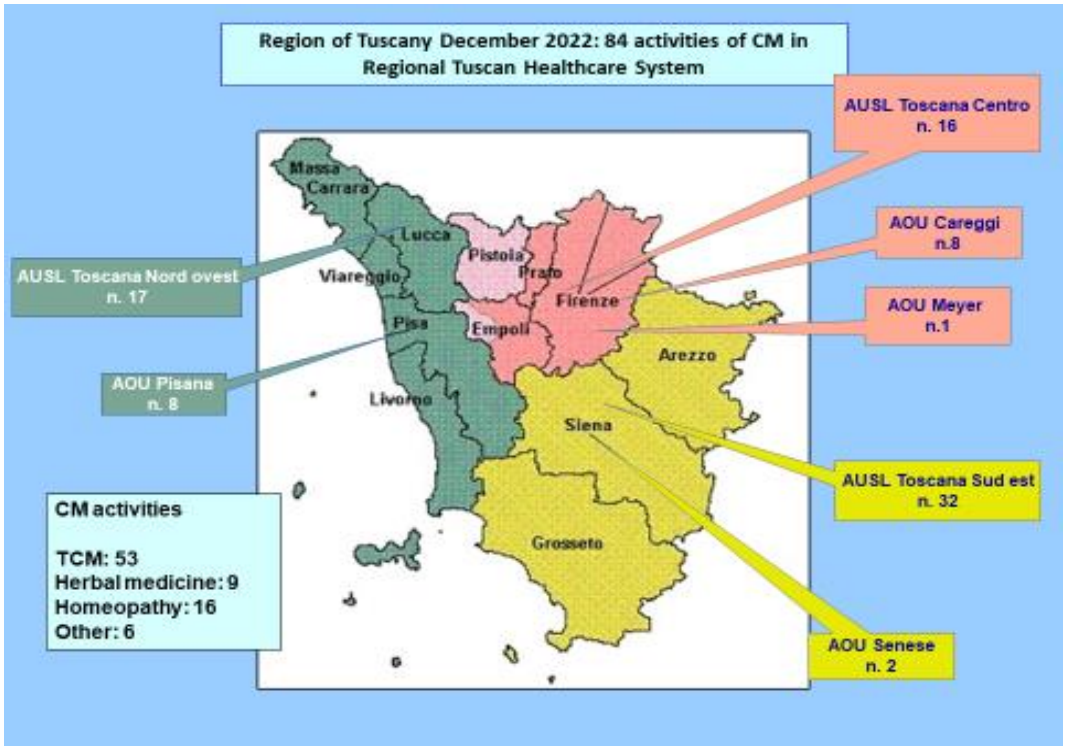
3.8 The Regional Centre for Integrative Medicine

The centre is part of the regional structures of clinical governance and is located at the Tuscan Health, Welfare and Social Cohesion Directorate. The operational structure includes a director and a Coordination Office.
The Centre guarantees the support for the regional activities of planning in complementary medicine and its technical-scientific coordination. It coordinates the integrative medicine activities, draws up regional projects in this field, defines the training programs for health personnel and proposes programmes for congresses and communication. Its objectives are the efficiency of the system, the quality and appropriateness of in the area of complementary medicine.
It carries out the annual updating of the census of CM activities, defines training and accreditation programmes for professionals and training schools, researches on the effectiveness and appropriateness of CMs. It also develops regional surveillance programmes on the adverse effects of complementary medicine and defines diagnostic and therapeutic guidelines.
The Centre develops its activity in cooperation with the Tuscan body for Clinical Governance, the Institute for the study, prevention and oncological network and other regional Commissions.

3.9. Data of the last survey of CM activities in Tuscany (December 2022)

The complementary medicine activities within the Tuscan Health Service are recorded in the annual survey conducted by our centre and according to the last data they were 84 (see map), plus 30 intramoenia activities .

- Payment of a **24.00 Euro** co-payment (similar to that for all other specialist visits).
- **Free of charge for** children <6 years old, for specific diseases (cancer patients), unemployed, elderly, etc.
- Average of the visit time: 30 minutes (+/- 15 min.)



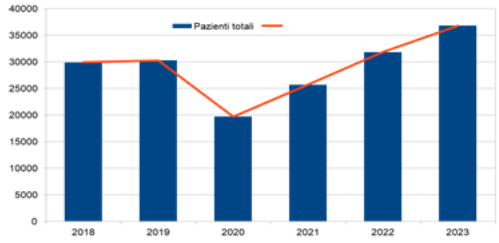
Hospital and outpatient facilities of all the local health authorities provide these services, which include acupuncture and traditional Chinese medicine (53), homeopathy (16), herbal medicine (9) and other therapies (6).

3.10 Visits and treatments of complementary medicine in the Tuscan healthcare system - 2022

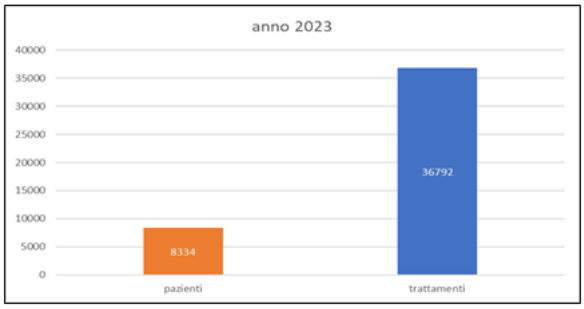
Local health autorithy	**n. of visits and treatments**
Local health authority north-western Tuscany	3,500
TCM	2,251
Herbal medicine	6
Homeopathy	1,243
Local health authority central Tuscany	13,595
TCM	12,786
Herbal medicine	627
Homeopathy	182
Local health authority south-eastern Tuscany	5,975
TCM	4,947
Herbal medicine	161
Homeopathy	844
Manual medicine	23
Pisa University hospital	1,437
TCM	1,410
Homeopathy	9
Herbal medicine	18
Siena University hospital	3,174
TCM	3174
Florence University hospital	**3,306**
TCM	2,581
Herbal medicine	718
Manual medicine	7
University Hospital Meyer, Florence	**833**
Manual medicine	833
Total	**31,820**

Number of MC visits within Tuscan Public Health System

2018	29.881
2019	30.253
2020	19.691
2021	25.716
2022	31.820
2023	36.792



Number of patients seen and CM visits delivered in 2023



4. Patient safety, clinical risk and pharmacovigilance in complementary medicine

- Regional referral centre for herbal medicine Careggi: telephone information on herbal medicine and pharmacovigilance
- Regional referral centre for homeopathy Lucca: Information on homeopathic medicines
- Collaboration with the Italian Institute of Health
- Campaign "CMs: know them to use them better" Information services to citizens carried out by regional referral centres, Italian Institute of Health and scientific societies in 2009-2010
- "Clinical risk and patient safety in Complementary Medicine", regional training course for health staff, publication of the Proceedings 'Safety of patients and clinical risk management in complementary medicine' MC Toscana Supplement no. 24
- Publication of the article "Patient Safety in Complementary Medicine through the Application of Clinical Risk Management in the Public Health System". Medicines (Basel). 2017 Dec 16; 4(4).

5. Communication and information to citizens

- Complementary medicine on the website of the Region of Tuscany https://www.regione.toscana.it/medicine-complementari
- Integrative clinics in oncology on the website of the Institute for the study, prevention and oncology network-Ispro https://www.ispro.toscana.it/rete_oncologica_toscana
- MC Toscana regional newsletter (52 issues), https://www.regione.toscana.it/-/notiziario-regionale-delle-medicine-complementari
- International and national events (Terra Futura - Florence from 2004 to 2009; Eco and Equo – Ancona etc.)
- Regional information campaign: 220 posters (6m x 3m) put up in Tuscan cities, 5,293 posters, 265 information boards hung on the main regional means of transport, 2000 posters for hospitals and healthcare facilities, press announcements in all regional newspapers and he regional pages of national newspapers.

6. University master courses in complementary medicine

• Faculty of Pharmacy of the University of Florence (2006-2007), II level Master in Traditional Chinese Phytotherapy
• Faculty of Medicine of the University of Florence (2006-2008), II level Master in Acupuncture and TCM
• Faculty of Medicine of the University of Florence – Empoli location (2007-2008), II level Master in Clinical Phytotherapy
• Faculty of Medicine of the University of Siena (2009-2018), Master in complementary medicines and integrated therapies
• Faculty of Pharmacy of the University of Pisa (2008-2012), 1st level Master in aromatic and medicinal plants
• Faculty of Medicine of the University of Florence (2011 – 2016), Master in Integrative Medicine with different addresses
• Faculty of Medicine of the University of Florence (2017 – 2023), Master in General and Clinical Phytotherapy.

7. CM training courses certified in Tuscany

For medical doctors and dentists (State-Regions Agreement of February 2013 and Memorandum of Understanding between the Tuscany Region and professional associations 2015)

- Three-year course in Acupuncture, School of Traditional Acupuncture of Florence
- Three-year course in Homeopathy, Effatà Association
- Three-year homeopathy course, Lycopodium Association
- Three-year course in Homeopathy, Society of Integrated and Homeopathic Medicine-SIOMI

For veterinary doctors and pharmacists (Regional Law 9/2007 and Memorandum of Understanding between the Tuscany Region and the professional associations 2015)

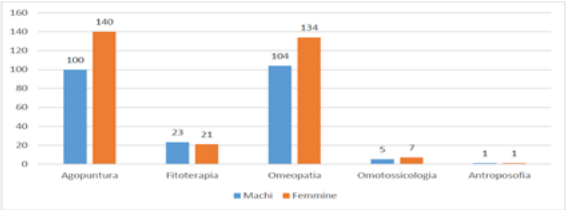
- Homeopathy course for veterinary doctors, Effatà Association
- Homeopathy course for veterinary doctors, Lycopodium Association – Homeopathia Europea
- Homeopathy course for veterinary doctors, International School of Homeopathic Veterinary
- Medicine Homeopathy course for pharmacists, Effatà Association
- Homeopathy course for pharmacists, SIOMI
- Acupuncture course for veterinary doctors, School of Traditional Acupuncture of Florence
- Traditional Chinese Phytotherapy Course for Pharmacists, School of Acupuncture of Florence.

7.1. Regional CME accreditation for training/educational courses in CM

The region of Tuscany has accredited the training events in CM promoted by the local health authorities since 2005.
According to the Regional Resolution n. 1014/2011 participants in the courses of CM schools, whose courses are accredited by the Tuscany Region, are entitled to exemption from CME credits for the period of attendance at the institutes, equal to or greater than 4 months.
Afterwards, the Regional Resolution n. 153/2019 established (point 4.1 annex 1.) that CM courses accredited by Tuscany entitle to annual exemption and that all healthcare professions are included in this exemption.

Experts in Complementary medicine registered with the provincial orders of physicians and dentists in Tuscany by discipline and gender (Tot. 685)

Genere (totale)									
Agopuntura		Fitoterapia		Omeopatia		Omotossicologia		Antroposofia	
M	F	M	F	M	F	M	F	M	F
100	140	23	21	104	134	5	7	1	1
M: 233 - F: 303									



8. Interregional Technical Group, Health Commission

The activities of the interregional complementary medicine group at the Health Commission began in 2007 and were co-ordinated by the Region of Tuscany.
Among the results of its activity, the "Guidelines for quality in training of Complementary Medicine", submitted, revised and approved by the Ministry of Health and the National Associations of Medical Doctors. The document was also the basis for drafting the "Guidelines for training in Medicine and non-conventional practices", which were approved by the National Associations of Medical Doctors in December 2009 and subsequently sent to the Health Commission as well as the State-Regions Agreement on practice and training in CM approved in February 2013.
Following a review of the interregional technical groups by the Health Commission of the Conference of Presidents of the Regions and Autonomous Provinces, the group ceased its activities in December 2015.

9. Agreement between the State, Regions and autonomous Provinces

The Agreement was signed at the Conference for relations between the State, the Regions and the autonomous Provinces on 7 February 2013: it concerns the criteria and methods for the quality certification of the training and practice of acupuncture, herbal medicine and homeopathy (including also homotoxicology and anthroposophy), by medical doctors, dentists, veterinarians and pharmacists. It set minimum and uniform criteria and requirements throughout the country for training courses suitable for qualifying health professionals who carry out these activities.
In July 2014, the Ministry of Health issued an explanatory note, which developed some points of the Agreement with indications to the Regions for its application.
At a national level, also other regions implemented the Agreement Sicily, Marche Piedmont, Umbria Puglia Emilia Romagna Lombardy, Sardinia and the Autonomous Province of Trento).

10. CM in oncology and collaboration with the Institute for study, prevention and the oncology network (ISPRO)

Complementary medicines are particularly widespread among cancer patients. Numerous studies conducted in Europe document that one in three cancer patients uses them, usually combining them with conventional oncological treatments. The United States, China, Korea, and Australia etc. reported similar trends.

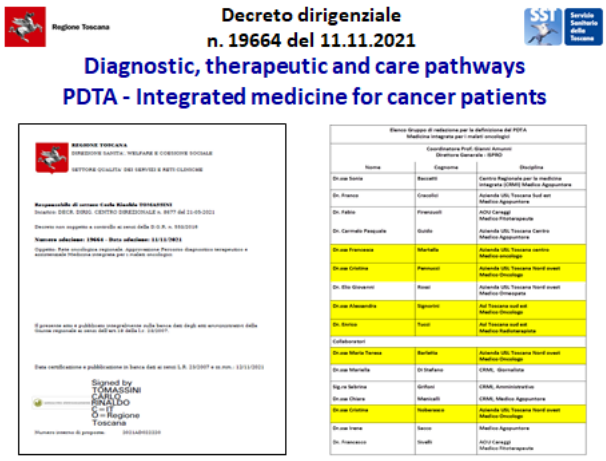
According to a multicentre survey conducted in five Italian hospitals, 48.9% of cancer patients have used a CM, predominantly women with a good level of education undergoing treatment in highly specialized facilities. According to a survey presented at the 2021 American Society of Clinical Oncology (ASCO) Congress, 73% of women with breast cancer report using at least one type of complementary medicine after diagnosis, and 43% of patients use these therapies during oncological treatments.

In Tuscany, a research conducted in six oncology departments in 2014 found that 37.9% of cancer patients use one or more types of complementary medicine, 66.3% inform their medical doctor of this choice and 89.6% experience the benefits.

The region of Tuscany identified oncology and cancer care as a priority sector of intervention for CM and, in agreement with ISPRO, some complementary therapies of documented efficacy and safety were included in oncology protocols, contributing to the multidisciplinary approach to cancer, in line with the Guidelines of the Italian Association of Medical Oncology (AIOM) since 2018.

The fundamental steps of the integration in oncology are:

- The Regional resolution n. 418/2015 "Integration of CMs in the oncology network of the Tuscan Cancer Institute". It stated that CMs are safe, effective, have few side effects and can improve the quality of life of cancer patients and underlined the importance of a multidisciplinary approach to cancer. It included CM with sufficient levels of evidence (acupuncture and TCM, herbal medicine, homeopathy).
- "Diagnostic, therapeutic and healthcare pathways" (DTHP) for breast cancer, in Annex A included integrative medicine for the treatment of the side effects of oncological therapy.
- ISPRO multi-year oncology guidance document (Regional resolution no. 634/2019) acknowledged the regional path for integration of acupuncture, herbal medicine and homeopathy treatments in the regional oncology network to improve the side effects of oncological therapies.
- Working Group "Integration of CMs in the oncology network" (Decree no. 11285/2020; ISPRO Director General Decree 15.04.21, ISPRO Note No. 1200 of 29.3.2022), with the task of monitoring, implementing and spreading integrative medicine in oncology pathways.
- 'Diagnostic, therapeutic and care pathways - Integrative medicine for cancer patients' (Decree no. 19664 11.11.21). Cancer patients can be treated with acupuncture and TCM, herbal medicine and homeopathy at every stage of their disease and in any type of cancer, to alleviate the side effects of therapies and symptoms related to the disease and to improve the quality of life.



The Region of Tuscany also participated as associated partner in the Joint Action European Partnership against Cancer - EPAAC (2011-2014) of the European Commission. It carried out a review of the literature on the effectiveness of acupuncture and TCM, herbal medicine, homeopathy, homotoxicology and anthroposophic medicine in the treatment of the side effects of oncological therapies and in improving the quality of life, published on EPAAC website (http://www.epaac.eu/). On this basis, a review of the scientific evidence was published in the book "Complementary medicines for cancer patients" (2015) and distributed in Tuscan healthcare facilities.

European survey of integrative oncology centres

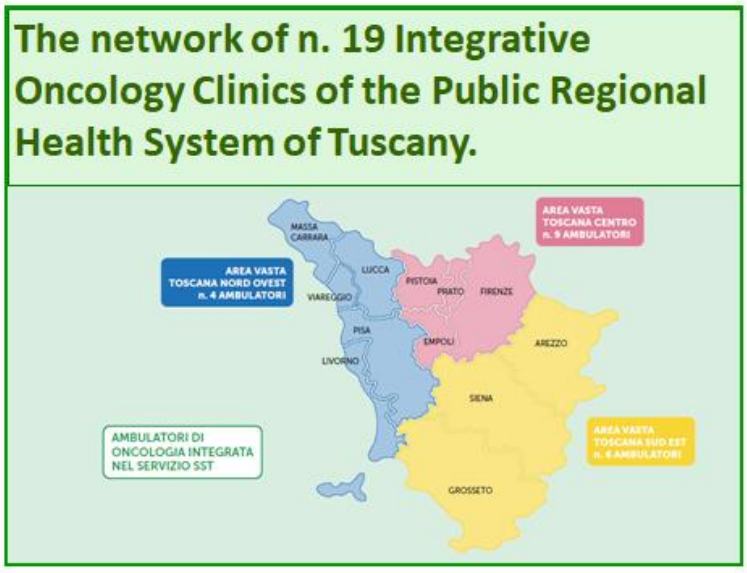
Frequency of CAMs provided to cancer patients by the surveyed centres

	Total		Italy		Other EU countries	
CAMs	n	%	n	%	n	%
Acupuncture	26	55.3	17	70.8	9	39.1
Anthroposophic medicine	10	21.3	2	8.3	8	34.8
Herbal medicine	18	38.3	12	50.0	6	26.1
Homeopathy	19	40.4	10	41.7	9	39.1
Homotoxicology	6	12.8	5	20.8	1	4.3
Traditional Chinese medicine	17	36.2	12	50.0	5	21.7
Other therapies	30	63.8	13	54.2	17	73.9

In the view of a correct communication and information on integrative oncological treatments in the public Tuscan health-care, the Tuscany Region published the brochure "Integrative medicine for cancer patients" (2018), which provided information on the opportunities of integrative medicine in oncology, healthy lifestyles and possible interactions between anticancer drugs and complementary therapies.
In June 2019, ISPRO, the region of Tuscany and Memorial Sloan Kettering Cancer Centre (MSKCC) signed a Memorandum of Understanding, which aimed at carrying out joint research on integrative medicine and updating and training programs for complementary medicine.

10.1 Survey on integrative oncology clinics of the Tuscan healthcare service

Presently, 19 clinics provide integrative treatments in oncology within Tuscan healthcare system (see map).



The Regional Centre for Integrative Medicine in collaboration with the regional referral structures conducted a survey of the activities and characteristics of the clinics providing integrative oncology treatments.
In 2022, 2,273 cancer patients were visited for 11,843 complementary medicine treatments (Table 1 and 2). The number of health staff and hours of activity was also reported (Table 3).

Table 1. Patients and treatments in 2022.

Clinics/Surgery	Therapy	Patients	Treatments
University Hospital of Careggi	Acupuncture and TCM	210	1,709
	Herbal medicine	630	1,390
Local health authority central Tuscany	Acupuncture and TCM	516	4,547
	Homeopathy	14	61

	Techniques of TCM	25	134
University Hospital of Pisa	Acupuncture and TCM	89	155
	Herbal medicine	4	24
	Homeopathy	9	11
Local health authority NW Tuscany	Acupuncture and TCM	135	679
	Homeopathy	154	345
University Hospital of Siena	Acupuncture and TCM	121	752
	Herbal medicine	23	45
	Homeopathy	/	8
Local health authority SE Tuscany	Acupuncture and TCM	165	1,330
	Herbal medicine	56	168
	Homeopathy	122	485

Table 2 – N. patients and treatments.

Therapy	n° patients	n° treatments
Acupuncture and TCM	1,236	9,172
Herbal medicine	713	1.627
Homeopathy	299	910
Techniques of TCM	25	134
Total	**2,273**	**11,843**

Table 3 – N. weekly hours and staff.

Location	Weekly hours	Staff
Local health authority NW Tuscany	20	9
University Hospital of Pisa	20	7
Local health authority central Tuscany	93	21
University Hospital of Careggi	38	14
Local health authority SE Tuscany	30	8
University Hospital of Siena	24	2

Figure 1. -Total of patients and treatments.

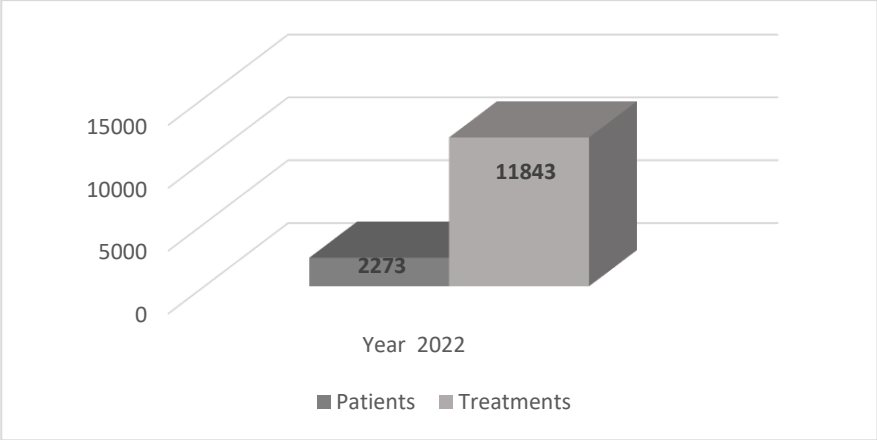


Figure 2 - Patients and treatments for each therapy.

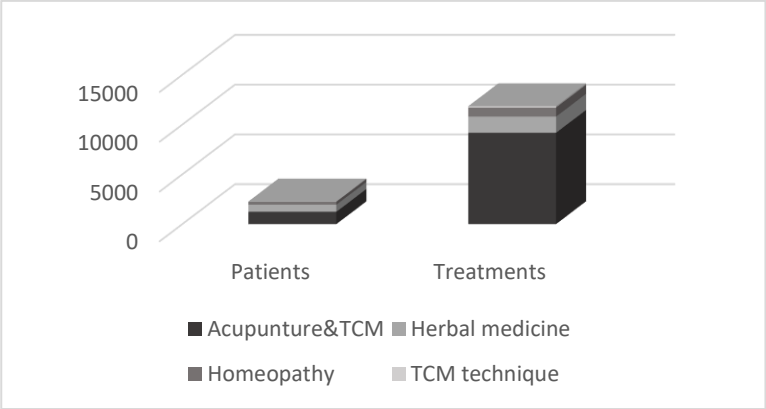
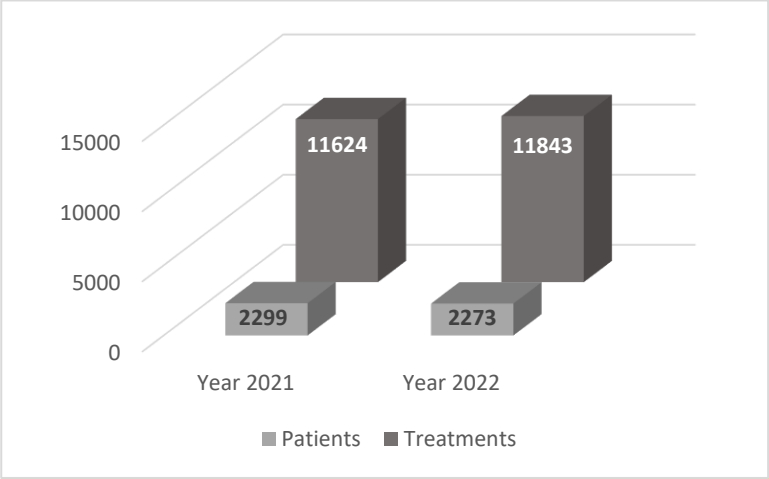


Figure 3. Comparison years 2021 and 2022.



11. Collaboration with the Regional Health Council and the Tuscan clinical governance body

11.1. Regional Health Council

- Opinion no. 54/2014 - Regional Council Resolution 1099/2014 "Pain control methods during labor and birth", includes complementary medicines among the non-pharmacological techniques for pain control during labor and birth.
- Opinion no. 33/2015 “Acupuncture and traditional Chinese medicine in the Tuscan Regional Health Service: guidelines”. It provided the health staff of the Regional Health Service with scientifically proven information on the benefits of acupuncture and traditional Chinese medicine treatment.
- “Menopause” Guidelines with a specific section on the use of complementary medicines in physiological and iatrogenic menopause, 2015.
- "Back Pain" Guidelines”, with a section dedicated to complementary medicines.

11.2. Tuscan clinical governance body-TCGB

Activities carried out in collaboration with the TCGB

• Opinion on the use of oxygen ozone therapy
• 'Regional care path for the care of people with fibromyalgia syndrome' for the part concerning complementary medicines approved with regional resolution no. 1311/2019
• Guidelines for breast cancer, approved with Decree no. 3823/ 2019 and updated in 2021 and 2023,
• Document 'The path and clinical network for headache or craniofacial neuralgia. Guidelines', approved with regional resolution n. 1286/ 2020
•“Everything will be fine… if we are able to change” Towards a return to “normality” New governance models for the appropriateness of care', Scientific Technical Committee Decision n. 09 2020.

12. CMs in support of natural childbirth

- Training course "Giving birth with energy" for 140 midwives from Tuscan birth centres aiming at teaching TCM techniques for the promotion of natural childbirth

- Training course on the use of TCM and homeopathy in Tuscan birth centres
- Regional Council Resolution n. 1099/2014 and Decree n. 2614/2015 "Recommendations on pain control methods during labor and childbirth ", therapeutic protocol for pain control in delivery of low-risk pregnancies with TCM and homeopathy.
- 'Guideline for pregnant and postpartum women who access complementary medicine in some hospital/consultancy', North West Tuscany Local Health Authority January 2022.

13. Regional training activities/courses

• Regional course 'The treatment of chronic pain in general medicine'.
• Regional course 'Promotion of complementary medicine in prison', promoted by the General Directorate of health.
• Course 'Pain control with TCM techniques', for nursing staff in home care, dialysis, hospices and palliative care, on the use of TCM techniques for pain control in vulnerable patients.
• Course 'Complementary medicines in labor and birth', for midwives and healthcare personnel.
• Webinar "Covid-19 and integrative medicine: strengthening the immune system and treatment of Long Covid", 19.3.2021, in collaboration with Formas.
• Webinar 'Integrative Medicine in Oncology', 1.10.2021, in collaboration with Formas.
• Webinar Women's health and integrative medicine, 26.5.2022, in collaboration with Formas.
• Webinar "Pain and integrative medicine", October and November 2023, in collaboration with Formas.

Training course Campo di Marte Hospital Lucca
Homeopathy and CM in labor and physiological delivery

13.1. AntiCovid-19 activity

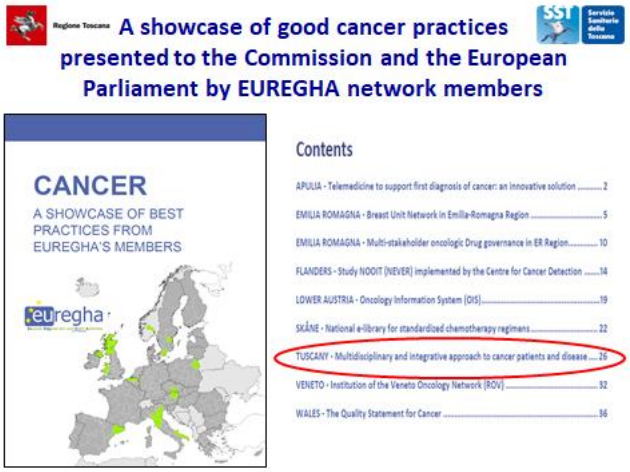
During the COVID-19 epidemic in Italy, hospital outpatient clinics progressively decreased their activities and in March 2020 they were closed except for emergencies. During this period, a number of medical doctors employed in Tuscan complementary and integrative medicine clinics worked in support of the regional health system, also in the intensive care units. Furthermore, the public Homeopathy Outpatient Clinic of Lucca aimed at guaranteeing a therapeutic continuity to patients by means of telephone or video consultations and cooperated in telephone health surveillance of infected patients at home, seroprevalence investigations using the capillary blood rapid test.
Noteworthy, the Complementary Medicine Working Group participated in the organization of the mission of COVID-19 Chinese experts in Tuscany in March 2020, who performed online training for health staff of the Tuscan Healthcare System.
Since the beginning of 2022, numerous patients with Post/Long Covid symptoms have received CIM treatments at outpatient clinics with good clinical results.

14. Activities in Europe

European projects

- Participation in the activities and seminar in Vienna of Work Package 7 of the European Cambrella project.
- Participation as an associate member in the Joint Action European Partnership against Cancer-EPAAC (2011-2014) in Work Package 7 Health Care, concluded in March 2014: drafting of the document reviewing scientific evidence on the use of CM in cancer care (www.epaac.eu) and publication on the European census of integrative oncology centres (Support Care Cancer 2014).

- • Antimicrobial resistance: participation in the EUROCAM project 'TCIM in the struggle against antimicrobial resistance'.
- • Inclusion of Integrative Oncology in the Tuscany Region as one of the innovative proposals in the brochure presented by EUREGHA to the Network of European Regions and to the European Commission (2021).
- • Participation in the Sino-EU PerMed project: Fostering the cooperation between Europe and China in Personalized Medicine (2021-22).



Collaborations in cancer care

• CanCon Project (Cancer Control Joint Action), initiative co-financed by the European Union, universities and institutes. The Tuscany Region was leader of Work Package 6, with the aim of defining models for integrating complementary medicines into cancer networks

• Joint Research Center (JRC) of Ispra, scientific centre of the European Commission: continuation and expansion of the survey of integrative oncology centres in Europe; design of a research protocol on CM for secondary menopausal disorders; definition of European quality criteria for the inclusion of CM in Breast Cancer Units and publication of the European Manual for services in Breast Units.

Relationship with European associations

- ✓ Association of European Cancer Leagues (ECL), a European organization made up of national and regional cancer leagues, aimed at cancer prevention and control.
- ✓ Anticancer Fund, a private foundation active in research on anticancer therapies that selectively finances the development of promising therapies.
- ✓ EuroCAM/CAMDOC, an association that brings together some of the most representative European associations in the sector.

15. International congresses

- International seminar 'Innovation and development in healthcare: the integration of complementary and traditional medicines in public healthcare systems', October 2008 Florence, organized by UNDP and UNOPS in the framework of the ART international cooperation initiative and the IDEASS Program and by the Tuscany Region. Delegations from Afghanistan, Albania, Austria, Bolivia, Chile, Cuba, Ecuador, Salvador, France, Gabon, Germany, Guatemala, India, Iran, Italy, Lebanon, Mali, Morocco, Mozambique, Dominican Republic, Serbia, Syria, Sri Lanka, South Africa, Venezuela approved the declaration "Complementary and traditional medicines in public health systems: towards integral medicine".
- Fifth European Congress of Integrative Medicine (ECIM) “The future of global patient care", Florence September 2012. Promoted by the Region of Tuscany, the University of Florence, and the Association of Medical Doctors and Dentists of Florence together with the Charité University of Berlin. More than 1,200 experts participated, over 1,000 medical doctors and healthcare workers; more than 500 scientific contributions received.
- International conference "New frontiers of integrative oncology - From research to integration in health services", Florence November 2016. Organized by the Central Tuscany Local Health Authority, ARTOI and the Tuscan Cancer Institute; approximately 450 Italian and foreign medical doctors, oncologists and researchers participated.

- International conference "Integrative oncology - The central brain and peripheral brains", Florence, 23-25 March 2018. Over 650 oncologists, researchers and integrative medicine doctors participated, illustrating the progress of scientific research and the national and international experiences of integration in oncology.
- "Integrative Oncology: Evidence and Clinical Experiences", Florence 2019, in collaboration with the Medical Association of Florence.
- 1st WHO Global Summit of Traditional, Complementary and Integrative Medicine, Gandinaghar Gujarat INDIA, 17-18 August 2023.
- 2nd World Congress Integrative Medicine and Health (WCIMH), Rome 20-23 September 2023; The Regional Centre of Integrative Medicine was a partner of the Congress.

16. International cooperation in CMs

- Support for the workshop "Refugees with Chronic Diseases between the Middle East and Europe: The role of traditional and integrative medicine in bridging gaps" at the World Congress Integrative Medicine & Health" Berlin 2017.
- Support for the international workshop 'Multi-disciplinary training program in anthroposophic and integrative manual therapies in integrative oncology practice' (2019).

Cuba

The activities of health cooperation of the Tuscany Region with Cuba started in 1994 and from 1998 to 2008 were developed within the framework of the Local Human Development Program (PDHL) of the United Nations.

Among the most relevant,

- Project in support of a natural and homeopathic medicine centre in Santiago de Cuba, at the "Hospital Clinico Quirurgico 10 de Octubre" in La Habana and in Pinar del Rio.
- Three-year project to set up a laboratory for the national production of homeopathic drugs
- Support for homeopathic training of veterinary doctors in La Habana
- Project for the renovation and consolidation of the Centre for Traditional and Natural Medicine (CMTN) in the historical centre of La Habana.

Senegal

Project "Fight against maternal and child mortality in Senegal" (2001), coordinated by the NGO Matraia Lucca in collaboration with the local partners in Thies and Mbao, the municipality of Florence with the economic support of the region of Tuscany.

Serbia

Project "Support for the integration of complementary medicines in the national and regional health system of Serbia" since February 2010. The project supported natural childbirth at the Obstetrics and Gynaecology Unit of the Municipal Hospital of Pancevo, Voivodina.

17. Wellbeing and natural disciplines – The Regional Law 2/2005

The Regional Law n. 2/2005 and the Regional Council Resolutions 1/2009 and 9/2010 regulated the so-called 'well-being and bionaturali disciplines'. These non-health techniques promote the well-being of the population and contribute to improve their quality of life. The definition included practises such as

naturopathy, shiatsu, craniosacral therapy, reflexology, tuina, pranotherapy, taiji-qigong, music therapy, yoga, osteopathy and the Feldenkrais method.

18. List of main publications produced in Tuscany Region (2005 – 2022)

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13. R. Ferreri: The process of Integrated Cares in Chronic diseases: experiences, critical points and highlights – International Journal of Integrated Medicine- Acupuncture and electro-therapeutis research- AEREDS 39 (3-4) – 2014 pp. 388-
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