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Editorial

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CAMbrella – Complementary Medicine Research in Europe

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It was in the year 1995 when I was invited for the first time to present my research in homeopathy at the newly founded Office of Alternative Medicine's (OAM) first conference on research methodology in complementary and alternative medicine (CAM) at the National Institutes of Health (NIH) in Bethesda, MD, USA, together with a couple of other researchers from Europe like Klaus Linde, Dieter Melchart, Andrew Vickers, George Lewith and others [1]. At that time we had something to contribute with our methodological reflection and our experience to the nascent movement of CAM research in the USA. In some areas we had already advanced beyond what was discussed at the meeting, and this was seen and honoured. And suddenly things changed. The OAM turned into the National Center for Complementary and Alternative Medicine (NCCAM) with a budget of roughly USD 150 million per year, and research started to flourish at such a quick pace that only our dreams could follow. Initially there were not enough competent reviewers so that even a couple of people from Europe were invited there to review the first proposals. Now, NCCAM is a major driver in the research agenda around CAM.

Roughly at the same time a small group around the homeopathic physician Michel van Wassenhoven, following up on a COST B4 action that brought together researchers from all over Europe, tried to lobby the European Commission to bring homeopathy and complementary medicine into the research programme of the EU [2]. It took at least 8 years of hard work, many meetings and many visits, until CAM was mentioned for the first time in the 5th Framework Programme (1998–2000) in 2000, in the text of the call 'Quality of Life and Living Resources'. That was only a short half-sentence in a document with more than 100 pages, but an important bit. This allowed 2 research projects to be funded, my own project on distant healing [3] and the CAM-Cancer project (*www.cam-cancer.org/*) that mapped out complementary cancer therapies. After that, nothing was heard, and we all feared that the initial momentum might be lost. It was thanks to the EURICAM initiative (*www.euricam.net/d-home.html*), being brought together and sustained by Susanne Schunder-Tatzber and Bettina Reiter in Vienna in 2006, that this momentum was upheld and grew into the first formal research call on CAM, not in the 6th, but in the 7th Framework Programme (2007–2013) in 2009. Thus, after roughly 16 years and lots of talks, unpaid work and time invested could it happen that the first pan-European research project on CAM, CAMbrella (*www.cambrella.eu/)* was approved. It had the remit to map the landscape of CAM in Europe: What do people mean, when the say 'complementary medicine' or 'alternative medicine', or 'natural medicine'? Which methods do they use, and how often? What providers are available and how are they regulated? What are the health services that are available for CAM, and what are the legal frameworks for them across Europe? What do people want, and do they get it? And finally, how should CAM be researched in the future?

This landscape of CAM provision, its reality and desirables, is now drawn out and published in this special issue of Forschende Komplementärmedizin/Research in Complementary Medicine. Wolfgang Weidenhammer, the head and organiser of the consortium, as well as editors of the journal have peer-reviewed the texts, which have undergone multiple cycles of review anyway. They consist of high-quality systematic reviews and expert consensus papers that are bound to become canonical texts for the years to come. They lay out the road of research in CAM and its future trajectory in Europe. Thus, they will be milestones for research here in Europe, and also world-wide. And they show: CAM research made in Europe has something to offer, not only to Europe, but to the world. We can only hope that our politicians have understood now that Europe is not only the strongest home for CAM in the western world, Europe can also benefit from

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it, and thus research in CAM is a strong asset for European countries, for European health systems and for European citizens. CAMbrella is the first step to developing an evidence base for a truly patient-centred medicine, which is neither alternative, nor complementary, but human, and we are curious about the further steps that will surely follow.

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Insights into the Current Situation of CAM in Europe:

Major Findings of the EU Project CAMbrella

Editors

Harald Walach, Frankfurt/O.
Wolfgang Weidenhammer, München

15 figures and 12 tables, 2012

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Guest Editorial

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CAMbrella – a Pan-European Research Network for Complementary and Alternative Medicine: From the Beginnings up to First Results

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In 2007, we started to work out an outline for the first research project on complementary and alternative medicine (CAM) intended to be funded by the 7th Framework Programme (FP7) of the European Commission (EC). This step was encouraged by the activities of an ad-hoc working group of which almost all members now can also be found as part of the CAMbrella group. Prior to this initiative, it took not less than 3 more years of intensive networking of the European CAM community to get the field of CAM incorporated into the essentials of the theme 'Health' for FP7.

In relation to this prehistory, the 3 years of CAMbrella's active project runtime are a rather short period. Networking and cooperation always have been common features during this entire period. Not without any reason, we published objectives, structure and work plan of the CAMbrella under the title '… to build European research network for complementary and alternative medicine' [1], in line with the nature of a 'coordination action', a specific funding type of FP7 that CAMbrella has been assigned to.

Numerous expectations are connected to the project and its results range from promotion of CAM for European health care to rigorous trials providing the evidence base for various CAM methods in different medical conditions. However, CAMbrella cannot meet all these requirements from different stakeholders for various reasons. Even though CAMbrella is not a research project in the narrow sense of the word, it is still research-oriented and so part of the EC's research promotion. In the early stage of the project this bizarre situation seemed to be contradictory, and it sometimes proved to be opaque for cooperation partners affiliated to universities. Consequently, due to the subject under observation, the articles compiled in this issue do not necessarily reflect commonly accepted scientific standards. It was not possible in all cases of data acquisition to focus on academic peer-reviewed articles as the basic source of information. In addition, other publications, such academic anthologies, governmental reports and surveys, or publications by CAM organizations were used in a more pragmatic way. Consequently, the rules for data collection in systematic literature reviews could not always be made standard practice.

Another limitation of the CAMbrella project is the lack of a shared understanding of the term CAM or complementary medicine, which runs like a golden thread through all work packages (WP) and also applies to the articles presented in this supplement. Although the CAMbrella project has been trying to overcome this issue by creating a separate WP, the new concepts and recommendations for the future use of terminology in the area of CAM will come too late to have an impact on all those project tasks already addressing existing sources of information. When focusing on the current situation in the field of CAM, the only way was to accept the terminology used by the authors in the identified articles and documents. This has to be distinguished clearly from any future arrangement of the preferred terminology.

This leads us to another basic principle of the CAMbrella project and its WPs [1]. According to its objectives one can identify a first batch of tasks related to the description of the 'current status' of CAM in Europe:

– WP1: to compile different ways of use of CAM-related terms and to suggest a pan-European definition of the overarching term 'CAM' (only the latter is presented here in a research report [2]) as well as a series of definitions for the terminology used to describe the major CAM interventions used clinically in Europe;
– WP2: to review the current legal status of CAM in EU member or associated states [3];

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– WP3: to explore the needs and attitudes of EU citizens with respect to CAM [4];
– WP4: to create a knowledge base that allows us to accurately evaluate the patients' needs and attitudes for CAM and the prevalence of its use in Europe [5];
– WP5: to explore the providers' perspectives on CAM treatment in Europe [6].

This list was complemented by the need to look beyond the European region on existing guidelines with respect to strategic reflections on research in the field of CAM:

– WP6: to consider the global perspective on CAM [7].

While the above-listed tasks and the corresponding WPs predominantly reflect the information that is already to be found, the second main target of the project is future oriented. The task is:

– WP7: to propose an appropriate research strategy for CAM that will help develop an understanding of CAM use and its effectiveness within an EU context in response to the needs of healthcare funders, providers and patients.

The first step in this WP was to collect and critically analyse CAM research methods used in the WPs 3–5 and to evaluate the clinical and epidemiological relevance of CAM in a systematic literature review. The results are included in this supplement [8], and served as a starting point for the development of proposals and recommendations regarding future CAM research. This second step was taken in order to develop a proposal for a roadmap of future CAM research. This part of project's work plan, the highly awaited CAM research roadmap, is still being finalised, and is currently not yet available; it will be published elsewhere later.

As already mentioned, networking, communication and dissemination of the information yielded in this project are vital measures for a successfully operating research community. A specific WP, WP8, dedicated to this subject matter also depicts and communicates its findings, concepts and ideas in the context of this special issue [9].

The analysis of the European situation of CAM provided by the CAMbrella project has been a first step. CAMbrella has undertaken the development of the roadmap for future research activities in this field, and it is clear that appropriate collaborative research projects on CAM are highly needed and should therefore follow as the next steps. The realisation of these projects requires public funding and, with respect to Europe, it would be highly desirable if 'Horizon 2020', the future Framework Programme of the EC, would offer the opportunity to apply for such funding. The roadmap will indicate the most relevant research topics for investigating how CAM could best contribute to the improvement of European health care.

Although CAM is used frequently by patients and applied by medical and non-medical providers in European countries, the available information about this kind of medicine is scarce, the terms and definitions of CAM methods are not clearly defined, the legal situation is heterogeneous all over Europe and the scientific evidence regarding efficacy, effectiveness and safety is limited. CAMbrella has confirmed this picture by gathering comprehensive information from all over Europe, which – among other things – will be incorporated into the roadmap of future CAM research. This is a valuable first step. However, in the long run, the success of CAMbrella will depend on its trigger function for meaningful CAM research projects in the future.

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Research Report

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Towards a Pan-European Definition of Complementary and Alternative Medicine – a Realistic Ambition?

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Keywords
Alternative medicine · Complementary medicine · Integrative medicine · CAMbrella · Health care reform · Consensus-oriented decision making

Summary
Background: The terms used for defining complementary and alternative medicine (CAM) including the methods, procedures and therapies vary greatly. The task of the CAMbrella working group on terminology was to explore the existing CAM terminologies and to develop a pragmatic definition of CAM that is acceptable Europe-wide. This can then be used to systematically research, e.g., its prevalence and legal status and to investigate the citizens' demands on CAM and the perspectives of providers of CAM in Europe. **Methods:** Terms and definitions were collected from both scientific and non-scientific sources. The terms and definitions identified were analysed and discussed among the CAMbrella working group participants on several occasions with the aim of arriving at a consensus. **Results:** We developed a proposal for a pragmatic European definition of CAM: 'Complementary and alternative medicine (CAM) utilised by European citizens represents a variety of different medical systems and therapies based on the knowledge, skills and practices derived from theories, philosophies and experiences used to maintain and improve health, as well as to prevent, diagnose, relieve or treat physical and mental illnesses. CAM has been mainly used outside conventional health care, but in some countries certain treatments are being adopted or adapted by conventional health care.' **Conclusion:** Developing a uniform, pragmatic pan-European definition of CAM was complicated by a number of factors. These included the vast diversity of existing definitions, systems, disciplines, procedures, methods and therapies available within the EU.

Introduction

There have been numerous efforts to define complementary and alternative medicine (CAM) over the last 3 decades. These attempts have been challenged by the fact that CAM may include everything from ancient traditional medicine systems that have determined health care for millennia to interventions with proposed mechanisms that reach far beyond most conventional medical logic and reasoning. The plethora of terms and the lack of a consensus about definitions can have negative implications for research and clinical practice. This might, for example, prevent effective inter-professional collaboration between conventional and CAM practitioners,

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which may in turn lead to impaired patient-centred care [1, 2]. The comprehensive CAMbrella project is an innovative and powerful response, which includes preparing the ground for future scientific research into CAM, that is appropriate for the health needs of European citizens and acceptable to their national research institutes and health care providers. To facilitate this response, our aim was to develop a pragmatic definition of CAM that is acceptable Europe-wide.

Material and Methods

We utilised a simplified version of the Consensus-Oriented Decision-Making model [3]. This offered a step-wise consensus process in which the working group outlined the process towards reaching a definition with the full participation of all members of the group. This model allowed the group to be flexible enough to make decisions when they needed to, while still following a format based on the primary values of consensus decision making. The working group comprised active researchers in the area of CAM from 6 European countries. The group members participated in several round-table discussions over the course of 32 months in addition to extensive electronic communication. Rough consensus was used with the aim to maximise the chance of accommodating the views of all group members. We systematically searched PubMed for definitions of CAM produced by different stakeholders, including citizens, patients and providers as well as global, European and national government agencies and academic institutions. The following search terms were employed with no language restrictions: definition, terminology AND CAM. In addition, a manual search of CAM-related journals and text books was made, which was complemented by an invited selection of relevant references to electronic and paper publications from the entire CAMbrella group, Advisory Board members and other experts in the field. Based on the various CAM definitions found and on their historical, cultural and geographic trajectories, we jointly developed and refined the proposed definition from the several rounds of discussions at a final project consensus meeting in May 2012.

Results

We were able to identify several high-impact conceptual definitions ranging from publications in the *New England Journal of Medicine* in 1993 [4] to the National Center for Complementary and Alternative Medicine, in the USA in 2000 [5]. We considered the most relevant and authoritative definition, albeit of Traditional Medicine, that was presented by World Health Organisation (WHO) in 2000 [6], while recognising that all the existing definitions left something to be desired. The WHO definition was selected as the best basis for the development of a pan-European definition due to its global relevance and endorsement by the WHO. The words in italics in the proposed definition are identical to the wording in the WHO definition, whereas the remaining wording was derived through our step-wise consensus process.

'Complementary and Alternative Medicine (CAM) utilised by European citizens represents a variety of different medical systems and therapies based on the *knowledge*, *skills* and *practices* derived from *theories*, philosophies and *experiences used to maintain* and improve *health*, as well as to *prevent, diagnose*, relieve or *treat physical and mental illnesses*. CAM has been mainly used outside conventional health care, but in some countries certain treatments are being adopted or adapted by conventional health care.'

Discussion

To facilitate future scientific research in CAM within Europe we have attempted to develop a European definition of CAM. The definition is similar in intention and wording to the current WHO definition of traditional medicine. This was deemed appropriate since most of the CAM systems and therapies used by European citizens are derived from different traditional medicine systems worldwide. These systems are used to maintain health, as well as to prevent, diagnose, improve or treat physical and mental illnesses. In addition, our definition also accounts for the unique and comprehensive European tradition of medicine, with its ancient Greek and Roman 'humoral' roots, including herbal medicine, manual methods, exercise and healthy nutrition. The proposed definition does not discriminate between the origins of a CAM therapy used or if it is provided by medical or non-medical practitioners, and it includes all CAM methods used by European citizens. We have also tried to accommodate the large variation in the acceptance and positioning of CAM in the conventional health care systems across European countries [7].

However, as we predicated, our definition suffers from several limitations. Using a more structured communication and consensus-building method, such as the Delphi method, would have allowed us to describe the process of arriving at our definition in a more transparent and quantitative manner. The proposed CAM definition does not discriminate between levels of evidence with respect to the safety and effectiveness of the various modalities and therapies. Our definition is difficult to operationalise because it does not tell us whether massage or omega-3 supplementation are CAM therapies in the same way that the Cochrane CAM field aims to do [8]. The many synonyms of CAM within the EU, such as alternative, complementary, unconventional, soft, natural and parallel, as well as the difficulties in universally defining specific CAM modalities are not addressed in this definition. These limitations and unresolved complexities are the reason why some researchers suggest that we should move beyond narrow and universal definitions of CAM [1].

We consider that it is not very fruitful to define CAM narrowly and universally as we have attempted to do. Since providers, researchers and policymakers often have different needs in relation to a CAM definition, each stakeholder should define exactly what they mean by the term CAM for each specific project. We wonder if considering an integrative health care system approach with a diversity of therapeutic

options and no particular differentiation between any evidence informed health care paradigms might be more appropriate [1]. This is clearly a challenge for future health systems and one that has also been identified by the director general of the WHO [9].

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What Attitudes and Needs Do Citizens in Europe Have in Relation to Complementary and Alternative Medicine?

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Keywords
Complementary and Alternative Medicine · Literature review · Attitudes · Needs · Information · Accessibility · Quality of care

Summary
Background: Surveys from several European countries suggest a European-wide increase in the use of Complementary and Alternative Medicine (CAM). To safeguard citizens' rights concerning their healthcare, it is critical to gain an overview of citizens' attitudes and to understand their expectations and needs regarding CAM. **Methods:** A review of literature was undertaken, based on systematic searches of the following electronic databases: PubMed, Web of Science, CINHAL, AMED, PsycINFO and PsycArticles; 189 articles met inclusion criteria. Articles were analysed thematically and their reporting quality assessed. **Results:** Despite the limited availability of research-based knowledge about citizens' attitudes and needs concerning CAM in many European countries, some trends can be noted. Many citizens hold positive attitudes to CAM and wish for increasing access to CAM provision. Citizens call for impartial, reliable and trustworthy information to support informed decision-making, and some citizens wish for greater support and involvement of biomedical healthcare professionals in facilitating their healthcare choices. While citizens value distinct aspects of CAM practice, they are also critical consumers and support clear regulatory and educational frameworks to ensure the quality and safety of CAM provision and medicinal products. **Conclusion:** To gain knowledge on citizens' needs and attitudes to CAM across Europe further research is required on 3 main issues: i) how citizens across Europe obtain information about CAM and the needs they may have for trustworthy information sources, ii) the local situations for accessing CAM and iii) citizens' perspectives on the quality of care and safety of CAM provision and products.

Introduction

Surveys from several European countries suggest the increasing use of complementary and alternative medicine (CAM) over the last decades, with up to 70% of citizens having used CAM [1]. This means that a large majority of citizens need information about CAM to be able to make informed decisions about the use of CAM. It is therefore critical to gain an overview of citizens' attitudes to CAM and to understand their expectations and needs regarding CAM provision and medicinal products.

The aim of this literature study is to provide an overview of citizens' attitudes and needs concerning CAM in Europe, based on the current state of research-based knowledge. In this context, we use the following definitions: *Citizen:* any individual, irrespective of whether or not they have used CAM modalities in the past, may use them in the future or are current users; *Attitude:* a disposition or state of being for or against something that is associated with emotions, feelings and values; *Need:* the starting point for the consideration of health needs is the World Health Organization (WHO) understanding health as a human right, i.e. 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being ...' (WHO constitution); *CAM:* where possible, the terms and understandings of CAM used by the author(s) of the identified articles were adopted in our reporting.

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Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
1 Design	1 no abstract
Quantitative	2 abstract not in English
Qualitative	3 presentation as abstract only
Literature reviews	4 outside EU (or Turkey, or Israel)
2 Participants	5 editorials, letters, opinion pieces
Citizens in the EU	6 duplicates
In any of the 39 EU countries	7 studies reporting on clinical treatment or treatment evaluation (e.g. RCTs, outcome studies)
All ages	
3 Languages	8 studies reporting on medicinal use of a single herb, herbal compound, homeopathic remedy, aromatherapy oil, natural substance or treatment technique for particular condition/s and/or by particular population group/s
Any EU language	

Table 2. Search terms

General search terms Searches 1 and 2	Specific search terms Search 1	Specific search terms Search 2
CAM	*citizen* (OR synonyms)	all databases:
PubMed:	PubMed:	information, quality of care, decision-making, disclosure, safety, access, cost, evidence, effectiveness, regulation
'Complementary therapies' (MeSH[a])	humans (MeSH)	
Remaining databases:	remaining databases:	
Complementary medicine* OR alternative medicine* OR complementary therap* OR alternative therap* OR integrative medicine* OR integrative therap*	Public, Population, Consumer, Inhabitant, Resident	
Europe	*attitude* (OR synonyms)	
PubMed:	PubMed:	
'Europe (MeSH) OR Turkey OR Israel'	attitude to Health (MeSH)	
Web of Science:	remaining databases:	
Additional data base search facilities	belief, awareness, acceptance, value, philosoph*, world view, choice, knowledge, inclination, perception, approach, outlook, position, opinion, point of view, openness	
Remaining databases:		
Selection made following the reading of title, abstract, and (if needed) full articles	*need* (OR synonyms)	
	all databases:	
	Demand, Reason, Expectation, Motivation, Barrier, Requirement	

[a]MeSH = Medical subject headings.

Methods

A review of literature was carried out based on systematic searches of the following electronic databases: PubMed, Web of Science, CINHAL, AMED, PsycINFO and PsyARTICLES, with date limits applied (January 1, 1989 to December 31, 2009). For inclusion and exclusion criteria, see table 1.

Two separate but related searches were carried out (for search terms, see table 2). The key themes used for selection of search terms were identified at a stakeholder workshop: citizens' attitudes and needs concerning i) access to CAM, ii) information about CAM and iii) quality and safety of CAM provision.

Search 1 was based on keywords reflecting the above themes and identified 2,796 abstracts; 323 were considered further. Few of the identified abstracts related to citizens' needs regarding CAM in Europe, when compared to the number of abstracts relating to – broadly speaking – citizens' attitudes to CAM in Europe. A second search, Search 2, with additional keywords identified from the articles from Search 1 was therefore carried out, which identified 3,698 abstracts; 194 were considered further.

After removing duplicates, 338 abstracts were included for further consideration. Full articles were retrieved and read, and further articles excluded; also excluded were non-systematic literature reviews and where only abstracts were available (see fig. 1). The remaining 189 articles were analysed thematically, based on identifying emerging categories, themes, and sub-themes [2].

The reporting quality in the articles was assessed according to internationally acknowledged standards [3, 4]. Systematic reviews were not subject to quality assessment and are included for discussion only. Based on the quality assessment, articles were grouped into 3 'reporting quality' categories: high, medium and low.

Results

The attitudes and needs of citizens in Europe concerning CAM were researched in 18 of 39 EU member states and associated countries included in this review (see fig. 2). Substantial research-based knowledge is only available from the UK.

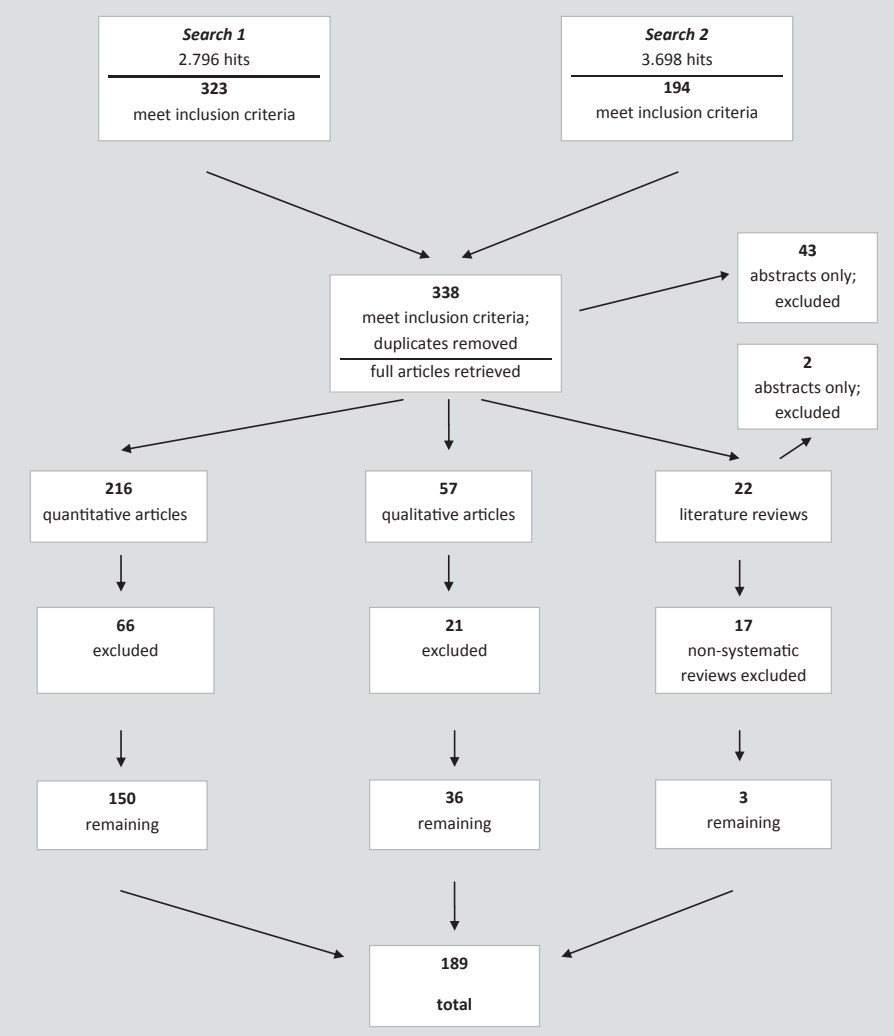

Fig. 1. Flowchart of identified abstracts and articles.

A medium number of articles were identified from Germany, Turkey, Israel, Switzerland, and Italy, and a small number from others; no peer-reviewed articles were retrieved for 21 countries. This means that countries are not explored in equal depth and over half are not examined at all. A further 5 articles reported Europe-wide studies, and 3 systematic reviews of literature examined literature internationally.

Of the articles, 37 investigated citizens' attitudes and needs explicitly, while 149 examined these topics as part of other research interests about CAM. Of these, 43 articles were considered of high, 96 of medium and 47 of low reporting quality, regardless of the quality of studies per se.

Access to CAM: A Complex Picture of Demands, Attitudes and Needs

UK studies show that a majority of healthcare users (54–66%) supports the provision of CAM in the National Health Service [5–7], as does the majority of citizens (82–96%) in Israel [8, 9]. In Norway, between 43 and 63% of citizens feel that CAM should be an option for cancer patients in hospitals [10, 11], although only 5% of the general population think that general practitioners (GPs) should recommend acupuncture for cancer patients [12]. In Germany and Switzerland, where CAM is often provided by GPs, close to 70% of primary care patients would like to be treated more frequently with CAM, especially by their GP [13, 14]. From the perspective of Italian physicians, patients express a high preference for CAM [15].

Several studies point to citizens' favouring diverse forms of CAM provision. For instance, UK and Israeli citizens support provision within and outside of public healthcare systems, e.g. receiving CAM from physicians with CAM training and CAM providers without biomedical training [9, 16, 17]. Such diversity is also supported by nearly half of UK primary healthcare workers [18].

Citizens experience multiple barriers when accessing CAM. A considerable barrier is the cost of CAM treatments paid for out-of-pocket when CAM is provided in the private sector. While some citizens, e.g. in the UK and Israel, are willing to pay for or contribute to the payment of CAM [5, 9, 19, 20], for others, such as some UK and Danish citizens, the cost of CAM may constitute a significant barrier [21–28]. In countries, such as Germany and Switzerland, where some CAM

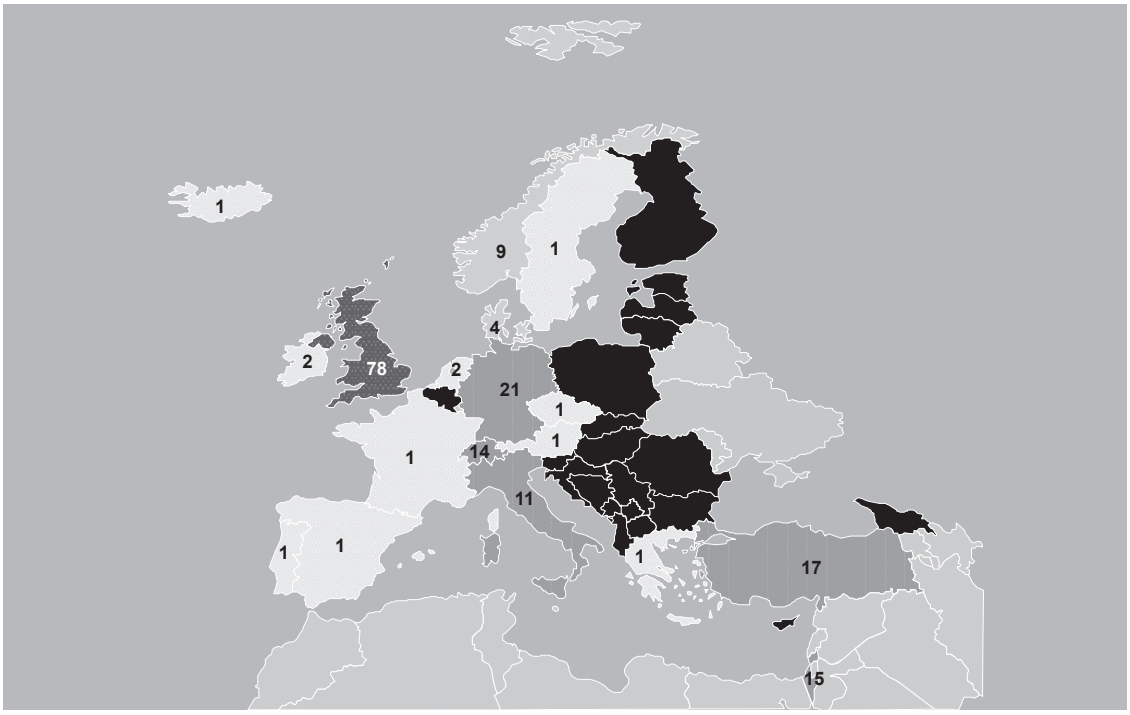

Fig 2. Geographical distribution of articles across the EU. Black, Countries without any articles (n = 21). For countries with articles (n = 18), more articles with increasing levels of grey; numbers indicate number of articles.

treatments (or parts thereof) are reimbursed through health insurance schemes, variable reimbursement is shown to have implications for citizens' treatment choices as they predominantly choose reimbursable CAM therapies [14, 27]. This indicates that many citizens in Europe pay for their CAM treatments of choice, leading to differential access by diverse groups of citizens [29, 30]. Financial cost as a barrier to CAM is, however, not confirmed in EU-wide studies [31–33].

The attitudes of biomedical professionals (e.g. general practitioners, hospital clinicians, nurses, midwifes and physiotherapists) to CAM also seem to form a barrier. Findings from the UK [16, 17, 34–36], Israel [9] and Switzerland [14] indicate citizens' wish for more support and knowledge about CAM from biomedical professionals. Biomedical professionals' lack of knowledge and support for citizens' interest in, and use of, CAM, as perceived by the citizens [37], may lead to non-disclosure of CAM in biomedical encounters, and constitute a significant barrier to accessing information about CAM or referrals to CAM provision via biomedical professionals.

A correlation can be tentatively drawn between the extent to which CAM is practised by biomedical professionals and citizens' disclosure of their interest in, or use of, CAM. Studies included in this review point to a spectrum of disclosure rates of CAM use in different EU countries that ranges from low disclosure, where the majority of CAM users do not discuss CAM with biomedical professionals (e.g. in Turkey [38–42]), to high disclosure, where the majority disclose their use of CAM (e.g. in Switzerland [43–45]. Countries in which CAM is often practised by biomedical professionals and where the practice is highly regulated (e.g. in Switzerland) appear to have higher disclosure rates. This indicates that biomedical attitudes to CAM influence the extent of discussion of CAM in biomedical encounters.

A link between the availability of information about CAM and citizens' non-use of CAM is reported from the UK [21, 46, 47], Germany [48, 49] and Italy [50]. This supports findings that suggest that the more information citizens have about CAM the higher their CAM use [51, 52], although this trend is not confirmed for all European countries [33].

Citizens' Information Sources about CAM

Two over-arching patterns can be identified in how citizens seek information about CAM: (a) citizens in some countries draw predominantly on their social networks of friends, family and other close associates as the main CAM information source; and (b) in countries where biomedical professionals are the citizens' main information source on CAM, social networks as information provider appear relatively less prominent. To a lesser extent, citizens also use the media and other sources [53].

The prominence of social networks as the main CAM information source is noted particularly, but not exclusively, in the UK [5, 7, 29, 35, 36, 54–59], Turkey [38, 39, 41, 42, 60–65], Israel [66–68], Norway [11] and Ireland [69], and is confirmed by studies examining CAM across a range of countries [33, 70–73]. Citizens in these countries appear to draw considerably less frequently on biomedical professionals for information about CAM. Qualitative studies confirm the importance of social networks [24, 25, 46, 74–80] and point to specific groups within social networks in directing individuals towards CAM: female family members of male cancer patients [74,

75]; older family members in the case of people of South Asian origin in the UK [79]; and Chinese migrant women's networks that span the UK and women's countries of origin [24]. While these studies unanimously highlight the centrality of social networks as CAM information sources, some studies from the UK [17, 74, 81–84] and Israel [9, 85, 86] also note that some citizens would like to receive information about CAM from biomedical professionals.

A second pattern of information seeking is noted in studies from countries where CAM is frequently practised by biomedical professionals. Here, biomedical professionals constitute a main information source about CAM, with social networks being relatively less prominent. This pattern is less explored and clear cut, although it is observed in Germany [87, 88] and Tuscany [89], but has not been confirmed for Italy as a whole [90] or for Germany [91]. Variations in the biomedical professional group and CAM therapy are noted in both countries [92–95].

Underpinning the information sharing through social networks is the importance of personal experience with CAM. Citizens' personal experience seems to influence initial and repeated use of CAM, as shown by studies from the UK [5, 21, 54, 74, 75, 79, 96], Ireland [69], Switzerland [14, 43, 97], Turkey [39], Israel [67], Germany [87, 91, 93], France [80], Norway [12] and Austria [98]. The trend of attitudes to CAM being shaped by personal CAM experience is also observed for biomedical professionals and students of biomedical professions [83, 99–105].

Quality and Safety of CAM: Citizens' Attitudes and Needs

Several studies show that citizens value the positive CAM provider-patient relationship and the patient-centred approach offered in many CAM consultations, where citizens perceive to have a voice in negotiating treatment options and to be enabled to take control of their own care. Communication between CAM users and providers critically contributes to this perception, particularly the experience of 'having time' for discussion and exploration and 'being listened to', compared to biomedical encounters, as noted in studies from the UK [22, 25, 58, 75, 106–109], Switzerland [110–113], Germany [114], Spain [115], Denmark [28] and France [80].

Citizens' appreciation of the values underpinning the practice of CAM is noted in several studies. The importance of personalised care, and the patient-centred and holistic approach advocated by CAM are particularly noted in the UK [19, 25, 58, 59, 116, 117], Norway [118], Germany [77, 119], Israel [120] and Switzerland [121]. Additionally, the provision of explanatory frameworks, which often constitute an integral part of the 'package of care' [23], can be central to the ways some CAM users make sense of their illness and its treatment [28, 80, 106, 109].

Some studies show that citizens are critical consumers who terminate treatment if they are dissatisfied with the treatment process and/or their relationship with the CAM provider. Reasons for discontinuing CAM treatments include similarities between CAM and biomedical treatments, lack of anticipated involvement and/or independence in decision-making concerning treatment options, an unexpected 'foreignness' of CAM, and a lack of information given by CAM providers [70, 122–124].

Citizens' stance as critical consumers is also noticeable with regard to the safety of CAM, as citizens do not automatically assume the safety and quality of CAM provision [54, 79]. Although studies show that many citizens across Europe perceive CAM and/or CAM products as 'natural' and, therefore, safer than biomedical treatment, and/or as not involving risk and/or side-effects [7, 16, 28, 32, 35, 43, 44, 46, 50, 61, 62, 64, 78, 79, 91, 120, 121, 124–132], several of these studies also indicate that citizens are critical, and at times doubtful, about CAM safety and efficacy [16, 79, 130, 131]. The historical use of acupuncture and herbal medicine is particularly argued to explain their safety [16, 75]. Citizens' perceptions of CAM as generally safe are often reinforced by their personal experience [33, 66, 70, 133–136] and supported by some research [137–140].

To assess and aim to ensure the quality of CAM, citizens draw on distinct strategies. Some studies show how citizens look for CAM endorsement and legitimacy conferred through biomedicine, such as receiving information about CAM from biomedical professionals [75, 84], favouring CAM provided through public health services [21, 34, 75] or by GPs [13, 14], or wishing for a GP referral to CAM providers [9]. Provider registration with professional CAM organisations increases UK citizens' trust in CAM provision [6, 16], a trend that has gained importance over time [6]. UK citizens also refer to CAM provider qualifications to ascertain the safety and potential quality of provision [6, 74]. Other citizens may trust the CAM services they use because they are provided by biomedical professionals, even though not all biomedical CAM providers have certified training in the CAM therapies they practise [15, 89, 102]. These findings reflect the opinions of key decision makers in German medical schools who associate the risks of CAM primarily with inadequate quality control of CAM provider training and the undifferentiated use of CAM by biomedical professionals [99].

Discussion

This literature study identified research-based literature on citizens' attitudes and needs concerning CAM in 18 of 39 EU member states and associated countries. The topic is largely examined indirectly, with poor reporting quality of many articles. These limitations highlight that citizens' attitudes and needs concerning CAM in Europe remain under-studied. Accordingly, the findings presented are only indicative of the European situation, and suggest tendencies rather than well-

established facts regarding citizens' needs and attitudes towards CAM in Europe.

A relevant context for a discussion of the identified tendencies and need for future research in this area is EU health policy, which is underpinned by an understanding of health as a human right, and a commitment to citizens' engagement and a patient-centred approach to addressing health issues across Europe [141]. Of particular relevance is the Second Programme of Community Action in the field of health (2008–2013), which acknowledges the importance of CAM for citizens' healthcare: 'The Programme should recognise the importance of a holistic approach to public health and take into account (...) complementary and alternative medicine in its actions' [142]. Given this acknowledgment, it is worthwhile considering how well citizens' attitudes and needs concerning CAM are investigated in relation to relevant EU health policies.

Our findings indicate that the wish of many citizens to make an informed decision about their healthcare by drawing on reliable, trustworthy and diverse sources of information about CAM remains unmet. This contrasts with a central EU objective emphasizing the need to increase the citizens' ability to make better decisions about their health and be protected from risks and threats to health that are beyond their individual control [143]. Thus, research on how to disseminate research-based knowledge on CAM best would support a fulfilment of this policy aim and further strengthen the citizens' ability to share responsibility for their health, as proposed by the EU [144].

There are indications that citizens wish to gather information about CAM from biomedical professionals, at least in some instances, while other research points to other strategies of information-seeking. Research investigating citizens' needs for reliable and trustworthy information about CAM on a Europe-wide basis would be relevant. Although the importance of information on CAM is acknowledged in EU health policies, such recognition may not be shared across all EU healthcare systems.

The cost of CAM paid for out-of-pocket constitutes a barrier to CAM use for many citizens. This contrasts with the values of universality, access to good quality care, equity and solidarity, which underpin EU health policies and aim to ensure equal access to healthcare according to need, regardless of ethnicity, gender, age, social status or the ability to pay [145]. The cost of CAM as a barrier to its use is, however, not confirmed across all European countries [31–33], which highlights the importance of examining citizens' access to individual CAM therapies in specific local contexts, their reasons for paying for CAM, and the specificity of local meanings of the term CAM.

The findings highlight that many citizens in Europe value the practice of CAM, particularly the CAM provider-patient relationship, and the patient-centred and holistic approach aspired to by many CAM providers. It would be valuable to explore to what extend CAM across Europe is characterized by these values and whether there are differences when CAM is provided by biomedical professionals or other CAM providers. The patient-centred care is in line with EU health policy that aims to shift responsibilities for health from health care providers to citizens [146]. Citizens are critical consumers of CAM, particularly with regard to the quality and safety of CAM provision, and form their own judgments about acceptable risks concerning CAM, although their assessment of these risks may differ from the sources and understandings of evidence used by biomedical professionals and health policy makers. This calls for more research into citizens' perspectives on the quality of care and safety of CAM provision and products.

Conclusion

Citizens' needs and attitudes to CAM have only been researched in half of the countries associated with the EU. Given the scarcity or lack of research-based literature on citizens' needs and attitudes to CAM in Europe and in light of EU health policies, further research is needed to examine how citizens across Europe obtain information about CAM and the needs they may have for trustworthy information sources. Further, we need research on local situations for accessing CAM and on citizens' perspectives on the quality and safety of CAM products and provision across Europe.

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Review Article

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A Systematic Literature Review of Complementary and Alternative Medicine Prevalence in EU

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Keywords
Systematic review · European Union · Prevalence · Complementary and alternative medicine

Summary
Background: Studies suggest that complementary and alternative medicine (CAM) is widely used in the European Union (EU). We systematically reviewed data, reporting research quality and the prevalence of CAM use by citizens in Europe; what it is used for, and why. **Methods:** We searched for general population surveys of CAM use by using Ovid MEDLINE (1948 to September 2010), Cochrane Library (1989 to September 2010), CINAHL (1989 to September 2010), EMBASE (1980 to September 2010), PsychINFO including PsychARTICLES (1989 to September 2010), Web of Science (1989 to September 2010), AMED (1985 to September 2010), and CISCOM (1989 to September 2010). Additional studies were identified through experts and grey literature. Cross-sectional, population-based or cohort studies reporting CAM use in any EU language were included. Data were extracted and reviewed by 2 authors using a pre-designed extraction protocol with quality assessment instrument. **Results:** 87 studies were included. Inter-rater reliability was good (kappa = 0.8). Study methodology and quality of reporting were poor. The prevalence of CAM use varied widely within and across EU countries (0.3–86%). Prevalence data demonstrated substantial heterogeneity unrelated to report quality; therefore, we were unable to pool data for meta-analysis; our report is narrative and based on descriptive statistics. Herbal medicine was most commonly reported. CAM users were mainly women. The most common reason for use was dissatisfaction with conventional care; CAM was widely used for musculoskeletal problems. **Conclusion:** CAM prevalence across the EU is problematic to estimate because studies are generally poor and heterogeneous. A consistent definition of CAM, a core set of CAMs with country-specific variations and a standardised reporting strategy to enhance the accuracy of data pooling would improve reporting quality.

Introduction

The use of complementary and alternative medicine (CAM) interventions such as acupuncture, homeopathy and herbal medicine has increased exponentially in western industrialised nations over the last 25 years [1–4]. CAM is mainly used in addition to conventional care for many chronic and some

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acute health conditions as well as for maintaining health. More than half of all breast cancer patients and up to 90% of people with chronic benign conditions, such as arthritis, use some CAM [5]. CAM is often used as a mechanism for minimising the use of conventional drugs and is frequently purchased over the counter (OTC) as a medicine in chronic disease. CAM is practised by both doctors and non-medically qualified individuals within the European Union (EU).

Recent reviews of CAM use in general populations across continents report prevalence rates of between 2.6 and 74.8% [6, 7]. Systematic reviews of CAM use in specific cancer populations suggest prevalence rates of between 11 and 91% [8–10] with rates in other conditions similarly wide ranging [11–13]. These reviews commonly report that the quality of included studies is highly variable, that there is a lack of a consistent operational definition of CAM, that the number and types of therapies included as CAM vary hugely from study to study and that prevalence is measured over differing time frames. Despite these short comings, reviews suggest that the prevalence of CAM use can be high.

Within Europe, surveys in the UK, Germany and Italy suggest that between 10 and 70% of the total population use CAM each year [2, 14, 15]. Despite data only being available from a few EU states, the global atlas of traditional and complementary medicine (World Health Organisation (WHO) Centre for Health Development) [16] suggests CAM is highly prevalent within the EU. Similarly, the European Information Centre for Complementary & Alternative Medicine (EICCAM) suggests that more than 100 million EU citizens are regular users of CAM, predominantly for chronic conditions [17]. There is an urgent need to identify accurate data on CAM prevalence across the EU so that we can develop an understanding of the medical and economic issues surrounding CAM use and its safe and legitimate provision to EU citizens. We therefore aimed to:

– address the prevalence of CAM use in Europe from (normally cross-sectional) population-based studies,
– determine which CAMs are used and for which conditions,
– explore the reasons why patients choose CAM,
– assess the quality of the data available and quality of reporting.

Methods

The details of the review methodology and data extraction tool were developed by the CAMbrella management group (appendix 1 available at *http://content.karger.com/ProdukteDB/produkte.asp?doi=342708*). We followed the PRISMA statement guidelines for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions [18].

Literature Search

Using the NCCAM definition of CAM [19], studies were identified through the electronic databases Ovid MEDLINE (1948 to September 2010), Cochrane Library (1989 to September 2010), CINAHL (1989 to September 2010), EMBASE (1980 to September 2010), PsychINFO including PsychARTICLES (1989 to September 2010), Web of Science (1989 to September 2010), AMED (1985 to September 2010) and CISCOM (1989 to September 2010) limited for date January 1, 1989 to December 31, 2009) and 'human studies' but not language. Papers in EU languages were translated into English. The last search was run on September 29, 2010. We also citation-searched all included studies, looked at reference lists of previously published reviews, requested further potentially relevant publications from CAM experts, CAM organisation and registration bodies and searched the electronic grey literature base OpenSIGLE.

We included population-based, cohort or cross-sectional studies of all ages of participants in any EU country and language, reporting the prevalence of use of CAM in general, or 1 or more specific CAMs broadly consistent with the National Center for Complementary and Alternative Medicine (NCCAM) definition [19], and with assessment of at least 1 socio-demographic variable. We excluded non-peer reviewed, non-cross-sectional or non-cohort studies, editorials, letters, theses and dissertations, case studies and congress abstracts. We further excluded unpublished or on-going studies, double publications and studies focussing exclusively on CAM use in disease-specific populations (e.g., cancer).

The full electronic search strategy for Ovid MEDLINE is reported in the on-line appendix 2 (available at *http://content.karger.com/ProdukteDB/produkte.asp?doi=342708*).

Selection of Studies

One reviewer (Susan Eardley) checked the literature search, excluding articles that were not at all related to CAM. The titles, abstracts and (if necessary) full text copies of all remaining articles were then assessed independently for eligibility by 2 reviewers (Susan Eardley and Felicity Bishop). Disagreements were resolved by discussion; inter-rater agreement was calculated by Cohen's kappa. Full text copies of all eligible papers were obtained and translated into English as necessary.

Data Extraction and Quality Assessment Process

Using the pre-designed data extraction tool, 1 reviewer (Susan Eardley) extracted data from all 87 included papers on CAM prevalence, types of CAMs, demographic data, reasons for use and conditions treated. A second reviewer (Felicity Bishop) independently extracted data from a randomly selected sample of 20% of studies with good inter-rater agreement (kappa = 0.8). A third reviewer (George Lewith) extracted data on overall CAM prevalence from all included studies, and agreement was 96.5%. We assessed study quality using a pre-existing quality assessment tool (QAT) [8] based on the STROBE statement checklist for observational studies [20] comprising 16 items in 4 domains (appendix 3 available at *http://content.karger.com/ProdukteDB/produkte.asp?doi=342708*). The questions were weighted for importance for overall quality by the assignment of points (maximum score 16.5 points). Scores were transformed into percentage points. Disagreements were resolved by discussion.

Methods of Analysis

We used standard descriptive statistics and Forest plots to depict prevalence rates of overall CAM use and of the more widely recognised CAM modalities. We planned to perform Cochrane's test for heterogeneity before a meta-analysis to combine the information from the different studies

Results

All additional data are available in our complete CAMbrella Work Package 4 report, including tables, figures and protocols (*www.cambrella.eu*).

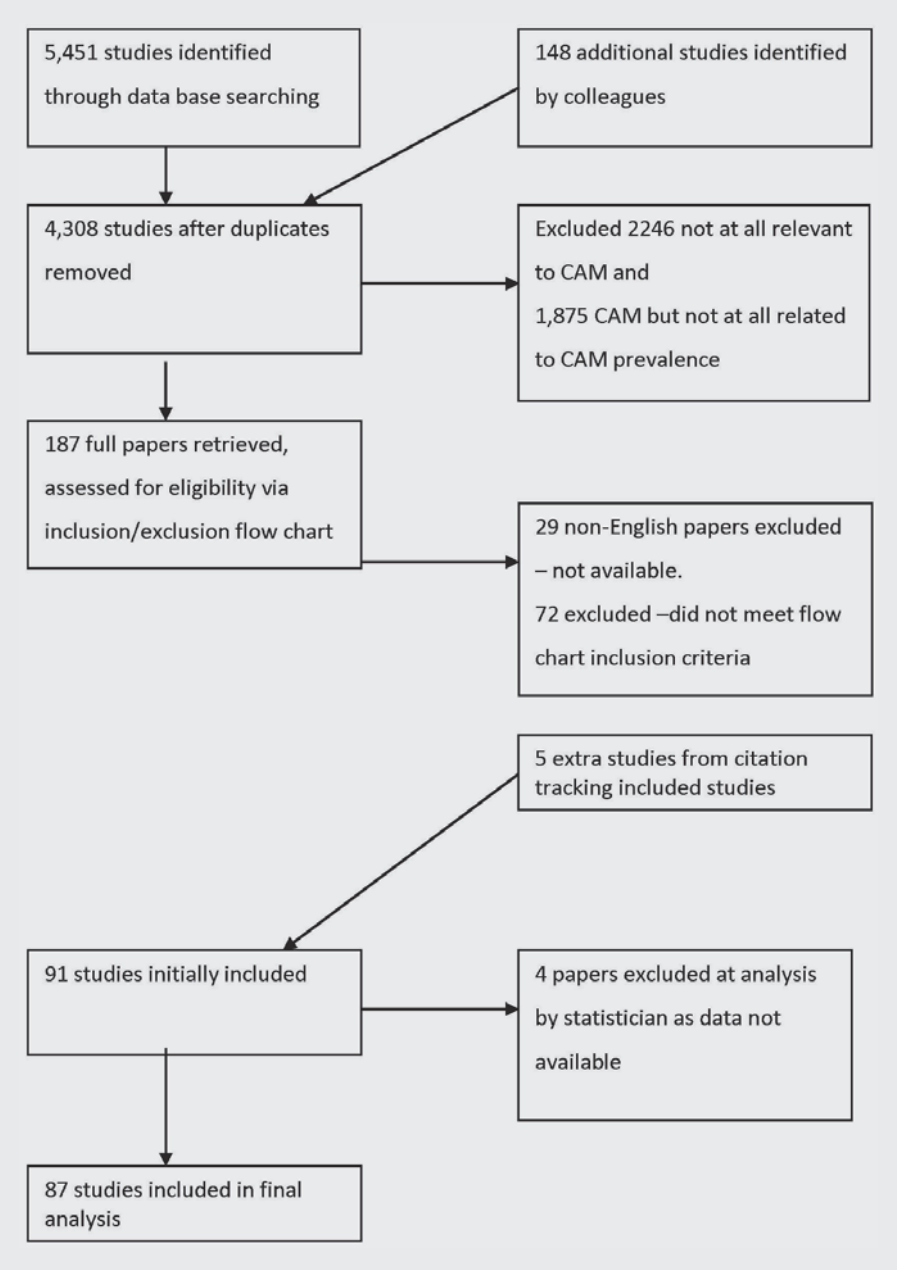

Fig. 1. Flow of information through the different phases of the systematic review.

Study Selection and Characteristics

Figure 1 reports the flow of information through the study. After excluding clearly ineligible studies, 187 studies were assessed in detail for eligibility (fig. 1). Inter-rater reliability for inclusion was good (Cohen's kappa = 0.70 [21]). No eligible studies were found in the grey literature. 87 studies that reported the prevalence of CAM use were included in the final analysis. Sample sizes varied from small studies of 92 participants [22] to population surveys of 57,717,200 [15] (median 1,785). We did not locate any general population data on CAM use for 22 (64%) EU member states and associated countries based on our study inclusion criteria (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Romania, Latvia, Lithuania, Luxembourg, Malta, Slovakia, Greece, Hungary, Liechtenstein, Montenegro, Albania, Bosnia & Herzegovina, Croatia, Republic of Macedonia, Serbia and Iceland). All the main characteristics of the included studies can be found in appendix 4 (available at *http://content.karger.com/ProdukteDB/produkte.asp?doi=342708*).

Quality of Reporting

Reporting quality was mixed (for full details see appendix 5 (available at *http://content.karger.com/ProdukteDB/produkte.asp?doi=342708*). Total QAT scores ranged from 15.2 to 78.8% (median = 48.5%). Studies scoring <50% were empirically defined as low quality and studies scoring >60% were considered to have higher quality [8]. Table 1 reports the number of studies in each percentage range.

Table 1. The number of studies in QAT score percentage ranges

Percentage ranges	Frequency of studies	Study no.	Frequency <50% QAT score
11–20%	1	71	44 studies
21–30%	9	14, 49, 51, 65, 66, 79, 82, 85	
31–40%	11	9, 19, 28, 32, 34, 46, 46, 50, 60, 86, 90	
41–50%	24	1, 6, 8, 10, 17, 20, 21, 24, 29, 31, 35, 39, 40, 42, 52, 58, 59, 67, 68, 74, 77, 78, 80, 89	
			>50% QAT score
51–60%	20	2, 3, 16, 22, 30, 33, 45, 43, 47, 48, 53, 56, 61, 64, 69, 72, 73, 81, 83, 87	43 studies
61–70%	16	4, 11, 13, 18, 24, 26, 27, 37, 38, 41, 54, 55, 57, 63, 70, 84	
71–80%	9	5, 7, 12, 15, 25, 44, 62, 76, 88	

QAT = quality assessment tool.
Study nos. 1 and 8 refer to 1 paper [92]; nos. 3, 48, 54 refer to 1 paper [32].

The main methodological weaknesses identified were: CAM was not defined to survey participants in 32% of papers [23–51]. Only 29% reported pilot studies of the questionnaire used [22, 24, 27, 28, 41, 43, 52–70] and 79% reported data collection strategies that were subject to recall bias (recall over 12 months or more) [2, 15, 22, 24–27, 29–36, 38–42, 44, 46, 48, 51–69, 71–97]. Only 45% of studies reported any adjustment for potential confounders in statistical analysis [2, 15, 24–26, 30–33, 35, 38, 41, 44, 46, 52–55, 57, 61, 62, 64, 67, 70, 71, 76, 78, 83–85, 89, 90, 92–94, 96, 98–100].

Prevalence of CAM Use

While there was a small number of rigorous prevalence studies based on nationally representative samples [1, 86], the vast majority of studies were small and of poor quality. Figure 2 presents a Forest plot of CAM use in the EU states for which we had information. The data were very heterogeneous. Therefore, Cochran's test for heterogeneity, which we had planned to perform, was determined to be both unnecessary and irrelevant. We were, therefore, unable to pool the data in a meta-analysis. The included studies did not report data consistently, thus the results are presented as a narrative. The prevalence of CAM use, reasons for use and conditions treated may be found in appendix 5 (available at *http://content.karger.com/ProdukteDB/produkte.asp?doi=342708*).

Since data had been collected over a wide variety of time periods ('last 24 hours' to 'ever used'), using different definitions of CAM, the use of 'any CAM at any time' was the only reasonable method of summarising prevalence of use. Overall use across countries was reported between 0.3 and 86% (median 29%, mean 30%, mode 10%). Table 2 reports prevalence of use by country.

Types of CAM Reported

The results of the top 5 most commonly reported therapies from countries for which we had data are reported in table 3.

Table 2. Prevalence of use by country

Country	Number of studies	Prevalence rates, %
Denmark	1	45–59
Finland	4	11–43
France/Ireland	1	21/15
Germany	15	4.6–62
Israel	12	5–43
Italy	4	16–84
Netherlands	1	17.2
Norway	7	9–53
Poland	1	14.4
Portugal	1	43.7
Slovenia	1	6.6
Spain	2	15–47
Sweden	9	5–64
Switzerland	3	5–57
Turkey	2	48–86
UK	22	0.3–71

Use of herbal medicine was reported in 31 papers [2, 15, 22, 26, 33, 48, 52, 53, 55–63, 65, 66, 68, 70–73, 75, 86, 88, 93, 94, 101, 102]. Prevalence rates varied from 5.9 to 48.3%, numbers of users 1–27,704,256, sample sizes 341–57,717,200; however, its use was not well defined (it may be included in naturopathy, folk medicine or Traditional Chinese Medicine) and variously categorised as medical herbalism, herbal remedies, herbal teas or phytotherapy. Some specific herbs were reported by name, e.g., St. Johns Wort.

Homoeopathy was reported separately in 25 studies. Prevalence rates varied from 2 to 27%, numbers of users 3–4,732,810 and sample sizes 341–57,717,200. We were unable to calculate the overall prevalence rate for herbal medicine or homoeopathy, either by country or across the EU, as they were reported as 1 possible method in a group of CAM therapies patients might have used in 10 of the studies. Indi-

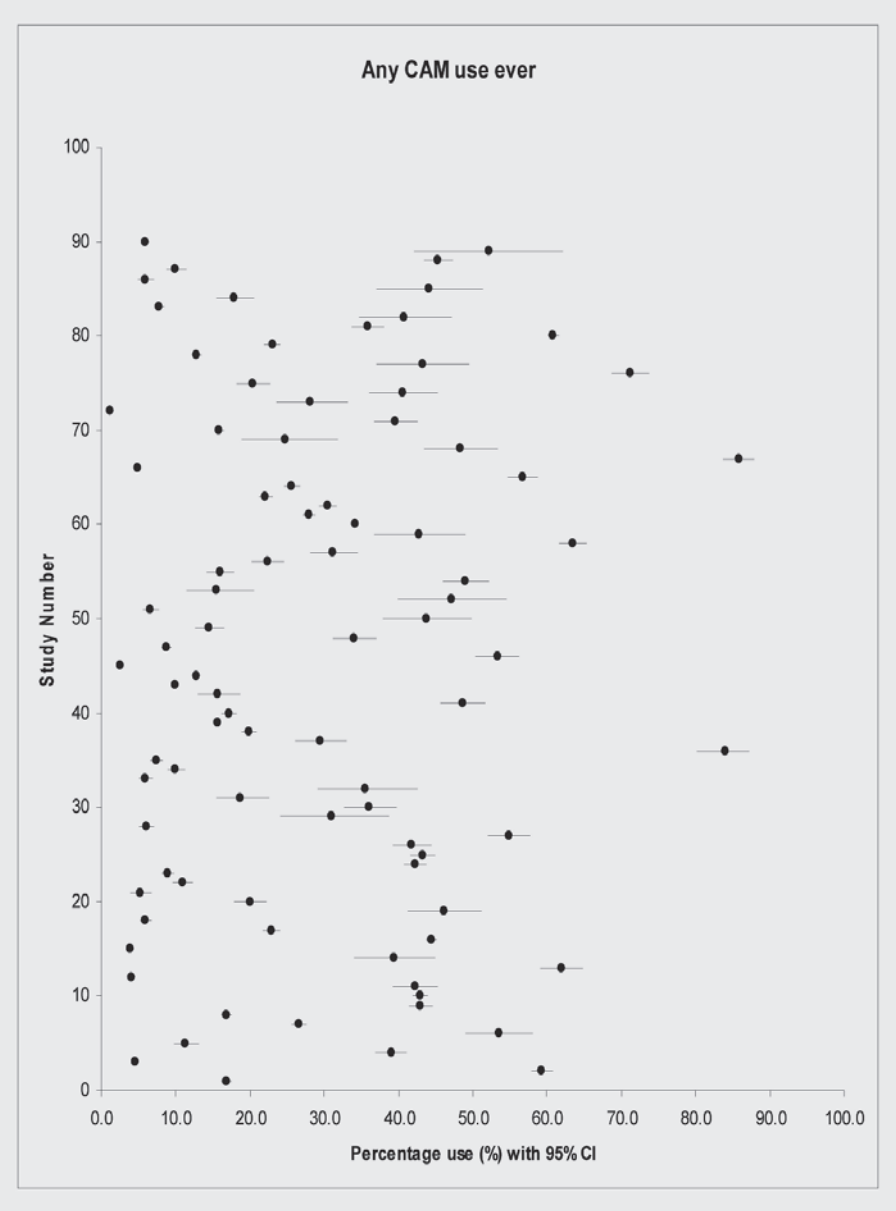

Fig. 2. Prevalence of any CAM use at any time.

vidual therapy prevalence rates for herbal medicine and homeopathy cannot be ascertained from these specific datasets. It could have varied from 'no use at all' to 'all participants using' in these papers. We were unable to differentiate between practitioner- or doctor-based prescriptions and OTC purchases.

Chiropractic was reported in 17 studies [2, 30, 32, 34, 55, 58–60, 62, 66–68, 74, 82, 85, 86, 94], as 'chiropractic or osteopathy' in 1 study [41], as 1 of a group of CAMs in 4 studies [28, 31, 53, 77], and as 'manual or manipulative treatments' in 2 studies [15, 61]. Prevalence rates were 0.4–20.8%, user numbers 5–4,040,204 and sample sizes of 152–57,717,200. Acupuncture was reported in 14 studies [2, 15, 24, 30, 34, 56, 58–60, 62, 66, 68, 80, 86] but was poorly defined. Prevalence rates were 0.44–23%, numbers of users 4–1,673,799, sample sizes 310–57,717,200. 8 further studies [28, 31, 46, 53, 67, 76, 77, 86] reported acupuncture as part of groups of CAMs. Reflexology was reported separately in 11 studies [30, 32, 58–60, 66, 68, 74, 77, 82, 86] and in a group of CAMs in 1 other study [28]. Prevalence rates varied from 0.4 to 21%, user numbers 10–3,505 in sample sizes of 341–15,465. We were unable to calculate the overall prevalence rate for chiropractic, acupuncture or reflexology by either country or across the EU.

Considering dietary supplements, calcium supplement use was reported in 9 studies [2, 22, 38, 45, 64, 72, 92, 103, 104]. Use of all other dietary supplements, vitamins, minerals, fish oils, glucosamine and other products was reported heterogeneously in groups, singly or combinations of supplements in 28 papers [22, 23, 35, 37–39, 45, 47, 49, 56, 57,

Table 3. The top 5 most commonly reported therapies

Therapy	Prevalence across countries, %	Reported singly, country & study number	Reported in a group, study number	Possibly included in, study number
Herbal medicine	5.9–48.3	Denmark 2 Finland 5 Germany 11, 13, 15, 16, 18 Israel 24–26, 30 Italy 36–39 Netherlands 40 Spain 52 Sweden 55–57, 63 Turkey 67, 68 UK 73, 74, 76, 78, 80, 86, 88, 89	5, 31, 53, 66, 73, 77	3, 7, 14, 21, 27–29, 31, 33, 35, 41, 42, 44, 47, 50, 51, 54, 65, 66, 71, 75
Homoeopathy	2–27	Denmark 3 Finland 4, 7 Germany 12, 13, 18 Italy 37–39 Norway 41, 43–45, 48 Spain 53 Sweden 54, 62 UK 73–76, 82–84, 88, 87, 95	55, 66, 77, 87, 96	7, 11, 14, 21, 26, 27, 29, 30, 31, 33, 35, 41, 47, 50, 51, 54, 57, 65–67, 71, 75, 84
Chiropractic	0.4–28.8	Finland 4 Germany 13, 18 Italy Norway 43, 44, 48 Sweden 54, 55 UK 73–76, 82–84, 88, 87	31, 38, 43, 55, 77	7, 11, 14, 21, 26, 27, 29, 30, 31, 33, 35, 37, 39, 41, 42, 47, 50, 51, 54, 57, 65–67, 71, 72, 75, 84
Acupuncture	0.44–23	Denmark Finland Germany 13 Israel 27, 29, 30 Italy Norway 42 Sweden Turkey UK 69, 73, 74, 76, 84, 87	36, 39, 43, 54, 55, 66, 77, 87	7, 11, 14, 18, 21, 26– 28, 30, 31, 33, 35, 37, 41, 42, 44, 47, 50, 54, 57, 65–67, 71, 75, 84
Reflexology	0.4–21	Denmark Finland Israel 28, 29, 31, 34 Norway Sweden 54 UK 73, 74, 76, 84, 87, 88	41	7, 11, 14, 18, 21, 26–28, 30, 31, 33, 35, 37, 41, 42, 44, 47, 50, 54, 57, 65–67, 71, 75, 84

60, 64, 65, 69, 71, 72, 78, 80, 87, 92, 100–106]. The different study data collecting or reporting methods meant that it was generally not possible to distinguish whether the dietary supplements were bought OTC or prescribed at consultations.

Further data about other therapies are available in our full report (*www.cambrella.eu*).

Who Uses CAM, Why and What for?

Musculoskeletal problems were reported as the condition most commonly treated with CAM (appendix 6 available at *http://content.karger.com/ProdukteDB/produkte.asp?doi=342708*). 18 papers (21%) [15, 22, 26, 27, 29, 54, 58, 62, 63, 66, 68, 72, 74, 75, 80, 82, 86, 95] reported reasons for use being primarily dissatisfaction with a medical doctor or western medicine, not wanting to take medical drugs with associated side effects, preferring natural methods and having a better therapeutic relationship with a CAM practitioner (table 4). Appendix 7 (available at *http://content.karger.com/ProdukteDB/produkte.asp?doi=342708*) reports the demographics of CAM users, which suggest that more women than men use CAM.

Table 4. Reasons why people use CAM

Author, study number	Reasons for using CAM
Bucker et al., 11	wish to take as few drugs as possible, doctors advice, dissatisfactory results from conventional medicine, coincidence, used before conventional medicine, disappointed by conventional medicine, more natural or wanted to try everything, few side effects, safer, medical doctor did not understand problem, medical doctor did not take enough time, medical doctor not interested in their case
Bernstein et al., 28	disappointment with the outcome of conventional treatment, wanted to try, did not want a lot of medications, did not want invasive procedures, there was no other solution, other reasons
Giveon et al., 30	strengthening body, prevention of disease
Shmueli et al., 34	did not want to take many medicines, did not want invasive care, disappointment with conventional medicine, there was no other solution, wanted to experience it, was readily available (provider is a friend, family), past good experience
Ben-Arye et al., 27	wanted to try, did not want to use medical drugs
Albertazzi et al., 36	cod liver oil is good for joints, multivitamins for general well-being, calcium prevents brittle bones, primrose oil for general well-being, glucosamine is good for joints, vitamin C prevents colds, garlic capsules for general well-being, selenium is an antioxidant, ginkgo is good for memory, zinc for general well-being, echinacea prevents colds
Buono et al., 37	advice of friends, family, general practitioner, specialist, own initiative
Menniti-Ipolito et al., 39	lower toxicity, only therapy available, greater efficacy, better doctor-patient interaction, cultural belief, do not know
Norheim et al., 42	lack of conventional medicine effect, experience of acupuncture, distinctive character of acupuncture, avoiding negative effects of conventional medicine, wanting additional therapy, desperation due to pain and other health complaints
Gozum et al., 68	treatment for health problems, maintaining health or preventing health problem, to prevent and to treat health problem
Cumming et al., 71	health risks associated with hormone replacement therapy, alternatives more natural, desperation, recommended by friend
Emslie et al., 73	doctor or health professional referred/recommended, read about it, looked it up in telephone directory, recommended by friend/colleague, practitioner known to me, local clinic available, other
Ernst et al., 75	helps relieve injury/condition, just like it, find it relaxing, good health/well-being generally, preventative measure, did not believe conventional medicine would work, doctors recommendation/referral, to find out about other ways of life/new thing, way of life / part of lifestyle, cannot get treatment on National Health Service/ under conventional medicine
Simpson et al., 84	word of mouth recommendation, dissatisfaction with conventional medicine, fear of side effects of conventional medicine, more personalised attention, having a child with a chronic condition
Sobal et al., 85	ensuring nutrition = 33, prevent illness = 27, tiredness = 27, more energy = 22, to feel good = 18, stress = 12, to feel stronger = 6, treat illness = 5, other
Thomas et al., 88	birthday treats, assist student, health spa, beauty treatment, gift voucher, prize, pleasure
Thomas et al., 87	treat illness for which conventional medicine advice had previously been sought, treat illness for which no conventional medical treatment had been sought, improve general health or prevent illness, recreational/beauty, other
van Tonder et al., 98	boost immune system, improve quality of life, pain relief, stress management

Discussion

Summary

While there are a few rigorous prevalence studies that are based on nationally representative samples, the vast majority is small and of poor quality. Consequently, we can only report descriptive, weak data, and lack any information at all for a number of EU countries. Reported prevalence rates of CAM use were 0.3–86% but, due to heterogeneity, we were unable to pool the data in a meta-analysis. Herbal medicine was the most frequently reported CAM. Musculoskeletal problems were the most reported condition and disappointment with

western medicine a main reason for CAM use, although it is not possible to derive definitive conclusions due to the small numbers of studies reporting these data.

Data Extraction

Our extraction protocol had been developed for a comprehensive and detailed report of CAM use, but the included studies reported so heterogeneously that we had large areas of missing data. Some of our categories were not reported in any study, e.g., medical or non-medical CAM provider; therefore, we cannot make any firm statements about the proportions of different types of provider. We have limited information on the economic issues surrounding CAM use. No study reported whether CAM was paid for by health insurance companies and only 1 study reported data pertaining to the out of pocket expenses for CAM.

We identified several limitations, e.g., wide-ranging definitions of CAM contributed to the variation in prevalence rates; therefore, the use of core definitions for the main CAM disciplines, variable by country, could improve the accuracy with which CAM use is measured. The accuracy of measuring instruments that were not piloted and validated is unclear as they are potentially subject to recall and other bias. A lack of standardisation in the collection of socio-demographic data hampered our ability to evaluate this information across the study population.

Prevalence of CAM Use

Prevalence rates in specific countries were wide and we were unable to determine whether their use was OTC purchase or practitioner delivered. Mansky et al. [5] reported the use of CAM by up to 90% of patients for some benign conditions, corresponding to those higher prevalence rates reported in this review, with the lower prevalence rates reported here being similar to previous surveys in the UK and Germany [2, 14]. Frass et al. [6] report a similarly wide range of prevalence rates, although data were included from non-EU countries. CAM use was measured as specific therapies, as groups of therapies or as umbrella terms such as 'complementary medicine' where no therapy was specified; therefore, we were unable to draw any meaningful conclusions about the prevalence of individual CAMs. We were able to ascertain the most commonly reported CAMs in countries for which we had data, although this is limited due to a lack of clear definitions of individual CAMs. Only 10% of studies reported the conditions for use: musculoskeletal problems were reported most commonly, reflecting the recent figures from the NCCAM [19]. Similarly, studies of acupuncture and chiropractic report musculoskeletal problems as the main condition treated [107]. While most of the included papers reported some demographic information, few reported this in sufficient detail for us to make any firm conclusions about the sections of the population who uses CAM. Previous studies report that more women than men use CAM [19], which was also suggested in our data.

Strengths and Limitations

The strengths of this study were the rigorous methodology, extensive searching and the detailed data extraction tool. Our quality scoring instrument also provided a detailed and comprehensive set of basic data and socio-demographic characteristics. Inter-rater agreements were good for data extraction.

Although our literature search was thorough, we could not locate studies from all the EU member states. Some studies we did locate were unavailable to us; therefore, it is possible that along with our inclusion and exclusion criteria, we missed some potentially relevant information. Our quality scoring instrument is potentially open to error because we are not certain which study characteristics may be associated with CAM use.

Comparisons with Other Studies

As in other studies, we were unable to draw firm conclusions about CAM use across the EU due to the heterogeneity of the studies we included and a lack of data from more than half of the EU member and associated states [16]. Our data concur with other studies indicating than CAM use may be highly prevalent [7], that women use CAM more than men [108], that musculoskeletal problems are the main conditions for which CAM is sought [19] and that dissatisfaction with orthodox treatment is a common reason for CAM use [109].

Improvements for Future Studies

Future studies of CAM prevalence should consider including: a set of core definitions (variable by country), standardised survey methodology according to good epidemiological practice [20], efforts to manage recall bias and utilise representative samples, definitions of CAM as practitioner provided or OTC purchase, collection of data on medical conditions for which CAM is used and reasons for use and a standardised set of socio-demographic variables to help enable data pooling and the accuracy of reports. It would also be important to understand how CAM use in the general population differs from ill population, as we are aware that CAM is used mainly in addition to conventional care, but that its use is not often disclosed. This is potentially problematic due to interactions with conventional medications [110], and comparison studies between these different populations would be pertinent. Future studies would ideally investigate reports from across the EU and particularly involved states for which we have no data. We suggest that Thomas et al. [68] offer a good model for conducting this type of research. It enquires about the CAMs commonly used in the target population, has a clear power calculation and a reliable response rate and reports data in a conservative and thoughtful manner.

Conclusions

There are limited conclusions about CAM use that may be drawn from this review, primarily due to the heterogeneity and poor quality of the studies we included. We considered

sub-group analyses by country and by type of CAM but did not find convincing evidence for these data being any more homogenous and suitable for pooling in a meta-analysis. We had data from less than half the EU member states with several countries only being represented by 1 or 2 papers so the overall picture of CAM use was unclear.

The need for a valid questionnaire on CAM use, standardised (but variable for different countries) would increase the accuracy of data collection and enable data pooling. Such a questionnaire has recently been piloted by the CAMbrella team for use across the EU member states [111].

In conclusion, we were unable to report the prevalence of CAM across the EU member and associated states due to the heterogeneity and poor quality of the included studies. We were able to identify the current most commonly used therapies as well as the large evidence gaps. Further high quality and standardised prevalence research is essential to enable us to build a picture of current use and future needs.

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Legal Status and Regulation of Complementary and Alternative Medicine in Europe

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Alternative medicine · Complementary medicine · Regulation · Government regulation · Legislation · European Union · Europe

Summary
Objective: The study aims to review the legal and regulatory status of complementary and alternative medicine (CAM) in the 27 European Union (EU) member states and 12 associated states, and at the EU/European Economic Association (EEA) level. **Methods:** Contact was established with national Ministries of Health, Law or Education, members of national and European CAM associations, and CAMbrella partners. A literature search was performed in governmental and scientific/non-scientific websites as well as the EUROPA and EUR-lex websites/databases to identify documents describing national CAM regulation and official EU law documents. **Results:** The 39 nations have all structured legislation and regulation differently: 17 have a general CAM legislation, 11 of these have a specific CAM law, and 6 have sections on CAM included in their general healthcare laws. Some countries only regulate specific CAM treatments. CAM medicinal products are subject to the same market authorization procedures as other medicinal products with the possible exception of documentation of efficacy. The directives, regulations and resolutions in the EU that may influence the professional practice of CAM will also affect the conditions under which patients are receiving CAM treatment(s) in Europe. **Conclusion:** There is an extraordinary diversity with regard to the regulation of CAM practice, but not CAM medicinal products. This will influence patients, practitioners and researchers when crossing European borders. Voluntary harmonization is possible within current legislation. Individual states within culturally similar regions should harmonize their CAM legislation and regulation. This can probably safeguard against inadequately justified over- or underregulation at the national level.

Introduction

The European Parliament [1] and the Parliamentary Assembly of the Council of Europe [2] have both passed resolutions recommending a stronger harmonization of, what they call, non-conventional medicine in Europe.

The European Union (EU) has, however, repeatedly confirmed that it is up to each member state to organize and regulate their healthcare system, and this will, of course, also apply to complementary and alternative medicine (CAM). Despite this confirmation, the recent Patients' Rights in Cross-Border Healthcare Directive 2011/24/EU [3] and other directives indirectly encourage some degree of harmonization. CAM professions can be registered in the European Commission (EC) database of regulated professions, and patients will probably have certain rights according to the Cross-Border Healthcare Directive. The EU has also passed directives regulating medicinal products that also cover CAM medicinal products [4–6].

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Previous studies on the European situation with regard to how CAM is regulated [7–9] have shown a diverse pattern. Reports from key CAM stakeholders have indicated that the regulatory situation has changed, and the CAMbrella consortium has therefore seen it as important to establish the current status in order to best prepare a roadmap for CAM research in Europe.

The aims of this study were to:

1 Review in 27 EU member states and 12 associated states:
   - ○ The legal and regulatory status of CAM.
   - ○ The governmental supervision of CAM practices.
   - ○ The reimbursement status of CAM practices.
2 Review at the EU/European Economic Association (EEA) level:
   - ○ The status of EU/EEA-wide regulation of herbal and homeopathic medicinal products.
3 Review and describe in all 27 EU member states and 12 associated states:
   - ○ The extent of country-specific market authorization of herbal and homeopathic medicinal products according to the EU directives.
4 Review at EU level:
   - ○ The status of EU-wide regulation of CAM practices.
   - ○ The potential obstacles for EU-wide regulation of CAM practices.

Methods

As an introduction we made a comprehensive overview of matters that may influence CAM in the European legislation. Descriptions of health issues, the legal and CAM terminology, and the interaction between conventional medicine and CAM vary both in the EU bodies and within the 39 countries included in this report. To address CAM-related legislation in the EU, we included both the EU legislation that influences the member states' national health legislation and various aspects of EU regulation of conventional medicine.

Data underlying this report were collected from the 39 countries by communicating with the Ministries of Health, Law or Education, governmental representatives, and members of national CAM associations. A search was also performed in the national websites/databases to identify official law documents. The scientific and non-scientific literature was also searched for documents and websites describing CAM regulation in each of the 39 countries. We also collected information from European CAM associations/coalitions, CAMbrella members, and stakeholders. Personal visits, including meetings with the ministries of health and CAM practitioners representing organizations, were made to 4 countries. Health authorities (if possible both legal and regulatory) were asked to verify the situation described for their specific country. 12 common treatment modalities have been described in detail in each country. In addition, a search was performed in the EUROPA and EUR-lex websites/databases to identify official EU law documents. We searched specifically for information about EU directives regarding European-wide healthcare-related regulation, as well as regulation of herbal and homeopathic medicinal products and their EU/EFTA/EEA implications.

A personal visit was also made to the EU offices and non-government organization (NGO) bodies in Brussels to establish firsthand updated information. Meetings were held with:

1 The counsellor for health and food safety at the Mission of Norway to the EU. At the Mission of Norway to the EU we received updated information mainly on the European Free Trade Association (EFTA)/EEA legal connection to EU legislation and the new Patients' Rights in Cross-Border Healthcare Directive 2011/24/EU [3].
2 The European Commission Central Library.
3 Meetings with the following NGOs provided important additional CAM documents and legal system information as well as viewpoints with regard to EU regulation:
   - ○ International Federation of Anthroposophic Medical Associations (IVAA)
   - ○ International Council of Medical Acupuncture and Related Techniques (ICMART) – EU Liaison Office
   - ○ The Association of the European Self-Medication Industry (AESGP).

We also collected information from European CAM associations/coalitions and other CAMbrella stakeholders.

This report covers 27 EU member states as well as 12 associated states. Each state is influenced by the EU legislation and has adjusted their national legislation depending on their connection to EU. The countries' status in relation to the EU is shown in figure 1.

Results

Country-Specific Regulations

CAM treatment is in general either unregulated or regulated within the framework of the public health system. The only common factor that we have found across all 39 nations is the amazing ability they have demonstrated for structuring legislation and regulation differently in every single country, no matter how small the size of the population.

Of the 39 countries, 17 have a general CAM legislation, 11 of these 17 have a specific CAM law and 6 countries have sections on CAM included in their health laws (like 'law on healthcare' or 'law on health professionals'). In addition to the general CAM legislation, some countries have regulations on specific CAM treatments (fig. 2).

The CAM regulations are either very general or very detailed, and we found no more similarities between the countries that have a CAM law or general CAM legislation than between the countries with only specific CAM treatment regulations. Some of the general regulations are only a specification of what CAM is, often to be supported by additional regulations or specifications issued by the Ministry of Health or the professions' associations. In some countries additional specifications have not been made. As an example, both Norway and Hungary have a CAM law. In Norway the CAM law is general without describing in detail the treatments or practitioners, in Hungary CAM can be regarded as an integral aspect of the healthcare system. We found few similarities in the regulations of the specific CAM treatments between the countries, and it is challenging to find out who is allowed to practice the different treatments.

The 12 common treatment modalities vary considerably with regard to how many countries regulate the profession or practice in some way or another. Acupuncture is regulated in

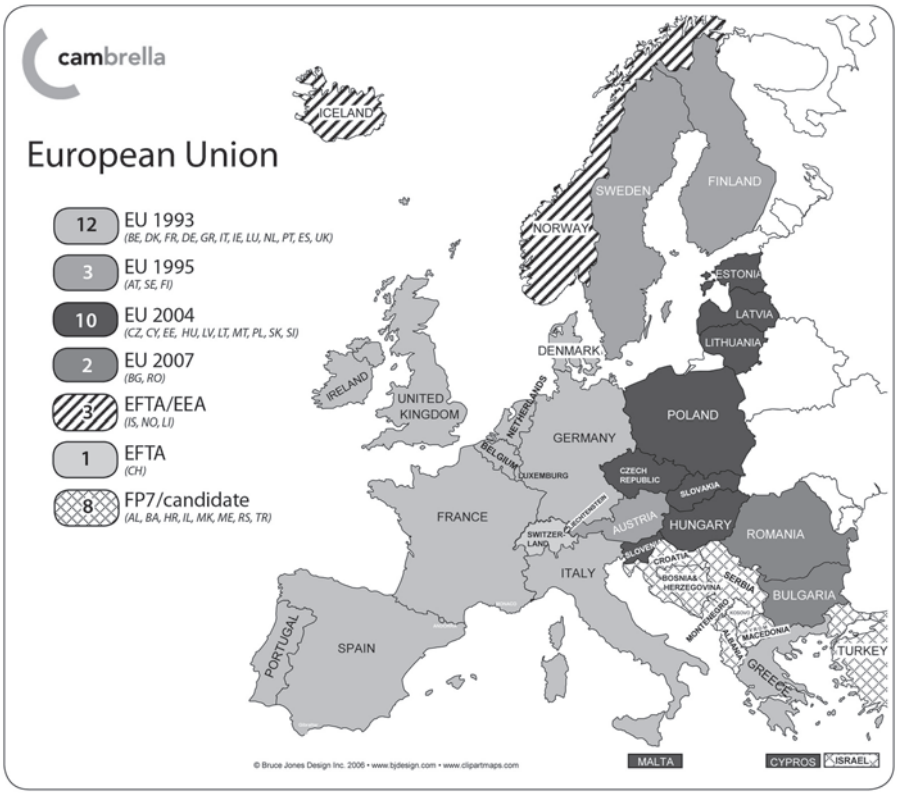


Fig. 1 The relationship of 39 countries to the EU.

27 countries, anthroposophic medicine in 8 countries, Ayurveda in 5 countries, chiropractic in 27 countries, herbal medicine/phytotherapy in 11 countries, homeopathy in 25 countries, massage in 20 countries, naprapathy (manual therapy) in 2 countries, naturopathy in 9 countries, neural therapy in 3 countries, osteopathy in 16 countries, and finally Traditional Chinese Medicine in 10 countries.

As an example, figure 3 shows the regulation of homeopathy across Europe. Switzerland has regulated homeopathy and has registered homeopath as a profession in the EU regulated professions database under 'natural health practitioner' as 'naturopath/homeopath'. 2 countries (Latvia, Liechtenstein) have regulations that may be seen as a regulation of a homeopathy profession. Latvia has regulated 'homeopathic doctors', Liechtenstein has registered 'natural health practitioner with a homeopathy specialty'. 22 countries have regulated homeopathy treatment. 14 countries have no specific homeopathic treatment regulations, but general CAM or other health legislation may regulate homeopathic practices.

Figure 4 'Homeopathy – Who may practise' is an example of how difficult it can be to understand the consequences of national regulation. We have, to our best knowledge, listed whether the different categories of practitioners in each country are allowed to practice homeopathy. If only medical doctors with additional CAM education are allowed to practice, we have put 'No' in the column for medical doctors. The same applies for other health personnel. If the regulation (or absence of regulation) was too unclear for us to be certain, we have inserted a question mark. Since the countries with CAM practitioners like 'Heilpraktiker', 'healer' and likewise may not be correctly represented, we decided not to introduce this table for other treatments because of the unclear situation.

Medicinal Products

Medicinal products are not defined as a part of health policy, and can therefore be regulated at the EU level. The individual states within the EU/EEA area are therefore no longer free to uphold a national regulation of medicinal products in violation of the following 3 EU directives.

1 Directive 2001/83/EC of the European Parliament and of the Council, of November 6, 2001 (on the community code relating to medicinal products for human use) [4].
2 Directive 2004/24/EC of the European Parliament and of the Council, of March 31, 2004 (amending, as regards traditional herbal medicinal products, directive 2001/83/EC on the community code relating to medicinal products for human use 2001/83/EC) [5].
3 Directive 2004/27/EC of the European Parliament and of the Council of March 31, 2004 amending directive 2001/83/EC on the community code relating to medicinal products for human use (Text with EEA relevance) [6].

Until April 30, 2011, herbal medicinal products that were marketed without authorization before this legislation came into force could continue to be marketed under transitional measures defined in directive 2004/24/EC [5]. Now that this

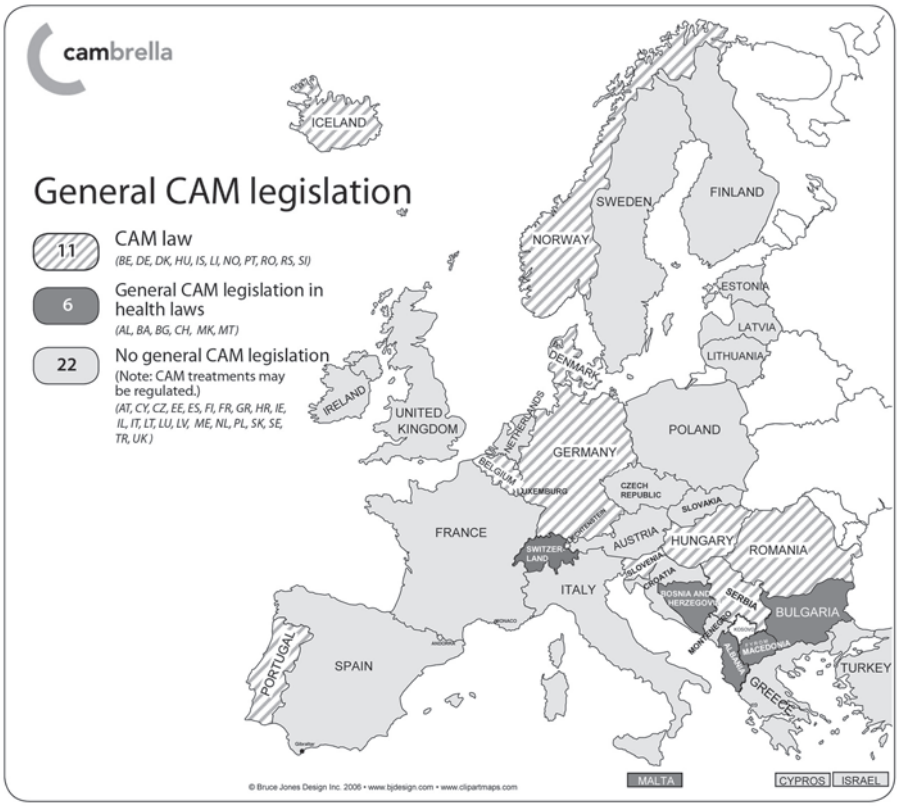


Fig. 2. The status with regard to CAM general legislation in 39 European countries.

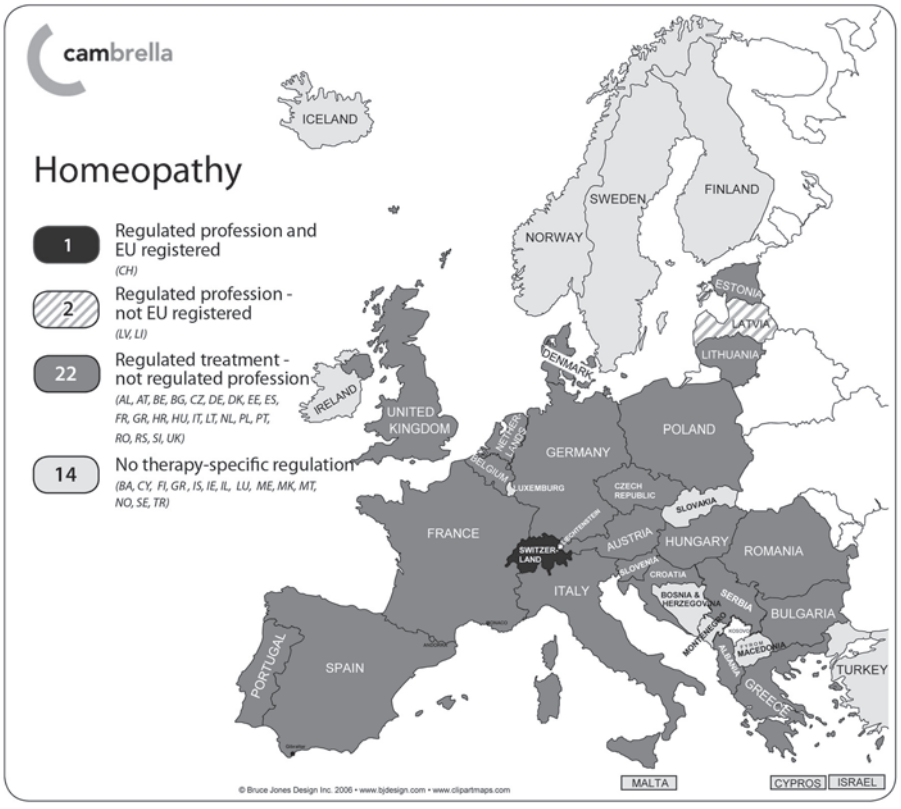
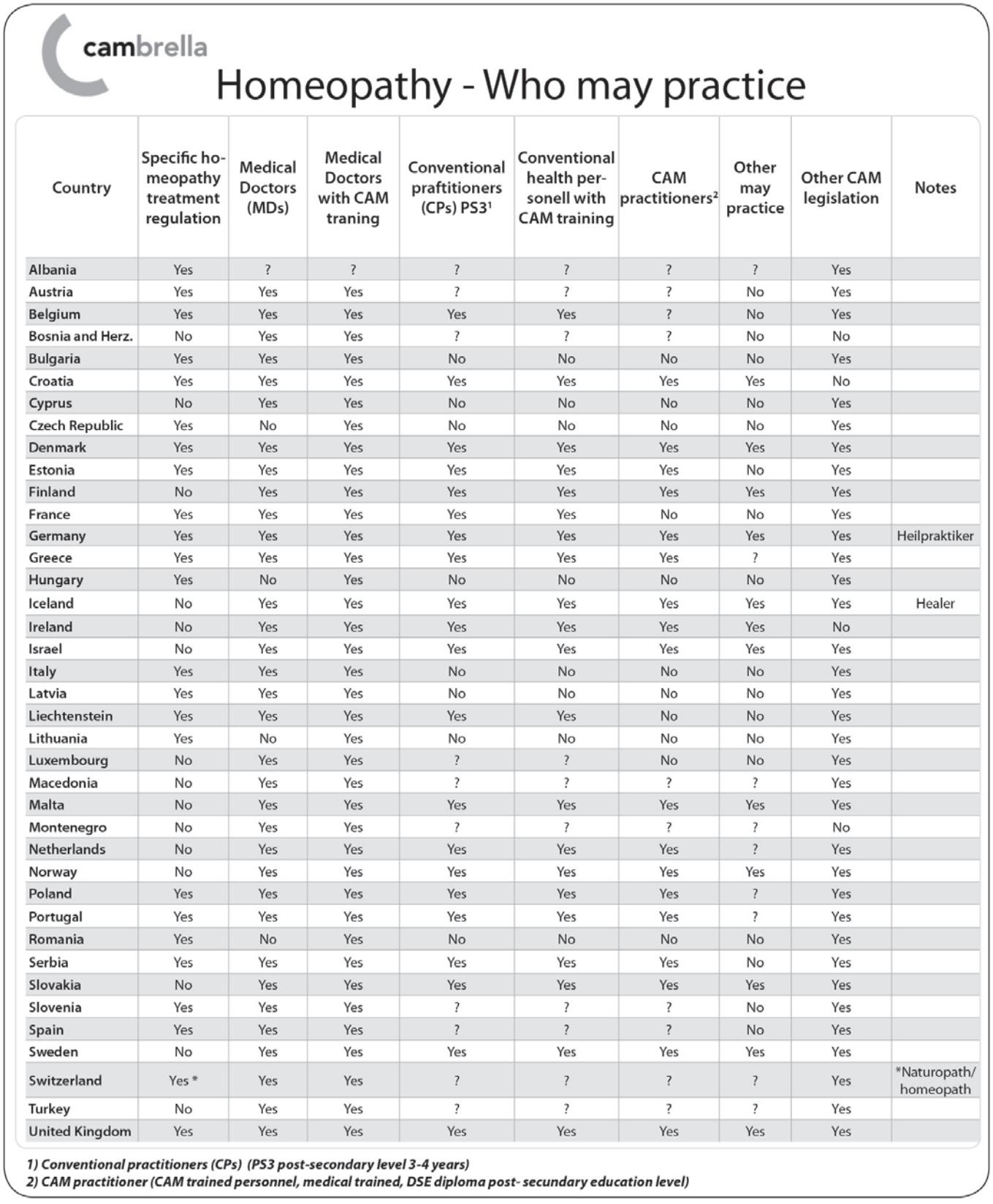


Fig. 3. Homeopathy regulation in 39 European countries.

time limit has expired, all herbal medicinal products that were previously unauthorized must have market authorization according to directives 2001/83/EC, 2004/24/EC, and 2004/27/EC [4–6] before they can be marketed in the EU/EEA states.

Marketing authorizations for herbal and homeopathic medicinal products are mainly given at the national level, but a central procedure can be used in some cases. Herbal and homeopathic medicinal products are subject to the



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Homeopathy - Who may practice

Country	Specific homeopathy treatment regulation	Medical Doctors (MDs)	Medical Doctors with CAM traning	Conventional praftitioners (CPs) PS3[1]	Conventional health personell with CAM training	CAM practitioners[2]	Other may practice	Other CAM legislation	Notes
Albania	Yes	?	?	?	?	?	?	Yes	
Austria	Yes	Yes	Yes	?	?	?	No	Yes	
Belgium	Yes	Yes	Yes	Yes	Yes	?	No	Yes	
Bosnia and Herz.	No	Yes	Yes	?	?	?	No	No	
Bulgaria	Yes	Yes	Yes	No	No	No	No	Yes	
Croatia	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	
Cyprus	No	Yes	Yes	No	No	No	No	Yes	
Czech Republic	Yes	No	Yes	No	No	No	No	Yes	
Denmark	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Estonia	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	
Finland	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
France	Yes	Yes	Yes	Yes	Yes	No	No	Yes	
Germany	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Heilpraktiker
Greece	Yes	Yes	Yes	Yes	Yes	Yes	?	Yes	
Hungary	Yes	No	Yes	No	No	No	No	Yes	
Iceland	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Healer
Ireland	No	Yes	Yes	Yes	Yes	Yes	Yes	No	
Israel	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Italy	Yes	Yes	Yes	No	No	No	No	Yes	
Latvia	Yes	Yes	Yes	No	No	No	No	Yes	
Liechtenstein	Yes	Yes	Yes	Yes	Yes	No	No	Yes	
Lithuania	Yes	No	Yes	No	No	No	No	Yes	
Luxembourg	No	Yes	Yes	?	?	No	No	Yes	
Macedonia	No	Yes	Yes	?	?	?	?	Yes	
Malta	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Montenegro	No	Yes	Yes	?	?	?	?	No	
Netherlands	No	Yes	Yes	Yes	Yes	Yes	?	Yes	
Norway	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Poland	Yes	Yes	Yes	Yes	Yes	Yes	?	Yes	
Portugal	Yes	Yes	Yes	Yes	Yes	Yes	?	Yes	
Romania	Yes	No	Yes	No	No	No	No	Yes	
Serbia	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	
Slovakia	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Slovenia	Yes	Yes	Yes	?	?	?	No	Yes	
Spain	Yes	Yes	Yes	?	?	?	No	Yes	
Sweden	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Switzerland	Yes *	Yes	Yes	?	?	?	?	Yes	*Naturopath/ homeopath
Turkey	No	Yes	Yes	?	?	?	?	Yes	
United Kingdom	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	

1) Conventional practitioners (CPs) (PS3 post-secondary level 3-4 years)
2) CAM practitioner (CAM trained personnel, medical trained, DSE diploma post- secundary education level)

Fig. 4. An overview of groups that can legally practice homeopathy in 39 European countries.

same application procedures as other medicinal products regarding manufacturing procedures, technical quality of the product, and all other requirements, with the possible exception of documentation of efficacy. There are 4 administrative procedures that can be followed to obtain a market authorization for these products (standard, well-established use, and 2 simplified registration procedures (one for homeopathic medicinal products and the other for traditional-use registration of herbal medicinal products)). The simplified registration procedures allow alternative documentation of efficacy.

Homeopathic medicinal products covered by a registration or authorization granted in accordance with national legislation on or before December 31, 1993 and herbal medicinal products already authorized in accordance with regulation (EEC) No. 2309/93 [10] or supplied in response to a bona fide unsolicited order can be marketed irrespective of the 2 directives. These uniform regulations aim to supply citizens with a predictable standard of all medicinal products (including herbal and homeopathic) across Europe. Several stakeholders raised concerns before the rules were implemented. The concerns focused mainly on leaving European citizens without access to beneficial products and the establishment of unnecessary additional authorizational bureaucracy around safe products.

EU-Wide Regulation

The directives, regulations and resolutions in the EU and the Council of Europe that may influence the professional practice of CAM, whether practiced by an authorized/licensed healthcare provider or by a provider without such authorization/licensing, will also affect the conditions under which patients can receive CAM treatment(s) in Europe.

We have found no direct EU legislation of CAM except for directives concerning CAM medicinal products described above. 2 resolutions deal with non-conventional medicine:

- Resolution A4-0075/97: 'Resolution on the status of non-conventional medicine'. This is part of the European Parliament resolution on how non-conventional medicine should be included more formally as a special field in the European legislation [1].
- Resolution 1206 (1999): 'A European approach to non-conventional medicines' of the Parliamentary Assembly of the Council of Europe resolution on non-conventional medicine [2].

How legislation connected to 'The 4 Freedoms' is handled in EU/EEA, influences the national CAM legislation and legislation that impacts directly or indirectly on CAM of the individual states. Of particular interest is how patients and health professionals are able to relate to diverse national CAM regulations. European CAM practitioners have different levels of training as a basis for their practice, whether they are formally licensed or not, and patients have varying expectations depending on experiences from their home country.

Harmonization of training and regulation of non-conventional disciplines is only marginally covered in the directive 2005/36/EC Professional Qualifications [11]. In many states only doctors or other health professionals are allowed to practice CAM according to national health regulation. The EU-regulated professionals database includes only a few CAM professions in some member states. We have found that the resolutions on the status of non-conventional medicine from 1997 and 1999 have not been followed up with harmonized CAM training or regulation.

Discussion

Our findings demonstrate an extraordinary diversity with regard to the regulation of CAM practice across Europe. At the same time the medicinal products that CAM practitioners will be prescribing or recommending are regulated uniformly across the same geographical area. This regulatory diversity will profoundly influence patients, practitioners and researchers when crossing European borders.

When *patients* cross borders in search of CAM treatment, they may encounter substantial differences in the professional background of apparently identical CAM providers who are mostly also working under completely different reimbursement systems. In post-modern Europe, where patient choice in healthcare is seen as a core value [12], this confusing European market makes any informed treatment-seeking challenging. This heterogeneous situation influences CAM patients' rights, access and potential safety, and constitutes a challenge to a harmonized national and European follow-up of the new Patients' Rights in Cross-Border Healthcare Directive 2011/24/EU [3].

When *practitioners* cross borders they will encounter a substantial variety of CAM practice in Europe. This raises serious concerns with regard to the predictability, quality and safety of healthcare delivery to European citizens. When CAM professions in some countries are tightly regulated, while the same professional categories in other countries are totally unregulated, establishing a common collegial ground is very challenging.

When *researchers* cross borders they will find that research on efficacy and effectiveness of CAM is severely hampered by the conglomerate of European regulation. Practices and practitioners are not comparable across national boundaries, and any observational or experimental study will therefore be generalizable only within a narrow national or cultural context.

The European Parliament resolution on non-conventional medicine from 1997 [1] stated that non-conventional medical disciplines should be clearly identified and defined. We have found few overall clear distinctions between conventional and non-conventional medicine in the EU legislation. An adequate regulation and supervision of CAM professionals and CAM

therapies will require special knowledge in the CAM field to take into account the special features of this field of healthcare. Developing the European legislation of CAM by simply adapting the criteria of conventional medicine will probably be inadequate for regulation of the CAM field. Similar to the way that CAM research needs some particular considerations compared to research on, e.g., conventional pharmaceuticals [13], the methods by which CAM is regulated must be specifically tailored to its inherent qualities.

In particular, the Patients' Rights in Cross-Border Healthcare Directive [3] respects the established differences in national healthcare systems. It aims to remove obstacles to the fundamental freedoms that enable patients from one EU member state to choose to seek treatment in another EU member state. The directive also outlines the responsibilities of EU member state healthcare systems to cover treatments given in other member states. Regional collaboration between providers, purchasers, and regulators from the different member states can ensure safe, high-quality, and efficient cross-Border healthcare at a regional level. Historical and cultural similarities between neighbouring countries would thus seem to potentially facilitate cross-border opportunities in the CAM area more than EU-wide directives, regulations and decisions.

The most important obstacles that hinder the European Parliament resolution call for 'a process of recognizing non-conventional medicine are the Treaties of Rome and Lisbon [14], which clearly state that the individual member states have the responsibility for 'the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the member states shall include the management of health services and medical care and the allocation of the resources assigned to them. This legitimizes and sustains the wide variations in CAM regulation across Europe.

Another obstacle is the unwillingness of the individual European countries to voluntarily harmonize their legislation and regulation of CAM with other European states. If this had been done to a greater degree, both patients and providers would be able to benefit from The Right to Move and Reside Freely Directive [15], the Professional Qualifications Directive [11], the Patients' Rights in Cross-Border Healthcare Directive [3], the Services Directive [16], and the Social Security Regulation [17].

There are in principle, therefore, 2 options that can be chosen to achieve a higher degree of harmonization: legislation and regulation at the EU/EEA level or voluntary harmonization. We do not foresee EU/EEA level legislation/regulation in the foreseeable future since the EU has repeatedly upheld its position of leaving this to the individual country. Voluntary harmonization is, however, possible within current legislation. We think it is important to encourage individual states within culturally similar regions to harmonize their CAM legislation and regulation. This broader regional perspective can probably safeguard against inadequately justified over- or under-regulation at the local level. The successful mutual recognition of physiotherapists across Europe shows how this can be done. Physiotherapy has a long tradition of being a recognized profession with well-established international research on the importance and effect of physiotherapy treatment. The European collaboration within the World Confederation for Physical Therapy Europe (WCPT-E) and the European Network of Physiotherapy in Higher Education (ENPHE) leads to exchange of experience and harmonized regulation, education and professional issues within the EU and the European countries. This could be a potential template for development of harmonized regulation of CAM professions in Europe [18].

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Complementary and Alternative Medicine Provision in Europe – First Results Approaching Reality in an Unclear Field of Practices

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Keywords
Complementary medicine · Economics · Effectiveness · Physician · Practitioner · Provision · Training

Summary
Background: The demand for complementary and alternative medicine (CAM) treatment in the European Union (EU) has led to an increase in the various CAM interventions available to the public. Our aim was to describe the CAM services available from both registered medical practitioners and registered non-medical practitioners. **Methods:** Our literature search comprised a PubMed search of any scientific publications, secondary references and so-called grey literature, a search of government websites and websites of CAM organisations to collect data in a systematic manner, and personal communications, e.g., via e-mail contact. Due to the different reliability of data sources, a classification was developed and implemented. This weighted database was condensed into tables and maps to display the provision of CAM disciplines by country, showing the distribution of CAM providers across countries. **Results:** Approximately 305,000 registered CAM providers can be identified in the EU (~160,000 non-medical and ~145,000 medical practitioners). Acupuncture (n = 96,380) is the most available therapeutic method for both medical (80,000) and non-medical (16,380) practitioners, followed by homeopathy (45,000 medical and 5,800 non-medical practitioners). Herbal medicine (29,000 practitioners) and reflexology (24,600 practitioners) are mainly provided by non-medical practitioners. Naturopathy (22,300) is dominated by 15,000 (mostly German) doctors. Anthroposophic medicine (4,500) and neural therapy (1,500) are practised by doctors only. **Conclusion:** CAM provision in the EU is maintained by approximately 305,000 registered medical doctors and non-medical practitioners, with a huge variability in its national regulatory management, which makes any direct comparison across the EU almost impossible. Harmonisation of legal status, teaching and certification of expertise for therapists would be of enormous value and should be developed.

Introduction

Complementary and alternative medicine (CAM) is a developing area associated with much conflicting debate. It appears that CAM services are in great demand by patients. Life-time CAM use prevalence rates of between 3 and 25% are reported internationally [1, 2]. CAM use has been documented across Europe for the UK, Germany and Italy and is used by between 10 and 70% of the population [3–8]. However, in practice, there is a varying provision of CAM within the European Union (EU). This review covers the providers' perspective and

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comprises an evaluation of service provision by certified medical and non-medical practitioners and their respective professional organisations. The aim of this review was to map CAM provision by medical and non-medical practitioners across the EU and associated countries. We also aimed to describe the economic perspectives of CAM service, CAM product manufacturers and their respective organisations, the CAM market and products. Research issues are not dealt with due to the description of work of CAMbrella Work Package 5 (WP5).

Methods

Terminology and Definitions

Keeping in mind that there is no commonly accepted definition of the term CAM, this study refers to CAMbrella WP 1 (terminology and definition of CAM methods) for appropriate definitions. In contrast to the US and Medical Subject Headings (MeSH) terms of CAM, spiritual healing and its related techniques are excluded from this study. The term 'disciplines' comprises CAM methods (e.g., acupuncture, diets), systems (e.g., ayurveda, homeopathy, traditional Chinese medicine (TCM)), and techniques (e.g., chiropractic, osteopathy) [9].

Providers of CAM are classified into i) physicians certified in both conventional medicine and CAM, ii) MDs with CAM training at various levels and iii) non-medically trained practitioners with different levels of education and regulation. The first category (I) of training and continuous education is certification according to requirements of international associations and registration in national medical registries. A second level (II) is determined by the requirements of training and continuous education through the respective professional regulatory bodies. The third level (III) is characterised by CAM school diplomas, which may not be associated with external review concerning content and legal requirements, e.g., Centre for Education and Development of Clinical Homeopathy (CEDH) [10].

CAM practitioners who are not organised or registered in this manner are excluded from this evaluation because they are almost impossible to identify systematically. We are aware that there are many of these practitioners, practising legitimately, within the EU.

Search Strategy

The search strategy to identify the main areas of CAM practice in each EU country used a top-down approach. The first step consisted of a PubMed search with the following terms: CAM provision, + European, + doctors/MD/practitioners, + EU/Europ*/ Germany/ Switzerland/ UK/ other EU 27+12 countries (others) + hospitals. The second step was checking references from the publications that had been found to identify other publications and the so-called grey literature. This included international, national, regional and local publications, manufacturer and pharmacists' publications and personal manuscripts as well as DVDs and CDs of congresses. The third step comprised contacts to the national bodies for each specific CAM method. Their areas of interest, training and requirements for continuing registration were checked through websites from international and national bodies of both CAM associations and health regulators. The fourth step consisted of designing a questionnaire for national CAM associations, representatives and health authorities to collect data in a systematic manner. The fifth step was to gain information by personal communication, e.g., via e-mail contact. After data acquisition, data were classified according to sources and displayed in tables and maps.

Classification

The following classification of the sources of prevalence data was used based on discussions within WP5 once the data became available (in order of decreasing reliability):

- official publications of independent international organisations (such as United Nations, World Health Organisation) or government organisations (e.g., Ministries of Health from the particular countries, regional Health Agencies)
- scientific peer-reviewed journals (well-conducted population surveys, prospective prevalence studies)
- national level professional CAM associations (with separate membership lists)
- insurance companies with programmes for CAM practitioners
- international or national associations for CAM promotion
- personal contacts, typically to scientists who have conducted surveys and who may have publications that are not widely available, e.g., doctoral dissertations, internal documents (the grey literature)
- other sources.

This classification proposal tries to systematise the obvious differences between countries with CAM regulations and those where reliable data are scarce but available, as well as including countries with no CAM regulations and almost no reliable data. This diversity needs to be taken into account when judging the reliability of the data acquired.

Data Display

Having completed data acquisition and classification, data were presented in tables to display CAM provision of disciplines in both the EU and per country, and in maps demonstrating the distribution of CAM providers across countries.

Results

Literature and Web Search

The PubMed literature search using the chosen terms revealed 'hits', which are displayed in figure 1. Clinically relevant publications were very scarce. 8 peer-reviewed papers dealing primarily with clinical European CAM provision and 2 reports financed by the Swiss and German government were identified over the last decade [11–20]. No grey literature was identified. An e-mail pilot to contact the national bodies for each specific CAM method was unproductive except for the UK and Switzerland. This was also the case for countries with national registration (e.g., German 'Heilpraktiker'). Thus, empiric meticulous search through websites from international, European and national bodies of both government and CAM associations were the main sources for collecting data in a systematic manner.

Gaps in publicly accessible data, especially for non-medical practitioners, were difficult to access and were obtained through personal communication with Advisory Board members and e-mail, telephone or personal contact with professionals, volunteers or personal networks. Considerable data gaps were present within the 27 EU states; overall, better data were available from the central and Northern EU States.

Health Professional CAM Organisations

There is no reliable world-wide CAM organisation that unites the different CAM associations. ICMART (acupuncture), IVAA (anthroposophic medicine) and LMHI (homeopathy) are international associations of MDs that involve specific therapies. For non-medical practitioners, the European Federation for Complementary and Alternative Medicine

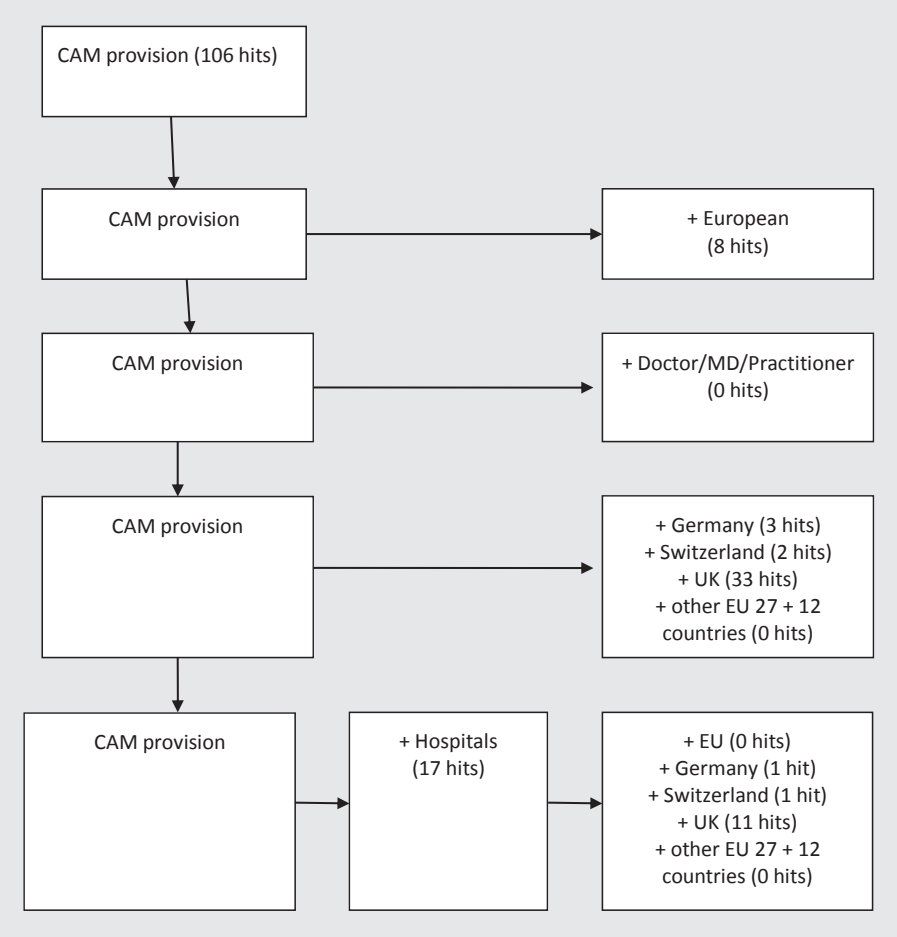

Fig. 1. Flow diagram of PubMed results.

(EFCAM) is based on pan-European professional organisation membership. The European Committee for Homeopathy (ECH, homeopathic MDs), the European Council of Doctors for Plurality in Medicine (ECPM), the International Council of Medical Acupuncture and Related Techniques (ICMART) and the International Federation of Anthroposophic Medical Associations (IVAA) constitute the CAMDOC Alliance. ANME (Association of Natural Medicine in Europe), ECCH (non-medical homeopaths), EHPA (herbal practitioners), EHTPA (herbal and traditional medicine practitioners), ESCOP (phytotherapy), ESF (shiatsu), ETCMA (TCM) and RIEN (reflexology) are other examples of European-specific professionally based CAM organisations.

There are only a few national CAM umbrella organisations, such as the doctors' Hufeland-Gesellschaft in Germany and UNION in Switzerland, the non-medical practitioners' APTN-COFENAT in Spain, FICTA in Ireland, KrY in Sweden and a number of organisations claiming national umbrella status in the UK. In Germany, specifically qualified and registered non-medical practitioners (Heilpraktiker) have at least 8 national and 2 regional superior organisations [21]. The Swiss have a nation-wide organisation dealing with quality control and financial issues for registered non-medical practitioners [22]. Most CAM disciplines do have national organisations with regional or municipal associations, although this depends on membership numbers.

Provision – Private Practice

Direct comparison is difficult between EU states due to the varying legal status. The following data are based on numbers provided by CAM societies and cross-checked with available governmental data. For non-medical practitioners, EFCAM provided EU-wide numbers. We could not verify this in every case, although we made repeated approaches to national medical regulators through questionnaires, mail and phone.

We identified at least 300,000 registered CAM providers in the EU, comprising 158,500 non-medical practitioners and 145,000 MDs. This suggests there are up to 65 CAM providers (35 non-medical practitioners and 30 MDs) per 100,000 inhabitants, compared to the EU figures for general practitioners (GPs) of 95 per 100,000 inhabitants [23].

Acupuncture (n = 96,380) is the most available discipline provided by both medical (80,000) and non-medical practitioners (16,380), followed by homeopathy (50,800; 45,000 medical, 5,800 non-medical practitioners). Herbal medicine (29,000 practitioners) and reflexology (24,600 practitioners) are almost exclusively provided by non-medical practitioners. Naturopathy (22,300) is largely provided by 15,000 (mostly German)

Table 1. Most frequently provided CAM disciplines in the EU 27+12 (usually by December 2010)

CAM discipline		Therapists			
		non-medical practitioners	MDs (physicians)	MDs + non-medical practitioners	therapists/100,000 inhabitants
1	acupuncture	16,380	80,000	96,380	21
2	individual homeopathy	5,800 (05/12)	45,000	50,800	11
3	herbal medicine/phytotherapy	29,000	??	>29,000	6,5
4	reflexology	24,600	?	>24,600	5,5
5	naturopathy (Germany: 'Naturheilverfahren')	7,300	15,000	22,300	5,0
6	antihomotoxicology (complex homeopathy)	20,000	??	>20,000	4,5
7	humoral/drainage therapy (purgation therapy)	17,000	?	>17,000	3,8
8	kinesiology	7,600	??	>7,600	1,7
9	shiatsu	7,400	??	>7,400	1,7
10	orthomolecular therapy	7,000	??	>7,000	1,5
11	manual therapies (chiropractic, osteopathy)	4,900	??	>5,000	1,2
12	anthroposophic medicine	(GER: 20!)	4,500	4,500	1,0
13	oxygen/ozone therapy	3,000	??	>3,000	0,6
14	Kneipp therapy (Germany)	2,500	?	>2,500	0,5
15	neural therapy (Huneke)	–	1,500	1,500	0,3
Total		~158,500 (?)	~145,000 (??)	~304,000 (???)	65(?)
Total per 100,000 inhabitants (population)		35	30	65	
Total GPs per 100,000 inhabitants (population)			95*		

*Reference: *www.eustat.eu.*

MDs. Anthroposophic medicine (4,500) and neural therapy (1,500) are mainly practised by MDs. MDs practising several other techniques identified in table 1 cannot be estimated accurately. Some therapists practise more than 1 complementary discipline or in different locations. This leads to individuals with registration in multiple organisations and it is impossible to accurately identify and correct this bias. Having broken down these global numbers to individual countries, discipline-specific maps demonstrate both the various distribution of CAM providers across countries and the existing gaps of data. Examples are shown in figures 2–4, additional data are available at *www.cambrella.eu.*

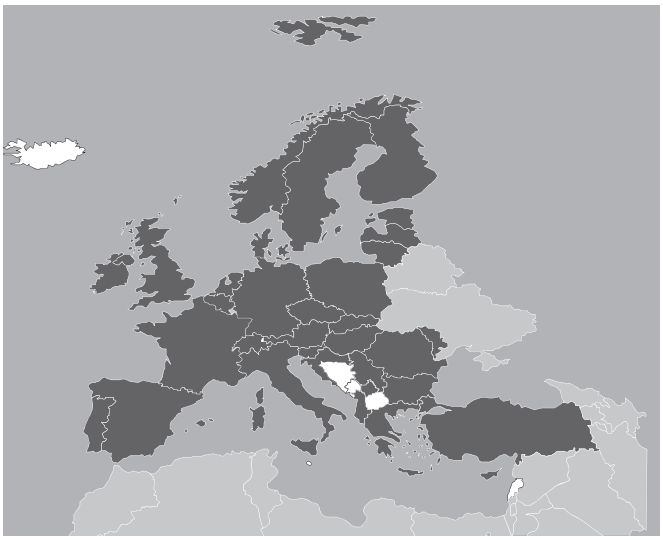

Fig. 2. Provision of acupuncture (average value: 21 therapists per 100,000 inhabitants; white = no provision, off-white = no data, light grey = < 1, grey = < 5, dark grey = < 10, black = > 10).

Provision – Hospitals

Of 5 homeopathic hospitals in UK, 4 are fully integrated into the NHS since its foundation in 1948: Bristol, Glasgow, Liverpool, London and Tunbridge Wells (which closed in 2007); 3 anthroposophic hospitals are fully integrated into the Swiss National Health Service (NHS) [24]. In Sweden there is 1 anthroposophic hospital and in Germany there are 5 with full integration into the German statutory reimbursement system. In Italy, an integrative medicine centre was recently (2011) established in the Pitigliano hospital (Tuscany) providing acupuncture, homeopathy and herbal medicine [25].

Practitioners

A few decades ago, in the UK, about a third of GPs had received some training in CAM, ~10% had completed CAM training and ~15% wished to acquire CAM skills [26]. Despite this, 59% of doctors thought that CAM techniques were useful to their patients: 76% had referred patients to CAM colleagues and 72% to non-medically qualified practitioners. Most responders voted for statutory regulations, preferable through an independent national body [26]. Similar recent data exist for Switzerland [11], Hungary [27] and the UK [28].

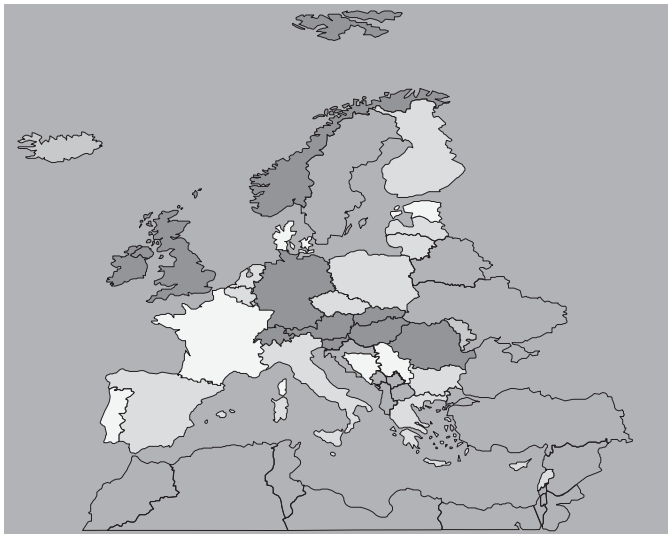

Fig. 3. Provision of homeopathy (average value: 11 therapists per 100,000 inhabitants; white = no provision, off-white = no data, light grey = < 1, grey = < 5, dark grey = < 10, black = > 10).

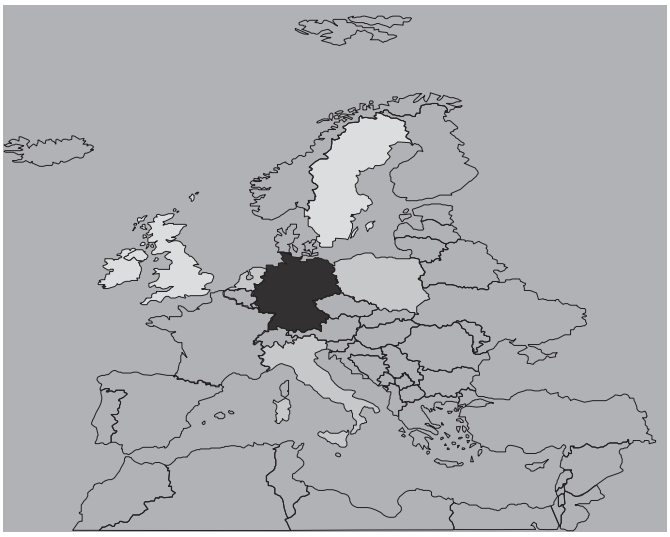

Fig. 4. Provision of herbal medicine (average value: 6.5 therapists per 100,000 inhabitants; white = no provision, off-white = no data, light grey = < 1, grey = < 5, dark grey = < 10, black = > 10).

CAM Familiarisation

During the last 20 years, some CAM familiarisation has become a part of many medical undergraduate courses in a wide range of European universities: France has CAM education or teaching at 8 universities, Poland at 7, Germany at 5, Spain at 4 universities and Hungary (Pécs) and Norway (Tromsø), 1 university each [29]. In Germany, 8 endowed chairs have been established: 3 at Charité, Berlin, 2 at European University Viadrina Frankfurt/Oder and 1 each in Essen-Duisburg, Munich and Rostock [30].

In Germany, since 1991, homeopathy has been included in the medical students' compulsory curriculum [31], and natural healing techniques have also been included since 1992 in connection with physical medicine and rehabilitation (Certification Rules (ÄAppO) § 27) since 2003 [32]. At the European University Viadrina, post-graduate training courses at MA level for doctors are given, teaching CAM and cultural sciences. In Greece, a 2-year MSc course in homeopathy for doctors and dentists is offered by the state-supported University of the Aegean [33], approved by the government in 2006 and supported by the Hellenic Homeopathic Medical Society (HHMS) and the International Academy of Classical Homeopathy [34]. In Hungary, at the University of Pécs, there is a 2 to 3-year Continuing Medical Education (CME) accredited course providing CAM knowledge, but no practice for doctors. In Italy, most of medical universities offer short elective informative CAM courses, while some (e.g., Bologna, Firenze, Messina, Milano Bicocca, Roma La Sapienza, Roma Tor Vergata, Siena, Urbino) offer post-graduate 2 or 3 years courses in 'Unconventional Medicines' or 'Natural Medicine'.

In Switzerland, there has been a subordinate public chair of natural healing techniques at the University of Zurich since 1994 and a chair of complementary medicine at the university of Bern, comprising anthroposophic medicine, classical homeopathy, neural therapy and TCM, including acupuncture, which has been publicly financed since 1995. In Zurich, chiropractors established an endowed chair for 20 students of chiropractic in 2008. In Bern, CAM lectures have been included in medical students' compulsory curriculum since 2009; in Zurich lectures are optional.

The General Medical Council in the UK suggests that all UK medical schools offer an optional CAM familiarisation course for all medical undergraduates. Most UK medical schools do provide an opportunity for this to their students but the level and quality of provision is very variable. There is a variety of UK university environments for CAM research and a number of mainly research professorial appointments in this field. 5 universities include CAM in their submissions to research and assessment exercises: Exeter and Plymouth, Southampton, Westminster and York.

Teaching of Skills

Teaching of skills is restricted to courses held by the respective CAM associations, sometimes as post-graduate courses in coordination with universities and based on international requirements (e.g., ECCH, ECH, ESCOP, ESF and ICMART). Various types of CAM schools have been maintained by the respective organisations, with curricula ranging from existing international standards down to a local introductory level, not always recognised by the national CAM body. For non-medically trained practitioners there is a single study, conducted 1980/81 in the UK, which showed that half of the practitioners have had formal education [35].

Discussion

Within the EU, CAM is provided by approximately 145,000 registered medical practitioners with additional training and certification, and probably about 160,000 registered non-medical practitioners. There appears to be about 65 CAM providers per 100,000 people within the EU as compared to 95 GPs per 100,000 people. There is huge variability in regional, national, European and international regulations, which makes any comparison of CAM practice and provision, in almost any respect, complex and difficult. Teaching and certification are managed by regional or national regulations. Due to a lack of commercial interest there are very limited data and public funding for research, so we understand little about the provision, outcome and the social and economic impact of CAM [35]. It is estimated that the CAM market, in total, amounts to approximately 1% of EU GPs [36]. The harmonisation of the legal status for CAM practice and teaching would be of enormous value within the EU.

Direct comparisons of the numbers and types of practitioners between countries, even within the EU, are impossible because of the varying national legal legislation [37]. This can occur even within 1 country, such as Switzerland with its 26 cantons. In some countries only MDs are allowed to practice CAM, while in other situations there is almost no regulation for non-medical practitioners. For practical reasons, we only refer to registered medical practitioners and non-medical practitioners as we cannot describe all practice. Consequently, a considerable number of therapists cannot be identified for a whole variety of administrative and legislative reasons.

The understanding of CAM in Europe and surrounding countries is very heterogeneous. Therefore, focussing on English language or English abstracts of scientific publications may create a selection bias. A second selection bias might have occurred when we were unable to identify 'provision' in the abstract or in key words. A possible overestimation of numbers might occur if the data are derived from associations primarily for CAM promotion. Provision of several CAM disciplines by individual therapists may also occur, leading to reporting bias; for instance, 1,665 individual therapies were provided by 995 non-medical TCM practitioners in Switzerland [38].

The scientific foundations and publications relating to CAM provision and the legal procedures involved are unsatisfactory in every respect due to lack of reliable information. It appears that many CAM doctors and non-medical practitioners appear to show minimal interest in being identified or in becoming involved in research. Organisations that are not restricted to just 1 EU state, collect, provide and share detailed data on CAM provision largely through websites or meetings. Where there are no such organisations, reliable data of CAM provision is almost impossible to obtain. There is a large difference between countries; in some, where CAM is regulated, reliable data are limited but available. However, in countries, where there is no national regulation, there are usually no reliable data available.

The best data acquisition was for registered doctors in central and northern Europe, with more limited provision in the South compared to the North, and in the East compared to the West. In the UK, CAM provision in GP practices increased from 12.5% to 50% between 1995 and 2001 [17]. This is in accordance with CAM provision in 37.8% of patient-care organisations [17]. In Germany, statistics available for naturopaths show a similar 3-fold increase [39]. There appears to be a growing demand for CAM treatments in hospitals [24, 40].

CAM familiarisation is beginning to become available as part of under-graduate education at many EU universities [41]. Teaching of skills, leading to qualification, diplomas and registered certification for both registered doctors and non-medical practitioners are confused and of variable standard. Ideally, this should be harmonised, at least at national level, and this is implemented for non-medical practitioners in Germany, Iceland and in part in UK [42], and is also planned for Switzerland in 2013.

In conclusion, CAM provision in the EU is maintained by approximately 300,000 registered MDs and non-medical practitioners with huge variability in their national regulatory management. This makes any direct comparison across the EU almost impossible. Harmonisation of legal status, teaching and certification of different levels for therapists would be of enormous value and should be developed. We will only understand this area properly with aid of more research and the introduction of national regulation for all CAM providers.

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International Development of Traditional Medicine / Complementary and Alternative Medicine Research – What Can Europe Learn?

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Complementary medicine · Research methodology · Qualitative study

Summary
Background: The aim of this study was to analyse global research and development (R&D) strategies for traditional medicine (TM) and complementary and alternative medicine (CAM) across the world to learn from previous and on-going activities. **Methods:** 52 representatives within CAMbrella nominated 43 key international stakeholders (individuals and organisations) and 15 of these were prioritised. Information from policy documents including mission statements, R&D strategies and R&D activities were collected in combination with personal interviews. Data were analysed using the principles of content analysis. **Results:** Key stakeholders vary greatly in terms of capacity, mission and funding source (private/public). They ranged from only providing research funding to having a comprehensive R&D and communication agenda. A common shift in R&D strategy was noted; whereas 10 years ago research focused mainly on exploring efficacy and mechanisms, today the majority of stakeholders emphasise the importance of a broad spectrum of research, including methodologies exploring context, safety and comparative effectiveness. **Conclusion:** The scarce public investment in this field in Europe stands in stark contrast to the large investments found in Australia, Asia and North America. There is an emerging global trend supporting a broad research repertoire, including qualitative and comparative effectiveness research. This trend should be considered by the EU given the experience and the substantial research funding committed by the included stakeholders. To facilitate international collaborative efforts and minimise the risk of investment failure, we recommend the formation of a centralised EU CAM research centre fostering a broad CAM R&D agenda with the responsibility for implementing the relevant findings of CAMbrella.

Introduction

While traditional medicine (TM) and complementary and alternative medicine (CAM) are widely used across the world, the research area of TM/CAM is relatively new. Although there is no apparent consensus regarding how TM/CAM research should be carried out, there is an emerging notion that research into CAM needs to be strategically developed. Consequently, a major goal of the EU-project CAMbrella was to propose a sustainable structure and pol-

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Table 1. Stakeholders and the type of organisation they represent

Name of stakeholder	Type of organisation
Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), India	state funded department/institute
Central Council for Research in Ayurveda & Siddha (CCRAS), AYUSH, India	state funded department/institute
China academy of Traditional Chinese Medicine, China	state funded department/institute
Consortium of Academic Health Centers for Integrative Medicine (here referred to as IM consortium) (CAHCIM), North America	research association
Federal Ministry of Health/Complementary and Alternative Medicine, Brazil	state funded department/institute
International Society for Complementary Medicine Research (ISCMR), International	research association
Japan Society of Oriental Medicine, Japan	research organisation
Korean Institute of Oriental Medicine, Korea	state funded department/institute
National Center for Complementary and Alternative Medicine, National Institutes of Health, USA	state funded department/institute
National Institute of Complementary Medicine (NCIM), Australia	research organisation (partly state funded)
Natural Health Product Directorate, Health Canada, Canada	state funded department/institute (time limited initiative)
Osher Program for integrative medicine, located centers in USA & Sweden	research organisation
Research Council for Complementary Medicine, international, UK based	research association
Samueli Institute, USA	research organisation
World Health Organization, Traditional Medicine, international	global health organisation

icy for CAM research and development (R&D) in Europe. The aim of the work package presented here was to analyse the global R&D situation for CAM to learn from previous and on-going CAM research initiatives and to inform the EU roadmap.

Material and Methods

Identification of Stakeholders

To identify global key stakeholders within TM/CAM R&D we sent out requests via e-mail asking for nominations of such individuals or organisations. 52 persons from the CAMbrella consortium and a selected group of external experts were contacted and asked to contribute nominations of individuals or organisations outside the EU playing a key role in TM/CAM R&D. Stakeholders from countries in which CAM R&D is integrated and publicly supported (e.g., US/Canada) were identified as well as stakeholders from countries where TM is widely used (e.g., China/India). 43 stakeholders (individuals and organisations) were nominated. These nominees were prioritised based on their international relevance as indicated by the number of publications, funded research projects and financial research allocations. 15 stakeholders were given first priority status (see table 1) and were grouped into 4 different organisational types: (i) government-funded departments or institutes; (ii) research organisations; (iii) research associations (with networking as primary goal); and (iv) global health organisations.

Policy Analysis

The analysis of TM/CAM policy was conducted in 2 main steps that involved data from documents, websites and interviews with selected stakeholders. A protocol for data collection was developed, partly based on the structure, process and outcome indicators published by the World Health Organization (WHO) used for the development of evidence-based national drug policies [1].

With guidance from this research protocol, we conducted interviews with 6 stakeholders selected on the basis of their representation of different types of organisations across the globe and their willingness and ability to participate in a face-to-face interview: KIOM (Korea), NCCAM/National Institutes of Health (NIH; USA), NICM (Australia), CCRAS/AYUSH (India), Samueli Institute (USA), NHPD/Health Canada (Canada).

Data from interviews and documents played a complementary role and were analysed using principles of content analysis [2, 3]. The first step in the analysis involved an exploration of descriptive data, e.g., stakeholders' funding, number of funded projects as well as an exploration of stakeholders' R&D strategies and mission statements, in addition to their testimonials during the interviews. The 5 categories of research approaches described by Fønnebø et al. [4] were used as a guiding framework for analysing R&D strategies.

While the analysis of the stakeholders' R&D strategies in step 1 aimed to show how stakeholders wanted their R&D practice to be implemented, step 2 of the analysis aimed to explore stakeholders' self-reported practice of CAM R&D. Self-reported activities were here defined as projects and publications that were mentioned by the stakeholders either on their website, in key R&D documents or listed as publications in PubMed. Completed and on-going projects were included. The websites and key R&D documents of stakeholders were extensively searched for any possible listings of research studies/publications. The goal was to find an abstract for each study. However, when this was not possible other information, e.g., the title, served as a basis for analysing the nature and content of the project.

Results

As described below in 3 separate sections, our findings point both to similarities and differences in stakeholders' TM/CAM R&D.

Descriptive Measures: Capacity and Funding

The 15 stakeholders vary greatly in capacity and funding (see table 2). Some Asian stakeholders began their work in the 1950s, while a number of stakeholders in high-income countries (North America and the Pacific region) date from the 1990s or 2000s.

Most of the financial support comes from public sources but, due to differences in the way budget figures are presented, it is difficult to compare budgets between stakeholders. For example, official fiscal budgets from 2010 range from almost €100 million to approximately EUR 5 million. The majority of stakeholders that conduct research also fund external research. Some stakeholders serve only as research networks (in table 2 referred to as research organisations) and do not have their own research budgets.

Mission Statements

By analysing the mission statements of 15 stakeholders, we have identified 4 main themes: i) The development of health care practice; ii) the scientific exploration of TM/CAM; iii) communication of TM/CAM-related research; and iv) TM/CAM focus areas. These themes represent both the expressed goals of the selected stakeholders and the means of achieving these goals. Although these themes overlap, they are distinct and not contradictory and are presented below under separate sub-headings. The excerpts presented in the results are used to illustrate the analytical points in each theme.

Development of Health Care Practice

The mission statements of a few stakeholders disclose a general goal to transform and improve health care and health of citizens:

'The mission of the Samueli Institute is to transform health care …' (Samueli Institute)

Other stakeholders express a similar goal if slightly different in terms of promoting integration between conventional health care systems and TM/CAM. The Osher Program for Integrative Medicine and the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), India Ministry of Health and Family Welfare are 2 such examples:

'… A third goal is to establish clinical treatment programs in which the knowledge and resources of integrative medicine can be used directly to help people as well as furnish training opportunities for medical students.' (Osher Program for Integrative Medicine)

'To mainstream AYUSH at all levels in the health care system…' (AYUSH).

The Scientific Exploration of TM/CAM

The most general and prevalent theme found in the mission statements concerns the scientific exploration of TM/CAM. Some stakeholders wish to increase the academic influence and interest in CAM by extending the evidence base and conducting rigorous science. This was exemplified by the mission statement of the Research Council for Complementary Medicine (RCCM) and National Center for Complementary and Alternative Medicine (NCCAM/NIH):

'Our aim is to develop and extend the evidence base for complementary medicine …' (RCCM)

'We are dedicated to exploring complementary and alternative healing practices in the context of rigorous science …' (NCCAM).

Communication of TM/CAM-Related Research

Another overarching goal expressed in the mission statements of many included stakeholders was to provide a communication platform for TM/CAM research. The specific focus of such communication activities ranged from providing a 'platform for information exchange' (e.g., ISCMR) to 'research translation and dissemination both to the public and professionals' (e.g., NCCAM):

'… and disseminating authoritative information to the public and professional communities. … A second goal is to reach out to the larger community with an emphasis on preventive care. The center seeks to educate both medical practitioners as well as the general public' (NCCAM).

TM/CAM Focus Area

Some stakeholders focused on specific areas of TM/CAM, such as a specific type of traditional medicine or natural product. Among the selected stakeholders there were examples of government-funded institutions focusing specifically on TM in China, India, Japan and Korea. Interestingly, the mission statements seem to indicate 2 lines of development: While KIOM, Korea, expressed striving towards modernisation and industrialisation of Traditional Korean Medicine, the mission statement of AYUSH, India, indicates that their intention for TM (in its present form) is to take a larger role within the general health care system:

'… to contribute to the improvement of human health through modernization and industrialization of TKM (Traditional Korean Medicine)' (KIOM).

'To mainstream AYUSH at all levels in the health care system; to improve access to and quality of health care delivery …' (AYUSH).

Interestingly, the Natural Health Products Directorate (NHPD) was the only selected stakeholder to explicitly emphasise the safety aspect in its mission statement:

Table 2. Descriptive measures for the included stakeholders. The figures are based on official documents and website information of the stakeholders

Stakeholder	Date established and time of operation	Budget estimates**	Financial support	Finances external research	Performs own research
Federal Ministry of Health (MoH), Brazil	1953–	total CAM investment (2003–2008): €4,740,596	federal	yes	yes
Natural Health Products Directorate (NHPD), Health Canada	2003–2008	total investment (2003–2008): €2,378,010 [NHPD, 2008]	federal	yes (~11.5% of budget for partnership)	no
Samueli Institute	2001–	€12,582,080 (2010) €10,437,973 (2009) €9,479,370 (2008)	private, not-for-profit	yes	yes
Osher Centers	centres in the USA (Harvard, 2001 & UCSF, 1998) and in Sweden (KI, 2005)	official budget figures not found	private, not-for profit	yes.	yes
The Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)	1995–	€142,645,082 (2010–2011) €127,699,902 (2009–2010)	federal	no	yes
CCRAS (AYUSH)	1978–	€19,574,744 (2010–2011) €20,342,381(2009–2010)	federal	no	yes
World Health Organization (WHO), Traditional Medicine (TRM)	date of establishment not found	not found	member state support; private/public funding	not been found	no
Research Council for Complementary Medicine (RCCM)	1983–	N/A	charity	no	no
Korean Institute of Oriental Medicine (KIOM)	1994–	€29,149,799 (2011) €19,944,599 (2010) €15,341,999 (2009)	federal	yes (~10% budget goes to external research projects)	yes
National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health (NIH)	1998–	*€101,260,265 (2011 planned); €98,795,573 (2010); €93,352,232 (2009)	federal	yes	yes
Integrative Medicine (IM) Consortium	1999–	N/A	memberships and philanthropic support	no	no
International Society for Complementary Medical Research (ISCMR)	2003–	N/A	non-profit organisation with membership finances	no	no
Japan Society of Oriental Medicine (JSOM)	1950–	official budget figures not found	non-profit organisation	not found	yes
China Academy of Traditional Chinese Medicine (CATCM)	1955–	official budget figures not found	federal	not found	yes
National Institute of Complementary Medicine (NICM)	2007–2009	€6,044,748 (2009)	€1,380,780 (2009) from federal support, and €4,663,968 from universities and other collaborative partners	no	yes

*This represents approximately half of the budget of research into CAM. The other half is primarily represented by the National Cancer Institute (NCI).
**Budgets are estimates derived from electronic sources which have not been confirmed by the stakeholders, and hence should be taken as pointers of investment and not be misinterpreted as actual spending.

'The mission is to contribute to improved knowledge of NHPD to enable Canadians to make informed choices about their safe and effective use' (Health Canada).

Stated R&D Strategies and Self-Reported Actual R&D Activities

In the analysis of the selected stakeholders' R&D strategies and activities, we found 3 main themes that seem to direct their R&D strategies: i) type of research; ii) utilisation; and iii) impact on society.

Type of Research: Stated R&D Strategies

A strong trend was a development, over the last decade, from a focus on biological mechanisms and component efficacy to a broader focus on the investigation of complex interventions with multiple and mixed methodology. The director of CCRAS, for example, referred to this trend as 'reversed pharmacology'. This broad focus on all research methods also applies to the newly established centre, NICM, in Australia. NCCAM, USA, also emphasised a broader mixed methods research focus. 1 exception to this trend was KIOM, Korea, who expressed a main focus on component efficacy and biological mechanisms.

Type of Research: Self-Reported R&D Activities

The analysis of stakeholders' self-reported activities revealed that their R&D activity largely depended on their organisational type. Firstly, it was found that government funded departments or institutes as well as research organisations openly reported most of their R&D activities. Research associations with networking as their primary goal and global health organisations did not report having R&D activities of their own. Secondly, it seemed that the type of reported R&D activities prioritised by government-funded research organisations cover the whole range of research categories as described by Fønnebø et al [4]. Thirdly, it was found that among the stakeholders that did have R&D activity, their mission statements were in general consistent with their self-reported R&D activities. Hence, no apparent theory-practice gap among the analysed stakeholders was found.

Utilisation

The analyses indicated that to some stakeholders utilisation was an important factor directing R&D strategies, whereas to others utilisation did not seem to explicitly direct R&D policy. In general, there seems to be a difference between stakeholders focusing on CAM compared with those focusing on TM. All stakeholders focusing on CAM (e.g., NCCAM, NICM, NHPD) seemed to include prevalence figures as an influencing factor in prioritising research activity. CCRAS and KIOM focusing on TM, however, did not explicitly mention prevalence as directing their R&D strategy. In summary, utilisation of TM/CAM may influence R&D strategies in 2 different ways through: (i) the popularity of a certain TM/CAM, and (ii) the disease burden related to the condition for which a particular TM/CAM is used, as exemplified by NICM and NCCAM:

'… high burden of disease where preliminary evidence is strong and demonstrates likelihood of positive impact' (NICM, Australia).

'extent and nature of practice and use…' (NCCAM, USA).

Impact on Society

The potential role of TM/CAM R&D for the society seemed to be an important factor directing R&D policy. 2 such examples involved collaboration with regulatory authorities and the natural health products industry. Many research initiatives funded by the NHPD were connected to the development of regulatory functions. Moreover, NICM-prioritised research projects involved collaboration with the natural health products industry. For stakeholders focusing on TM (e.g., CCRAS), the issue of intellectual property rights was mentioned but not considered to be an obstacle, thanks to different initiatives including the Traditional Knowledge Digital Library.

Discussion

R&D strategies and activities among the selected stakeholders range from providing professional networks to having a comprehensive R&D policy and communication agenda. Despite this heterogeneity, 2 issues were of common priority to most stakeholders: (i) How to set priorities for CAM R&D and (ii) how to conduct CAM R&D.

Directing the Research – Types of Research and Prioritisation

A strong trend that was found was a development, over the last decade, from a research focus on biological mechanisms and component efficacy to a broader focus on the investigation of complex interventions with a broad range of research methodologies. This was favoured by most stakeholders and supported also by data from the interviews with the representatives of the WHO. This development is also reflected in the scientific literature both in medicine (e.g., Thorpe et al. [5]) and CAM (e.g., Witt et al. [6]). The importance of researching contextual factors in relation to CAM, and applying qualitative methodology can be illustrated by the research conducted by Kaptchuk et al. [7]. This trend provides an important recommendation for CAMbrella and the EU given the experience and size of research funding committed by the included stakeholders.

The issue of strategic CAM R&D was a difficult topic to discuss for various reasons, including the inherent national political nature of specific CAM modalities. For example, we found a spectrum of critical opinion regarding the NCCAM-funded research in the USA. At 1 end of the spectrum were

claims that CAM approaches are inherently implausible and justified only by 'pseudoscience' that peer-review processes are inferior and that the research agenda is driven by political pressures rather than scientific considerations, etc. At the other end of the spectrum were claims that NCCAM research fails to evaluate CAM as it is actually used in 'real-world' practice settings, that the field is dominated by reductionist scientific approaches or inappropriate methodology, and that there has been insufficient focus on health and wellness. In general, such contrasting views and opinions are likely to be common in many countries, including the EU member states, and may impact substantially on any CAM R&D initiative, pointing to the need for independent, public investments in the field. The NIH has in fact increased their expenditure on CAM research from approximately USD 100 million in 1999 to USD 520 million in 2010 [8]. The investment of the NIH in the NCCAM, and a number of similar public institutions around the world, as shown in this paper, stand in stark contrast to the European public investments in the field – despite the prevalent use of CAM among European citizens and the fact that many researchers in the field are based in Europe. This critique has also previously been pointed out in individual European countries such as the UK (e.g., [9, 10]), where public investments in CAM research have been showed to constitute 0.08% of the total research budget [11].

The contrasting views and opinions about CAM research found in our analysis could possibly explain why several of the stakeholders expressed aiming towards a balance between the many types of research methodology. This was also confirmed by our analysis of the actual CAM R&D projects carried out. This, however, seems to apply mainly to initiatives in high-income countries. In contrast, in China and South Korea, the focus appears to be predominately on component efficacy and biological mechanisms. However, India seems to support a shift of focus from efficacy towards 'real world' comparative effectiveness research, stated by the director of CCRAS, as a 'reversed pharmacology' research approach. Despite the aim of many stakeholders to invest in a broad spectrum of research methodologies, priority setting is vital for any organisation given the limited R&D funding available. Priority setting was suggested to occur for both NICM and NCCAM considering the popularity of a certain CAM and the disease burden.

The lack of R&D focus with regard to safety of CAM indicates that the reasons or lack of reason behind this should be studied further. It should be noted that, for example, the Uppsala Monitoring Centre, a WHO Collaborating Centre, has for a long time had systems for reporting and analysis of adverse events following herbal product use [12]. Given the extensive use of TM/CAM products across the world, the low number of reported adverse events published in the scientific literature is notable. Such findings may challenge funding of costly general regulation of CAM products and therapies that have a broad therapeutic application and that have been used extensively among populations for many years. On the contrary, reports on, e.g., high levels of heavy metals in Ayurvedic preparations (e.g., Saper et al [13]) point to the need for targeted regulation.

Impact on Society and Intellectual Property Rights

Moreover, our results indicate that some stakeholders support health care reform with the aim of including TM/CAM where this is compatible with their current national health legislation. While the KIOM works for modernisation and industrialisation of TKM, CCRAS/AYUSH, India, aims for TM to take a larger role within the general health care system in its present format. The issue of intellectual property rights was raised by stakeholders focusing on TM as an obstacle to R&D efforts. Stakeholders pointed out that this was because most TM modalities cannot be patented, and indigenous knowledge may, hence, be exploited for commercial purposes without any benefit to the nation or indigenous population.

Methodological Considerations

To our knowledge the presented study is the first stakeholder analysis on this topic. The data on which these results are based are largely dependent on the level of transparency of the included stakeholders. The views of individuals representing an organisation may sometimes differ from the organisation as a whole. However, the triangulation of different data sources was a way of reducing this. The limitations of drawing conclusions from mission statements should also be considered, since mission statements may not reflect current thinking and activities of the stakeholders. In addition, our approach to review actual practice by the stakeholders reflects the totality of the stakeholders' engagement, which may not be reported through such sources. However, the coherence between theory and practice in R&D indicates that R&D activities were justly reported. Finally, we have not been able to include stakeholders from the Africa or Middle-East, and this is a limitation to our conclusions.

Conclusion and Recommendations

The conclusion and recommendations from this study could be summarised as follows:

- A broad range of mixed methods research strategies should be used to investigate CAM within the EU. The choice of method(s) for any particular project or experiment should be based on the specific scientific question and should focus on delivering safe and effective health interventions to EU citizens.
- The CAM research strategy for Europe should be based on the popularity of a specific intervention and be related to the national or regional public health needs and disease burden.
- We recommend the formation of a centralised and academically supported EU CAM research centre with responsibility for operationalising CAMbrella strategy for the EU.

The inherent complexity and political nature of the CAM field may negatively influence any CAM R&D initiative in general, and on the CAMbrella roadmap in particular. Our recommendation includes the formation of a centralised EU CAM research centre with the responsibility of operationalising the CAMbrella recommendations in collaboration with selected EU member states and academic institutions. This would facilitate collaborative efforts and would increase synergies and minimise the risk of duplication of R&D investments internationally.

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Key Issues in Clinical and Epidemiological Research in Complementary and Alternative Medicine – a Systematic Literature Review

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Clinical research · Epidemiological research · Research methodology · Complementary and alternative medicine · Systematic review

Summary
Background: In the last 2 decades there has been a large increase in publications on complementary and alternative medicine (CAM). However, CAM research methodology was heterogeneous and often of low quality. The aim of this systematic review was to investigate scientific publications with regards to general issues, concepts and strategies. We also looked at research priorities and methods employed to evaluate the clinical and epidemiological research of CAM in the past to identify the basis for consensus-based research strategies. **Methods:** We performed a systematic literature search for papers published between 1990 and 2010 in 7 electronic databases (Medline, Web of Science, PsychArticles, PsycInfo, CINAHL, EMBASE and Cochrane Library) on December 16 and 17, 2010. In addition, experts were asked to nominate relevant papers. Inclusion criteria were publications dealing with research methodology, priorities or complexities in the scientific evaluation of CAM. All references were assessed in a multistage process to identify relevant papers. **Results:** From the 3,279 references derived from the search and 98 references contributed by CAM experts, 170 papers fulfilled the criteria and were included in the analysis. The following key issues were identified: difficulties in past CAM research (e.g., randomisation, blinding), utility of quantitative and qualitative research methods in CAM, priority setting in CAM research and specific issues regarding various CAM modalities. **Conclusions:** Most authors vote for the use of commonly accepted research methods to evaluate CAM. There was broad consensus that a mixed methods approach is the most suitable for gathering conclusive knowledge about CAM.

Introduction

CAMbrella is a European Union (EU)-funded coordinated action in the field of complementary and alternative medicine (CAM). To address the increasing use of CAM and the lack of scientific knowledge concerning CAM use, the CAMbrella Work Package 7 (WP7) group is developing a 'roadmap for further clinical and epidemiological research in CAM'. Here

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we report the results of a systematic literature review on general issues in CAM research as a first step towards the development of a research roadmap. Research in CAM has been a controversial topic (for a broad overview on CAM research see [1]), and our aim was to create a comprehensive evaluation and analysis of the methodological and conceptual issues involved.

We therefore performed a systematic review of literature dealing with the complexities and general methodological issues involved in the evaluation of CAM in clinical and epidemiological research. Ultimately, the outcome of this review, the subsequent discussion and the final roadmap for further research, should lead to a basis and framework for further CAM research in Europe.

Methods

A structured systematic literature review was conducted. Before starting this review, a systematic review protocol was developed (initial draft by the WP7 leader), which was submitted to the whole WP7 group for notes and suggestions for changes. The final version of the review protocol (including the search terms) was approved by the whole WP7 group.

Literature Search

In 2010, 7 electronic databases (Medline, Web of Science, PsychArticles, PsycInfo, CINAHL, EMBASE and Cochrane Library) were searched for relevant articles published between 1990 and 2010 (until December 16/17). Table 1 shows the search terms entered into the databases. In addition to the database search, all experts and the advisory board involved in the CAMbrella project were asked to submit any relevant publications.

Selection

Duplicates were excluded. We mainly aimed for full articles and original works, but comments, editorials, letters and 'grey' literature were included when a substantial original contribution to the topic was found. The title and abstract of the remaining references were screened by 1 researcher (Florian Junne) to exclude irrelevant references that were not related to CAM at all, not in a European language, on basic research only or on animal studies. Secondly, the title and abstract of the remaining articles were evaluated by 2 reviewers (Florian Junne and Felix Fischer) to identify publications that included investigations, analysis, discussion, proposals or statements concerning the following: i) qualitative and quantitative methods, ii) clinical and epidemiological research methodology, iii) priorities or priority setting or iv) methodological complexities involved in the scientific evaluation of CAM.

Articles with a corresponding judgment from both reviewers were included in further analysis. Kappa as measure of inter-rater agreement was calculated. For non-corresponding judgments, the 2 reviewers discussed the title and abstract of the publication until an agreement regarding inclusion or exclusion was achieved. Publications contributed by CAM experts (additional references were contributed by the authors of the review and the CAMbrella Advisory Board members Nora Laubstein, Ton Nicolai, Peter Zimmermann and Stephen Gordon) were also reviewed and included in full-text analysis if they met the inclusion criteria after rating of title and abstract.

Full-Text Analysis and Data Extraction

All included publications entered full-text analysis. The eligibility of the publications was re-examined with respect to the above-mentioned inclusion/exclusion criteria. At this stage, publications were also excluded if 1 of the following additional exclusion criteria was fulfilled: (i) it mainly addressed research methodology of basic and experimental research; (ii) it primarily addressed the reporting of clinical trials; (iii) it primarily assessed methodological quality/rigour of CAM-evaluation trials; (iv) it presented a case study or abstract only; or (v) it mainly reported a specific study design or research tool.

Full-text analysis and inclusion/exclusion based on the full text was conducted primarily by 1 reviewer (Felix Fischer). To check the rigour of the exclusion process, excluded articles underwent a second review and inclusion/exclusion was discussed by 3 reviewers (Felix Fischer, Benno Brinkhaus, Claudia Witt) until consensus was found. All arguments appearing within the included references were categorised and relevant information was extracted. Categories emerging from the original publications were continuously reordered and discussed within the WP7 group.

Table 1. Search terms for electronic databases

AND		
Complementary therapies$	research	
Complementary medicine	method*	
Complementary therap*	methodological research	
Alternative medicine*	research design	
Alternative therap*	study design	
Integrative medicine*	whole system research	
Integrative therap*	complexity research	
Unconventional medicine*	complex interventions research	
Unconventional therap*	qualitative research	
Traditional medicine	research priorities	
Supplement*	research strategy	
Herbal		
Homeopathy		
Osteopathy		
Acupuncture		
Traditional Chinese medicine		OR
Mind-body therap*		
Naturopathy		
Meditation		
Massage		
Ayurveda		
Chiropractic medicine		
Manipulation		
Biofield therap*		
Reiki		
Therapeutic touch		
Yoga		
Aromatherapy		
Prayer		
Anthroposophic medicine		

Results

The literature search resulted in 3,279 hits and CAMbrella members contributed 98 additional references. After the exclusion process, 170 studies were included in the qualitative synthesis. See figure 1 for additional information.

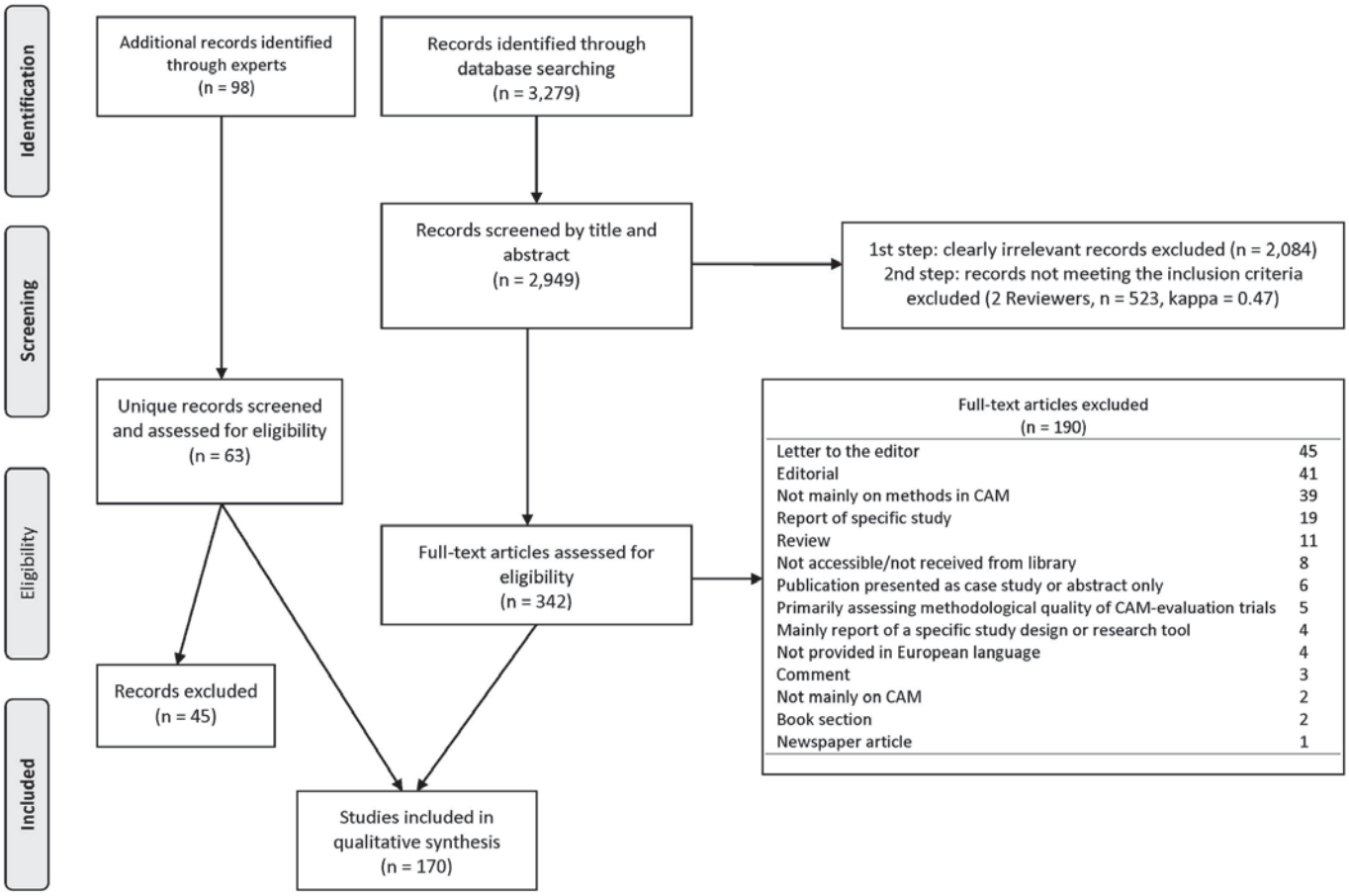

Fig. 1. Flowchart of literature review process.

Practical Problems in Research into CAM

We found a large number of publications dealing with practical problems when conducting research in CAM. These problems and relevant references are categorised in detail in table 2.

Choice of Research Methods

The choice of research method depends on the question asked [2–6]. In some publications, explicit research questions and appropriate methods were given by the authors [2, 5, 7–11]. However, there was clear agreement about the value of different research methods in CAM research [12–16]. Most authors suggested a research-question-driven integration of diverse methods into the research agenda [6–8, 13, 16–29].

Quantitative Research Methods

Randomised controlled trials (RCTs) are considered to be the gold standard to assess specific effects and efficacy and to determine causal relationships in biomedical research. Most authors stated that RCTs with high methodological quality are possible in the field of CAM and can therefore produce valid data [4, 11, 17, 30–48], but they must be rigorously performed and CAM-specific challenges must be addressed, such as the lack of external validity due to strict standardisation of diverse treatments and study participants [3, 30, 32, 37, 38, 41–43, 48–59]. However, a consensus emerged that clearly implied that RCTs do not answer all research questions [28, 36, 52, 60–64] and are expensive to conduct [18, 30, 32, 52, 65, 66]. Some authors argue that placebo-controlled RCTs might be inappropriate for some specific CAM modalities [67–69]: a position that has raised considerable controversy [47, 70]. Integration of diverse research methods [2, 12, 27, 38, 61, 71], preference trials [3, 72, 73] or the use of different outcome measures [74, 75] could help overcome these shortcomings. Feasibility studies are a vital preliminary phase in the design of high-quality RCTs with adequate power [3, 4, 10, 76–79]. When individualised and standardised treatments are to be compared [3], or if specific and non-specific effects need to be separated [80], RCTs can be extended to more than 2 treatment arms to account for preference towards a specific treatment in preference trials [20, 28, 72, 73].

Pragmatic trials – as promoted in Comparative Effectiveness Research (CER) – can be conducted to assess outcomes

Table 2. Problems experienced in CAM research

Problem	Short description	Possible solutions	Relevant references
Complexity of interventions	therapies in CAM typically consisting of a number of different procedures and/or interventions; isolation of parts may lead to underestimation of effect	research into overall effects/effectiveness; refined methodological approaches	[12, 17, 30, 31, 49, 60, 87, 99, 130, 146, 149]
Assessment of specific and non-specific effects	unclear nature of unspecific effects in CAM, little external validity of research into specific effects so far, RCTs rule out possibly important nonspecific effects	development of a clear definition of nons-pecific effects, consideration of specific/non-specific effects in trial design, prioritisation of effectiveness research	[2, 12, 17–19, 31–33, 50, 61, 62, 72, 80, 130, 136, 137, 151, 165]
Choice of control group(s)	appropriate control group depends on the research question asked (especially placebo); specific control group conditions not feasible in some cases	different control conditions are possible, even within the same trial. Placebo treatments must be carefully developed	[18, 30, 34–37, 51–53, 63, 72, 99, 101, 143, 144, 151, 152, 158, 166, 167]
Randomisation	randomisation is desirable, but might be hindered by patients' preferences making them unwilling to participate in studies when allocated to placebo treatment	take preferences into account in trial design (preference trial) and statistical analysis; when randomisation is impossible, assess baseline differences	[20, 30, 32, 33, 37–39, 53–55, 62, 67, 72, 84, 87, 88, 111, 115, 127, 146, 147, 168]
(Double-)blinding	(double-)blinding is desirable, but not achievable in all trials of CAM treatments (e.g. blinding of an acupuncturist)	assess success of blinding technique; if blinding impossible, blind outcome assessor, data analyst, diagnostician	[2, 3, 33, 35, 37, 40–43, 49, 51–53, 55, 68, 101, 102, 115, 152, 154, 169]
Handling of different diagnostic frameworks	treatment allocation within studies could differ between different diagnostic systems of CAM and conventional medicine	differences between diagnostic systems must be assessed and should be taken into account when allocating treatment	[33–35, 43, 44, 49, 103, 123, 134, 170]
Definition of treatment; standardisation vs. individualised treatment	standardisation leads to loss of external validity, since most CAM treatments are considered as necessarily individualised; individualised treatment hinders reproducibility of trials	use of semi-standardised treatment regimens; implementation of individualised and standardised treatments as study arms	[3, 13, 17, 18, 21, 31, 34, 39, 42, 49, 68, 134, 152, 153, 166, 171, 172]
Time frame for expected results	observation time for CAM studies might need to be longer, e.g. in the treatment of chronic illness	extending study duration and regular follow-ups	[17, 30, 35, 39, 49, 65, 88]
Choice of outcome parameters	treatment effects/outcomes in CAM might be different from conventional medicine	objective and subjective outcomes should be assessed (if possible) and cover different domains; when outcomes are unclear different potential outcomes should be considered	[20–23, 30, 39, 41, 44, 49, 56, 67, 76, 89, 97, 101, 107, 130, 173, 174]
Study setting and treatment providers	CAM is often applied by practitioners with little experience in research; treatment provided by different practitioners might be hard to standardise	research needs to be conducted in collaboration with experienced researchers and clinicians	[14, 74, 86, 89, 138]
Lack of knowledge underlying the mechanism of interventions	lacking theoretical basis of treatments complicates the planning of valid studies and might compromise results	implementation of research into foundations of CAM	[4, 13, 17, 24, 55, 57, 58, 76–78, 93, 108, 152, 156, 160, 175]
Inconclusive study results	study results are controversial, e.g. in homeopathy, acupuncture & dietary supplements	development of guidelines in trial design, enhance methodological quality by development of research infrastructure	[5, 7, 15, 43, 45, 52, 134, 144, 156, 159]

RCT = Randomised controlled trial.

of a treatment within a real world clinical setting (clinical effectiveness) [36, 69, 81–83]. Pragmatic trials enable comparison of clinical treatment alternatives, inclusion of a wide variety of patients in diverse practice settings and address a broad range of patient relevant outcomes [2, 83]. Over the years, the general nature of research questions in CAM has shifted from efficacy to effectiveness [2, 36, 81]. Pragmatic trials involve randomisation [20, 33, 83, 84] and treatment has to be defined adequately and clearly [53, 83, 85]. In contrast to the wide use of explanatory RCTs addressing efficacy, pragmatic trials have greater external validity [19, 20, 38, 44, 52, 83, 85, 86]. They also allow the evaluation of complex interventions triggering a variety of specific and non-specific effects [29, 36, 87, 88], can include cost evaluations [52, 84], but cannot identify specific mechanisms of action within a treatment [18, 20, 82, 83].

Observational studies might be a feasible method for evaluation of CAM and sometimes lead to results that are comparable with RCTs [15, 17, 20, 44, 52, 59]. This approach could represent a potential alternative if RCTs are seen to be inappropriate, too expensive or too complicated [13, 20, 67, 69, 89], if general effectiveness of an intervention is the focus of interest [24, 52] or to assess CAM use in the population [45]. Results of observational studies can influence the design of further interventional trials [17, 42]. Uncontrolled observational studies, however, give little information about effects of treatment [47], and their weak internal validity must be addressed [20]. A particular method that has been discussed is the Best Case Series [29, 90–92].

The use of quantitative methods, such as factorial and experimental designs [20, 24, 63, 72, 93], has also been proposed. N-of-1 trials (repeated intervention of 1 approach in 1 person) were discussed extensively as a methodology to achieve valid results on the level of the individual patient. It could be appropriate when studying customised treatment of many CAM modalities [20, 49, 72, 74, 94, 95]. However, these trials are uncommon in published research and need to be planned and executed carefully [96].

Qualitative Research Methods

In relation to studies of outcomes of specific therapies, qualitative research may be used to assess the subjective views of individuals [14, 8, 25, 26, 44, 97, 98]. This can help to establish a patient-centred mechanistic understanding of the intervention and its impact, irrespective of whether mechanisms and objective outcomes of treatments are known [16, 26, 56, 97–100]. Qualitative research is unsuitable when trying to establish causal relationships or specific physiological outcomes [101], but is relevant for the investigation of changes in subjective approaches to health and illness [5]. Specific qualitative research methods have been introduced in the literature, such as ethnographic research, interviews and focus groups [5, 16, 98, 102–104]. Case reporting and case studies are particularly valuable to establish complex and contextualised views of the topic under study [67], to gather basic knowledge about CAM treatments [89] or to identify relevant, but uncommon outcomes [89, 105]. However, rigour and sophistication of case reports could be improved [10, 67, 106].

There was a strong consensus that both qualitative and quantitative methods are valuable and should be combined in the CAM research agenda, e.g., qualitative methods to formulate hypothesis on mechanisms (which might be tested by quantitative methods) as well as in specific clinical studies, e.g., to assess reasons for dropouts, identification of the most relevant outcomes or to generally improve interventions [2, 14, 16, 18, 22, 25, 26, 28, 42, 71, 98, 100, 102, 107–110]. The use of qualitative methods has been particularly discussed as a preliminary basis for preparation of clinical trials [25, 28, 29, 79, 97, 101].

Applying Research Methods Used in Conventional Medicine to CAM

Research methods used in conventional medicine can and should be used for research in CAM as well [7, 15, 17, 44, 55, 73, 81, 87, 111–114]. Most authors agreed that the methodological standards of medical research can be applied to CAM research [4, 11, 13, 17, 29, 32, 35, 40, 46, 47, 70, 115, 116], but it might be necessary to adapt the research designs in some areas [6, 12, 15, 43, 57, 58, 62, 69, 87, 88, 117, 118] to account for the complexity of CAM interventions [15, 17, 87, 119, 120]. This is the case not only for CAM, but also for complex and individualised treatments in conventional medicine [72]. However, some authors felt that the underlying assumptions between conventional medicine and CAM differ so fundamentally [8, 18, 39, 64, 121, 122] that specific research methods for CAM are necessary.

Research Priorities

No definite statement can be made concerning the question of which kind of research should be prioritised in CAM, but it was argued that the specification of research priorities is important, as the methods of assessment must be derived from the research question and not vice versa [13]. Various criteria were proposed for deciding on the priorities of future CAM research in general, such as prevalence of use and burden of disease [7, 8, 29, 45, 46, 81, 82, 92, 107, 123–126], and also for specific fields and modalities of CAM [76, 78, 114, 123, 127, 128], where priorities might differ [129]. The context, foundations and philosophical background of CAM treatments [13, 26, 28, 57, 58, 71, 76, 97, 99, 119, 121, 130–132] are an important basis through which to understand the differences between CAM practices and conventional medicine. The safety of different CAM treatments needs to be assessed [46, 57, 58, 64, 82, 89, 91, 119, 133] to protect patients using CAM [46], even though CAM is generally considered safe [55, 81].

There were 2 contradicting views regarding effectiveness versus efficacy studies. Although there seems to be no disa-

greement that both types of research have their own place, validity and importance [13, 33, 36, 66, 82, 88], some authors argue [11, 36, 48, 57, 58] that efficacy research should be prioritised over effectiveness research to legitimise the use of CAM and to help to increase acceptance [55, 108, 134]. Other authors state that efficacy research to examine specific effects should not be undertaken until overall effectiveness of the therapy in question is demonstrated to prevent misuse of scarce resources [76, 81, 119, 135]. This discussion also reflects different opinions on the importance and value of specific and non-specific effects within the whole of clinical practice [18, 19, 36, 53, 66, 78, 81, 82, 85, 86, 136–140].

An integrative research approach has been described as simultaneous research into mechanisms and overall effectiveness of CAM treatments [13, 31, 88]. The health economic evaluation of CAM treatments was seen as particularly relevant in modern healthcare [141, 142]. Research into the mechanisms of placebo, context or meaning effects were also seen as important to determine appropriate control groups and their respective explanatory power [143–145], to explain potentially contradictory study results [144] and to maximise these effects in clinical practice [46, 144].

Research Strategies and General Frameworks on Research in CAM

Some authors have developed general frameworks for CAM. A number of frameworks are applicable; many have overlapping concepts and may be described as 'whole systems research' [20, 89, 99, 130], 'outcome research' [44, 52, 66, 105, 146–148] or 'health services research' [76]. These approaches focus on the investigation of processes and outcomes in a systemic manner [130] in routine clinical practice [76]. They primarily reflect the concepts of effectiveness research and are designed to take the complexity of CAM into account [20, 87] while ensuring maximal external validity and clinical relevance [130, 149].

An approach that has received considerable attention is the 'reversed research strategy' for CAM, in contrast to drug research [57, 58, 76, 81, 119], where initial observational research in the context of areas, such as usage and safety, is followed by research into the overall effectiveness and then by efficacy research.

Concepts, such as the 'evidence house' [13], the 'circular research model' [12] or the 'rational sequences of research designs' [81] put emphasis on a broad perspective of research designs to gather evidence on the effects of CAM. A general framework to explore 'healing relationships' is suggested [23], again with emphasis on methodological pluralism. Cognition-based medicine (CBM) [150] is suggested as an alternative or additional framework for studying the perceived causality of treatment effects.

The Role of Different Modalities in CAM Research

Issues concerning a broad range of different CAM modalities in CAM research have been discussed in the literature, with acupuncture (as part of Chinese medicine) and homeopathy being the specific CAM modalities addressed most frequently. Use and design of RCTs in acupuncture research have been discussed extensively [3, 15, 32, 40, 43, 48, 50, 55, 151–153]. A major issue is the choice of appropriate control groups (including the design of credible placebo and sham treatments) and blinding [32, 33, 102, 143–145, 152, 154, 155]. Specific acupuncture-related suggestions for further research have also been given [57, 58, 85, 108, 127, 145]. Similarly, specific issues involving in the design of homeopathic studies have been discussed in detail [75, 112, 113, 156, 157], e.g., the separation of non-specific and specific effects [68, 80] and the handling of patient preferences within a randomisation procedure [88]. The shift from efficacy to effectiveness studies in homeopathy [78, 84] has been suggested to be of more clinical value.

A specific argument that has been raised regarding dietary supplements and herbal medicine is their varying quality and/or composition since there is no adequate standardisation of production for these medicines [30, 55, 158, 159]. Developing an appropriate placebo is crucial especially when there is a difference of taste between the active drug and suggested placebo [49, 99, 158]. There were fewer modality-specific publications for Ayurveda [21], bodywork (such as Feldenkrais) [37], chiropractic [18, 25, 76, 89], classic Arabic medicine [103], diet [73, 120], healing [22, 23, 53, 56, 107, 131], hypnosis [86, 136], traditional Japanese medicine [123], massage [93], meditation [2, 100], Oriental medicine [6], (intercessory) prayer [24, 42, 160], Qigong [51], reflexology [9], Tai Chi [62] and Yoga [115].

Discussion

This literature review summarises and reflects the on-going discussion within the scientific community regarding CAM research over the last 20 years. To the best of our knowledge, this is the first systematic review, following a clearly defined protocol, aimed at assessing the current situation of clinical and epidemiological research methodology in CAM. However, developing definitions of inclusion and exclusion criteria has been proved difficult. Also, although 2 reviewers conducted reference selection and 3 reviewers checked the full texts, first screening was only done by 1 reviewer.

In light of the current literature on CAM research methodology there is broad consensus that the commonly accepted research methods that are used in conventional medicine can and should be applied to evaluate CAM. This applies especially to RCTs. However, the literature reflects a movement from double-blind, placebo-controlled, randomised trials (to explain specific mechanisms and efficacy, as conducted in

drug-research) towards more pragmatic trials that compare meaningful clinical alternatives in heterogeneous groups of patients. Efficacy research was hampered by a lack of consensus-based and testable underlying theories for many CAM modalities, e.g., when designing appropriate placebo or sham treatment. The assumptions underlying the rationale of double-blind placebo-controlled RCTs were also difficult to fulfil for most CAM modalities, e.g., patient and treatment-provider blinding. Consequently, the results of efficacy research have often been inconclusive and difficult to interpret. On the other hand, research into the overall clinical effects of CAM promises more relevant results for clinical decision-making, and within the framework of comparative effectiveness research RCTs of high methodological quality are possible. These challenges and the current trend towards the evaluation of treatments in clinical contexts are not restricted to CAM but affect all areas of complex interventions in medicine [161–163].

Giving priority to comparative effectiveness research does not devalue the importance of basic research on mechanisms of action in CAM, which is needed to facilitate interpretation of efficacy and effectiveness research. A previous independent advisory group [164] stated that trials into effectiveness and cost-effectiveness are primarily needed, but the mechanisms of action of CAM also need to be assessed. In addition, further basic research is needed on the mechanisms of action of placebo intervention or sham controls.

Most authors are in favour of a broad integration of different research methods to gather evidence about the clinical effects of CAM. There is a strong consensus that both qualitative and quantitative methods are valuable and should be combined within the CAM research agenda using a mixed methods approach. This would involve qualitative methodology, for example, to understand the feasibility of running a study, developing the appropriate outcomes and formulating hypotheses about the psychological mechanisms involved in the complex intervention. This information would then be evaluated utilising quantitative methods in specific clinical studies.

The above-mentioned aspects in clinical and epidemiological CAM research were discussed at a CAMbrella workshop with distinguished experts in the field of CAM research to develop recommendations for further research into CAM. The invited experts were Wayne Jonas, Klaus Linde, Hugh MacPherson, Charlotte Paterson, Harald Walach and Claudia Witt and as members of CAMbrella's Advisory Board Seamus Connolly and Peter Zimmermann. These recommendations form the basis of the CAMbrella 'roadmap for future clinical and epidemiological research in CAM'.

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Review Article

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Building a Sustainable Complementary and Alternative Medicine Research Network in Europe

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CAM research · FP7 · Science communication and dissemination · Networking · Stakeholder

Summary
Background: Since CAMbrella is a networking project funded by the European Commission explicitly to build and sustain a complementary and alternative medicine (CAM) research network in Europe, communication and dissemination play a large role and form a work package of their own. The present article gives an outline of the communication and dissemination work in the CAMbrella consortium. The intensive building of sound internal communication is an essential part in establishing a functioning structure for collaboration in a diverse group of 16 partner institutions from 12 countries, as exists in the CAMbrella project. **Methods**: The means and tools for dissemination of results to the scientific community and the European public at large, as well as to the European policy makers, are presented. The development of the corporate design and a dissemination strategy are described in detail. In addition, some basic information regarding previous CAM research efforts, which might be interesting for future consortium building in the field of CAM research, is given. **Results**: Internal communication within a heterogeneous research group, the maintenance of a work-oriented style of communication and a consensus-oriented effort in establishing dissemination tools and products will be essential for any future consortium in the CAM field. **Conclusion**: The outlook shows the necessity for active political encouragement of CAM research and the desideratum of a Pan-European institution analogous to the NIH (National Institutes of Health) in the USA.

Introduction

CAMbrella is the acronym of an EU-funded project in the Seventh Framework Programme (FP7) of the EU, running between January 2010 and December 2012. The outline, design and the goals of CAMbrella have been described in detail in a previous article recently published in this journal [1]. The project's funding category is 'coordination and support action', i.e., support for activities aimed at coordinating or supporting research activities and policies (networking, exchanges, trans-national access to research infrastructures, studies, conferences, etc.) [2, 3].

An explicit task is the establishment and sustained maintenance of a European research network in complementary and alternative medicine (CAM) [4]. Therefore, CAMbrella has a strong focus on communication and dissemination of its processes and results. This focus in itself has to reflect the different needs that derive from different target groups and informational interests. The project has to ensure the networking process of the consortium internally, as well as the dissemination of the results to the scientific community and to various stakeholders.

The active communication of the scientific results to the wider public is a fundamental task of a project considered as a 'coordination and support' action. This relates to the level of the political decision makers (national and European) as well as to the European public at large. Work Package 8 (WP8) – 'dissemination and communication' has to ensure these claims. The fact that CAMbrella has its own working group on 'soft matters' like communication and dissemination reflects the need to establish a sound informational policy in CAM. The EU Commission (EC) recently underlined the importance of actively communicating scientific results to the

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broad public by funding several projects within FP7 specifically dedicated to science communication issues, e.g., 'CommHERE – Communicating European Health Research' started in October 2011 [5], or 'CommNET – Communicating the Bioeconomy' in January 2012 [6]. The overall aim of these projects is to improve communication on the outcome of EU-funded projects in a research area to the media, the general public and other target groups, including the EC throughout Europe. The EU project on Traditional Chinese Medicine [7] is another example for an undertaking with distinct emphasis on networking, and brought together 29 beneficiary and 81 non-beneficiary collaborating partner organisations.

Identification of Target Audiences for Dissemination

Starting the CAMbrella project, a leading task was to actively search and look out for people in Europe involved in CAM research (and education) who at that point were not yet known to us. Consequently, we extended the fundaments of a coherent network of CAM related organisations in Europe, using personal contacts in the existing network, asking the Advisory Board (which represents different groups of stakeholders such as consumers, practitioners, providers, and manufacturers of CAM medicinal products) to name relevant contacts in European countries, especially in Eastern and Southern Europe, and via our website.

51 institutions have registered via the website as potential stakeholders with an interest in CAM. They come from 16 European countries and India, Australia and Canada; they mostly represent health professional organisations or private and academic centres. They all will receive the final report and be asked whether they want to be listed in a research networking database.

Results from the Stakeholder Survey/Workshop

To discover more about the needs and wishes in terms of information and decision making, we tried to actively involve European stakeholders for health topics, but not directly related to CAM, in a dialogue.

A web-based survey was conducted and a workshop held in Brussels in April 2012. We invited approximately 40 European stakeholders in the health field to this workshop, the topic of which were: The informational needs of the European public about CAM – are they met by the existing channels, what else is needed? – Do the stakeholders feel CAM a relevant field in health care provision, and if so, do they feel that they know enough about it to feel safe in their recommendations and attitude towards CAM?

The response rate of the survey was 50% and based on the data of 20 organisations. The main findings of the survey were the following:

- 70% found the CAM issue of some relevance, important or very important for their organisation.
- 80% found the European citizens' access to reliable information about CAM poor or very poor.
- 95% found it important or very important to meet the EU citizens' need for more information on CAM in the future.
- 54% found the level of CAM information provided by EU health authorities poor or very poor.
- 60% of the organisations found their own access to information regarding the CAM situation in the European countries difficult or very difficult.

The most important informational needs regarding CAM in Europe concern:

- evaluation of treatments (77%)
- guidelines for CAM users (46%)
- access to research data (46%)

The workshop assembled a group of 13 people from different health backgrounds in a lively discussion about information accessibility, about providers and treatment methods, quality standards in education and information alike, and observable shifts in the public opinion as well as in the positions of policy makers. This provided useful insights for the dissemination strategy, with the attendants' viewpoints markedly differing from what we had expected before the workshop. Attendants, for example, pointed out the strong interest in CAM for some European Parliament Members (MEP) compared to other health-related fields.

The Dissemination Strategy

The WP8 Programme included the development of a strategy of dissemination. This implies a twofold process: (i) the dissemination of results to the public, and (ii) internal communication in the group and development of a coherent message for the whole project. In the end (i) will enter (ii).

Dissemination of Results to the Public

The first step was the development of a corporate design (CD), including a project logo, poster, leaflet, brochure, website and newsletter, as well as letterheads to be used in correspondence by the consortium partners. This task was accomplished in spring 2010 – with the website (*www.cambrella.eu*) being online since 1 April 2010 and the logo at the disposal of the partners via the web-based working platform that hosts all the projects documents (*www.projectplace.com*).

The website gives the general information about the participants, the goals, the distribution of work and all the contact details. There is also an invitation to subscribe to the quarterly newsletter and/or to the registration as a CAM stakeholder in Europe, thus trying to actively involve CAM-related research centres and other interested parties in the communicative process.

The quarterly newsletter is sent to around 800 recipients, collected either via self-registration on the website or using the existing networks of the participants. The newsletter combines information about the participating countries and their respective CAM situations, with portraits of relevant stakeholders in CAM and information about the project itself. By the end of the project, 12 newsletters will have been distributed.

In 2011, a Facebook profile (*www.facebook.com/CAMbrella.eu*) was set up to enable and enhance the communication with the wider public interested in CAM, and to learn more about the use of social media in a mixed context of research-related, but also a general informative setting; in March 2012 and with an eye on organising the final conference (29 November 2012), we added a CAMbrella Twitter account (*https://twitter.com/#!/CAMbrellaEU*), thus completing the social media presence of the project.

While the web-based tools of website and social media are directed at the general public, and may randomly hit someone actively involved in CAM research not already involved in the wider network, the dissemination to the political decision makers' level has to use and implement different tools. Therefore, WP8 will produce a 'Policy Brief' [8], i.e., a condensed brochure on the findings of all the WPs to inform the EC and the European Parliament. Other examples of dissemination tools tailored for different target groups are press releases aiming at the public at large and this special issue of Forschende Komplementärmedizin/ Research in Complementary Medicine aiming at the scientific community.

The scientific dissemination has also taken place at scientific conferences like those organised by the 'International Society for Complementary Medicine Research' (ISCMR) and the 'European Congress for Integrative Medicine' (ECIM), and via scientific publications like the papers assembled in this special issue of Forschende Komplementärmedizin/ Research in Complementary Medicine.

Internal Communication and Development of a Coherent Project Message

From the beginning, the whole consortium has been actively involved in the dissemination activities such as the CD development and the assessment of the quality of communication. As an internal steering tool for the latter, we conducted an online survey in spring 2011 amongst the consortium members asking them about their impressions on the quality of communication and their proposals for improvement, if needed. Results show that the communication process is fairly well rated, but there is still room for some improvement. This survey will be repeated in summer 2012.

Another feature of this active involvement was the process of finding a single project slogan to be the 'marketing tool' of CAMbrella. This slogan will be based on the reports of the different WPs (deliverables). WP leaders were asked to sum up their findings in 'key messages' that formed the material for WP8 to mould the project slogan.

The overall slogan plays an important role in the non-scientific dissemination, but it will also help scientists to relate to the CAMbrella findings. The process is currently not yet finalised and the slogan will be presented during the final conference in November 2012 and published in all CAMbrella dissemination pathways.

CAM Networking within the EU so far

From 1993 to 1998 the EC set up the 'COST B4' project on unconventional medicine in Europe. In expert meetings over a period of 7 years, participants from 13 European countries tried to sort out questions about therapeutic significance, cost-benefit ratios and cultural and social importance of unconventional medicine. The project resulted in complex recommendations for future work in the CAM field, but these were never taken up in a consecutive project. Networking stayed personal and did not reach a structured level.

The FP5 funded a CAM project, the 'Concerted Action for Complementary and Alternative Medicine Assessment in the Cancer Field' (CAM-Cancer); CAM-Cancer aimed at providing evidence-based information on CAM treatments for cancer and assembled systematic reviews on various topics in this field. It is now hosted by the National Information Centre for Complementary and Alternative Medicine (NIFAB) at the University of Tromsø, Norway.

Even before the start of CAMbrella, there was a fairly well established informal network of CAM researchers with workshops and meetings of people from the European CAM community taking place since 2004 with the explicit goal of establishing a European consortium for EU funds to come into the CAM field. These informal meetings entered 'EURICAM', an interest group to explicitly get a European-funded CAM project going.

Most of the consortium members of CAMbrella were already involved in the EURICAM network and played an important role in achieving a consensus among a heterogeneous group of researchers about general research ideas. International ad-hoc meetings alongside of scientific conferences were used to gain support for this preparatory work. The development came along with tremendous efforts made by numerous CAM stakeholder groups organised on national and European levels.

The bridge-building function of the national contact points was also implicated. This networking process passed off in an increasingly more coordinated manner and gained momentum, when, in 2008, the WP for 2009 on the specific programme 'Cooperation', theme health was published by the EC, which incorporated a topic on CAM from which in the end CAMbrella evolved.

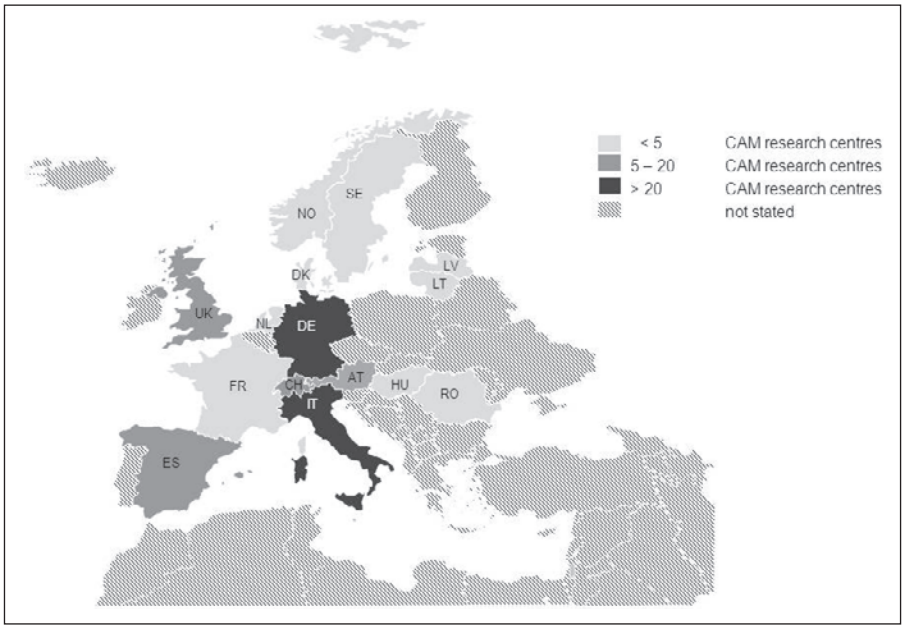

Fig. 1. Distribution of CAM research centres over Europe.

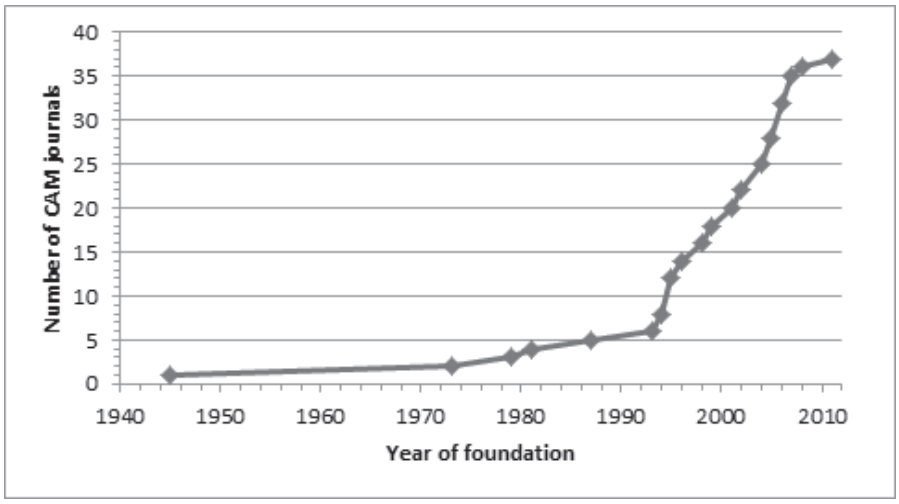

Fig. 2. Development of the number of international journals on CAM over the last 7 decades.

Experience with Pan-European Cooperation

Due to the prior experience of good cooperation and collegial atmosphere at the informal EURICAM meetings, the ground for a fruitful collaboration was already well prepared when the project started in 2010 with a kick-off event in Munich. Most of the people knew each other and the integration of the new partners were easily managed. The cooperation of the 16 partners from 12 countries was thus quickly and thoroughly established, helped by the fact that the WP leaders had very good co-workers in their teams to manage the daily work and the day-to-day-communication matters.

The same characteristic of friendly cooperation applies to the Advisory Board, whose members took a very active interest in the on-going work of the project and involved themselves in debates about the general lines of the project. They were also very helpful in giving practical advice and infrastructural support, if needed.

Furthermore, the CAMbrella consortium built up contacts and started cooperation with other organisations in the field, e.g., PedCAM (Pediatric Complementary and Alternative Medicine Research and Education Network; *http://www.pedcam.ca/*), the EU Pediatric CAM initiative, the CAM-Doc Alliance (comprising ECH, ECPM, ICMART and IVAA; *http://www.camdoc.eu/*), the EURO-CAM group (alliance of European umbrella organisations of patients, physicians and practitioners in the field of CAM) or special MEP interest groups (CAM interest group or MEPs against cancer).

CAMbrella has maintained close relationships with the International Society on Complementary Medicine Research (ISCMR; *www.iscmr.org*), which established a special interest group, the European Chapter, in 2008. This organisation con-

Table 1. International journals on CAM

Name	ISSN	Scope	Impact factor (2010)[a]	Issues/year	Year of first issue[b]
Acupuncture & Electro-Therapeutics Research	0360–1293 (print) 2167–9010 (online)	basic and clinical research in acupuncture, electro-therapeutics, and related fields	0.250 (2009)	4	1998
African Journal of Traditional, Complementary and Alternative Medicines	0189–6016	applied medicinal plants, traditional medicines, complementary alternative medicines, etc.	0.457	3	2004
Alternative Medicine Review	1089–5159	alternative and complementary therapies	3.571	4	1996
Alternative Therapies in Health and Medicine	1078–6791	provide health care providers with continuing education to promote health, prevent illness, and treat disease	not stated	6	1995
BMC Complementary and Alternative Medicine	1472–6882	interventions and resources that complement or replace conventional therapies	2.200	12[c]	2001
Chinese Journal of Integrative Medicine	1672–0415 (print) 1993–0402 (online)	integrative medicine as well as complementary and alternative medicine	0.578	12	1995
Chinese Medicine	1749–8546	all aspects of Chinese medicine	1.240 (unofficial impact factor)	12[c]	2006
Chiropractic & Manual Therapies	2045–709X	evidence-based information that is clinically relevant to chiropractors, manual therapists and related health care professionals	not stated	12[c]	2005
Complementary Therapies in Clinical Practice	1744–3881	effective and professional integration of complementary therapies within clinical practice	not stated	4	1995
Complementary Therapies in Medicine	0965–2299	objective and critical information on complementary therapies	1.484 (5-year impact factor: 1.990)	6	1993
European Journal of Integrative Medicine	1876–3820	strengthen the understanding and cooperation between conventional medicine and evidence-based complementary and alternative medicine	1.200	4	2008
Evidence-Based Complementary and Alternative Medicine	1741–427X (print) 1741–4288 (online)	complementary and alternative medicine modalities, particularly traditional Asian healing systems	2.964	4	2004
Explore: The Journal of Science and Healing	1550–8307	evidence-based healing practices from a wide variety of sources, including conventional, alternative, and cross-cultural medicine	0.795 (5-year impact factor: 1.055)	6	2005
Fitoterapia	0367–326X	medicinal plants and to bioactive natural products of plant origin	1.899 (5-year impact factor: 1.884)	8	1999
Focus on Alternative and Complementary Therapies	2042–7166	present the evidence on complementary and alternative medicine (CAM) in an analytical and impartial manner	not stated	4	1996

Table 1 continued on next page

Table 1. Continued

Name	ISSN	Scope	Impact factor (2010)[a]	Issues/year	Year of first issue[b]
Forschende Komplementärmedizin/ Research in Complementary Medicine	1661–4119 (print) 1661–4127 (online)	traditional and complementary/alternative medicine (CAM) on a sound scientific basis, promoting their mutual integration	1.059	6	1994
Homeopathy (formerly known as British Homeopathic Journal)	1475–4916	improving the understanding and clinical practice of homeopathy	1.000	4	1945
Integrative Cancer Therapies	1534–7354 (print) 1552–695X (online)	scientific understanding of alternative medicine and traditional medicine therapies, and their responsible integration with conventional health care	1.716	4	2002
Journal of Complementary and Integrative Medicine	1553–3840	evidence concerning the efficacy and safety of complementary and alternative medical (CAM) whole systems, practices, interventions and natural health products, including herbal medicines	not stated	1	2004
Journal of Ethnobiology and Ethnomedicine	1746–4269	promote the exchange of original knowledge and research in any area of ethnobiology and ethnomedicine	1.280 (unofficial impact factor)	12[c]	2005
Journal of Ethnopharmacology	0378–8741	exchange of information and understandings about people's use of plants, fungi, animals, microorganisms and minerals and their biological and pharmacological effects based on the principles established through international conventions	2.466 (5-year impact factor: 3.216)	18	1979
Journal of Experimental and Integrative Medicine	1309–4572 (print) 2146–3298 (online)	entire field of biomedical sciences, particularly concentrated on the background of physiological and pathopysiological mechanisms from molecules to organ systems	not stated	4	2011
Journal of Manipulative and Physiological Therapeutics	0161–4754	advancement of chiropractic health care	1.418 (5-year impact factor: 1.458)	9	1999
Journal of Medicinal Food	1096–620X (print) 1557–7600 (online)	chemistry and biochemistry of the bioactive constituents of food and substantiates their efficacy, safety, and potential uses	1.461	12	1998
Journal of Medicinal Plants Research	1996–0875	medicinal plants research, ethnopharmacology, phytomedicine etc.	0.879	12[c]	2007
Journal of Natural Medicines	1340–3443 (print) 1861–0293 (online)	naturally occurring medicines and their related foods and cosmetics	1.469	4	2006
Journal of Traditional Chinese Medicine	0255–2922	clinical and theoretical research in this branch of medicine	not stated	4	1981
Medical Acupuncture	1933–6586 (print) 1933–6594 (online)	evidence-based clinical papers, case reports, and research findings that integrate concepts from traditional and modern forms of acupuncture with conventional medical training	not stated	4	2007
Neural Regeneration Research	1673–5374	neural stem cells, neuroengineering, neurodegeneration and traditional Chinese medicine and acupuncture intervention	not stated	12	2006
Phytomedicine	0944–7113	phytopharmacology, phytotherapy and phytotoxicology	2.662	14	1994
Phytotherapy Research	0951–418X (print) 1099–1573 (online)	medicinal plant research	1.878	12	1987
Planta Medica	0032–0943	medicinal plants and natural products	2.040	18	2006

Table 1 continued on next page

Table 1. Continued

Name	ISSN	Scope	Impact factor (2010)[a]	Issues/year	Year of first issue[b]
Research Journal of Medicinal Plant	1819–3455 (print) 2151–7924 (online)	botany, biochemistry, phytochemistry, ethnopharmacology, phytomedicine, phytotherapy, ethno-medicine and pharmacognosy	not stated	6	2007
The American Journal of Chinese Medicine	0192–415X (print) 1793–6853 (online)	traditional or ethnomedicine of all cultures	1.383	6	1973
The Journal of Alternative and Complementary Medicine	1075–5535 (print) 1557–7708 (online)	to evaluate and integrate complementary and alternative medicine (CAM) into mainstream practice	1.498	12	1995
The Journal of Complementary Medicine	1446–8263	authoritative, practical and relevant information on complementary medicine to its readers' daily practices or businesses of maximising patient and customer well-being	not stated	6	2002
The Journal of Dietary Supplements (formerly known as Journal of Herbal Pharmacotherapy)	1939–0211 (print) 1939–022X (online)	important issues that meet a broad range of interests from researchers, regulators, marketers, educators and healthcare professionals	not stated	4	2001

[a]Published by Thomson Reuters (ISI) in 2011 if not stated otherwise.
[b]According to information stated on the journal's website.
[c]No printed issues (open access).

stitutes a platform for researchers involved in complementary medicine, and promotes exchange and cooperation within Europe [9]. The CAMbrella network will stay in close contact with the European Chapter, thus enabling the maintenance and further sustainable development of the European network.

To facilitate the search for potential partners regarding future CAM research projects, we have generated a list containing the institutions of all our partners in the consortium and information on further institutions named by those partners and the advisory board members. This list will be stored on the project's website (*www.cambrella.eu*) and is planned to expand continuously. Consequently, this list is not intended to be exhaustive. To get first insights into the distribution of those centres that have been listed up to now see figure 1.

Increasing Research on CAM

There is not only a demand for more research on CAM but also an increased output by researchers working on CAM topics. This is evident by looking at the increasing number of international journals focusing on CAM over the last decades.

We looked at 37 international journals on CAM selected using the publications of Cong and Chen [10] and Fu et al. [11] as a basis, and established our own list by leaving out some of the journals that seemed too specific for us and adding some others that were known to us (table 1).

Figure 2 shows the development of the number of international journals on CAM over the last 7 decades. This graph results from data (year of foundation) that we found by web research. A strong increase in the number of journals since the mid 1990s can be seen.

It may be hypothesised that the increase during the late 1990s accompanied the growing claims for evidence-based medicine and the differentiation into various sub-topics (e.g., into pharmaceutical and basic research, especially in Asia). Recently, a shift can be observed that separates the 'traditional' CAM journals from the 'integrative medicine' journals that have established themselves at the borderline of conventional medicine.

Conclusions and Outlook

Europe lacks proper funding for CAM research. In comparison to the US where funding is provided by the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH), there is nothing similar in the European context.

An outcome of the WP8 stakeholder workshop in Brussels was the strong and joint opinion of participants that such an institution, similar to the NIH in the US, was urgently needed

in the Europe, i.e., a joint research and quality standards assessment body that is independent from regional and national influences and from industry – and other stakeholder interests.

A well-funded 'European NIH' would be the agent to get CAM research going on a broader scale and with the inclusion of the currently missing countries. A second drawback for CAM research is the diversity of CAM providers and educations. In most countries there are no academic centres for CAM research at all, and in many medical educations CAM is not represented.

The non-medical sector of CAM provision is even less represented in the research field, due to lack of academic backgrounds and interests of the providers, but also due to scientific biases and inaccessibility of funds for non-mainstream treatment methods and provisions. Research in this area has to be pushed further by the interested parties – CAM research does not happen on its own. Programmes have to be pressed into existing schedules, because existing schedules still not pay attention to the CAM field, as if it would not be part of medicine.

CAMbrella has proven that the European research network functions well and has achieved a sustained organisational level – but still with a strong bias for the Western European countries, and a lack of representative presence of Eastern and Southern European countries. The present CAM scene in Europe is – with the start given by the CAMbrella findings – prepared to go on. CAMbrella will support this process by maintaining the network structure, including the website as a central platform for information and communication. An essential starting point for any future research will be the proposal for a research roadmap to be published soon by CAMbrella WP7 group.

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