

## **REVIEW**

By prof. Stoyanka Tzvyatkova Zheleva-Popova,  
Scientific specialty: „Social medicine and Organization of Health care”

Member of Scientific Jury, following an order of the Rector of  
Medical university - Varna № P-109-556/01.12.2020r

**Re.** Dissertation work on the topic „Complementary and alternative medicine – development and place in Bulgarian health care “ under the procedure for obtaining the Educational and Scientific degree "Doctor" - Field of Higher education 7. “Health care and sport”, Professional direction 7.1. „Medicine”, Scientific specialty „Social Medicine and Organization of Health Care and Pharmacy“ of D-r Iskra Staneva Kapincheva, doctoral student in independent form of study.

**Supervisor:** Assoc. Prof. d-r Desislava Vankova, Ph.D.

### **Procedure details:**

By order of the Rector of the Medical University-Varna № R-109 – 113 /07.03.2019 d-r. Iskra Kapincheva has been enrolled as a doctoral student in independent form of study in the Department of Social medicine and Health care Organization - Scientific specialty „Social Medicine and Organization of Health Care and Pharmacy”. A protocol for successfully passing the doctoral exam from October 25, 2019 is presented. On the basis of a decision of the Council of the Department of Social Medicine and Health Care Organization, for the readiness for public defense and a proposal for a Scientific Jury, by Order of the Rector of the Medical University-Varna № R-109-556/ 01.12. 2020, d-r. Iskra Kapincheva was directed to a public defense. The doctoral student has submitted precisely all the necessary documents, according to the Law of development of academic staff of Republic of Bulgaria.

### **Biographical data and career development of the candidate**

D-r Iskra Kapincheva graduated Medical university –Varna in 1988. She acquired Specialty “Social medicine and Health care management” (2010). Her professional career began as a therapist in Polyclinic – Dalgopol. In the period 1995 – 2008 she was a main expert in NCPH – Head of Museum of History of Medicine and health care –Varna. Since 2004 she has practiced Homeopathy, supported by numerous specializations and diplomas from National and International institutes. She passed a course “Cigun” in International university of Traditional Chinese medicine, Tyandzin, China. D-r Kapincheva is a lecture in Classical Homeopathy and Shusler salts – German homeopathy union. She is fluent in French, English and Russian.

### **An overall characteristic of the dissertation.**

**The dissertation**, developed by Iskra Kapincheva, is in volume of 130 pages, including two appendixes. It consists of following main parts - Literature Review, Material and

Methods, Results and Discussion, Conclusion, Contributions, Bibliography. 14 figures, 2 tables and 3 annexes illustrated the work. The bibliographic reference contains 232 sources, 97 of which are in Cyrillic and 135 in Latin, presented correctly. The sources are issued in a large period of time – from 40-ty of XX century to 2020, defined by the aim of the work.

### **Assessment of the actuality of the topic**

Factors of different nature revive the interest and the growing demand for unconventional methods of treatment not only in Bulgaria but also worldwide. The growing practice of medicine, which has acquired the name "complementary and alternative" is associated with many unknowns about the prevalence and reasons for demand, the effectiveness and safety of its application, the qualifications of the practitioners.

On the other hand, a number of historically originated and developed traditional methods of treatment have proven their positive healing effects. Can they be transferred to conventional medicine, and used as complementary, is the integration possible between them and to what extent?

These and other questions can only be answered by presenting scientific evidence. However, they are very scarce at this stage. There is a need the accumulated therapeutic experience in the field of CAM to be analyzed by scientific methods. The WHO supports the development of local and regional policies related to CAM and traditional medicine, which is impossible without relevant scientific data.

With the intention to draw attention to these issues in our country, studying the historical and scientific development of complementary and alternative medicine, and its place in Bulgarian health care by collecting and summarizing scientific literature and official documents, the accumulated practical experience in the field, the present dissertation is relevant, meaningful, attractive and provocative.

### **Literature review (LR)**

I can define the Literary Review (LR) as conceptual in terms of CAM and related terms, methods and approaches. It is based on scientific literature, official sources and normative documents, structured in 4 parts.

The introductory **first part of the LR** presents the definition, origin and development of the concept of CAM. The main focus is on the pan-European research project CAMbrella from 2010, which serves as a methodological basis for research in the field of CAM. The tasks of the CAMbrella project are presented, aiming at reaching a consensus with the terminology, harmonization of the methodological approaches of the research in the field of CAM and their promotion. The author draws attention to the fact that despite the importance of the CAMbrella project, covering 12 European countries, Bulgaria does not participate in it.

Taking into account the increased interest in CAM in recent years, which is seen as an opportunity to meet the health needs of European citizens and the associated increase in the number of scientific studies in the field, Dr. Kapincheva considers it as her duty to assist with her research to fill the gap of data in this direction and "mapping" of Bulgaria on the CAMbrella European map.

A significant part of the LR is dedicated to **the types of therapeutic methods of CAM**, applied in Europe and included in the CAM territory according to the CAMbrella project (**second part**). 14 methods of CAM are presented with a unified description of their structure, nature, historical development and current state, prominent representatives, official recognition, associations and unions.

The author paid the greatest attention to homeopathy. The choice is related not only to her personal interest, but also supported by data from European studies, registers of practitioners of unconventional methods, professional organizations of the physicians, practicing homeopathy, centers for postgraduate training in homeopathy, showing it as the most popular unconventional CAM method in Europe, incl. in Bulgaria. Data on the prevalence of homeopathic therapy are cited. Authors of serious research from the last 15 years are cited, providing evidence for the effectiveness of homeopathy in both veterinary and human medicine.

**Part three of the LR** is dedicated to the general approaches of CAM therapies, which the author very competently considers in their connection with modern conventional medicine and the new public health, (such as the holistic approach), with health promotion (salutogenesis, prevention, health literacy and empowering patients, developing personal responsibility and participating in the healing process).

Other therapeutic approaches are assessed as positive, and could be developed as complementary to conventional medicine (supporting the individual potential of each person to cope with the disease process, healthy and balanced relationship between physician and patient, focus on adaptability and ability of the human organism to cope with change and environmental stress, to restore balance and a sense of well-being and health).

In **the fourth part of the LR**, Dr. Kapincheva focuses on scientific research in the field of CAM, which testifies her wide awareness of the issue. It is noted that they broadly follow the strategic guidelines provided by the CAMbrella project in terms of priority research areas, methodology and research infrastructure.

It's obvious, that dr. Kapincheva is familiar with the research carried out by foreign and Bulgarian authors on the use of CAM and reporting results of applied CAM methods, which are correctly cited in the review. At the same time, it is found that research in Bulgaria is extremely insufficient to answer the numerous questions related to the use of alternative methods of treatment in our country.

Here the author emphasizes several important and controversial issues in the literature related to the application of CAM, namely:

- factors favoring the spread and integration of CAM;
- study of the clinical effectiveness in the treatment of CAM and the methods for its measurement, incl. health-related quality of life;
- development of the normative base in Bulgaria and guaranteeing the safety of the patients when using CAM;
- public financing of services and their inclusion in social security systems;
- the need to develop the methodology and special tools ensuring comparability, validity and reliability of the results;
- creation of scientific portals, specialized in the field of CAM.

This summary gives proof of the need and importance of the research presented in the dissertation and points to its purpose and tasks.

LR as a structure and content deserves high evaluation and shows a very good awareness of the world and national scientific literature on the subject with a focus on aspects that are the subject of further own research. The author is acquainted in detail with the WHO documents regarding the problem and bases her research on their recommendations.

### **Methodology**

The study is based on a perfectly constructed and well-motivated methodology, presented in great detail, clearly and accurately. The main goal is correctly formulated: "To study the historical and scientific development of CAM and its place in Bulgarian health care (with emphasis on homeopathy) and decomposed into 5 tasks. Three hypotheses are formulated.

The methods used are adequate to the set tasks. The study is based on the Converging Parallel Mix-Method Design, which includes the collection, analysis and mixing of quantitative and qualitative data and is carried out in three phases. The design of the study is very well illustrated in the attached Fig.5.

During the first phase a study of the historical, international and national context of CAM is set, for which the Historiographical method (historical-medical research of CAM methods in Bulgaria), documentary method (study of normative documents, publications in the field of CAM), classical SWOT analysis are used.

In the second phase, quantitative analysis of data obtained from an observational multicenter study is planned, using a standardized questionnaire for subjective health self-assessment - EQ-5D-3L. Criteria for inclusion of the participants in the study have been formulated. It is worth assessing the knowledge and application of tools, validated and proven in a number of European studies. The questionnaire is presented in great detail. A set of statistical methods (descriptive, correlation and graphical analysis) is applied. The data was processed with the SPSS software product.

Qualitative research through semi-structured interviews was conducted in the third phase. The target group is parents who have chosen to treat their children with homeopathy for more than a year.

The author has participated in all phases of the study. Both the quantitative and the qualitative research are in accordance with the ethical requirements and approved by KESR of MU-Varna.

### **Results and discussion from own research**

Emphasizing the lack of sufficiently reliable data to create a comprehensive CAM profile in Bulgaria, allowing comparability with other countries in Europe, in Chapter IV of the dissertation the author provides results from her own research as a contribution to filling the information gap. The presentation of the results is structured in 4 parts in the order corresponding with the set tasks.

In this connection, in the first place, documents, regulating the normative framework for the practice of CAM in Bulgaria were found and analyzed – The Act of Health (2005), which lists the regulated unconventional methods for beneficial effects on

individual health; The Law on Medical Products in Human Medicine (2007) defining the specific requirements and the procedure for registration of homeopathic preparations and traditional herbal medical products; Ordinances of the Ministry of Health, regulating the right to practice unconventional methods; the registration, the obligations and the requirements to the persons who practice CAM.

The conclusion, confirmed also by WHO report, is that Bulgaria is among the Member States that recognize the use of CAM and have created legislation related to the application of CAM, which, however, is insufficient or not observed. This has its negative consequences, such as offering unregulated methods, practicing by people without the necessary qualifications.

An interesting part of the dissertation is the historical-medical study of unconventional methods in Bulgaria, and in addition to those included in the European project CAMbrella, are included those that reflect the many years of healing experience preserved in the folk traditions of Bulgaria and other alternative methods with a long history in Bulgaria.

The work is enriched with data about their prominent representatives Dr. Petar Dimkov and Dr. Kiril Yordanov, whose life and work are related to Varna, whom Dr. Kapincheva explored by working on authentic documents as director of the Museum of the History of Medicine in Varna, which is a personal contribution.

The analysis of the positioning of CAM in Bulgaria and the Bulgarian healthcare, by applying the technique of SWOT-analysis, deserves high valuation. Using external sources (official WHO documents), as well as our normative and other official documents, and available scientific literature, the author systematizes the current global and national environmental factors, which are opportunities or threat to the development of CAM, and the relevant conclusions have been done.

Using the approaches of CAM, Dr. Kapincheva convincingly presents the advantages of the methods practiced in our country, which make them preferred to conventional medicine, which forms the strengths of CAM in our country.

Weaknesses of CAM were connected with 3 factors:

1. The provider (doctor, healer) - his education and competence;
2. The user (patient) - his responsibility and participation in the process;
3. The remedies used in CAM.

The SWOT-analysis is very well performed, and Fig.7 illustrates the main characteristics of CAM and the factors of the environment in which it exists.

The author accepts the results of SWOT-analysis as a basis for developing national strategies for the development of CAM and integrating its methods with conventional medicine in 3 directions:

1. Collaborative strategies (collaboration of CAM specialists with researchers in conventional medicine);
2. Communication (lobbying for influencing attitudes and law);
3. Constructive strategies (development of CAM, as part of the overall structure of health care in Bulgaria).

To perform the fourth task of the dissertation, a **quantitative study** was conducted among chronically ill patients of 4 homeopathic practices, meeting pre-set criteria regarding the providers in the cities of Varna, Sofia, Burgas and Veliko Tarnovo. 211 persons were recruited on the principle of the first respondent in the time period June 2016 to December 2017. To the standardized questionnaire EQ-5D-3L the DR. Kapincheva added additional questions related to the treatment with CAM and channels for information about homeopathy. A pilot study was conducted to test the questionnaire.

The results provide an information in several directions:

- They allow to outline the profile of patients with chronic diseases using homeopathic treatment. The conclusions support the author's second hypothesis regarding the socio-demographic characteristics of patients treated with homeopathy, overlapping with the European profile. The high percentage of healthcare workers, who use homeopathic treatment is impressive.
- Lack of sufficient information about homeopathy in society. Those who turned to alternative treatment received information from their immediate surroundings and the Internet, and only 5.7% from their personal physician or other medical professionals. The majority of patients need more information about homeopathy (62.6%). There is a feeling among the participants that not only patients need more information about homeopathy, but also doctors.
- Results supporting homeopathic treatment were obtained: 76% of the respondents rated their health as “much better” or as “better” after one year of treatment. More than 60% of patients were on unsuccessful conventional therapy before seeking alternative therapy, 30.3% used homeopathic therapy as complementary to conventional therapy, and 69.2% (146 patients) were treated with homeopathy alone. A significant number (64%) of patients were treated with homeopathy for a long time - more than 3 years, and they reported higher QoL in all five study areas. A positive correlation was found between the duration of homeopathic treatment and VAS self-assessment.

As part of the quantitative study, the author carried out a pilot study on a small group of patients to follow the assessment of QoL after six months homeopathic treatment, but achieving reliable results requires working with a larger number of studied patients.

The successful application of the EQ-5D-3L-questionnaire for self-assessment of the quality of life of patients gives to Dr. Kapincheva a reason to recommend to homeopaths the use of a standardized generic questionnaire as a reliable and scientific tool for evaluating the results of homeopathic treatment.

The **qualitative research** provides an opportunity to obtain information in four thematic areas related to the choice of homeopathy, decision-making process, influencing factors and environment, parent-patient-homeopath relationship, factors determining the choice of the particular doctor-homeopath. The survey was conducted according to the rules for semi-structured interviews - they are audio-recorded or on paper, transcribed, summarized and illustrated with the words of the respondents.

The results suggest that homeopathy attracts with its peculiarities, which patients and parents consider a disadvantage of conventional medicine - the desire to limit the use of antibiotics, to meet a doctor who shows empathy, professionalism and confidence. To a large extent, the results of the two studies are mutually confirmed.

As a result of the conducted research and the literature reference for CAM in Bulgaria, the doctoral student determines the health system in Bulgaria according to the WHO classification based on the degree of integration of conventional and CAM as incorporative. The author points out a number of factors that must be overcome in order to achieve an integrative system in our country.

The author concludes that the integration of conventional and CAM modalities based on medical science, education and legislation can lead to more successful management of chronic diseases.

The dissertation ends with **5 detailed conclusions**, written competently and corresponding to the work done. The motivated conclusions serve as a basis for the given **7 recommendations** to political, educational and scientific institutions, professional and patient organizations.

**The contributions of the dissertation work** indicated by the doctoral student are in two categories: original and practical-applied, which I accept as a logical result from the fulfillment of the set goal and tasks.

Remarks: The author could avoid unnecessary deepening in detail when presenting the methodology, which can be justified by the desire for a more complete motivation, as well as repetitions of the text when presenting the results and discussion.

In connection with the dissertation, Dr. Kapincheva presented three **publications and three participations in scientific forums**, two of which abroad. The articles have been published in "Social medicine", „Asclepius", and one in "BMC Public Health" (2019) 19: 1648, Impact Factor: 3.275. I believe that these publications and participations reflect different stages of the realization of the research goal and help to promote the achievements of the doctoral student among the scientific community.

**The abstract** reliably reproduces the content of the dissertation. It has been prepared in a volume of 58 pages and consists of parts that present the most significant results, conclusions, recommendations and contributions of the dissertation, as well as the publications related to it.

### **Conclusion**

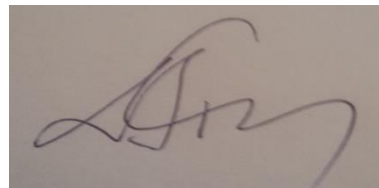
The dissertation is one of the first in-depth studies in our country on the emergence, development and spread of CAM in Bulgaria and is undoubtedly a contribution to the development of adequate policies for its practice. It points to a real and widespread phenomenon - CAM, which seeks its recognition, place and development, based on strict regulations and guarantees of security and safety for citizens, political and scientific support. In this light, the research conducted by Dr. Kapincheva and the presented results are necessary and supportive.

**The dissertation reflects the professional orientation, theoretical training and many years of experience of the author in the field of homeopathy and history of medicine, as well as her belonging to the professional organizations in these fields. The impression remains that the author accepts and develops this topic as a mission and a challenge.**

Taking into consideration the above in terms of actuality, relevance and significance of the topic, applied methodology, analysis of results, the nature of the contributions, as well as my personal impressions of the author, **I give a positive assessment of the dissertation and my vote for the conferment on Iskra Staneva Kapincheva the scientific and educational degree “Doctor” in the scientific specialty „Social Medicine and Organization of Health Care and Pharmacy“.**

08.02.2021

Signature:

A rectangular box containing a handwritten signature in dark ink on a light-colored background. The signature is cursive and appears to be 'S. Popova'.

(Prof. Stoyanka Popova, MD)