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**COMPLEMENTARY AND ALTERNATIVE  
MEDICINE- DEVELOPMENT AND PLACE IN THE  
BULGARIAN HEALTHCARE**

**DISSERTATION**

For the acquisition of the educational scientific degree  
“DOCTOR (PhD)”

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The dissertation contains 130 pages and is illustrated with 2 tables and 14 figures. The bibliographic reference includes 232 literary sources, of which 97 are in Cyrillic and 135 are in Latin.

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## **ABBREVIATIONS:**

<b>AM</b>	Alternative Medicine
<b>CAM</b>	Complementary and alternative medicine
<b>CM</b>	Complementary medicine
<b>EU</b>	European Union
<b>HrQoL</b>	Health-related quality of life
<b>IM</b>	Integrative Medicine
<b>T&amp;CM</b>	Traditional and complementary medicine
<b>TCM</b>	Traditional Chinese Medicine
<b>TM</b>	Traditional medicine
<b>WHO</b>	World Health Organization
<b>VAS</b>	Visual Analogue Scale

## **DEFINING BASIC TERMS IN THE DISSERTATION**

### **Conventional medicine**

The term "conventional medicine" refers to the broad category of medical practice whose study is included in the programs of higher medical schools. Conventional medicine is also called Western medicine, biomedicine, scientific medicine, allopathic medicine or modern medicine. These terms are synonymous.

### **Unconventional medicine**

Unconventional medicine combines treatment methods, the study of which is not included in the curricula of higher medical schools. These methods must not cause deterioration in the health of citizens and are applied only in order to achieve a beneficial effect on individual health.

### **Holistic medicine**

This approach examines the human body on a physical, emotional and mental level, observes its interactions with the factors of the natural and social environment. The purpose of holistic therapy is to restore balance in the human body and restore health.

### **Alternative medicine**

The term "alternative medicine" refers to medical practices that are used instead of conventional medicine.

### **Complementary medicine**

The term "complementary medicine" refers to medical practices that are used in conjunction with conventional medicine.

### **Complementary and alternative medicine**

The term CAM defines a variety of medical systems and therapies based on knowledge, skills and practices derived from theories, philosophies and experiences used to maintain and improve health, as well as to prevent, diagnose, alleviate or treat physical and mental diseases. CAM therapies are mainly used outside conventional health services, but in many countries some therapies are accepted or adapted to conventional health systems.

### **Traditional medicine**

Traditional medicine is the body of knowledge, skills and practices based on theories, beliefs and experiences rooted in different cultures, whether explainable or

not, used to maintain health as well as to prevent, diagnose, improve or treat physical and mental illness.

### **Naturopathy**

Naturopathy uses natural remedies to prevent, treat and maintain health. It originates from Hippocrates and the traditional healing systems in Western Europe. The means used stimulate the healing processes and are: water, sun, exercises and massages, nutrition (fasting, fasting), herbs, placement of suction cups, bloodletting, treatment with honey and others.

The terms: Naturopathy, Traditional European Medicine, Naturopathy, are synonymous and are used equally in the medical literature.

### **Traditional and complementary medicine**

A term introduced by the WHO that covers products, practices and practitioners of traditional and complementary medicine.

### **Integrative medicine**

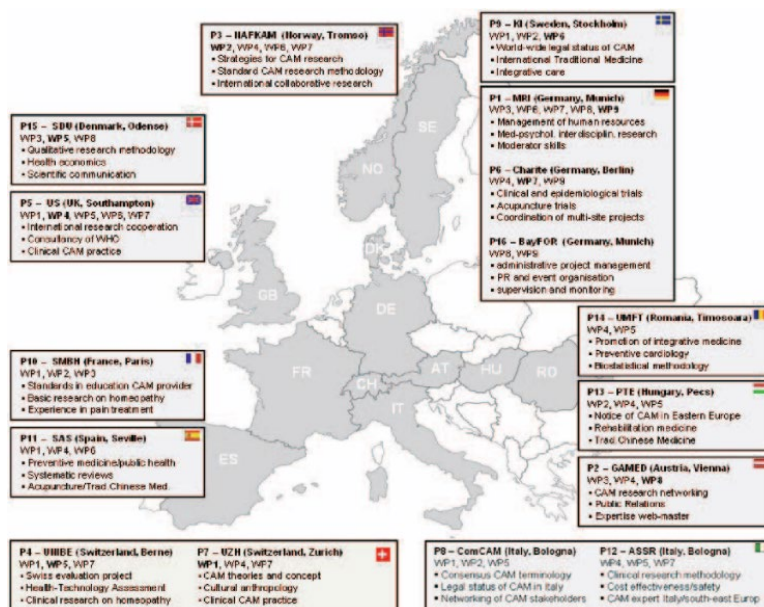
Integrative medicine focuses on the patient's personality, strengthens the doctor-patient relationship, and is based on research and uses in a coordinated manner all known treatment practices (conventional and unconventional), as well as the means of environmentally friendly lifestyle. The aim is to achieve optimal results in the preventive and curative processes. As a term, IM is the newest and brings together conventional and unconventional medicine, health promotion and disease prevention.

# INTRODUCTION

In January 2010, the pan-European research project CAMbrella was launched with a research focus - complementary and alternative methods (CAM) in medicine and their importance for improving the public and individual health of Europeans (Grant Agreement № 241951). The main tasks of CAMbrella were:

- 1) to create consensus-based terminology, widely recognized in Europe, to define and outline the types of KAM;
- 2) to study the needs, attitudes and attitudes of the citizens of the European Union (EU) regarding CAM;
- 3) to paint an accurate picture of the prevalence and frequency of the use of CAM, and all this by promoting research in the field of CAM. In recent years, there has been an increased interest in CAM, as an innovative concept and as an opportunity to effectively and efficiently meet the health needs of European citizens today and in the future.

The CAMbrella project involves 16 research centers from 12 European countries (Norway, Denmark, Sweden, the United Kingdom, Germany, France, Spain, Italy, Switzerland, Austria, Hungary and Romania) (Fig. 1).



**Fig. 1.** Map of the countries and research centers participating in the European project Cambrella according the work packages (WP). Source: <https://cam-europe.eu>.

CAM, as a field of medicine, is defined as follows: "The concept of CAM, as used by European citizens, is a variety of medical systems and therapies based on



knowledge, skills and practices derived from theories, philosophies and experience, used to maintain and improve health, and to prevent, diagnose, alleviate or treat physical and mental illness. CAM therapies are mainly used outside of conventional health services, but in many countries some therapies are accepted or adapted to conventional health systems. ”

The Cochrane collaboration also establishes a definition for the purpose of harmonizing approaches to the growing body of research in this field: CAM refers to a group of systems and practices considered outside the field of conventional medicine that are used to prevent or treat diseases and / or to promote health and well-being.

As a result of the pan-European project CAMbrella, the following therapeutic methods are included in the CAM territory, listed in alphabetical order (Fig. 2): acupuncture; anthroposophic medicine; Ayurveda; yoga; kinesiology; naturopathy; osteopathy; reflexology; Tibetan medicine; traditional Chinese medicine (TCM); phytotherapy (Herbal medicine); chiropractic; homeopathy (Homeopathic medicine); shiatsu.



*Fig. 2. CAM in Europe (according the Cambrella-frame).*

In the different European countries there are other methods that have become necessary according to traditions and national characteristics. For the purpose of this study, the framework of the CAMbrella project is adopted, and the above-mentioned therapeutic approaches are defined as follows:

**Acupuncture** is part of Traditional Chinese Medicine (TCM), which aims to prevent and treat diseases by piercing with needles at specific points on the surface of the body (acus - needle and punctum - point). Diagnosis and treatment are carried out in accordance with the individual characteristics of the disease and are based on traditional Chinese concepts, centuries of experience and modern scientific and clinical research.

**Anthroposophical medicine** is a healing art based on the spiritual and scientific knowledge of man and nature, whose postulates were developed by Dr. Rudolf Steiner (1861-1925) in the early twentieth century.

**Ayurveda** ("science of life") is an ancient Indian teaching, applied for more than 5000 years. It is a system of principles for a harmonious and healthy life, which includes both practices for maintaining health and therapeutic measures for physical, mental, social and spiritual development.

**Yoga** is a system of physical and respiratory practices, relaxation, diet, positive thinking and meditative techniques that establish harmony in the body, soul and environment. This is an ancient system, and the word itself is in Sanskrit and means "union."

**Kinesiology** is a science that studies the movements of the human musculoskeletal system and uses knowledge of biomechanics, musculoskeletal anatomy and neurophysiology. The origin of the word is from Greek - kinesis (movement) and logos (science).

Applied kinesiology is the science of health as a system for adaptation of the organism to the external environment (exchange of matter, energy, information), diagnostics of the level of the existing abilities of the organism, selection of methods for their recovery and expansion.

**Naturopathy** uses natural remedies to prevent, treat and maintain health. It originates from Hippocrates and the traditional healing systems in Western Europe. The means used stimulate the healing processes and are: water, sun, exercises and massages, nutrition (starvation, fasting), herbs, placement of suction cups, bloodletting, treatment with honey and others.

**Osteopathy** is a medical system according to which the body can heal itself by normalizing the natural healthy structural relationships, environmental conditions and nutrition. Therapists use a variety of manual techniques to work on the musculoskeletal system and seek to find the cause of the pain rather than simply relieving it as a symptom.

**Reflexology**, also called reflexology or zone therapy, divides the human body into ten vertical zones, similar to the meridians. According to Chinese medicine, within each zone fall certain organs, systems and muscle groups that connect to the central nervous system through certain points in the area of the feet, hands and ears. By pressing and acting on certain reflex points and areas on the feet, hands, ears, a calming and healing effect is achieved.

**Tibetan medicine**, Sowa Rigpa (science of healing), is a traditional healing system from Tibet (also applied in India, Nepal, Bhutan, Mongolia, etc.). It is a complete treatment system with its physiology, pathogenesis, general and specific pathology, diagnosis and treatment.

**Traditional Chinese Medicine** (TCM) originated in Ancient China thousands of years ago and reflects ancient Chinese philosophical thought. It has its own methods of diagnosis (pulse, language, etc.) and its own methods of treatment (acupuncture, massage, herbs, movements, etc.).

**Phytotherapy** (from the Greek phyton - plant, therapy - therapy) or herbal medicine generally means a method of treatment with the help of medicinal plants. Phytotherapy is not only an alternative method, but also part of modern pharmacognosy - a science that deals with the study of medicinal plants and drugs derived mainly from plant and less often from animal species.

**Chiropractic** is a primary contact medical profession with its own unique principles and practice. Manual care, including diagnosis and treatment, focuses on the relationship between structure, spine and function through the nervous system. The terms chiropractic and manual therapy are synonymous. Chiropractic (a system of mechanical work with the hands) is a treatment system that focuses on the problems of the musculoskeletal and nervous systems and their impact on overall health.

**Shiatsu** is a traditional Japanese therapy, which means "finger pressure". It is officially recognized as a method of physical therapy in many countries of the European Union.

**Homeopathy** is a healing practice with its own specific principles and laws, which were formulated by Dr. Samuel Hahnemann more than two hundred years ago. A basic principle is the Law of Similarity - Similia similibus curentur - the like is treated with the like. "... In order to be able to cure, medicines must first and foremost be able to cause in the human body an artificial disease as close as possible to the disease to be treated... It not only overshadows but eradicates and destroys the disorder caused by the natural disease..." (Organon of the healing art, S. Hahnemann).

In Europe, homeopathy is the most widely used CAM method. A new map of homeopathy users in Europe shows the prevalence of this alternative therapy. Three out of four Europeans are familiar with homeopathic therapy, and 29% use homeopathic treatment (Fig. 3).

## Употреба на хомеопатични лекарства в Европейския съюз

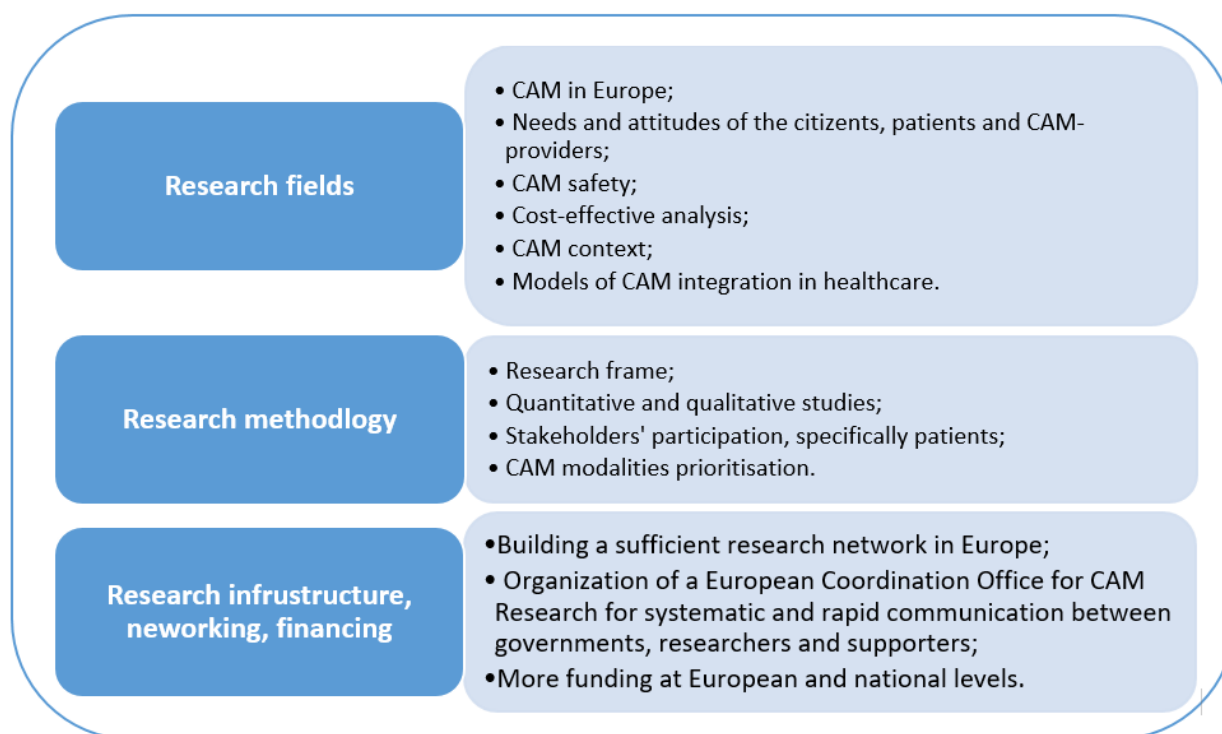
Близо 40 милиона граждани на ЕС са се лекували с хомеопатия през последните 12 месеца.



*Fig. 3. Data on the use of homeopathy in Europe. Source: ECHAMP, 2019.*

Data from European studies, from public registers of practitioners of unconventional methods in regional cities, professional organizations and centers for postgraduate training in homeopathy show that this is the most popular unconventional method in our country, which supports the emphasis of research interest on the place of homeopathy. in Bulgaria.

The CAMbrella project prepared the research community for future CAM research by strategically outlining priority research areas, methods and networks (Fig. 4).



*Fig. 4. Research directions formulated by consensus in CAMbrella.*

In Bulgaria there are no socio-demographic and epidemiological data on the application of CAM. On the other hand, our country has a long tradition in naturopathy. On the territory of the Medical University of Varna successfully operates the only academic "University Center for Eastern Medicine" in the country, where research and training are conducted. Homeopathy is a method that also has a long history in our country, and more and more people seek the help of a medical doctor-homeopath. In Bulgaria, unconventional therapy has been legally regulated since 2005, but the data about the CAM field is scarce. The first research analyses regarding non-conventional medicine are performed in the National Center for Public Health and Analysis (NCPHA), namely by the Assoc. Prof. Dr. Iliana Yaneva-Balabanska. A dissertation on alternative and complementary medicine in general practice is defended in 2017 (Trakia University, Medical Faculty, Stara Zagora).

CAM is an innovative concept that has its place in the European healthcare. Theoretical and field research related to CAM approaches and scientific research on the effectiveness, efficiency and safety of CAM methods is timely and necessary.

# I. AIM, OBJECTIVES, METHODS, DESIGN

## Methodology and organization of the study.

### 1. Aim and objectives of the study.

**The aim of this dissertation is to study the historical and scientific development of complementary and alternative medicine (CAM), and its place in the Bulgarian health care with an emphasis on homeopathy as the most used CAM method in Europe.**

To achieve this goal, the following research objectives are set:

**The first objective:** To define, study and present the innovative European concept CAM and its place in the Bulgarian healthcare.

**The second objective:** To outline the CAM approaches on a national scale and to study the historical and scientific development of the types of CAM therapies in Bulgaria.

**The third objective:** To make a situational analysis of CAM in the Bulgarian healthcare, including a classic SWOT analysis based on the studied world and European experience.

**The fourth objective:** Study of the socio-demographic profile and health-related outcomes of patients with chronic complaints<sup>1</sup>, who have been treated for more than a year with homeopathy - the most used CAM method in Europe. Tracking attitudes and awareness related to homeopathy.

**Fifth objective:** To study the reasons for the choice of homeopathy in the medical treatment of children.

### 2. Working hypotheses.

**The main hypothesis** of the project is that CAM is a scientific field of application, covering many unconventional medical methods, which are increasingly sought after by patients and increasingly studied and applied by doctors, pharmacists and other health professionals.

**Hypothesis regarding own research related to patients with chronic complaints treated with homeopathy:** the socio-demographic characteristics of patients treated with homeopathy overlap with the European profile of this type of

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<sup>1</sup> These are patients who have diseases that require long-term care and show usually slow progression as a result of a combination of genetic, physiological, environmental and behavioral factors.

patients: mostly people in the younger age group, with higher education and predominantly women; sources of information are the immediate environment and the media (internet); the duration of treatment determines a better quality of life.

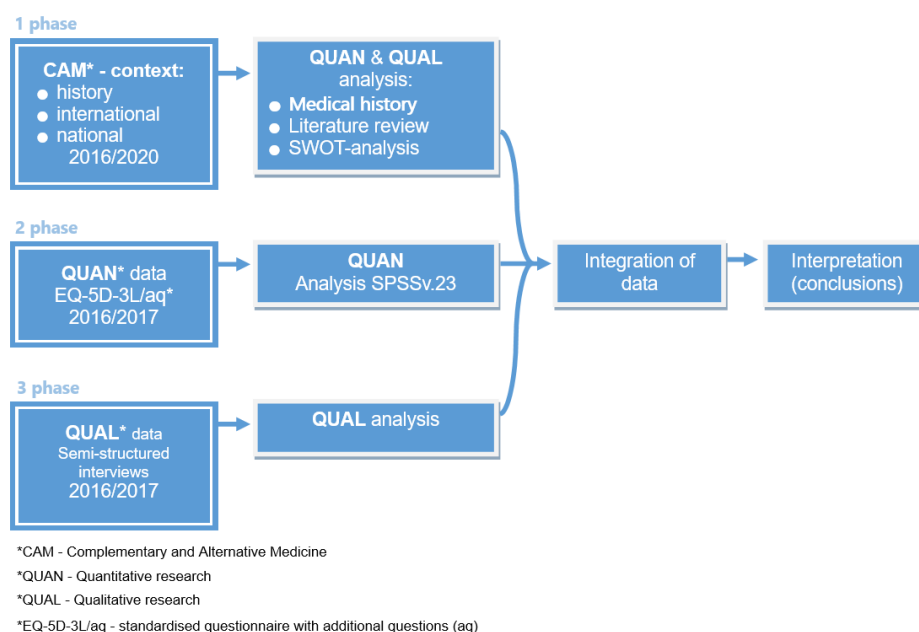
**Hypothesis regarding the research related to the treatment of children with homeopathy:** the choice of homeopathic treatment is secondary, as a result of dissatisfaction with conventional therapy incl. antibiotics; as well as primary choices in families leading an environmentally friendly lifestyle.

### 3. Study design - mix-methods approach - converging parallel mix-methods design

The present work is a result of an intellectual project, which arose as an individual idea and continued its development thanks to the support and participation of a wide social network of like-minded people and professionals from various fields related to CAM and public health. The research methodology was developed by the dissertation. The doctoral student participated in all phases of the study (creation of the idea and methodology, preparation, literature review, pilot study, conducting the entire study and data analysis, publishing the results).

A mixed-method approach is applied, in which both quantitative and qualitative data are collected, analyzed and "mixed" in order to study in-depth the set scientific objectives.

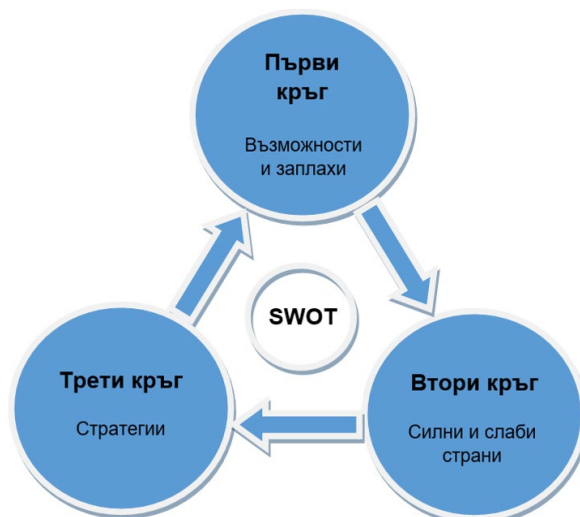
This study followed the mix-methods approach, applying a converging parallel mix-method design, which consists of three separate parallel phases with the same priority, whose data are then integrated to be interpreted and to draw conclusions and recommendations at the end of the study. Both quantitative and qualitative methods are applied (Fig. 5).



*Fig. 5. Study design- convergent parallel design.*

### **First phase: CAM context: historical, international and national analysis.**

- Historical-medical research of documents through documentary historiographical method: review of documents, the normative base, scientific developments.
- Literary scientific analysis of scientific publications in the field of CAM, ancient and modern history of medicine, Bulgarian teaching materials for different CAM methods.
- In the present study, a SWOT analysis in healthcare is applied to assess the status of CAM in our country and the place of CAM in Bulgarian healthcare. The experience of the research team related to the application of the classical tool for situational assessment supports the application of SWOT-analysis. For maximum benefit, SWOT requires strict discipline and consistency. A simple but powerful framework of three rounds of data collection and analysis of external and internal factors has been adapted. (Fig. 6)



*Fig. 6. SWOT analysis of CAM in Bulgaria - three rounds to sustainable strategies for development and support.*

### **Second phase: Quantitative analysis by observational multicenter study, direct survey.**

During the second phase, quantitative data were collected using a survey method using a toolkit - a standardized questionnaire for subjective health assessment, EQ-5D-3L Health Index Health Questionnaire - Bulgarian version<sup>2</sup> (see Annex 1).

The EQ-5D-3L is a generic health status questionnaire developed by the EuroQol Group that has been validated in several countries and allows for economic, political

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<sup>2</sup> EQ-5D-3L Health Questionnaire – Bulgarian version is provided for the purpose of the study by creators EuroQol Research foundation, Rotterdam, The Netherlands.



and clinical assessment. The validity and reliability of the questionnaire has been tested in many studies and in different populations and patient groups.

The reasons for choosing the EQ-5D-3L questionnaire are the following:

- The recommendations of the scientific community after a representative study in six European countries and Brazil on "homeopathy and quality of life related to health" is to use a standardized questionnaire next time.

- The use of the EQ-5D-3L, imposed as the gold standard in Europe, allows for international comparisons.

- Promoting the EQ-5D-3L instrument among CAM researchers and practitioners as practical, standardized and cost-effective for measuring health outcomes. The conclusion made during the first national population survey in the UK to measure and assess health status with EQ-5D-3L proves it as such.

Short description of the tool: EQ-5D-3L defines health in relation to five areas / domains: Mobility, Self-care, Usual activities (work, study, household, family and leisure), Pain / Illness, Anxiety / Depression. The interviewee should assess "their health today". The EQ-5D-3L consists of two parts. The first part is "descriptive", including the five areas - mobility, self-care, normal activities, pain / discomfort, anxiety / depression. Each area has three levels of assessment: no problems, some problems, problems. Participants (respondents) were asked to mark for each group statements that best described "what is their state of health today". The second component is a 20 cm Visual Analogue Scale (VAS), the upper end of which corresponds to "the best health you can imagine" and the lower end to "the worst health you can imagine".

The parts listed above represent the basis or core of the EQ-5D-3L questionnaire. In addition, socio-demographic data are usually collected. In the present survey, questions related to CAM were added to the survey.

In the present study, the questionnaire consists of a total of 5 pages. The first three pages are provided by EuroQol Group: the first page with the logo, the second - the descriptive part (describe your health today), the third page - EQ VAS - Thermometer. On the fourth page, as mentioned, questions related to age, gender, education, profession, treatment with homeopathy and other CAM, awareness about homeopathy are added. The fifth page contains a definition of unconventional methods according to the current Ordinance No. 7 of 2005.

The target population is patients with chronic complaints who have been treated homeopathically for a year or more ( $\geq 18$  years, Number: 211). Data on the socio-demographic characteristics of patients ( $> 18$  years of age) who sought homeopathic

treatment were also obtained from this group. Patients are also asked to provide information on the duration of homeopathic therapy; for the use of other CAM therapies or conventional treatment; about the need for information and the sources / channels through which they received information about homeopathy as a therapeutic method, the Patient was asked how he assesses his overall health after treatment with homeopathy today compared to a year ago (change in the severity of complaints after homeopathic treatment - the patient assesses the change in his / her state of health after homeopathic treatment on a 4-point scale from “my health is much better” to “worse”). At the end of the questionnaire, the patient can freely comment on the reasons for choosing homeopathic treatment and add additional information related to the treatment and the questions asked above. The design of the study was presented at the First European Congress of Homeopathy in Vienna (Vienna, 17-19.11.2016). After written informed consent, the patient is included in the study. Patients were included until a certain deadline, namely December 25, 2017. The questionnaire was completed by the participants in the direct survey, regardless of their homeopath.

Framework for selection of the actual study: Multicenter study in clinics of homeopaths with over 20 years of experience, with a European diploma in homeopathy, in the cities of Burgas, Varna, Veliko Tarnovo and Sofia.

Methodology for sampling: The formation of the sample follows a specific algorithm presented in the section "Results of own quantitative research in the field of homeopathy" (Fig. 10).

Organization and time of holding: 2016, 2017.

Ethical framework of the quantitative phase: A form has been prepared for each participant, containing written information about the nature and expected benefits of the study, depending on the phase in which the particular patient is involved. Each participant completed an informed consent form, again depending on their role in the survey.

### **Third phase: Qualitative research through semi-structured interviews.**

**Objects of the study:** The target population are parents who have chosen the homeopathic method for the treatment of their children.

**Selection framework:** Qualitative study with semi-structured interviews of a target group of parents who have been treating their children with homeopathy for more than a year.

This type of interview provides an opportunity to reflect the opinion of so-called "experts" (people with a high level of awareness in a specific area). These are not only professionals, but also people who, due to various circumstances, have increased

interest and accumulated experience and knowledge in a given field. In the present study, parents with young children are "experts" in the field of child rearing and care. 19 parents of 35 children are included (the standard requirements are that their number is not less than 10 and not more than 25-30 people). Semi-structured interviews were audio-recorded or on paper, transcribed, summarized and illustrated with the words of the respondents. The average duration of an interview is half an hour.

Predefined thematic circles with guide questions:

**First area: Choice of homeopathy**

Questions: Share your experience with homeopathy? Why did you choose to treat your child with classical homeopathy? When do you use homeopathy for your child (prevention, treatment)? What do you treat your child with homeopathy for?

**Second area: Decision-making process related to the choice of homeopathy for treatment and / or prevention of the child within the family.**

Questions: Who are your family members? Who in your family decides on the treatment / prevention of the child with homeopathy? Do all family members support you and does it matter to you?

**Third area: Supporting / non-supporting environment**

Questions: Do your friends / colleagues support you when choosing homeopathy for your child? Does the support of the external environment (friends, colleagues) matter to you?

Do you encounter obstacles in choosing homeopathy for your children? If "Yes" follows - What obstacles do you encounter when choosing homeopathy for your children?

**Fourth area: The parent-patient-homeopathic relationship**

Questions: How do you choose a homeopath for your child? What determines your choice of homeopath?

Ethical framework of the qualitative research: A form has been prepared for each parent or guardian, containing written information about the nature and expected benefits of the research.

The overall research was approved by the Commission on Research Ethics at Medical University of Varna, with Protocol № 57 / 3.11.2016. The final report of the project was accepted with Protocol № 75 / 07.06.2018.

#### **4. Material and methods of the overall study:**

**Material:** Bulgarian and foreign literary sources, publications, abstracts and articles related to CAM. Statistics and studies for different types of CAM methods. Public registers of persons practicing unconventional methods for beneficial effects on individual health in Bulgaria.

##### **Methods:**

- Historiographical method - historical-medical research of the CAM methods in Bulgaria - documentary method through review of documents, on a normative basis, publications and scientific developments in the field of CAM.
- Literature scientific analysis and method of systematization of information from publications covering the first 20 years of the XXI century (from the year 2000 to the present), related to CAM and following the purpose and objectives of the study.
- SWOT analysis - situational analysis of the strengths and weaknesses, the favorable opportunities and the threats / risks of the state of CAM in Bulgaria.
- Quantitative sociological methods for gathering information and analysis: direct standardized questionnaire (the patient reads and answers in writing the questions in the questionnaire).
- Qualitative sociological methods for gathering information and analysis: Semi-structured interviews with parents. They are conducted as a conversation - there are pre-formulated questions and leading topics, but there are no pre-listed answers from which the respondent can choose.
- Statistical methods - descriptive statistical methods are used. A descriptive analysis was performed to identify the required characteristics of the sample from the slice study. A variational analysis was applied to present the mean and standard deviation of the quantitative variable "health self-assessment". A correlation analysis was also performed to measure the direction and strength of the linear relationship between the duration of homeopathic treatment and HrQoL.
- Graphical method - to present the results of the statistical data.

## **II. CAM IN THE BULGARIAN HEALTHCARE. RESULTS FROM OWN RESEARCH AND DISCUSSION**

In Europe, CAM has been in the research and health policy focus for more than 20 years. In the latest WHO report from 2019, regarding the development of T&KM, the need to overcome the huge lack of reliable and official data related to CAM is also mentioned. For these reasons and in fulfillment of the set tasks in the dissertation the normative, legislative framework in Bulgaria will be presented initially. Based on it, a situational analysis of CAM will be made. We also present our own research in the field of homeopathy, one of the CAM methods.

### **1. CAM in Bulgaria - regulations**

In Bulgaria, the Health Act, SG No. 70 / 10.08.2004, Chapter VI defines the unconventional methods for beneficial effects on individual health and who can practice them.

Only practitioners of homeopathy must have a master's degree in the professional field of "Medicine" or "Dental Medicine".

Persons who practice unconventional methods shall register with the regional health inspectorate in the area where they practice, by submitting an application indicating the unconventional methods and means that the person will practice. The Regional Health Inspectorate creates and maintains a register of persons who practice unconventional methods.

Ordinance 7 of March, 2005 for the requirements to the activity of the persons, who practice unconventional methods for favorable impact on the individual health, gives a definition of the terms in the law.

### **2. SWOT analysis of the state of CAM in Bulgaria.**

CAM has been present in the Bulgarian healthcare for centuries, but so far there is no complete picture of the proposed methods, their suppliers and consumers. Although there is legislation, it is insufficient or not observed. This creates conditions for offering unregulated methods by people without the necessary qualifications, and thus security and safety in the use of these services by citizens cannot be guaranteed.

It is necessary to analyze the nature of unconventional methods - their internal characteristics, and the conditions in the world and in Bulgaria, which favor or hinder the integration of these methods in modern Bulgarian healthcare. Such a tool for understanding the situation and for strategic planning is the SWOT analysis. It provides

the necessary framework for reviewing the organizational strategy and direction of development.

### **FIRST ROUND of SWOT:**

**EXTERNAL FACTORS** favoring the spread and integration of CAM in healthcare can be systematized in a global and national context.

#### **1. Global factors**

The application of CAM contributes to solving the emerging new problems for healthcare:

- Chronic diseases - their treatment requires long-term use of drugs, which is more likely to lead to the manifestation of their side effects. Polypragmatism and drug diseases worsen the quality of life of these patients.

CAM-possibilities: CAM-co-administered with conventional therapy improves health and reduces the number and dose of drugs.

- Antibiotic resistance - As a result of the widespread and improper use of antibiotics and mutations in pathogens in recent years, antibiotic resistance has become a major problem for health authorities. This problem is also related to the widespread use of these drugs in animal husbandry. The WHO and the European Parliament identify antibiotic resistance as a major public health problem, to which financial and expert resources are allocated as a priority.

CAM- possibilities: CAMs can reduce the need for antibiotics by creating healthy habits, and can be an effective alternative to antibiotics. Serious research is needed in this direction, to protect the health of both humans and animals.

- Disease prevention. All WHO directives and standards emphasize disease prevention and health promotion. Prevention is a set of measures aimed at isolating risk factors, preventing diseases and reducing their consequences (chronicity and disability), and premature death.

CAM - possibilities: CAMs can effectively increase the body's defenses to prevent disease or to deal successfully with the disease.

- Population aging: In the world, life expectancy is rising and the population is aging. The global response to these positive demographic processes includes adapting the health system and introducing cost-effective care.

CAM-possibilities: CAM-methods are cost-effective and at the same time improve therapeutic results, including quality of life.

- Palliative care is also a resource burden on public health. Terminal care is the most expensive. Healthcare costs are increasingly high in terms of expensive technology and life support at all costs.

CAM-opportunities: CAM can improve the condition of terminally ill people, reduce their suffering before the end.

Support from international organizations:

In the second half of the last century, the WHO recognized that the use of traditional methods and CAM is expanding and gaining popularity not only in primary health care for the poor in developing countries, but also in countries where conventional medicine predominates in the national health system. As a result, the WHO has developed a series of guidelines such as: “Guidelines for the Evaluation of Herbal Medicines”, “Guidelines for the Evaluation of Clinical Research in Acupuncture”, “General Guidelines for Methodologies for Research and Development of Traditional Medicine” and others. The WHO recommends the development of regional policies and legislation that regulates the development of CAM worldwide.

The European Parliament supports the development of CAM and earmarked funding for research cooperation in the field of complementary and alternative medicine.

## **2. National factors**

In Bulgaria, folk medicine, naturopathy and other alternative methods have a rich centuries-old history. Their widespread use in our time has been proven by many ethnographic and medical research.

Bulgarian legislation and health regulations are in line with European standards.

## **EXTERNAL THREATS**

In the external environment there are factors that hinder the establishment and development of CAM in Bulgaria. They are typical of most countries in the world or have a strong national character.

### **1. Global threats / obstacles to be overcome**

WHO in its report on T&CM from 2019. defines the main obstacles facing the opportunities for integration of T&CM in national health systems.

These problems, which are to be overcome, can be systematized in six directions:

- Lack of a database of scientific publications and evidence-based research;
- Lack of financial support for the implementation of such research;

- Lack of criteria for who can practice CAM and lack of international universal training standards. Often the methods are not practiced by doctors.
- CAM practices and CAM medicinal products in most countries are not regulated and their safety for human health cannot be guaranteed;
- Lack of mechanisms for control and regulation of advertising - each of the CAM methods has its capabilities and limitations, which need to be qualitatively differentiated and defined.
- Globally, lack of experts in the circles of the national health and control bodies, competent in the field of CAM. Need for additional qualification related to CAM of healthcare experts.

## **2. National threats / obstacles to be overcome**

Systemic problems in Bulgarian healthcare affect the development of unconventional medicine. The main factors hindering the establishment of CAM in Bulgaria can be formulated as follows:

- Problems in the Bulgarian legislation.
- There are no standards for training and practice.
- The Law on Medicinal Products in Human Medicine determines the specific requirements and the procedure for registration of homeopathic preparations and traditional herbal medicinal products. Therefore, the control over other types of CAM products is not regulated, quality control during production cannot be guaranteed, there is no defined registration regime, there are no procedural guarantees for the safety of these products.

After the systematization of the modern factors of the environment - global and national, which define the external conditions influencing the CAM, the internal characteristics are identified, ie. the strengths and weaknesses of CAM in Bulgaria.

### **SECOND ROUND SWOT:**

#### **STRENGTHS OF CAM**

CAMs are characterized by a number of specific approaches and tools in the processes of maintaining health and treatment. These are:

- Holistic approach

CAM with its holistic approach analyzes the patient on a physical, emotional and mental level. This leads to the creation of a treatment plan that optimally meets the needs of people.

- Health as a dynamic, not a static state



The human body is an open nonlinear dynamic system that is capable of self-regulation. Allostasis is the way the body keeps all systems in balance.

CAM systems, such as yoga, dietetics and curative starvation, manual practices, naturopathy, and others, contribute to the dissemination of ideas of a natural lifestyle that includes diet, exercise, alternation of work and rest, and leads to a strong immune system. , emotional stability and rapid restoration of balance in the human body.

- Supports the body's internal defenses

CAM by acting on the PNEI-axis (psyche-nervous system-endocrine system-immunity) enhances the resilience, resistance and immune status of the individual.

- Individual approach

CAM-approaches with their individual approach to each person become preferred and bring greater satisfaction around the world.

Salutogenesis is central to CAM, as an approach focused on factors that maintain human health and well-being, rather than on factors that cause disease. The "salutogenic model" is related to the relationship between health, stress and coping.

Therapeutic relationship doctor-patient-parent.

In CAM therapies there is a positive functioning partnership between the patient and the medical professional.

Responsibility for one's own health.

CAM therapists help patients develop the sufficient levels of self-awareness needed to change unhealthy patterns of behavior and improve their health. Thus, the patient is not a passive participant; the patient and the medical professional work together as partners.

## **WEAKNESSES OF CAM**

Weaknesses are those internal characteristics that can hinder the development and success of the integration of CAM in the Bulgarian healthcare.

- The CAMbrella report confirms that European research on CAM is limited and there is almost no significant investment in any EU Member State.
- CAM is organized as a practice and education mostly in and by private providers and has a weak presence in academia.
- There are no unified schemes for CAM and the prescription is in accordance with the individual condition of the patient at the given moment. Three factors are very important:

1. The provider (doctor, healer) of CAM - his competence, which is determined by his education and experience. There is no official academic education for CAM. For some systems, European training standards have been adopted (anthroposophy, homeopathy, etc.), but they are not mandatory for individual countries.

2. The user (patient) who must responsibly participate in the treatment process. On the one hand by giving accurate information and on the other with responsibility in following the treatment plan.

3. Medicinal products used by CAM - only homeopathic preparations are registered under the Law on Medicinal Products. The others are like food supplements. There is a lack of trust in society in quality assurance processes nationwide.

After filling in the SWOT matrix with information (by listing different points in each of the 4 quadrants, for example, or by keywords, etc.) the main characteristics of CAM and the factors of the environment in which they exist are illustrated (Fig. 7).

Силни страни на КАМ	Слаби страни на КАМ
<ul style="list-style-type: none"> <li>❖ Индивидуализиран профилактичен и терапевтичен подход. Емпатия в отношенията лекар-пациент.</li> <li>❖ Холистичен подход. Подкрепя вътрешните защитни сили на организма.</li> <li>❖ КАМ са икономически ефективни.</li> <li>❖ КАМ са безопасни и ефикасни.</li> <li>❖ Иновативни и динамични - интегрират древни лечебни практики и съвременни модели на общуване с пациентите.</li> <li>❖ Все повече научни публикации за ефективността на КАМ-терапиите.</li> </ul>	<ul style="list-style-type: none"> <li>❖ КАМ е хетерогенна област и не всички методи са достатъчно развити в областта на медицината базирана на доказателства.</li> <li>❖ КАМ-методите са с вековни традиции, но в науката се развиват отскоро. Лечебният ефект не винаги може да бъде оценен количествено.</li> <li>❖ КАМ – лечебните средства не се регистрират по Закона за лекарствените средства (с изключение на хомеопатията).</li> <li>❖ КАМ-терапиите като цяло са слабо застъпени в университетското медицинско образование.</li> </ul>
<ul style="list-style-type: none"> <li>❖ Подкрепа от международните организации - СЗО, ЕС.</li> <li>❖ Глобално, КАМ предлага решения на проблеми като: антибиотичната резистентност; качество на живот при хронично болните; застаряване на населението (терминални грижи, палиативно лечение);</li> <li>❖ Повишено търсене от страна на хората/пациентите.</li> <li>❖ В България народната медицина, природолечението и други КАМ-методи имат богата и дългогодишна история.</li> <li>❖ Българското КАМ-законодателство - в съответствие с европейските стандарти.</li> <li>❖ Практикуването и обучението по КАМ - определено в Закона за здравето (2005г.)</li> <li>❖ Силни съсловни и пациенски организации.</li> </ul>	<ul style="list-style-type: none"> <li>❖ Липса на бази-данни с научни публикации;</li> <li>❖ Липса на финансова подкрепа за осъществяването на научни изследвания;</li> <li>❖ Липса на стандарти за това, кой може да практикува КАМ и липса на международни универсални стандарти за обучение;</li> <li>❖ Често методите не се практикуват от лекари;</li> <li>❖ КАМ-практиките и лекарствените КАМ-продукти в повечето държави не са регламентирани и не може да се гарантира тяхната безопасност за здравето на хората;</li> <li>❖ Липса на механизми за контрол и регулиране на рекламата - контрол на качеството.</li> </ul>
Възможности за развитие на КАМ	Заплахи за развитие на КАМ

\*Съкращения: **КАМ**- комплементарна и интегративна медицина; **СЗО** - Световна здравна организация; **ЕС** - Европейски съюз

**Fig. 7.** SWOT analysis of the opportunities and threats for development based on the strengths and weaknesses of CAM.

### THIRD ROUND of SWOT

#### Formulation of strategies:

**1. Collaborative strategy** - Collaborative work of CAM specialists with researchers from scientific medicine is needed.

**2. Communication strategy** - A communication strategy is needed to reach target groups that define and influence health attitudes and norms: politicians, stakeholders and the public.

**3. Constructive strategy** - The construction or upgrading of a stable and developing CAM, as part of the overall structure of health care in Bulgaria requires:

- Change in the legislation with the inclusion of all unconventional methods and the definition of standards and criteria for their practice, which will ensure the safety and security of citizens in the use of these services.
- Development of a national strategy for education related to CAM.
- Establishment of a unified modern public register of persons practicing unconventional methods.

The introduction of new strategies is a public necessity, because CAMs are really present in our healthcare.

### **3. CAM in Bulgaria - methods.**

In the present part of the dissertation a historical-medical study of the CAM methods in Bulgaria is made according to the framework adopted by the European project CAMbrella, but in accordance with our national peculiarities. There are centers for Traditional Chinese Medicine and Ayurveda in the country, but they are organized by specialists from China, India or other countries. Tibetan medicine is not presented as a system, but as separate practices - gong therapy, singing Tibetan bowls, aura diagnostics, etc. Osteopathy and kinesiology are still in their infancy and have only individual representatives. The specialists in Bowen therapy and Scanar therapy are very widespread and organized, so these methods are included in the description of CAM methods in Bulgaria.

#### **Acupuncture**

Since 1960 Bulgarian medics start training in acupuncture. In 1976 by order of the Minister of Health, acupuncture offices were opened at the Clinics of Neurology, Dermatology, Internal Medicine and Physiotherapy of the Medical Academy in Sofia, as well as in the major district hospitals of the country. An acupuncture section was established at the Bulgarian Scientific Society of Neurology.

The Scientific Society of Acupuncture was officially re-registered in 1991. as the Bulgarian Society of Traditional Chinese Medicine (BDTCM).

#### **Anthroposophical medicine**

In 2001 The Anthroposophical Society in Bulgaria (AOB) was established in Sofia. Several working groups in different cities of the country are registered with it.

Anthroposophical medicine is not sufficiently known to our society and is little practiced unlike other European countries.

### **Bowen therapy**

In recent years, the popularity of Bowen therapy has been growing in Bulgaria. In 2008 The Bulgarian Bowen Therapy Association (BABT) is established. In 2012 Georgi Ilchev is defending his dissertation on the topic - Bowen for symptomatic treatment of patients with lymphedema due to breast cancer, at the Faculty of Nursing at the University of Arizona, USA.

### **Traditional (folk) Medicine**

Folk medicine is a collection of oral information about the ways and means of treatment, passed down from generation to generation. It is a long-term healing experience preserved in the folk tradition.

Information about the Bulgarian folk medicine in the XVIII - XIX century is contained in the travelogues of foreigners who passed through our lands. At the end of the 19th century, Mihalaki Georgiev and Stefan Vatev published instructions for collecting materials on folk medicine, and since then many intellectuals and specialists have recorded valuable information about the traditional healing practices in our lands. They are published in the Collection of Folk Tales, Science and Literature.

Nowadays, folk recipes, rituals and practices continue to be collected mostly by ethnographers in museums around the country and are stored in the archives of the Institute of Ethnology and Folklore with the Ethnographic Museum, in the archives of the Departments of Slavic Philology and Ethnology at SU "St. Kliment Ohridski "and in the archives of the historical museums.

### **Phytotherapy**

In Bulgaria, phytotherapy is developed as part of folk medicine - herbal medicine, and as part of the training in pharmacognosy in the faculties of pharmacy. In the Medical Faculties it is studied as an optional subject.

The interest in medicinal plants in our lands dates back to antiquity. The Greek naturalist and philosopher Theophrastus wrote in his Plant Studies that Thrace was the richest region of medicinal plants in the world at the time. Dioscorides - a Roman military doctor, in his work "On Medicines" describes a large number of plants used to treat the Thracians. In 1975 Assoc. Prof. Dr. Vladimir Vassilev published his work "Medicine in Ancient Thrace", in which he translated Dioscorides and systematized the known materials about the healing practices in our lands.

A valuable historical and medical source is the Bogomil work "Zeleynik", written in the X or XI century, in which medicinal plants and their application are collected and described.

### **Naturopathy**

The history of naturopathy in Bulgaria follows the development of this healing system in Europe, but it also has its national peculiarities.

Many healers and doctors contribute to the establishment and development of these healing practices in our society, such as: Dr. Ivan Teodorov, Dr. Paraskev Stoyanov, Peter Dimkov, Dr. Kiril Yordanov and others.

Only some strokes in the history of naturopathy in Bulgaria are outlined, which are directly related to the professional and research activity of the dissertation.

### **Healing fasting**

In the twentieth century, curative starvation was revived as an idea and found thousands of supporters. The book "The Miracles of Starvation" by the American nutritionist Paul Bragg has been republished many times around the world.

In Bulgaria, Lydia Kovacheva creates a unique healing system with a softened form of fasting - fruit and tea unloading regime. It is different from the existing ones in the world, unaffected and not borrowed from them. Eating fruit during starvation treatment accelerates the process of cleansing the body of accumulated toxins.

### **Manual medicine**

In 1971 The first manual therapy courses were organized in Bulgaria. In 1984 A Manual Therapy Section was established at the Society for Physical Therapy and Rehabilitation. In 2001 The Bulgarian Society of Manual Medicine (BDMM) was founded in the town of Pavel Banya

### **Yoga**

In Bulgaria the first yoga groups were organized in 1937. The Bulgarian Yoga Federation was registered in 1990. and has its own statutes and Management Board.

Yoga therapy consists of mastering the philosophy and exercises, which helps in healing, leads to recovery after illness and carries out prevention and health promotion.

### **SCENAR therapy**

Since the end of the last century, many specialists have appeared in Bulgaria, offering a new method for the country, which quickly spread. This is SCENAR therapy, which is a non-invasive energy-information medical technology aimed at activating the

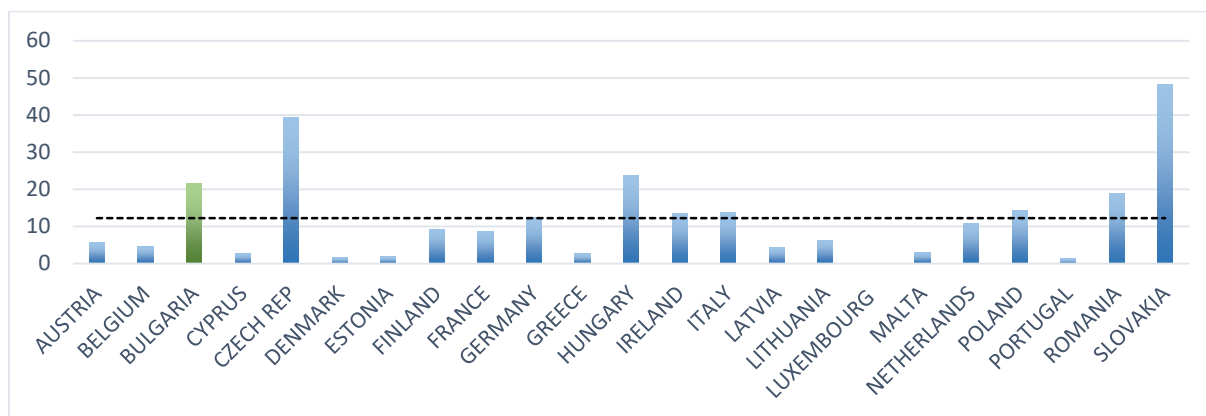
body's reserves and supporting its adaptation capabilities. On April 20, 2002. The Bulgarian SCENAR Society (BSD) was established.

## Homeopathy

Historical data on the development of homeopathy in Bulgaria dates back to the second half of the 19th century. The Museum of the History of Medicine in the city of Varna keeps a homeopathic set of the German company “Dr. Willmar Schwabe”. It belonged to a teacher from the town of Tryavna, who practiced homeopathy in the second half of the 19th century.

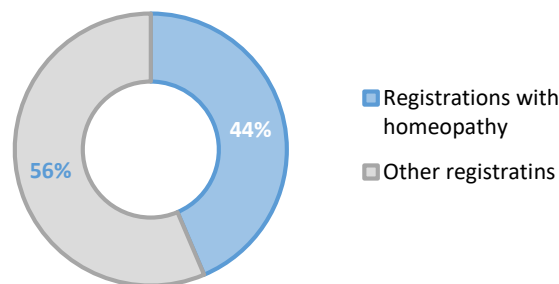
Dr. Georgi Valkov Mirkovich (1828 - 1905) is considered to be the first homeopathic doctor in the historical and medical literature.

Data from European studies show that in Bulgaria 64% of general practitioners and pharmacists recommend homeopathy for the treatment of a wide range of common diseases. Bulgaria (Fig. 8), along with the Czech Republic, Hungary, Italy, Germany and Poland, is among the countries in which the number of doctors prescribing homeopathy per capita is above the European average (10.6 per 100,000 population, for 2015).



**Fig. 8.** Number of homeopathy prescribers (medical doctors or certified health professionals) per 100,000 inhabitants of the population of a given country, 2012, for the countries of the European Union. Source: ECHAMP, 2012.

The data from the available registers of the 28 Regional Health Inspectorates in Bulgaria are summarized. After an analysis of the available public information, it was found that out of 468 registered practices by unconventional methods for the whole country as of December 2019, in 44% (204 practices) the method “homeopathy” is applied - Fig. 9.



*Fig. 9. Proportion of the practices in Bulgaria that are registered only with homeopathy or with homeopathy together with other unconventional methods of treatment.*

Two other healing practices originate from the homeopathic healing method, which use some of the principles of homeopathy, but also have their main characteristics defining them as separate systems. These are the Schussler's salts and the Bach flower remedies.

### **The biochemistry or salts of Dr. Schussler**

The method is named after its creator and is widespread not only in Europe but throughout the world. It has been established in Bulgaria for the last 10 years.

### **The Bach flower remedies**

Flower therapy uses infusions of the flowers of 38 plants to achieve fine harmonization of the emotional and mental state of man. The founder of this method, Dr. Eduard Bach, was a famous physician and homeopath with extensive practice in London.

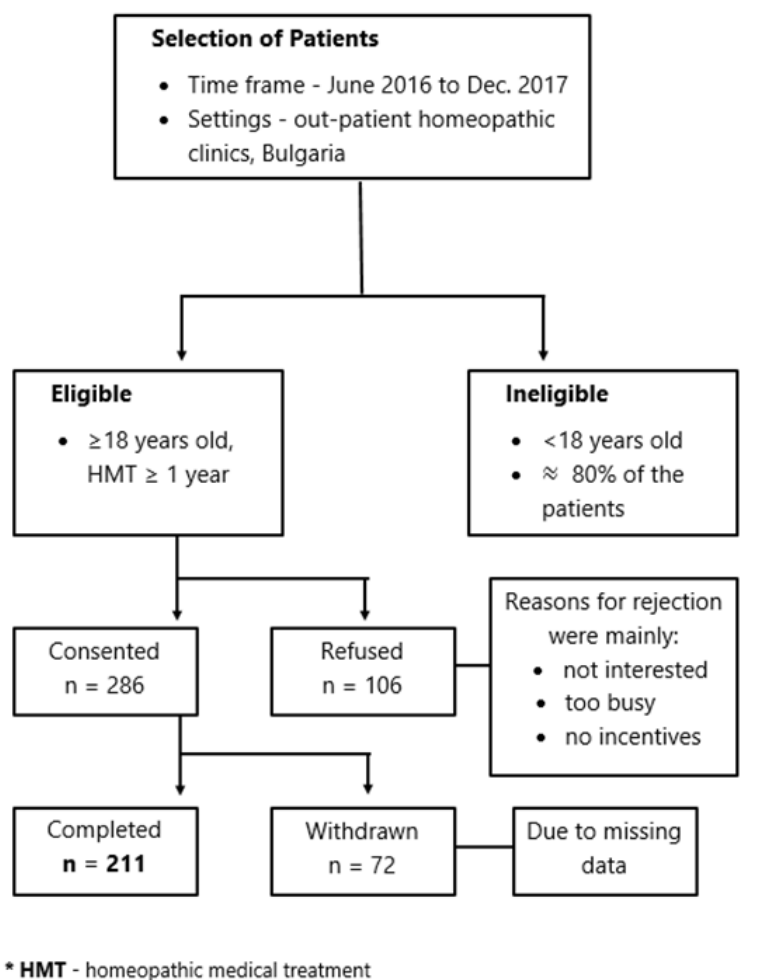
The data from the European studies, from the analyzes of NCPHA, from the registers of the practitioners of unconventional methods in the regional cities and from the professional organizations show that homeopathy is the most popular unconventional method in our country, which supports the increased research interest in the place of homeopathy in Bulgaria. the results of own research related to homeopathy presented in the next part of the dissertation.

## **4. Results of own quantitative research in the field of homeopathy**

In the period 2016-2018 year a scientific study was conducted in homeopathic clinics in the country. In fulfillment of the fourth task of the dissertation, the presented original study is three-component: 1) The socio-demographic profile of adult patients with chronic complaints ( $\geq 18$  years) who choose homeopathic treatment in Bulgaria is outlined; 2) The sources and needs of the patient for information about homeopathy and the reasons for using homeopathy are identified; 3) Health-related indicators are

measured in patients with chronic complaints (patients who have diseases requiring long-term care and show usually slow progression as a result of a combination of genetic, physiological, environmental and behavioral factors), study participants.

This study was conducted as a multi-center observation between June 2016 and December 2017 in Bulgaria. The target population of the study were patients with chronic complaints who had received homeopathic treatment for at least one year and had visited homeopathic follow-up clinics during the study period. The EQ-5D-3L tool was attached with an additional questionnaire on socio-demographic characteristics; for health data; for sources and the need for information. The sample consists of 211 respondents, recruited on the principle of the first respondent in the time period June 2016 to December 2017. The formation of the sample follows a specific algorithm (Fig. 10).



*Fig. 10. Flow diagram of sampling process and patient enrollment.*

## Results of the quantitative study

The obtained data were entered and processed with the statistical package SPSS for Windows ver. 23.0. MS Excel 2010 is used for tabular and graphical presentation of the results. The sociodemographic profile of the sample is presented in Table 1.



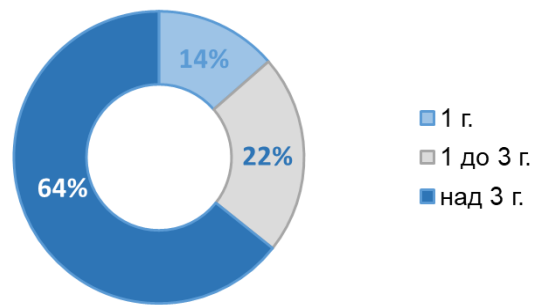
**Table 1: Sociodemographic characteristics of the sample ( n = 211, ≥18 years old)**

<b>Gender</b>	<b>Percentage (Number)</b>
<b>Female</b>	81% (171)
<b>Male</b>	19% (40)
<b>Age</b>	
18 – 24 years	3.32% (7)
25 – 29 years	7.11% (15)
30 – 34 years	14.69% (31)
35 – 39 years	31.75% (67)
40 – 44 years	23.22% (49)
45 – 49 years	8.53% (18)
50 - 54 years	4.27% (9)
55 - 59 years	4.27% (9)
60 - 64 years	1.42% (3)
> 65 years	1.42% (3)
<b>Education</b>	
Higher (University)	73.93% (156)
Secondary	22.27% (47)
Primary	3.8% (8)
<b>Profession</b>	
Health-related	18.96% (40)

**Analysis of socio-demographic characteristics of the sample** - women are 81% (171) of patients; 73.93% (156) of the patients have higher education. Although the professional profile is heterogeneous (stewardess, IT specialist, merchandiser, lawyer and many others), 18.96% (40) of patients work in various fields of public health, among them doctors, physiotherapist, speech therapist, medical representative, social worker , dentist, nurse, veterinarian and others. Younger patients predominate - 80.09% of the sample are people between 18 and 44 years old.

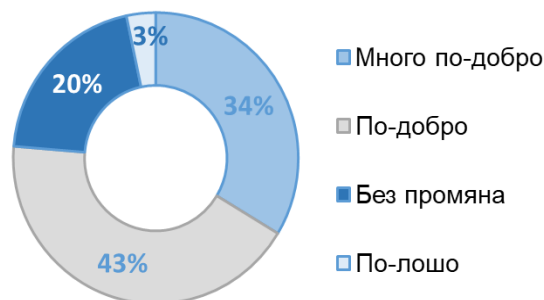
Regarding the duration of treatment with homeopathy - 13.7% (29 patients) are treated for 1 year; 22.3% (47 patients) were treated for 1 to 3 years; the largest number - 64% (137 patients) were treated with homeopathy for more than 3 years (Fig. 11). A positive correlation was found between the duration of homeopathic therapy and QOL3

( $R = 0.176$ ;  $p = 0.013$ ). Patients treated for more than 3 years reported higher LVH in all five areas.



**Fig. 11.** Proportion of patients regarding longevity of treatment with homeopathy.

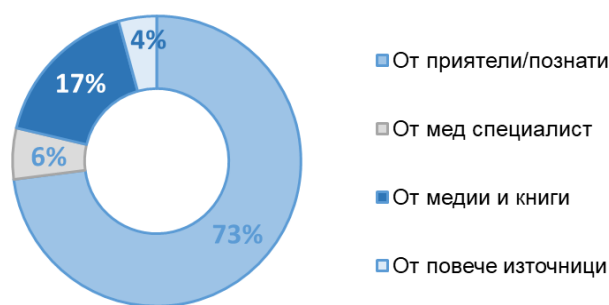
Patients were given the opportunity to assess their current health status with this 12 months ago on a four-point scale. The answers show that 33.6% (71 patients) rate their health as "much better", 42.7% (90 patients) rate their health as "better", 20.4% (43 patients) rate their health as "unchanged", and only the remaining 3.3% (7 patients) rated their health as "worse" (Fig. 12).



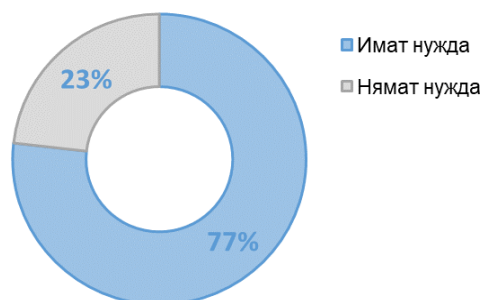
**Fig. 12.** Proportion of patients according to the current self-assessment level in comparison to the health status 12 months ago (in four levels scale - from "much better" to "worse").

To the question - "Before homeopathic treatment have you been on another type of therapy (conventional or other type of CAM)?" - 73.9% answered "Yes", as 66.4% (140 patients) were on conventional therapy. At the time of the study, 30.3% (64 patients) used homeopathic therapy as complementary to conventional or other types of CAM treatment, and 69.2% (146 patients) were treated with homeopathy alone.

The sources and need for information about homeopathy were studied (Fig. 13). The largest percentage of patients - 73% (154 patients) have learned about the homeopathic treatment method from acquaintances and friends; only 5.7% (12 patients) from their GP or other medical professional, and 17.1% (36 patients) from books, media (television, radio, internet), 4.3% (9 patients) received information from more than one from the indicated sources of information. The majority of patients need more information about homeopathy - 62.6% (132 patients) (Fig. 14).



**Fig. 13.** Sources of information about homeopathy (% patients with the multiple-choice answer).



**Fig. 14.** Needs for information from the patients - proportions of the answered "yes" or "no".

### Analysis of measurement results through the standardized EQ-5D-3L tool

Self-assessment-description of current health status: 30.3% (n = 64) of patients with good HrQoL or patients who did not report problems in any of the five areas, while 63% (n = 133) reported problems in at least one of areas; extreme problems were noted in 13 of the patients in one of the five areas. The main and summarized results of the study are presented in Table 2.

**Table 2:** Number and proportion of patients in the five EQ-5D-3L domains, according to responses/levels (absence or reporting of problems).

Level of problems*	Mobility		Self-management		Usual activities		Pain/Discomfort		Anxiety/Depression	
	Number	%	Number	%	Number	%	Number	%	Number	%
No problem	179	84.8	204	96.7	174	82.5	76	36.9	64	30.3
Some problems	32	15.2	7	3.3	36	17.1	132	62.6	133	63.0
Extreme problems	0	0	0	0	1	0.5	3	1.4	13	6.2

\* Leve of self-assessment of the problems-related to health

**Self-assessment with a thermometer (VAS):** Rate your health today: [on a scale from 0 (the worst health you can imagine) to 100 (the best health you can imagine)]. The mean health status reported through VAS in the study was 75.31 (SD  $\pm$  18.227), which is a higher mean than many of the representative population studies performed with the EQ-5D-3L. At the end (4<sup>th</sup> page of the questionnaire) the patient has the opportunity to add comments that complement their answers.

### **Conclusion from the own quantitative research:**

The results of the study outlined the country-specific socio-demographic profile of sick homeopathic patients with chronic complaints in Bulgaria: they are mostly women, with higher education and in the age groups between 30 and 50 years.

An EQ-5D-3L questionnaire to measure the quality of life of patients is attached, thus promoting the use of a standardized generic tool among homeopathic doctors as an additional reliable and scientific tool for evaluating the results reported by patients treated with homeopathy. The analysis of the comments showed that the main reasons for choosing homeopathy are:

- because it is a safe and "soft" treatment method,
- to avoid excessive use of antibiotics,
- due to lack of result from conventional treatment.

The study confirms the need for more scientific information about homeopathy. Participants state that the curriculum of medical universities must keep pace with developments in the field of CAM.

A key message is that the future of successful chronic disease management lies in the integration of conventional and CAM modalities, and these processes need to be facilitated through health legislation, modern medical education and high-level research. The presented study is a supportive action in this direction.

## **5. Results of own qualitative research in the field of homeopathy**

CAM is used to treat and prevent children around the world for many conditions and diseases.

19 semi-structured interviews were conducted with parents of 35 children (all children in the family are treated with homeopathy) with an average duration of half an hour. Some parents chose to write down their answers on paper.

Socio-demographic characteristics of the participants: By education - all have higher education; By gender: 2 fathers (parents of 3 children) and 17 mothers (parents

of 32 children, one mother was pregnant with a third child); Age - between 20 and 45 years.

Results: The parents' answers are grouped in the pre-set thematic circles / frameworks with orientation questions (10 open-ended questions):

### **First area: Choice of homeopathy**

**Questions:** Share your experience with homeopathy? Why did you choose to treat your child with classical homeopathy?

The main reasons for choosing homeopathy for the treatment of their children are: "This is a way to stimulate the immune system of the body"; "Many years of experience with homeopathy - from 18-20 years the whole family is treated with homeopathy"; "We have chosen because it is fast, effective, harmless, more gentle, safe, non-burdensome treatment"; "Ineffective treatment with standard medicine"; "Avoiding the frequent use of antibiotics"; "To avoid the constant use of antibiotics, which were prescribed to our children as often as vitamins"; "Before that (to discover homeopathy) we were in the so-called "vicious circle" of antibiotic treatment."

An interesting cultural feature - many parents call conventional therapy "traditional" or "standard", probably because it is the most widely used and recognized.

**Questions:** When do you use homeopathy for your child (prevention, treatment)? On what occasion do you treat your child with homeopathy?

The predominant answers are: "Always", "For treatment (in summary: viral and bacterial infections, allergic reactions) and prevention". Here is an eloquent comment: "Whenever we need - both for prevention and treatment. We use the family doctor (GP) only because of the mandatory vaccines and documents needed for kindergartens, schools, etc. "

### **Second area: Decision-making process related to the choice of homeopathy for treatment and / or prevention of the child within the family.**

**Questions:** Who are your family members? Who in your family decides on the treatment / prevention of the child with homeopathy? Do all family members support you and does it matter to you?

Decisions are made within the family and most often by the mother, but are not always supported by elderly parents. In general, a supportive family environment is paramount for the parents interviewed. There is no interviewee who does not note the great importance of a supportive family environment. Here are some opinions: "Me and my husband. We make the decision. No, older parents and parents-in-law, grandparents do not understand this method of treatment and believe in traditional

medicine. We are constantly accused of neglecting the health of children.”, “Mother, father and two children. The mother makes decisions. The family supports. Their support is very important. ”

### **Third area: Supportive / non-supportive environment**

**Questions:** Do your friends / colleagues support you in choosing homeopathy for your child? Does the support of the external environment (friends, colleagues) matter to you? Do you encounter obstacles in choosing homeopathy for your children? If yes - what obstacles?

Most of the interviewees are of the opinion that the environment is not decisive for their decision to treat their children and themselves with homeopathy: "Yes, friends and colleagues get in position and respect the choice. In general, the external environment does not matter, but their constant contempt and criticism of homeopathy is quite annoying. "; " In most cases, Yes."; “In the beginning, Yes (support mattered), now doesn't matter because I'm convinced of the success of the treatment. ”.

The need for the support of the family doctor comes first: "The full support and approval of our personal doctor is extremely important to me."

Some are quite emphatic: "No, I do not encounter obstacles."; "Those who use it (homeopathy) yes, others are a little reserved. It does not matter".

Others see conservatism in the environment as a major but not decisive obstacle: "The obstacles are in the stereotypes we are used to, as well as the negative attitude of some doctors."

Another conclusion from the interviews is that the parents believe that they do not encounter any obstacles to the use of homeopathy, both in terms of access to a homeopath and in finding the prescribed homeopathic medicine. "Self-medication rarely works."

### **Fourth area: The parent-patient-homeopathic relationship**

**Questions:** How do you choose a homeopath for your child? What determines your choice of homeopath?

Most of the interviewed parents are of the opinion that the key characteristics for choosing a homeopath are empathy, competence, experience, professionalism and trust: "It is crucial - the correct diagnosis of the condition and successful treatment" and "To be good and experienced"; "My homeopath was recommended to me, and then I started recommending him."; “The attitude, attention and calmness that I receive during each visit is decisive ”; “Personal contact is decisive for me. The results then rule out any doubt. Trust is crucial. ”.

In fact, the requirements for a homeopath are quite high: "Our choice was made after a recommendation from friends and so we have been treated by this doctor for almost 10 years. The determining factors are many: 1. To adequately treat my children - after a conversation to prescribe the right medicine. 2. To answer my calls outside working hours, and on weekends, holidays - so I feel calm. 3. Visits to the homeopath should not burden me and I can calmly talk and share my worries, anxieties and joys. 4. Children should like the doctor and feel at ease during examinations. And more: "At first it was the recommendation of friends. We are now sticking to the choice we have already made, because of the good professional and personal attitude and the visible results. "

## **6. Discussion of the conducted own research**

### **Discussion of the quantitative study:**

The presented study provides the country-specific socio-demographic profile in relation to people with chronic complaints who are treated with homeopathy.

The study was conducted in one of the largest outpatient homeopathic clinics in four of the largest cities in Bulgaria (Burgas, Varna, Veliko Tarnovo and Sofia), where patients from all over the country are treated. This increases its representativeness.

The presented socio-demographic characteristics (See Table 1) largely coincide with the data from other European surveys.

The levels of self-reported health problems of patients in this study are even lower than the levels reported in a previous population survey in Bulgaria. In general, patients in the study cohort ( $n = 211, > 18$  years) reported high levels of HrQoL. In addition, the longer patients received homeopathic treatment, the higher their self-esteem (VAS scores). There is a positive correlation between the duration of homeopathic treatment and the self-assessment of VAS ( $R = 0.171; p = 0.013$ ). Patients who have been using homeopathy for more than 3 years report higher BP in all five dimensions (mobility, self-medication, normal activities, pain / discomfort, anxiety / depression), but the results are not statistically significant ( $R = 0.120; p > 0,08$ ). However, at the time of the study, more than a quarter of patients ( $n = 64, 30.3\%$ ) were using homeopathic remedies as adjuncts to conventional or other forms of CAM therapy, such as traditional Chinese medicine, Schussler therapy, folk medicine, and etc .; while 69.2% are treated with homeopathic medicines only. Therefore, higher levels of HrQoL may be the result of homeopathic treatment, but further studies are needed to prove the correlation and causation. In addition, in order to register an improvement or deterioration in HrQoL, it is necessary to monitor subjective health over a period of time.

The comprehensive quantitative study confirms the public need for more scientific information on homeopathy. Many participants share the idea that not only patients need more information about homeopathy, but also doctors. The curriculum of medical universities must be harmonized with modern research related to CAM, which means that the study of unconventional medical methods in universities should be mandatory, not recommended, as medical professionals and health professionals should be competent in terms of CAM modalities. The fact that 18.96% (40) of patients work in the healthcare sector as humane doctors, nurses, veterinarians, medical representatives in pharmaceutical companies, physiotherapists, speech therapists, social workers, dentists, etc., shows that the adoption of homeopathy among The professionals community is growing. In the future, integration between conventional and CAM methods is needed and these processes need to be facilitated through education and research.

### **Discussion of the qualitative research:**

It is an indisputable fact that more and more parents choose CAM for their sons and daughters, grandchildren, for the children they are guardians of.

Parents' decision to use CAM for their child is often influenced by various factors. One such factor is interaction with family, friends, health professionals and teachers. From a social point of view, the media can also play a significant role in the decision-making process of parents. Worryingly, many parents are influenced by information read on the Internet, which has an unclear source and is not always accurate. It has been found that people who follow a nature-friendly lifestyle try to treat themselves and their children with CAM methods.

Benefits for the research team from own research: data collection and development in an area of interest to the team. The study led to a clear outline of the concept of CAM and to deepen the knowledge related to the benefits of CAM and in particular homeopathy. Such a study - "CAM, homeopathy and HrQoL" - is done for the first time in Bulgaria and has the potential to continue if possible.

Benefits for participants: by assessing HrQoL, patients receive additional attention and individual care, which is an added value / benefit to homeopathic therapy.

## **7. Place of CAM in the Bulgarian healthcare - final integration and interpretation of the scientific results**

The WHO defines three types of health systems according to the degree of official integration of T&C in public health: Integrative system, Inclusive system and Tolerance system.



According to the mentioned criteria of the WHO and the analysis of the CAM in Bulgaria made so far, the system in our country is inclusive.

In order to achieve an integrative system, some obstacles need to be overcome:

- Not all unconventional methods are included in the legislation.
- There is no general register of practitioners of unconventional methods in Bulgaria.
- Ensuring patient safety, quality and efficiency of CAM services requires standards in education and research.
- It is also important to achieve accessibility and rational use of CAM.
- The main task should be the generation and dissemination among society and in professional and student communities, scientific knowledge and evidence related to the benefits of CAM.

The analysis of the presented own researches and conclusions in the field of homeopathy leads to the formation of the following approaches: 1) wider understanding and social promotion of homeopathy as CAM in Bulgaria; 2) greater appreciation of the importance of evidence-based homeopathy for public health; 3) growing interest in the use of HrQoL-tools as patient-reported results in the monitoring of therapies for chronic conditions, including CAM and in particular homeopathy. Subjective assessment of health is a way to "hear" the patient's voice. Such research in the Bulgarian and regional context has not been conducted and published. This fact shows the social significance of the present study.

### **III. CONCLUSIONS, RECOMMENDATIONS AND CONTRIBUTIONS**

#### **AUDE SAPERE!**

#### **CONCLUSIONS**

In connection with the aim of this dissertation, the study went through five objectives, the implementation of which led to the formulation of the following conclusions:

1. The development of the European concept of "complementary and alternative medicine" (CAM) is the result of more than 20 years of research and policy efforts provoked by WHO strategic documents.

2. After the situational analysis, including a classic SWOT analysis, it can be said that for the establishment of CAM in the Bulgarian healthcare it is necessary to use the following types of strategies: collaborative, communication and constructive.

3. CAM on a national scale - the historical and scientific development of the types of CAM therapies in Bulgaria shows that they are actively present in society and need to be correctly and comprehensively represented in the scientific community, the medical community and civil society. This requires the dissemination of information and networking of stakeholders.

4. Conclusions from the study of the socio-demographic profile and health-related results of patients with chronic complaints who have been treated for more than a year with homeopathy - the most common CAM method in Bulgaria.

- The presented study showed that the socio-demographic profile of patients treated with homeopathy is similar to the European profile of homeopathic patients.
- Awareness regarding the CAM method - homeopathy is insufficient.
- EQ-5D-3L - the questionnaire is a practical and a valid way to measure subjective health during treatment with CAM.

5. Conclusions from the study of the reasons for the choice of CAM-method, specifically of homeopathy, in the treatment of children.

- The choice of homeopathy for the treatment of children is primary (parents strive to lead a healthy lifestyle) or secondary (after not achieving the desired result of conventional therapy).

- The decision is made by the family, but the environment is also very important, which in most cases is not supportive.
- Communication with and trust in the therapist is very important for parents.
- Parents treat their children with homeopathy for a long time, because acute conditions respond quickly, chronic complaints decrease or disappear and they trust the doctor - homeopath.

## RECOMMENDATIONS

The WHO recommends that each country should develop policies to develop T&CM. Every national policy must reflect the cultural specifics, but the general one is planning and future direction, leading to the integration of CAM in the health care of each country.

After creating the picture of the CAM methods in Bulgaria, analyzing the specific situation and taking into account the national peculiarities and the conclusions made, the following recommendations are formed:

**Recommendations at the level of national health policy for CAM** - it is necessary to cover all CAM practices that are widely used in our country.

Any successful and sustainable policy is based on a detailed study of the area it will regulate. The initial study of CAM in the specific country, which precedes the creation of a national policy, allows for a real classification of the types of therapies according to the specifics of CAM specifically for Bulgaria. This is the basis of appropriate policies and adequate regulations concerning CAM products, therapies and practitioners, as well as promoting equal access and integration of CAM in the national health system. For this purpose, it is necessary to involve CAM experts in the creation of specific legal provisions related to CAM at the national level.

**Recommendations for investing in CAM research** - Knowledge-based policy is the key to integrating CAM into national health systems. Research must be prioritized and financially supported to generate knowledge. Although much can be learned from controlled clinical trials, other research approaches also provide valid and reliable scientific information. These include post-marketing studies of results and effectiveness, as well as comparative studies of effectiveness, use patterns and other qualitative methods.

Recommended priority areas for research, based on WHO guidelines: efficacy, safety and cost-effectiveness of each therapy; study of the mechanisms of action and models of response to treatment; public health research to motivate patients seeking and using CAM.

**Recommendations at educational level:** Creation of educational standards in the field of CAM. The guarantee of quality CAM therapies also requires standards for the education of the providers of these therapeutic services. There is also a lack of regulated postgraduate training of conventional specialists on the basic CAM methods.

**Recommendations at the level of professional integration:** Communication is needed between conventional doctors and CAM practitioners. Insufficient to absent,

and communication about CAM capabilities between conventional physicians and users (eg, between family physician and patient) is much needed.

**Recommendations at the social level:** In general, the gap of missing information in the society for rational use of CAM methods should be filled - when, how and how much to use and combine with other methods.

**Recommendations at the level of legal and ethical aspects:** Guaranteeing the rights of health care users - free choice based on information. The use of CAM is increasing rapidly, but risk assessment and recommendations on how to avoid these risks are not guaranteed.

**Recommendations of professional and patient organizations:** In Bulgaria there are strong professional (of the providers of CAM) and patient organizations, which should be considered and allowed representatives of these organizations as experts in the process of forming national and regional policies, as well as in the formulation of priority scientific directions.

## **CONTRIBUTIONS**

Contributions of an original character:

1. For the first time an attempt is made to create a complete picture of CAM in Bulgaria and the factors influencing the integration of CAM in healthcare are analyzed. In this direction, the first steps are being taken to stimulate the development of a national policy to ensure the quality, safety and accessibility of CAM methods.

2. For the first time, the concepts of CAM, homeopathy and HrQoL are brought together in one study, which is a contribution to the research in the field of CAM.

3. For the first time in our country a study is conducted in the field of CAM, specifically in patients treated with homeopathy, to assess the health status of patients using a standardized generic questionnaire for the assessment of HrQoL. A tool developed and validated by the European Expert Group EuroQol - EQ-5D-3L - Health Questionnaire - Bulgarian version is applied.

**Contributions of a practical character:**

1. The application of a converging parallel mix method design, consisting of three separate parallel phases with the same priority, the data of which are subsequently integrated to be interpreted and to draw conclusions and recommendations at the end of the study, is an innovative approach. in the field of research related to CAM. The present study shows that when used in combination, quantitative and qualitative methods complement each other and allow for a comprehensive analysis.

2. The own research shows in practice how the quality of life related to the health of patients can be studied and possibly monitored. The EQ-5D-3L Health Questionnaire used is an accessible and easily applicable tool for measuring subjective health assessment.

## CONCLUSION

From the presented research and analysis, it can be concluded that the present dissertation reflects public health trends and approaches.

In 2017 The WHO's T&C department has been renamed with the introduction of the term "Integrative Medicine" (IM) to cover the integrative approaches of both T&KM and conventional medicine in terms of policy, knowledge and practice. The department is now officially called "Traditional, Complementary and Integrative Medicine" (TCIM). The term "integrative medicine" combines conventional methods, health promotion, research and CAM, and "the compound makes strength" (Latin Virtus Unita Fortior)!

Great advances in diagnostic and treatment technologies in conventional medicine, together with proven in history and practice holistic treatment methods, and with the active participation of the person responsible for their health, can create harmony and prosperity in society.

### **Publications related to the topic of the dissertation:**

1. **Kapincheva, I.**, 2017. Homeopathy - basic principles and historical review of development in Bulgaria, Asklepios, East-West: Sofia, Volume 13, issue 1, pp. 164-168.

2. **Kapincheva, I.**, Vankova, D., 2018. The European concept of "complementary and alternative medicine" (CAM) - history, nature and place in public health, Social Medicine, issue 2, pp. 18-22.

3. Vankova, D. & **Kapincheva, I.**, 2019. Investigating the sociodemographic profile and health-related outcomes of chronically ill homeopathic patients: results from an observational multi-centered study in Bulgaria, BMC Public Health, 19: 1648. <https://doi.org/10.1186/s12889-019-7914-7> , *Impact Factor: 3.275 (for 5 years)*

### **Participation in scientific and educational forums related to the topic of the dissertation:**

1. **Kapincheva, I.**, Vankova, D., 2016. Health-related Quality of Life (HrQoL) and Homeopathy: a Mixed-Methods (MM) survey in Bulgaria, accepted as a poster presentation in the Methodology Session (Friday, Nov. 18., 2016- 13.25-13.40) at the First European Congress for Homeopathy, Vienna 17-19.11.2016 - участие с постер

2. **Kapincheva, I.**, September 14-15, 2018. - lecturer in a course in the history of medicine for postgraduate education, organized by the Bulgarian Society of the History of Medicine and the Department of Social Medicine and Health Care Organization -

Medical University - Varna - IV module - participation with a lecture on "History of the concept CAM and its historical development in Bulgaria".

3. Vankova, D., **Kapincheva, I.**, 2019. Mixed–Methods (MM) Homeopathy Research of the 3 H<sup>s</sup> : History, Health-related Quality of Life (HrQoL) and Hearing the voices of the parents in Bulgaria, HRI 4<sup>th</sup> International Homeopathy Research Conference Cutting Edge Research in Homeopathy London, 14-16 June 2019 - участие с постер



# ПРИЛОЖЕНИЕ 1. EQ-5D-3L ВЪПРОСНИКЪТ



**Въпросник за здравословното състояние**

**Българска версия**  
*(Bulgarian version)*

*Отделете ни 10 минути, за да инвестирате в своето здраве!*

<i>Попълва се от изследвателя</i>					
ID					
Здравословно състояние					
Термометър					

За всяка група твърдения по-долу, моля, отбележете кое твърдение описва най-добре какво е здравословното ви състояние днес. Поставете кръстче в квадратчето срещу твърдението, което сте избрали (има само един възможен отговор).

### **Подвижност**

Нямам никакви затруднения, когато ходя насам - натам.

Имам известни затруднения, когато ходя насам - натам.

Прикован/а съм на легло.

### **Самообслужване**

Нямам никакви затруднения да се самообслужвам.

Имам известни затруднения, когато се мия или се обличам.

Не мога сам/а да се мия или да се обличам.

### **Обичайни дейности** (*напр., работа, учене, домакинска работа, дейности, свързани със семейството или с прекарване на свободното време*)

Нямам никакви затруднения, когато извършвам обичайните си дейности.

Имам известни затруднения, когато извършвам обичайните си дейности.

Не съм в състояние да извършвам обичайните си дейности.

### **Болки/Неразположения**

Не изпитвам никакви болки или неразположения.

Изпитвам умерени болки или неразположения.

Изпитвам изключително силни болки или неразположения.

### **Тревожност/Депресия**

Не съм тревожен/тревожна или депресиран/а.

Умерено съм тревожен/тревожна или депресиран/а.

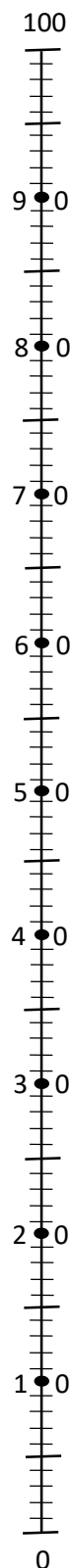
Изключително много съм тревожен/тревожна или депресиран/а.

За да Ви помогнем да определите доколко добро или лошо е здравословното Ви състояние, сме начертали скала, приличаща на термометър. В горния ѝ край със 100 е означено най-доброто състояние, което можете да си представите, а в долния с 0 - най-лошото.

Моля, отбележете на скалата доколко добро или лошо, според вас, е здравословното Ви състояние днес. За да направите това, моля, прекарайте права от черния правоъгълник по-долу до онази точка на скалата, която показва колко добро или лошо е здравословното Ви състояние днес.

Вашето  
здравословно  
състояние днес

Най-доброто здравословно  
състояние, което можете да  
си представите



Най-лошото здравословно  
състояние, което можете да  
си представите

#### 4<sup>та</sup> страница за пациенти лекувани повече от една година.

Анкетата е анонимна. Моля, отговорете на зададените по-долу въпроси, като маркирате в квадратчетата, или напишете вярното твърдение !

1. На каква възраст сте, в години? ..... ГОДИНИ

2. Вие сте: МЪЖ  ЖЕНА

3. С какво образование сте?

Висше – магистър, /бакалавър

Средно гимназиално (до 12<sup>-ти</sup> клас)

Друго, моля посочете.....

4. Работили ли сте или работите сега в здравеопазването или в социалната сфера?

Да , Не

Ако „Да“ - Какво точно работите? .....

5. От кога сте на хомеопатично лечение?

От 1 година , от 1 до 3 години , повече от 3 години

6. Преди хомеопатичното лечение били ли сте на друг вид терапия?

Да , Не

(вижте определенията за 'алтернативна терапия' и 'конвенционална терапия', посочени на последната страница)

Ако 'Да', каква точно?

Конвенционална ,

алтернативна (неконвенционална) ,

друга терапия  - Каква точно?.....

7. Сега заедно с хомеопатичното лечение използвате ли друг вид терапия?

Да , Не

**Ако ‘Да’, каква точно?**

- конвенционална ,
- алтернативна ,
- друга терапия  - Каква точно?.....

**8. Как ще оцените цялостното си здравословно състояние днес в сравнение с това преди 12 месеца? Моето здравословно състояние днес е:**

- Много по-добро ; По-добро ; Без промяна ; По-лошо

**9. От къде научихте за хомеопатията като лечебен метод?**

- От книги, медии (телевизия, радио, интернет) ;
- от познати ;
- От личния си лекар или друг медицински специалист

**10. Имате ли нужда от повече информация за хомеопатията?**

- Да , Не

**11. Моля, добавете, ако желаете, коментари, които биха ни помогнали да разберем по-добре отговорите ви!**

.....

.....

.....

.....

.....

## **Пояснения:**

### **Наредба №7 от 1 март 2005 г.:**

“Неконвенционални методи за благоприятно въздействие върху индивидуалното здраве” са методи, чието изучаване не е включено в учебните програми на висшите медицински училища. Тези методи не трябва да предизвикват влошаване на здравословното състояние на гражданите и се прилагат единствено с цел постигане на благоприятно въздействие върху индивидуалното здраве.

*Настоящата анкета се провежда в рамките на проучване, което изследва хомеопатията като лечебен метод и неговото влияние върху качеството на живот, свързано със здравето.*

*Вашето участие е важно за нас. Благодарим Ви!*

## ACKNOWLEDGMENTS

I have gone through many trainings and practices in my life.

I am grateful to all my teachers!

I would especially like to thank **Assoc. Prof. Dr. Nevyana Feschieva**. A very dear person and a teacher for me not only in social medicine and the history of medicine, but also in life. Thank you!

Thanks to my supervisor **Assoc. Prof. Dr. Desislava Vankova**. Without her, I would not have succeeded.

Thanks for the exceptional teamwork and for the lessons I learned!

And if what is written in this dissertation seems to you only a theory and you do not believe in these methods, I want to say:

**We are all connected in an amazing, beautiful world in which no one is alone and the path is never the only one. Let's listen to each other, let's help each other, let's go together!**

**Let it be light!**