

Clinical Research in Homeopathy (Literature Review)  
M.S. Tomkevich  
(Research Institute of Traditional Medicine GOU VPO RGMU Roszdav, Moscow)

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MS Tomkevich  
SRI of traditional medicine SEI HPE RSMU Roszdav (Moscow, Russia)

#### RESUME

This article provides an overview of modern clinical investigations in homeopathy. Various conditions of these investigations are discussed. A need of metodological discussion to look for optimal way for determining of homeopathic remedies efficacy is discussed. There is a signed opinion that there must be various investigation ways depending on kind of using of homeopathic remedies - classical way, way of symptomocomplex and affinity of remedy, or in accordance with medical indications.

Keywords: homeopathic remedies, Clinical investigations, Placebo-controlled blind investigations, design of cinal investigation for homeopathic remedy.

#### SUMMARY

The literature review provides the latest data on clinical trials in homeopathy. Possible conditions for conducting research according to general rules and the need for discussion on the most adequate study of the clinical efficacy of homeopathic medicines are discussed. An opinion is expressed about the need for a different approach to research, depending on the purpose of the homeopathic drug - its use for medical indications, or individualized, or according to the rules of homeopathy in accordance with the affinity of the drug.

Key the words: homeopathic medicines, clinical research, placebo controlled blind studies, clinical trial design for a homeopathic medicine.

#### Introduction

The struggle for the drug market has been going on ever since the pharmaceutical industry began to develop. The present period of time also has all the signs of this struggle, which is characterized by competitive relationships between different manufacturers of pharmaceutical products and their joint opposition to the development of the production of homeopathic medicines and an increase in their consumption. This is what underlies the periodically appearing bursts of information that someone has already banned or should be banned from the use of homeopathic medicines. For example, the 2010 Memorandum of the Royal Pharmaceutical Society of Great Britain [56] states that it is necessary to develop methods that can prove the effectiveness of homeopathic medicines, and until this is not the case, the idea of effectiveness should be abandoned and patients should be informed that there is no scientific basis for the existence of homeopathy. In addition, the question of what exactly attracts patients - the effectiveness of drugs or the "homeopathic package of services" itself, in which the psychological aspects of counseling play an important role, should be explored. It is necessary to find out whether homeopathy by its existence compromises conventional medicine, as well as to find out the price-effect relationship for homeopathic treatment.

Partly in this formulation of the question there is the fault of the homeopaths themselves, who are so confident in the action of drugs that they neglect the accepted methods of assessment and do not have or do not have enough evidence to refute.

However, one should take into account the fact that homeopathy, like all traditional medicine, is built on a different principle - here the medical approach is based on the methodology characteristic of each direction of traditional medicine, and not a formalized technology adopted to assess the effectiveness in evidence-based medicine. This is the very "bottleneck", the "weak link" of a small (in the sense of a market segment), but significant (in terms of centuries-old traditions) traditional



pharmaceutical treatment is insufficient. According to Kienle et al. [41], the effectiveness in the treatment of Alzheimer's disease is 30%, bronchial asthma - 60%, cardiac arrhythmias - 60%, rheumatoid arthritis - 50%, etc.

Two years ago (since October 2009), a detailed review of the homeopathy method was carried out by the Scientific and Technical Committee of the British Parliament at the initiative of a group of young scientists and the pharmaceutical association. The discussion discussed the following: what studies are known, what pros and cons exist, what studies will meet the needs of patients and contribute to the development of the method. The same young scientists, by the way, not doctors, employees of University College London, achieved in WHO a ban on homeopathic treatment of human immunodeficiency, influenza, malaria, tuberculosis and childhood diarrhea, although randomized clinical trials were carried out on these diseases with positive results in Nicaragua, India and other countries, summarized by meta-analysis [18, 35, 48]. A particularly large number of clinical trials are known for influenza-like syndromes in homeopathy [25, 63]. How can homeopaths respond to such a struggle of ideologies, are they ready not with words, but with research to defend their life's work? Looking ahead, the British Parliament debate ended in support of homeopathy.

There are different areas of research activity regarding homeopathic medicines - provings, i.e. determination of the properties of drugs according to F.H.S. Hahnemann, demonstration and analysis of the effectiveness of a homeopathic drug in accordance with the drug affinity (for example, the effect of arnica on microcirculation), the so-called "standardized" therapy, the classical homeopathic approach, the so-called "individualized" therapy, clinical trials of homeopathic medicines (mono- and complex) for widespread use for medical reasons. In the aspect of clinical trials, it should be understood that each option for applying the method requires careful thought and understanding of the work even at the level of setting the problem, so that statistical processing becomes a tool of assistance, and not a punishing right hand.

#### Provings, or the first stage of modern clinical trials

215 years ago F.H.S. Hahnemann, among other rules of homeopathy, proclaimed that it is possible to find out the properties of medicines by causing the use of this substance in a healthy volunteer to have a medicinal disease (pathogenesis of the medicine). These trials in homeopathy came to be called provings, from the English word for proof.

The International Homeopathic League, together with the European Committee for Homeopathy, have developed rules for conducting provings. According to these rules, provings are carried out in strict accordance with the rules for the first phase of clinical trials [31]. To confirm the validity of provings according to this methodology, a blind clinical study was carried out [75], in which the necessary participation of homeopaths was to determine whether the signs of a developing drug disease were consistent with the known properties of drugs. The study lasted 4 weeks - the first 7 days of follow-up, then 5 days of drug intake and 16 days of follow-up. Healthy volunteers - participants in the study - were divided into three groups: a placebo and two homeopathic preparations diluted with C12, which should have been taken five grains a day for five days. According to the developing symptoms, the homeopaths-participants of the study identified with high accuracy the drugs they were taking - Arsenicum album and Natrium muriaticum.

The author of this review for many years (long before the introduction of new proving rules) included proving as a routine technique in the learning process. Taking the drug for 3-5 days, as a rule, always caused the development of drug pathogenesis, which had a rapid reverse development.

#### Placebo or medication

Research in homeopathy more often looks at the effectiveness of homeopathic dilutions versus placebo. The current view is that homeopathic counseling itself has a curative effect that can be independent or synergistic with the prescribed medication. The present work [76, 77] is aimed at defining and assessing the role of "active participants" in the homeopathic approach. It is assumed that in the action of homeopathic treatment there is a contribution of the psychological aspect of the medical consultation itself. Does the drug itself have biological activity? This has been shown many times experimentally [1]. In a clinical study [77], while prescribing an individualized homeopathic medicine, half of

18 patients had homeopathic deterioration, one had proving symptoms, several responded not to the first dose, but to subsequent ones - all this indicates that the homeopathic medicine cannot be considered a placebo, which means that it has a certain biological activity. However, the authors suggest that it is more correct in the studies conducted to compare the effect of a homeopathic medicine not with a placebo, but with a standard of treatment or with the action of another, similar homeopathic, consultation. The placebo does not reflect the essence of the task, because the homeopathic consultation carried out has a certain curative effect.

In another study [61], the authors compared the placebo effect in 25 paired, double-blind, placebo-controlled clinical trials of classical homeopathic medicines and pharmaceuticals. The criteria for comparison were the severity of the condition, the duration of treatment, and the final results. In this study, the role of placebo was comparable to that of classical homeopathic medicines.

Many articles suggest that the design of homeopathic trials should be improved in order to bring it closer to the accepted concept of clinical trials, but not lose the features inherent in homeopathy [42].

Based on the personal experience of the author of this article, when discussing study design, it should be borne in mind that there is little point in double-blind studies in homeopathy. 20 years ago, the author took part in a large study on the effectiveness of the homeopathic method of treatment for skin diseases, organized at the Research Institute of TML of the Ministry of Health of the Russian Federation (director - Academician of the Russian Academy of Medical Sciences V.G. Kukes) and observed the senselessness of "blinding" a homeopathic doctor. A week later, at the second visit, the "blinding" of the doctor disappears, and the study design remains the same. A similar attitude towards blind research in homeopathy is expressed in the article [58].

P. Fisher et al. [26] report different options for conducting clinical trials in dermatitis and a wide range of results, according to which it can be concluded that there is a significant difference between the results of a "blinded" and non-blind study.

Other articles [79, 13] criticize modern homeopathic research as being conducted by a diverse group of researchers - either university researchers or homeopathic practitioners. The first focus on blind and randomized trials, the second on case description, selection of an individual means, i.e. both sides speak different languages. Therefore, the authors propose that professional homeopaths and clinical trials be included in the study without fail.

Their correctness is indirectly confirmed in the following work. The study was carried out in the center of Norway in the town of Trondheim with a population of 150,000 [73, 74] and included all frequently ill children under 10 years of age living in this town. In the work, carried out in principle without the participation of homeopaths, for the prevention of morbidity, the three drugs most often prescribed by homeopaths were selected (*Calcarea carbonica*, Sulfur, *Pulsatilla* in C30 dilution). Of the three proposed remedies, the most appropriate was chosen by the parents according to the description of the drug. There was no positive effect on disease prevention when followed for 12 weeks in this study. However, a global conclusion about the ineffectiveness of the homeopathic method cannot be made in this case, since there are doubts about the correct prescription of drugs.

Of interest is a cohort study of long-term treatment outcomes for a large group of patients [82]. The study included patients who first applied to one of 103 general medical practice offices in industrial cities of Germany and Switzerland, in which doctors additionally mastered the homeopathic method. A total of 3981 patients over the age of one year were under observation. The authors showed that the quality of life of patients and the severity of his disease during observations for 24 months had a positive trend. The authors believe that homeopathic treatment may play a predominant role in the long-term management of patients with chronic diseases. Homeopathy appears to be scientifically implausible, but it is widespread [47]. The work is aimed at to evaluate the clinical effects of homeopathic medicines in a randomized clinical trial and how they differ from placebo. 185 studies were analyzed, 119 had inclusion criteria, 89 had adequate data for a meta-analysis, and two studies assessed reproducibility. 89 studies show a high level of confidence in favor of the homeopathic method. In the rest of the cases, the reliability was questionable, however, a trend of difference from placebo was indicated. The authors argue that research in homeopathy lacks consistency to demonstrate reliability and reproducibility. The Memorandum of the British Homeopathic Association [55] provides data 89 had adequate data for meta-analysis, and two studies evaluated reproducibility. 89 studies show a high level of confidence in favor of the homeopathic method. In the rest of the cases, the reliability was questionable, however, a trend of difference from placebo was indicated. The authors argue that research in homeopathy lacks consistency to demonstrate reliability and reproducibility. The Memorandum of the British Homeopathic Association [55] provides data 89 had adequate data for meta-analysis, and two studies evaluated reproducibility. 89 studies show a high level of confidence in favor of the homeopathic method. In the rest of the cases, the reliability was questionable, however, a trend of difference from placebo was indicated. The authors argue that research in homeopathy lacks consistency to demonstrate reliability and reproducibility. The Memorandum of the British Homeopathic Association [55] provides data to demonstrate reliability and reproducibility. The Memorandum of the British Homeopathic Association [55] provides data

complete systematic reviews of randomized clinical trials in homeopathy, which concluded that homeopathy was different from placebo [43, 17, 21, 47] (Tables 2, 3).

table 2

Summary table of clinical trial results relative to different controls

Результаты клинических испытаний (всего 142)				
Контрольная группа (142 исследования)	Положительные результаты	Отрицательные результаты	Статистически незначимые результаты	Всего
Плацебо (85 %)	52 (43 %)	3 (3 %)	65 (54 %)	120
Другие виды сравнения, не плацебо (15 %)	11 (50 %)	8 (36 %)	3 (14 %)	22
<b>Всего</b>	<b>63 (44 %)</b>	<b>11 (8 %)</b>	<b>68 (48 %)</b>	<b>142</b>

Table 3

Summary table of clinical trial results in relation to different methods prescribing the drug

Результаты клинических испытаний (всего 142)				
Способ назначения препарата	Положительные результаты	Отрицательные результаты	Статистически незначимые результаты	Всего
Индивидуализированный	18 (45 %)	3 (8 %)	19 (47 %)	40
Стандартизованный	45 (44 %)	8 (8 %)	49 (48 %)	102
<b>Всего</b>	<b>63 (44 %)</b>	<b>11 (8 %)</b>	<b>68 (48 %)</b>	<b>14</b>

One review pointed to “insufficient evidence to conclude efficacy in all cases” [47]. Another systematic review concludes “there is little evidence for the specific effect of homeopathic medicines” [70], and the methodology of this review and its conclusions have been challenged [50]. These studies have shown efficacy for childhood diarrhea, postoperative ileus, seasonal allergic rhinitis, and dizziness. It has not been shown to be effective for ADHD and migraine. The value of such comprehensive systematic reviews is limited due to the small number of randomized clinical trials conducted in homeopathy, the different criteria used by reviewers to analyze the data, the different levels of homeopathic research, the narrow focus in placebo-controlled trials, different levels of medical conditions (diseases) studied in a particular situation, as well as those factors that are given in the first part of this article. One of the first and most comprehensive systematic reviews was the review by Kleijnen J. et al. [43]. The data of this analysis are presented in table. 4.

Table 4

The results of the analysis of clinical trials in homeopathy according to Kleijnen J. et al. [43]

Патология	Позитивные данные из общего числа исследований
Сердечно-сосудистые заболевания	4 из 7
Инфекции дыхательных путей	13 из 19
Другие инфекции	6 из 7
Болезни желудочно-кишечного тракта	5 из 7
Постоперационный илеус	5 из 7
Поллиноз	5 из 5
Ревматические болезни	4 из 6
Травмы и боли	18 из 20
Психологические проблемы	8 из 10
Другие заболевания	13 из 15

The attitude towards homeopathy in the United States [57] is associated with a lack of quality clinical research and educational programs. Recently, however, there have been good works published in peer-reviewed journals. For several reasons, critics of homeopathy in the United States are alarmed - even well-organized research does not lead to practice. The main direction of treatment is individualized. Critics believe that such differentiated (individualized) treatment is inappropriate in research. Maybe it is worth changing the rules of research, rather than adjusting age-old methods to the newly emerging rules? Research protocols that include complex homeopathic medicines for other reasons fall into the same category of non-eligible. One of the most common problems cited in these cases is the lack of examination. Homeopaths, in turn, they criticize clinical trials and their analysis for choosing the wrong homeopathic medicine, or dilution, or conditions of use, and also object to conducting a meta-analysis of clinical trials in homeopathy. For example, the design and subsequent conduct of a study with negative results in migraine is heavily criticized by Vithoulkas (report to the International Congress of the Homeopathic League, 1997).

But while the debate around homeopathy takes place in the academic medical community, the population is increasingly opting for homeopathic counseling and homeopathic medicines. In many countries, homeopathy and other complementary areas are integrated into the arsenal of the modern doctor. According to research done in 1995 (published in: the Journal of the American Board of Family Practice [41]) 69% of family doctors in the United States are interested in and study homeopathy. This interest is growing and demands academic quality of work from the practicing physicians of homeopathy.

As an interesting historical fact, one can cite information about the sponsorship of the research on homeopathy by the British government during the Second World War. These studies were related to the prevention and treatment of lesions with a chemical warfare agent such as mustard gas. As a means of prophylaxis, the effect of mustard gas itself was studied in a dilution of C30, and for treatment - the effect of homeopathic preparations *Rhus toxicodendron* C30 and *Kalium bichromicum* C30. The study obtained positive results, published in 1944 [9]. Curiosity! In the heat of the struggle for a place under the sun in the world of medicines, other implementations of the homeopathy method in different directions of our life remain unnoticed.

#### Clinical trials for standardized and individualized prescriptions homeopathic medicines (examples)

Homeopathic medicine *Arnica montana* is one of the most commonly used homeopathic medicines. In homeopathy, this drug is widely used in trauma and hematomas, as well as to restore microcirculation. Various studies have been devoted to clarifying the effectiveness of *Arnica* in different dilutions for pain due to muscle stress, trauma, in the pre- and postoperative period and other situations. When *Arnica* 200C was used in a double-blind study for problems after muscle load [65], it was shown that muscles recover faster with an increase in their volume; muscle enzymes used to control their damage quickly restored their original value. A pilot study evaluated the efficacy and safety of *Arnica* 12C in patients in the pre- and postoperative period.

with phlebectomy [83]. Ernst E., Pittler MH [23, 24] describe the benefits of Arnica in 16 patients. And in randomized clinical trials on the postoperative efficacy of Arnica, no clear result was found [12]. When discussing the problems of homeopathy in the British Parliament, Mr Wilson [81] reported data on a study conducted at the Charité Hospital in Berlin. This study involved 3700 patients, which showed the great benefits of using Arnica in patients with long-term chronic situations, including bleeding tendencies and in the postoperative period. There are similar data in other articles [49, 69].

Over the past 30 years, 83 studies, known in the literature, have been carried out on the effectiveness of the homeopathic method for the treatment of respiratory allergies, upper respiratory tract infections, ENT diseases and rheumatic diseases. The analysis included randomized and non-randomized trials [12]. It has been found that the homeopathic method can play an essential role in some situations. For example, the homeopathic preparation *Galphimia glauca* (in low dilutions) has been shown to be highly effective in allergic rhinoconjunctivitis, *Anas barbariae* (in high dilutions) in influenza-like syndromes, classical individualized homeopathic treatment for otitis media, allergic problems and fibromyalgia, and complex low dilutions of homeopathic remedies in sinusitis, rhinoconjunctivitis, arthritis, etc. It is shown that the result of the provision of primary care with homeopathic medicines is not worse than that of the one usually used in conventional medicine. There are reviews on the effective use of homeopathic remedies in children [4], in rheumatic diseases [36], in oncopathology [59], as well as for the treatment of complications from chemotherapy [38].

147 cases of respiratory allergies (allergies of the ear, nose, throat, lungs) showed a high reliability (87.6%) of the effectiveness of homeopathic treatment [20]. The most commonly used drugs were *Lycopodium*, *Pulsatilla*, *Sulfur*.

30 patients with chronic primary insomnia in a randomized, double-blind, placebo-controlled study received individualized homeopathic treatment [60] with a pronounced positive effect.

There are 4 positive systematic reviews on the treatment of allergies with homeopathy [10, 11]. There are conceptual and historical links between homeopathic medicine and allergic desensitization. In both cases, small doses of substances that can cause symptoms are used in order to prevent or treat the hypersensitivity condition [78]. The article analyzes the positive results of using the method of homeopathy for respiratory allergies. The results of 4 double-blind randomized clinical trials of the effect of homeopathic medicines in 30C dilution [34] in allergic asthma and rhinitis have been published. One of the most recent studies on house dust allergy shows preliminary results that the effect of homeopathic medicines differs from placebo, which is explained by the complex theory of the functioning of the organism as a whole. Hamre HJ et al. [32] conducted an interesting analysis comparing two large groups of patients from the USA, Austria, Germany, Great Britain and the Netherlands who received standard therapy (301 people - group 1) and homeopathic medicines, including anthroposophic, or herbal remedies (963 people - group 2) in the treatment of acute diseases of the upper respiratory tract. The performed analysis indicates a statistically significant improvement registered in patients of the 2nd group in the period from 1st to 3rd day and on the 7th day of the disease, as well as the preference of patients with this particular type of treatment. who received standard therapy (301 people - group 1) and homeopathic medicines, including anthroposophic ones, or herbal remedies (963 people - group 2) in the treatment of acute diseases of the upper respiratory tract. The performed analysis indicates a statistically significant improvement registered in patients of the 2nd group in the period from 1st to 3rd day and on the 7th day of the disease, as well as the preference of patients with this particular type of treatment. who received standard therapy (301 people - group 1) and homeopathic medicines, including anthroposophic ones, or herbal remedies (963 people - group 2) in the treatment of acute diseases of the upper respiratory tract. The performed analysis indicates a statistically significant improvement registered in patients of the 2nd group in the period from 1st to 3rd day and on the 7th day of the disease, as well as the preference of patients with this particular type of treatment.

Homeopaths choose a remedy for depression based on the individualization of symptoms and case history. This study was devoted to clarifying what is more important: the specific effect of individualized Q-potencies of the drug or other approaches to case consideration in relation to a control group of patients receiving fluoxymelin [2]. An attempt was made to evaluate the specific effect of the homeopathic medicine and the effect of the consultation itself in depression, especially acute. Objectifying these questions can be useful information in the current debate about evidence in homeopathy.

The most recent reviews of research findings in homeopathy have been carried out in the UK by the British Homeopathic Association in connection with the aforementioned discussion in Parliament and the Working Group of the International Homeopathic League and in connection with recurrent accusations of ineffectiveness of homeopathy. The results of this analysis are summarized in table. 5.

Table 5

Summarizing the results of clinical trials conducted by the Working Research group of the International Homeopathic League (with abbreviations)



Состояние	Препарат	Результат	Исследователь	Комментарий
Боли в спине	Spiroflor SRL, Creme Capsici comp (CCC)	Положительный	[71]	Нет других исследований
Стимуляция родов	Гомеопатия и плацебо	Статистически значимой разницы не выявлено	[8, 22]	Нет оснований для рекомендаций
Синдром хронической усталости	Индивидуализированная гомеопатия и плацебо	2 исследования, одно положительное, другое – без выраженных результатов	[5, 80]	Прослежена положительная тенденция
Аллергическая астма	Engystol, Pflugerplex H, Препараты домашней пыли, Изопатия, Blatta orientalis и плацебо	Положительный эффект с Энгистолом	[52, 53, 46, 68, 29]	Исследования плохого качества, нельзя сделать выводы
Послеоперационное беспокойство у детей	Aconitum и плацебо	Положительный эффект Aconitum	[3]	Выводы позитивные
Беспокойство у взрослых	Argentum nitricum 12D и плацебо	Статистически незначимые результаты	[6]	Выводы неопределенные
Беспокойство у взрослых	Argentum nitricum 12D и плацебо	Наблюдали положительный эффект	[72]	Выводы позитивные
Нежелательные реакции лучевой терапии, лучевой дерматит	Cobaltum 30C Causticum 30C и плацебо	Уменьшение нежелательной реакции на 30%	[45]	Эффект умеренный, но достоверный
Нежелательные реакции лучевой терапии, лучевой дерматит	Belladonna 7C X-ray 15C	Значительное уменьшение тяжести состояния	[7]	Эффект достоверный
Нежелательные реакции лучевой терапии, лучевой дерматит	Местно Calendula и тролзамин	Местное применение календулы значительно превышало положительный эффект тролламина	[66]	Выводы позитивные
Фибромиалгия	Arnica, Bryonia, Rhus и плацебо	Значительное уменьшение боли, улучшение сна	[27]	Результаты достоверные, но группа мала, следует повторить исследование
	Индивидуализированная гомеопатия	Субъективное улучшение, а также по шкале боли	[14, 15]	Следует изучать, обещающие результаты
ВИЧ	Индивидуализированная гомеопатия	Статистически значимое увеличение CD4 и CD8	[67]	Гомеопатические лекарства могут дополнять лечение или быть альтернативой
	Смесь потенцированных ростовых факторов и плацебо	Статистически значимое увеличение CD4	[19]	
Острый ринит	Eupatorium 2D и аспирин	Эффекты в двух группах сопоставимы	[30]	

### Clinical Trials of Homeopathic Medicines Used for Medical Indications

There are a lot of such works. This kind of research is carried out by manufacturing companies, releasing drugs that are targeted for widespread use for medical reasons. In the registration service of our country, there is a rule that open access drugs used for medical indications must be confirmed efficacy in accordance with approved clinical trial protocols. Thus, drugs registered in our country that are used for medical reasons have a statistically reliable confirmation of their effectiveness.

Table 6 shows some data from foreign literature on clinical trials with complex homeopathic preparations used for medical indications.

The presented data clearly show the acute problems that need to be solved by specialists in homeopathy in tandem with medical organizers for an optimal study of the features of homeopathic medicines and their introduction into medical practice to improve the health of the country's population. These issues are well documented in a memorandum from the British Homeopathic Association [55]: "Establishing a solid evidence program requires agreement between homeopathic practitioners, patients and clinical pharmacological investigators on what and how to assess and on relevant results. Core research should be conducted in the most promising areas, choosing between the demands of the time and the demands of patients. Everything should be well thought out in advance, including an agreement on

Table 6



Clinical trials on complex homeopathic preparations used in  
medical indications (examples)

Состояние	Препарат	Результат	Автор
Нежелательные реакции лучевой терапии, лучевой стоматит	Траумель и плацебо	Значительное улучшение состояния	[62]
Головокружение	Vertigo-Heel и Gingko biloba	Эффект сопоставим	[37]
ОРЗ	ГриппХель и аспирин	Эффекты в двух группах сопоставимы	[51]
Синусит	Синфронтал и плацебо	Эффект позитивный	[84]

In conclusion, it remains only to join the words that Prince Charles said at the 58th Assembly in May 2006: "I am convinced that patients should receive treatment that is integrated from two worlds - complementary and orthodox medicine. The West must learn from the East, and the new from old traditions. It is a shame and wrong when, in attempts to modernize, many excellent treatment approaches that have proven their viability are declared old-fashioned. It shouldn't be that way. "

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Author's address

Dr. med. Tomkevich M.S.

Research Institute of Traditional Medicine GOU VPO RGMU Roszdrav

mtomkevich@gmail.com

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