Methodology and principles of scientific research in traditional medicine (based on based on the recommendations of the World Health Organization)

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Methodology and principles of scientific research work in traditional medicine (according to World Health Organization guidelines)

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SUMMARY

The article discusses the methodology, scientific principles, features of conducting and evaluating the results of clinical trials in modern traditional medicine, in the light of the decisions and recommendations of the World Health Organization.

Key words: traditional medicine, scientific research,Clinical Research, World Health Organization.

RESUME

Methodology, scientific principles and peculiarities of research work and evaluation of results in modern traditional medicine methods are considered basing on World Health Organization guidelines.

Keywords: traditional medicine, scientific research, world health organization.

Traditional medicine (TM), as defined by the World Health Organization (WHO), is the sum of knowledge, skills and actions based on theories, explainable or inexplicable beliefs of different cultures, which are used in health care and prevention, diagnosis and treatment of physical or mental diseases. In some countries, the terms “complementary”, “alternative” and “non-conventional medicine” are used interchangeably along with the term “traditional”.

Despite the long existence of traditional medicine, its long-term use for many centuries and wide popularity among the population in a number of countries, it has not yet been officially recognized. Traditional medicine theories and methods vary significantly from country to country as they are influenced by factors such as national culture, history, interpersonal relationships and philosophy.

At the International Conference on Primary Health Care

Held in Almaty in 1978, WHO and conference participants for the first time called on countries and governments to include traditional medicine as an important component of primary health care. From this moment, the use of the English-language term traditional medicine begins [1].

Realizing its guiding and coordinating role, WHO considers it expedient and necessary to integrate traditional medicine methods into national health systems and for this purpose develops international standards and guidelines, supports strategic clinical research in the field of traditional medicine methods.

In 2000, WHO prepared and published General Guidelines for Research Methodology and Evaluation of Traditional Medicine [2]. In 2002, WHO decided on a new strategy for the development of traditional medicine for 2002-2005 and advocated the comprehensive integration of traditional medicine into the existing system of university health care [6].

The implementation of the new WHO strategy has identified a number of problems that have arisen in the course of integrating TM into the university health system. Among the main problems identified by WHO, there are: the problem of classifying TM areas, the problem of standardizing international terminology, the development of research methodology and evidence-based assessment of the results of using TM methods, insufficient development and implementation of new information medicine technologies, as well as solving the problems of the basic international standard for teaching students and doctors and the development of the regulatory framework.

Unfortunately, the leaders of official medicine often do not contribute to the introduction of TM into practical and scientific health care. And in some cases, they hinder the development of TM methods or create conditions under which the services of traditional medicine specialists become inaccessible to the general mass of patients. All this is the result of obstruction of TM by officials of official medicine. In this regard, it should be reiterated that WHO strongly recommends that health authorities not create obstacles to the use and development of traditional medicine. Research guidelines developed by WHO focus on the appropriate use and development of traditional medicine.

The WHO guidelines define the following main objectives:

- harmonization of the use of terminology in traditional medicine;
- summarizing key issues in the development of research methodology and assessments in traditional medicine;
- improving the quality and value of research in traditional medicine;
- providing an objective assessment of traditional medicine methods for development of the regulatory framework.

The long history of the use of traditional medicine, including the experience passed down from generation to generation, can testify to the safety and effectiveness of its means and methods of treatment. However, scientific justification and research is needed to provide additional

evidence of the safety and effectiveness of the means and methods of traditional medicine. The guidelines note that when conducting research and evaluating the quality of traditional medicine, researchers should respect the knowledge and experience gained over the years.

The methodology for research and evaluation of traditional medicine methods should be based on the following basic principles. Despite the complexity of the problem for national health authorities, WHO strongly recommends, on the one hand, to guarantee the safety and effectiveness of the means and methods of treatment of traditional medicine, on the other, not to create obstacles to the use and development of methods of traditional medicine.

The WHO recommendations indicate that in traditional medicine, the concepts of "diagnosis and treatment" are historically based on a holistic approach to the patient, and pathology is considered at the physical, emotional, mental, spiritual and environmental levels at the same time. Thus, most of the methods of traditional medicine can be used in complex treatment together with the methods of classical medicine. A physician who is a professional in the field of classical and traditional medicine can combine therapeutic approaches of different directions for the patient's benefit.

When conducting research, WHO recommends that effective measures be taken to ensure their safety, using high-quality equipment, as well as adequate theoretical and practical training of medical practitioners. It is also noted that the attending physician should be aware of the necessary safety measures if the patient does not respond to the therapy, or if an unforeseen situation arises during the treatment. For some traditional medicine methods, WHO has developed guidelines, for example, there is a WHO Guide on basic training and safety precautions for acupuncture (WHO Guidelines on basic training and safety in acupuncture) aimed at preventing potentialnegative consequences in patients for whom the methods of treatment were incorrectly selected [3].

A clinical study of any type of therapy involves an assessment of the effectiveness and safety, which should be carried out in accordance with the current WHO recommendations (WHO's guidelines for good clinical practice) [4]. At the same time, WHO clarifies that the assessment of the safety of traditional medicine methods should not always prevail due to many years of experience in application. In addition to assessing the safety and efficacy of conventional medicine, clinical trials may have other goals:

- evaluation of traditional medicine methods within its own theoretical base;
- assessment of traditional medicine methods from the standpoint of theoretical foundations classical medicine;
- comparison of the effectiveness of various methods of traditional medicine and / or classical medicine.

According to modern requirements, the preparation of a study should begin with a literature review, including a description of the method under consideration or

means (if any) available knowledge of efficacy and safety.

A clinical study that evaluates traditional medicine methods may include the principles of conventional research, such as randomization of controlled trials and observational studies. Conventional clinical trial planning principles can be difficult to apply to assess different systems and methods of traditional medicine. In such circumstances, the choice of research plan should be discussed on a case-by-case basis with experienced traditional medicine practitioners. Also, in the WHO recommendations, it is separately noted that it is necessary to take into account the seasonal variability of the patient's condition.

For a study, out of a variety of known clinical research plans, the scheme that, in the opinion of the researcher, is the most adequate for assessment in a specific area of traditional medicine, can be selected.

When describing the therapeutic effect, it is necessary to indicate the means and equipment used. Particular attention should be paid to the description of the dose, frequency and duration of treatment, while the term "dose" should be understood as a combination of factors inherent in each therapeutic effect. The choice of exposure dose should be based on existing literature data and available practical experience. The evaluation of the results should be carried out in accordance with the objectives of the study. Results can be assessed qualitatively or quantitatively, by primary or secondary criteria, by general or specific effect. The duration of observation of the patient should correspond to the nature of the disease, for example, 24 hours for the treatment of acute conditions, on the order of several months for chronic diseases.

Since the methods of traditional medicine are used not only for the prevention, diagnosis and treatment of diseases, but also to maintain health and improve the quality of life of patients with diseases such as cancer and AIDS. In such cases, WHO recommends assessing changes in quality of life in accordance with the relevant recommendations (WHO QOL user manual) [5]. Patient selection is an important element of research design, since the sample must represent a population of patients that allows for the generalization of the results. The health status of patients should be clearly described in terms of classical and traditional medicine. Patient selection criteria, their inclusion or exclusion from the study should be fully described and specified. In the case when the research involves methods that depend on individual skills that differ from practitioners, in order to increase the reliability of the results, such a study should be carried out by several specialists. It is advisable to consider the variability of treatment outcomes both for one specialist and for a group of specialists. The number of patients in the study must be adequate to ensure that so that any clinically important differences between the study groups can be identified. In accordance with the research design, the statistical methods used should be consistent with the methods used to analyze the research results.

Since the use of Control Groups contributes to an objective assessment of the effectiveness of treatment, free of subjective factors or factors introduced during the research process, groups of patients can act as control groups, where one of the following forms of therapy is performed (not in order of priority):

- lack of treatment;
- a well-studied method of therapy;
- different doses of the investigated method;
- placebo;
- full-scale therapy;
- minimal therapy;
- alternative treatment.

In clinical trials, different types of control can be used to obtain a more correct answer to different questions. It is advisable to use a placebo whenever possible, since it is studies using placebo that provide the maximum evidence of the effectiveness of a therapeutic effect, allowing researchers to reliably distinguish between active and non-effective effects. This is not only of academic interest, but also of practical importance, especially for the development of new modes of action in traditional medicine.

The principle of randomization is equally important when comparing groups of patients in order to assess the therapeutic effect. However, there are many situations where randomization is impossible or unethical. Probably the best way to deal with this problem is through appropriate treatment choices in the control group. Randomized controlled trials require at least one control group. Blindly assessing the results of conventional therapies can be difficult, impractical, or even impossible due to the lack of awareness of what kind of treatment patients are receiving. Therefore, it is advisable to conduct a blind assessment of the results of the study as a whole.

For each patient, a study protocol should be kept containing informed consent, medical history, description of therapeutic effects, brief results of all examinations, results of observation in dynamics, laboratory data.

Research should follow the International Ethical Guidelines for Biomedical Research with Human Participation. Clinical trials must be carried out within the framework of state legislation. In accordance with the requirement of WHO, a completed clinical study must contain:

- description of the applied method of traditional medicine;
- substantiation of the reasons for choosing a treatment method;
- a description of the principles of choosing approaches to assessing the results of therapy;
- a description of the results of treatment, taking into account the validity and reliability of the data;
- a complete protocol for assessing the results of therapy, indicating how and when it was carried out;
- indication of the results for which statistical processing was carried out

data.

In conclusion, it should be noted that at present, traditional and classical medicine need each other. Traditional medicine needs versatile, multifaceted research, carried out taking into account the vast experience of conducting scientific work in classical medicine, and classical medicine increasingly needs dialectical thinking and an understanding of what could be designated by the philosophical concept of “unity of the surrounding reality "

Literature

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Kulikov, V.V. Methodology and principles of scientific research in traditional medicine (based on the recommendations of the World Health Organization) / V.V. Kulikov // Traditional medicine. - 2010. - No. 4 (23). - P.5-8.