

**Clinical Trials in which main treatment is acupuncture**

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**Abstract**

Acupuncture is a medical treatment, part of the Traditional Chinese Medicine which is based on applying small needles on the specific points of the human body called acupoints. As explained in the Traditional Chinese Medicine, the acupuncture is influencing the vital energy called qi, and is harmonizing the Yin and Yang in the human body. The aim of acupuncture is to open blockage if there is one or to reduce the flow of the Qi energy. Although the origins of the acupuncture are from People's Republic of China, a lot of countries are accepting it as a treatment for some diseases, however only in few countries the health care system accepts acupuncture and Traditional Chinese Medicine as a legit treatment. A lot of trials have shown the efficacy of acupuncture in treatment of numerous of diseases such as: back pain, cancer pain, headaches and migraine, facial nerve paralysis, etc. From most of the patients the response after acupuncture is positive. The number of adverse events that have occurred after acupuncture is low if the acupuncture is made by educated acupuncturist. In lot of countries, it is as an essential alternative treatment for numerous diseases. A lot of materials have been collected regarding the efficacy of the Acupuncture as a treatment, and a lot of clinical trials which are involving acupuncture as a treatment have been conducted, however the number of high quality organized clinical trials is not that big. The clinical trials in which the patients are receiving acupuncture are Interventional and observational. Organizing this kind of clinical trials is showing the desire of the professionals that are working with acupuncture to show to the world that it is effective, and it should be taken in consideration as a treatment for diseases. If not like a primary treatment but as a combination of previously approved treatments and acupuncture can give excellent result in treatment of lot of diseases.

Key words: Acupuncture, Clinical Trials, Traditional Chinese Medicine, Acupoints, Qi energy

## **Introduction:**

The aim of this article is to provide information regarding the number of organized clinical trials in which treatment with acupuncture is the main intervention. What type of clinical trials were organized, were the clinical trials were organized only in People's Republic of China or there are some other countries in which this kind of clinical trials were organized, and for how many of them results are available after they were completed.

The organized clinical trials in which treatment with acupuncture is the main intervention are an excellent opportunity to the Medical Professionals for collecting new information regarding some of the diseases and to discover new ways of treatments for diseases. Organizing this type of trials is providing better opportunities to the patients and their health.

The organized and completed studies are from interventional and observational type, which is indicating that the first group of patients, the one that were part of the interventional type, have active disease and they are actively receiving a treatment for their disease, in this group the patients are treated with acupuncture, or depending on the study they can also receive some other provided medicine. The provided medicine can be some previously approved eastern medicine, or some medical products that can be used for treatment of a disease from the western medicine.

In most of the observational studies the safety usage of acupuncture is examined, however there are some studies in which besides the safety, also the efficacy of the treatment is examined. These are only observational studies, in which additional information regarding possible adverse events or some not expected situations are collected.

As a treatment acupuncture is becoming more and more popular and its popularity is expected to become higher, this is due to the fact that the people that are receiving acupuncture are satisfied after the treatment and most of them have positive opinion about it.

Even though acupuncture is gaining more and more popularity and people are approving the usage of it, the mechanism of how acupuncture works, is yet to be determined and explained. Functional MRI has detected physiologic changes in the central nervous system during the acupuncture treatment. [1]

There are only couple of conditions that can be considered as contraindications for acupuncture. It can be used for treatment of young pediatric population and pregnant woman without risks that some adverse event can occur. People taking warfarin or other anticoagulants, as well as people with bleeding disorders history, are not contraindication to acupuncture [2]. For organizing clinical trials, the lower number of contraindications for the patients can only mean that the number of potential participants of a clinical trial can

be higher which can lead to faster collection of the planned data at the beginning of the study.

The complicated part of the organization and conduction of a clinical trial in which the patients are receiving acupuncture is the fact that the legit acupuncture done to one single patient is individualized. That part makes a planned standardization in a clinical trial to be difficult.

So far have been proven that acupuncture helps in conditions as: Low back pain, osteoarthritis, rheumatoid arthritis, migraine, headache, cancer pain, nausea and vomiting fatigue and etc. Acupuncture is also effective in the treatment of obesity and interestingly, has showed some benefits and weight loss. [3] Pain is probably the most common reason for people to ask for acupuncture treatment. [4] For all the mentioned conditions official and non-official clinical trials have been performed. For most of them the data is showing positive effects after acupuncture treatment. [5]

The effectiveness of the acupuncture treatment is improved with an interprofessional care approach. Doctors and other medical stuff should have a baseline understanding of the treatment option and also to be open to their patients utilizing complementary and alternative medicine. [4]

#### **Materials and methods:**

The research of this study includes review of reported and published information about the Clinical Trials available on <https://clinicaltrials.gov/> which is the biggest and the most reliable source for information of this kind. It is a database web page of privately and publicly funded clinical studies conducted all around the world.

ClinicalTrials.gov, a repository of information about clinical studies and their results, together with specialized search tools, provides a unique window into the clinical research enterprise, which includes all initiated, ongoing, and completed or terminated clinical studies.

Researchers are increasingly using information from the database to assess research reporting practices, or to characterize the clinical research enterprise. [6]

The filters that were used to get the results are:

1. Intervention/ treatment used in the Clinical Trial is selected Acupuncture,
2. Status of the study is chosen completed.

The first filter will give information only about clinical trials in which the main treatment is Acupuncture.

The second filter will give information only about completed clinical trials, clinical trials that are still ongoing or were terminated earlier than planned are not part of this research.

Also, there will be information about the type of the clinical trial, is it interventional or observational clinical trial, the countries in which the clinical trial occurred, and there will be information about the number of clinical trials from which results are available after the completion of the trial.

After getting the results, some of the results are sorted into diagrams for better visual display.

**Result & discussion:**

According to the statistical analysis and the data reported on <https://clinicaltrials.gov/>, overall, there are 951 completed clinical trials in which the intervention is acupuncture.

The number of 951 completed clinical trials is expected, however since well-known fact is that Acupuncture as a treatment is used in Chinese health care system the number is expected to become higher in the upcoming years. In meanwhile the overall number of clinical trials completed and not completed is 1883. Another fact that directly or indirectly affects the number of organized clinical trials with acupuncture as a prime intervention, is the COVID 19 Pandemia. On one hand there are a lot of clinical trials organized in which pneumonia or some other condition related to covid virus was treated, on the other hand the conditions for organizing clinical trials in time of the pandemic were not that easy. So, we can conclude that the pandemic affects a lot on the number of organized clinical trials. In close future we are expecting a bigger number of organized clinical trials and more relevant data published about the efficacy of acupuncture. With that data the people can become more and more aware about the positive effects of acupuncture.

From the available data, we can see that from the 951 clinical trials which are completed by now, 910 were from interventional type, and 41 were from observational type.

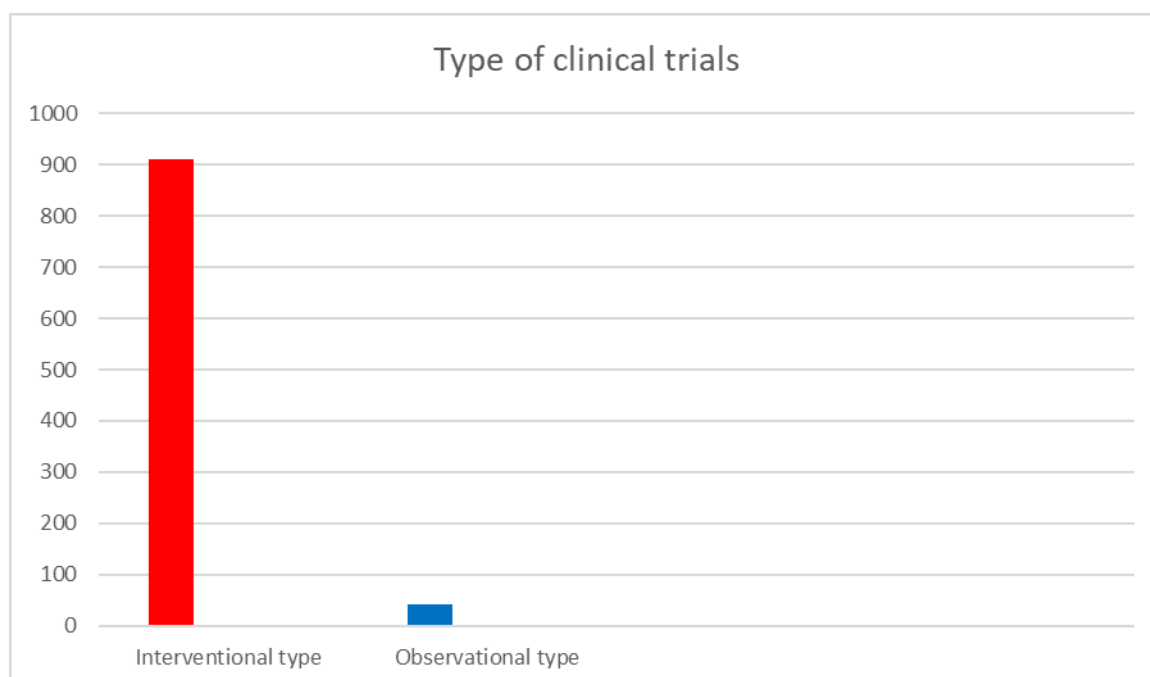


Chart 1. Type of clinical trials

This result is expected, since the fact that biggest part of organized clinical trials is from the interventional type in which the patients are receiving some intervention for treatment of relevant disease. On the other hand, the observational type is taking in consideration previously approved treatment, new possible adverse events are examined. So, in this group only observation and some possible outcomes are measured.

From the 951 clinical trials that are reported as completed for 107 of them results are already available. For the rest of 844 studies, the result is not yet available. This can be due to the fact that at the moment some of the examiners are working on reviewing and completing the collected data. After that for sure the data will be reported. For biggest part of the trials for which publications are made after completion of the clinical trial there is a conclusion that acupuncture seems to be safe and effective in a treatment of the relevant disease.

Information is available for 918 of the reported completed clinical trials regarding the country in which the clinical trial has taken place. For 33 of all the reported completed clinical trials information for the country is not available.

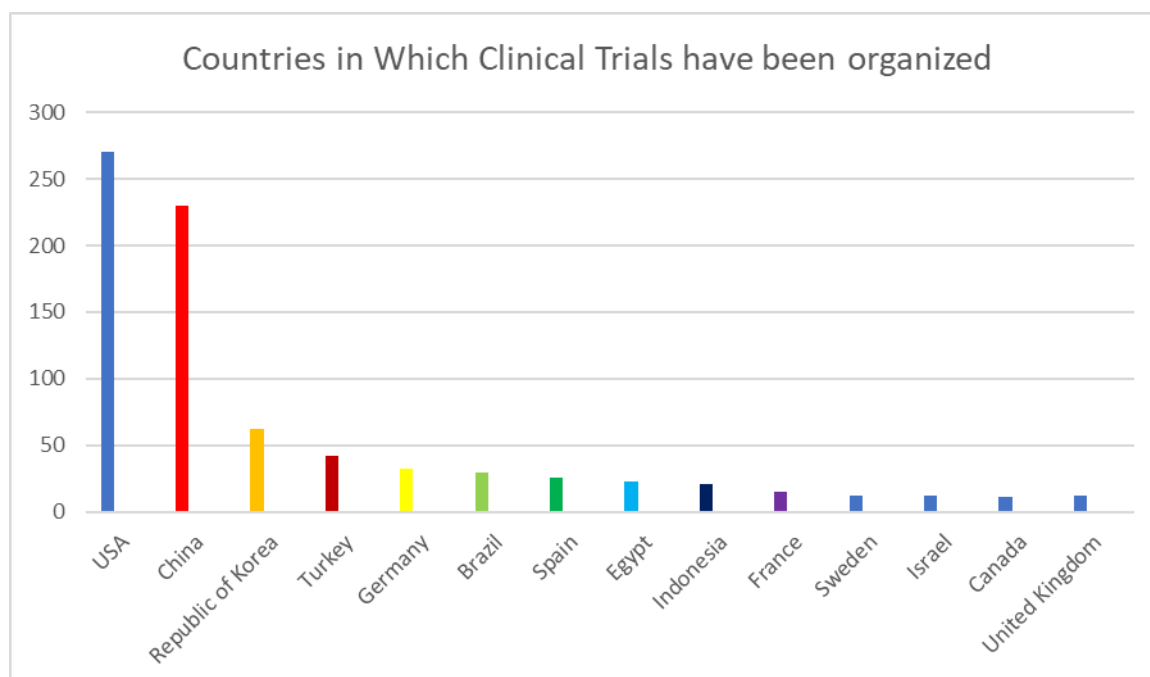


Chart 2. Countries in which the clinical trials have been organized.

The data of countries in which clinical trials have been organized is not expected, because the highest number of organized clinical trials is in United States of America with 270 of all the 951 organized and completed clinical trials. In People’s Republic of China, the overall number is 230. While collecting the data for this study, it was expected that the number of organized and completed clinical trials in which main treatment is acupuncture will be the highest one, however the data is placing clinical trials organized in People’s Republic of China to be on the second place. This number can be due to the fact that most of the investigators and organizations from People’s Republic of China are reporting their results from this kind of clinical trials on the platform International Traditional Medicine Clinical Trial Registry which is also online register of clinical trials

that have been conducted in the field of traditional medicine. However, for now this is only our assumption, and it needs to be investigated.

From The other countries in which this type of clinical trials has been organized, the number is higher in Republic of Korea, Turkey, Germany, Brazil, Egypt, and Indonesia, with numbers of 62, 42, 32, 29, 23 and 21 in Indonesia. In the other countries the number is lower than 20. It was not expected that the number of clinical trials will be really low in Japan, only 1 reported clinical trial, same in Russia, and only 1 in India, however, again there is possibility that the clinical trials organized in these countries are reported on a different platform, but this must be investigated before final conclusion is reached.

### **Conclusion:**

The study is based on a data about the Clinical Trials available on <https://clinicaltrials.gov/> which is the biggest and the most reliable source for information of this kind. It is a database web page of privately and publicly funded clinical studies conducted all around the world.

From the available reported data, we can see that the number of clinical trials in which main treatment is acupuncture is high and in future is expected to be higher.

A lot of the organized and reported clinical trials are made available in collaboration between investigational centers and hospitals from People's Republic of China, and centers and hospital from other countries in the world.

This is due to the fact that more and more countries are accepting the acupuncture as a treatment method.

It was expected that the number of interventional clinical trials is higher compared to the number of observational clinical trials.

We can see that this kind of clinical trials are organized almost in the whole world.

The one point that was not expected during the preparation of this study was the higher number of organized clinical trials that are involving acupuncture in USA compared to the number in People's Republic of China. However as mentioned this number can be due to using different platforms for reporting of the data.

It was not expected that the number of organized clinical trials in which acupuncture is the main treatment is so low in countries like Japan, Russia, and India. However as mentioned this needs to be investigated, because there is possibility that the research centers and the investigators are using different platforms for reporting this kind of clinical trials. It was not expected that the number of organized clinical trials will be higher in Egypt, compared to a lot of countries.

It was expected a few clinical trials from this type organized and conducted in Hungary, due to the fact that Hungary is the only country from the European Union that is

recognizing Traditional Chinese Medicine as a therapeutical Method. Since the connections are really good between Hungary and People's Republic of China it is expected that scientist from both countries to start and organize clinical trials from this type.

Regardless of that, the fact that more and more such kind of clinical trials are organizing is encouraging. With this type of organized clinical trials the information about safety and efficacy of using acupuncture in treatment of different diseases is more and more available which can led to opening up of more and more countries for using acupuncture as a treatment method.

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