

Completed Clinical Trials in Traditional Chinese Medicine

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Abstract

Traditional Chinese Medicine is a complex system which includes a lot of procedures for treatment and diagnosis of diseases and health issues that the patients have. It is used for treatment but also for diagnosis and prevention for more than 2200 years. The earliest written prove found about TCM is from the period of the 3rd century BCE. So far there have been a lot of theoretical theories for TCM that are giving the basics for today's usage of it. During the past period a lot of Clinical Trials, clinical investigations and a lot of materials have been collected, so TCM can be considered as a medical intervention that can be beneficial for the patients. The WHO recommends acupuncture, which is part of the Traditional Chinese Medicine for treatment of more than 100 diagnosis, part of this more than 100 diagnoses are, Abdominal pain, bell's palsy, cancer pain, insomnia, etc. The European union does not recognize TCM as a therapeutical method. From the European Union members, only Hungary accepts TCM as a therapeutical method and practitioners who have completed the 5 years of education in TCM can practice TCM. On the International Traditional Medicine Clinical Trial Registry (ITMCTR) which is an online register of clinical trials (research) being conducted in the field of traditional medicine. It is operated by China Center for Evidence Based Traditional Chinese Medicine, so far there are 4380 records for registered clinical trials and collected documents, from clinical trials that have goal to prove the efficacy of TCM in treatment and diagnosis of diseases and health issues of the patients. Reported are different clinical trials in which different practices used in Traditional Chinese Medicine have been tried. Acupuncture, Moxibustion, Herbal Medications, Cupping Therapy and Tui na massage.

Key Words: Clinical Trials, Traditional Chinese Medicine, Acupuncture, Moxibustion, Cupping, Tui Na, Herbal Mediations

Introduction

The aim of this article is to provide more information to the readers regarding the reported organized and completed Clinical Trials which are involving TCM. The types of the clinical trials and the location where the clinical trials are conducted.

Organizing of this type of clinical trials can be beneficial for both the participants of the trials and the organizer of the clinical trial. There are 3 different types of clinical trials reported on this platform, Interventional Clinical Trials, Observational Clinical Trials, and Preventive Clinical trials. The Interventional Clinical Trials are trials in which the participants of the Clinical Trial are receiving some form of therapy for the disease that is intended to be treated during the Clinical Trial.

A lot of new treatments related to TCM are discovered during conduction of Interventional Clinical trials. The new treatments discovered are in all the forms that TCM can be provided to the patients.

The Observational Clinical Trials are trials in which the condition of patients who are receiving previously approved therapy is observed. The observation is done for possible new Adverse Events, or new situations that did not occurred during the previous phases of a clinical trial. In Traditional Chinese Medicine most of the observational clinical trials are related to new Herbal Medications. The rest of the observational clinical trials that are not related to new Herbal Medications are clinical trials in which participants who are receiving some forms of treatment are also treated with acupuncture, or other form of TCM, and the result of the patients treated with combination of western medicine and TCM, and patients treated only with western medicine is compared.

During COVID-19 times a lot of observational clinical trials were performed, in most of them the efficacy of TCM in combination with western medicine was proven.

Regarding the study design of the clinical trials in which TCM is involved, almost same designs as the one used in the western medicine are used. In most of the studies the main goal is to provide the safety, efficacy, and the mechanism of action of some new investigational medical product [1] [2]

The biggest part of clinical trials involving Traditional Chinese Medicine are organized and conducted in People's Republic of China. This is due to the fact that in People's Republic of China there is formal educational system for Medical Doctors practicing TCM, and the health care system in People's Republic of China recognize TCM as a treatment for a lot of diseases.

Traditional Chinese Medicine or some form of it is also used in other Asian countries, however the usage of it in People's Republic of China is higher compared to the usage in the rest of the countries.

TCM accounts for around 40% of all health care delivered, and it is used to treat approximately 200 million patients annually in People's Republic of China [2]. 69% of the Korean population has experienced TKM. 60–70% of allopathic doctors in Japan prescribe herbal medicines for their patients [3].[4]

In People's Republic of China, it is called Traditional Chinese Medicine, in Korea is Traditional Korean Medicine and in Japan it is Oriental Medicine.

Even though the usage is also not low in Korea and Japan, there are not a lot of available data for clinical trials involving Traditional Medicine. In this article we will focus on the clinical trials organized and completed in hospital, research centers and organizations in People's Republic of China.

Materials and Methods

The research of the study includes review of reported and published information about Clinical Trials in which Traditional Chinese Medicine is involved. The data is reported and available on <http://itmctr.ccebtcn.org.cn/>. It is an Online register of clinical trials (research) being conducted in the field of traditional medicine. ITMCTR is regulated by the China Center for Evidence Based Traditional Chinese Medicine. The register is also part of ICTRP which is monitored and supported by the world health organization (WHO).

Filters used during this research were:

Recruiting status. Recruiting status was selected as completed, which means that all the clinical trials which will be presented in this research are completed and in them there is no recruitment of new participants.

During the research in consideration were taken also filters for the study type, to get information if the study is observational, interventional or some different study type. And, in consideration was taken the filter for the study design, to check if the study design is randomized or non-randomized, if it is randomized is it from the cross over design, or parallel design. Is there some of the clinical trials with different study design or all the reported trials are from the randomized or non-randomized study type.

After applying the filters, we figured out the total number of reported completed clinical trials for treatments that are part of the Traditional Chinese Medicine.

We got exact numbers of the types of the conducted clinical trials.

We got numbers for the study design of the reported and completer clinical trials.

We got information about the year in which the reported clinical trials have been registered.

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

Result & discussion

According to the statistical analysis and the data reported on the International Traditional Medicine Clinical Trial Registry, reported is number of 183 completed clinical trials in which Traditional Chinese Medicine and its therapeutical methods are involved. All of the reported clinical trials are conducted in People's Republic of China. The number of not

completed clinical trials in which TCM and its therapeutical methods are involved is 4198. Most of these 4198 clinical trials are still ongoing and in them patients are actively recruited. However, some of them have been discontinued due to different reasons and most of them still have not started with the recruitment process. The total number of clinical trials that have not started with recruitment process is 2316.

The total number of organized clinical trials reported on this platform is 4381. This total number of 4381 clinical trials is from the period of 17th of April 2019 to 24th of July 2024.

The number of 183 completed clinical trials is expected due to the fact that the reported starting period is from the end of 2019. A lot of clinical trials that are in interventional or observational phase needs longer period of time to be completed, and also starting from 2020 the COVID 19 pandemia took places, that slowed down the organizing, conducting and reporting the processes of clinical trials. Also, there are 2316 trials that does not have started with recruitment. In the upcoming years the number of completed clinical trials in which TCM is involved is expected to be higher.

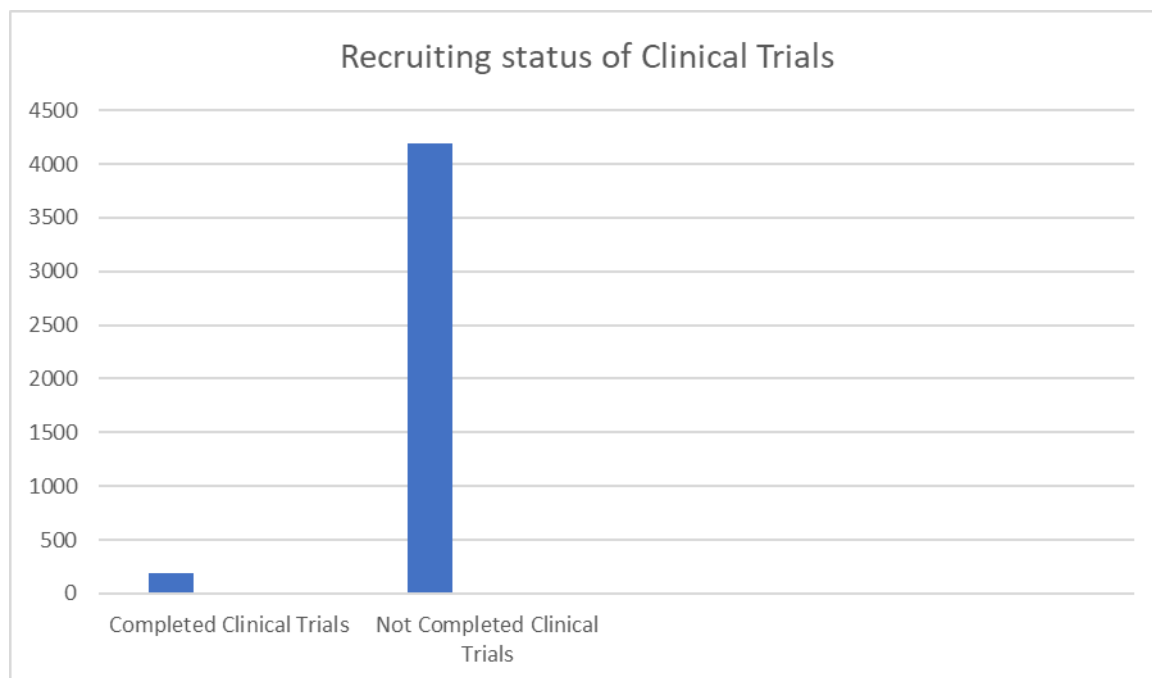


Chart 1. Recruiting status of Clinical Trials

Regarding the type of the conducted clinical trials: From 183 reported completed clinical trials, 152 are in group of interventional type of clinical trials. 24 are in the group of observational type of clinical trials, 2 are clinical trials in the group of prevention as a study type, 1 is cause/ relative factors study, 4 are in a group of basic science clinical trials.

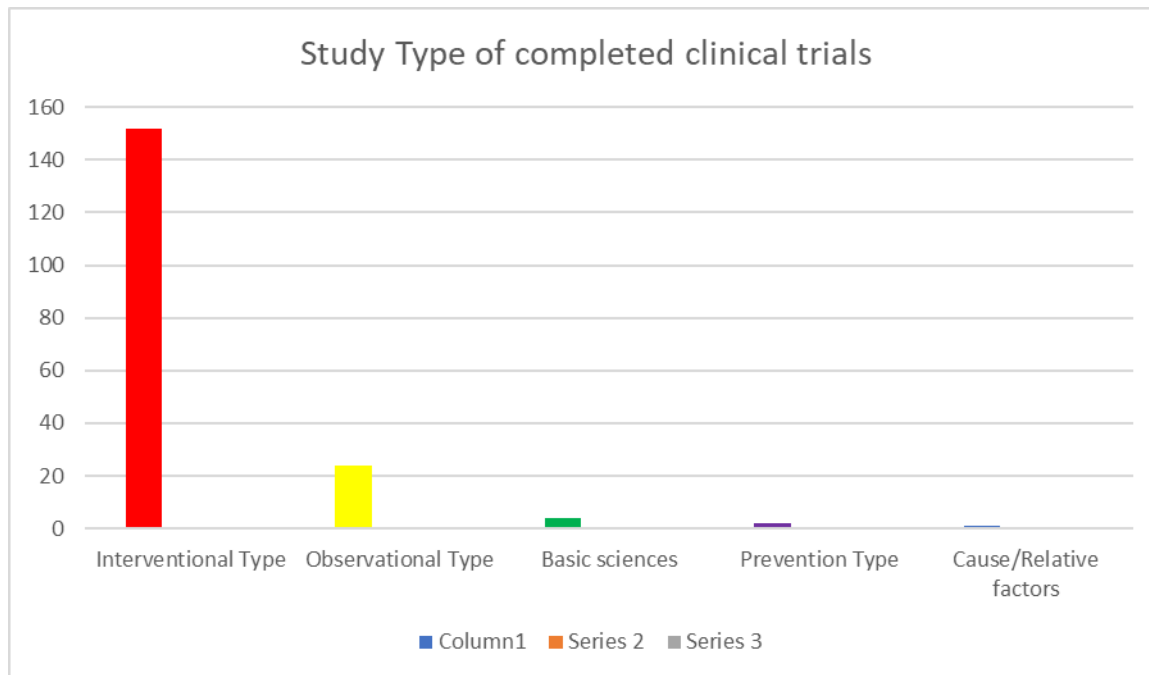


Chart 2. Study Type of completed clinical trials

The number of the study types of the completed clinical trials is expected. From all the conducted clinical trials the most of them are from the group of interventional type, the same situation is in here too with a number of 152 clinical trials. The Observational type is the second one with 24 conducted clinical trials, in this number of 24 conducted clinical trials are clinical trials regarding herbal medicine, which is observed after the approval for its usage was obtained. For new not expected Adverse Events, and new patient's situations that were not seen prior to the approval of the medication. Also, there are some observational clinical trials in which the patient's condition is observed while the patient is treated with combination of both western and eastern medicine. From the group of basic sciences there are 4 conducted clinical trials. In this situation the basic mechanisms of action of the patient's body are observed, and more information about some diseases are collected. In the prevention type of clinical trial, the main goal is to prevent some expected condition to happen.

Regarding the study design of the completed clinical trials, from the reported 183 clinical trials, 134 are with a study design in randomized controlled trials (a parallel group design), 5 are with a study design in randomized controlled trials (cross-over design), 10 of the reported clinical trials are with factorial study design, the factorial study design is allowing the investigators to use various combinations of treatments that are proposed in the study protocol. 8 of the reported clinical trials are with sequential study design, the sequential study design is a study design that is allowing potential interim analysis to change the way how the clinical trial is conducted, based on the collected data. 6 are with non-randomized study design, 6 are with cohort study design, the cohort studies are collecting data from a group of patients, the group of participants is followed for a period of time 6 of the reported clinical trials are single arm clinical trials, 4 are in the group of

quasi-randomized controlled clinical trials, 2 are case-controlled designs, 1 with randomly sampling study design and 1 is with a cross-sectional study design

The study designs of the reported completed clinical trials are also expected since the fact that most of the conducted clinical trials in both eastern and western medicine have this kind of study design.

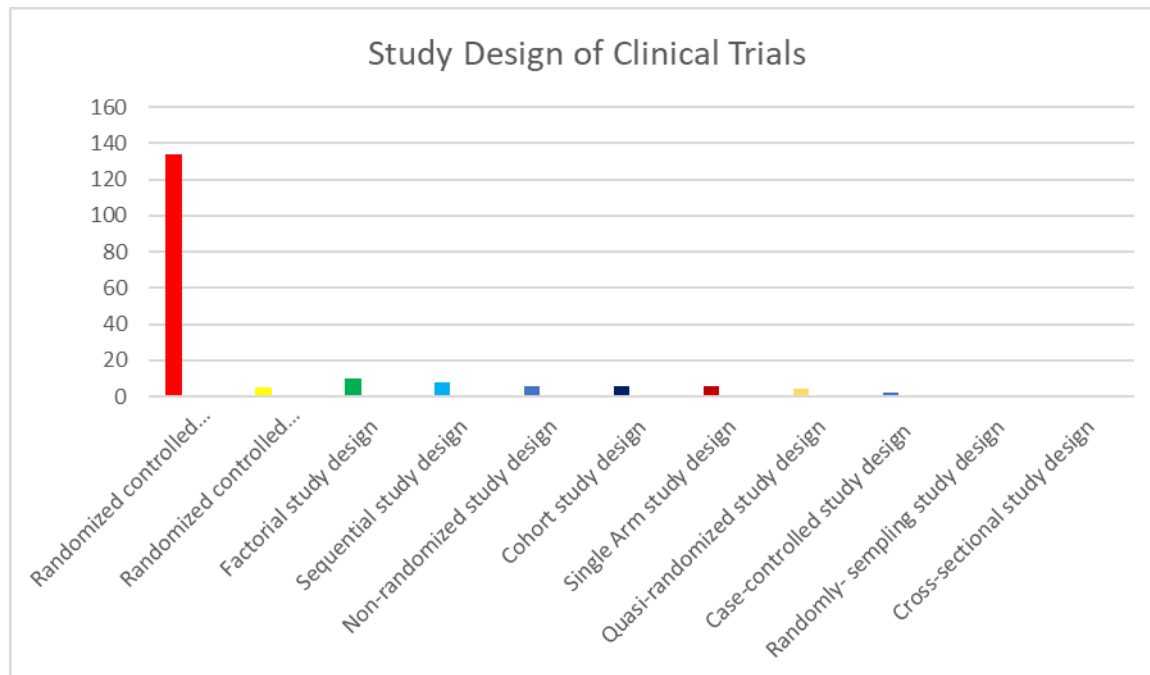


Chart 3. Study Design of clinical trials

Conclusion

The study is based on a data reported and available on International Traditional Medicine Clinical Trial Registry, <http://itmctr.ccebtcn.org.cn/>. It is an Online register of clinical trials (research) being conducted in the field of traditional medicine. ITMCTR is regulated by the China Center for Evidence Based Traditional Chinese Medicine. The register is also part of ICTRP which is monitored and supported by the world health organization (WHO).

From the available data we can see that the number of Registered clinical trials is relatively high, from the first period of reported clinical trial by 24th of July 2024, 4381 clinical trials are reported. Knowing that Traditional Chinese Medicine is practiced a lot the number is expected to be higher in the upcoming years. The number of the reported clinical trials would have been higher, but in the reporting period the COVID 19 pandemic took place and for sure it has stopped a lot of started or planned activities. Even though from all the reported clinical trials in this period the number of clinical trials which are involving patients positive on COVID 19 is significantly high. As for study type and study design, the numbers of the reported clinical trials are expected. Most of the reported completed clinical trials are from Interventional type of

clinical trials, as it is in most of the conducted clinical trials, and for most of the reported completed clinical trials the study design is randomized controlled trials (a parallel group design) which is also expected, since in both eastern and western medicine most of the organized clinical trials are with this study type.

From the reported data we can see that the Medical Doctors and the scientist in People's Republic of China are working hard to provide evidence that practicing Traditional Chinese Medicine is beneficial for all the patients. Reporting this data shows their desire to share Traditional Chinese Medicine with the rest of the world, outside of People's Republic of China. This practice is good because accepting other methods for treatment of disease not just the known practices is a good way to provide better health care to the people around the world.

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