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Clinical trials in which main treatment is cupping therapy Kire Stojkovski¹, Evgenija Dameska-Stojkovska², Vladimir Stojkovski³, Mihail Petrov Mihaylov⁴

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Abstract

Cupping therapy is an ancient medical treatment, for which it can be now said that it is an alternative medical treatment, the main goal of this therapy is an inflammation and pain relief, relaxation, well-being of the patients that are receiving the therapy and also as a form of deep-tissue massage of the patients treated with it. For this kind of therapy different type of cups are used. Most common cups that are used are: Glass cup, bamboo cup, earthenware cup, plastic cup, silicon cup.

For usage of different cups, different methods for practicing the cupping therapy are used. Although, nowadays the usage of this therapy is increasing a lot, it dates from past years as a part of ancient Egyptian, middle eastern culture and also as a part of the Traditional Chinese Medicine. From known data, the Egyptians introduced this type of therapy to the Greek people and the Greeks used it as a treatment for almost every known and not known disease. In the Traditional Chinese Medicine, the cupping therapy is well connected with the usage of acupuncture, and the flowing of qi energy in the patient's body. In the Islamic prophet the type of therapy that is used is known as Hijama. In the past times when different materials of cups were now used, the practitioners that were treating patients with this therapy were using some animal horns. There are two known types of cupping therapy: Dry cupping therapy and wet cupping therapy.

In both of the types, the practitioners are putting flammable substance such as alcohol or some form of herbs which is put on fire. After the fires goes out the cup is putted on the surface that needs to be treated which leads to rise of the skin and redden as blood vessels are expanding. It is known that cupping therapy can be beneficial in blood disorders, high blood pressure, migraines, anxiety and depression, fertility problems, skin problems, rheumatic disease and many more conditions. So far there have not been organized a lot of clinical trials that will prove the efficacy of cupping therapy, however in

most of the organized the results of the treatments are positive. In general, a lot more clinical trials should be organized so more information can be collected for this treatment.

Key words: Cupping therapy, dry cupping, wet cupping, cups, Hijama, treatment

Introduction

The main goal of this article is to provide the total number of reported organized clinical trials in which cupping therapy is the main intervention as a treatment on the clinical trial. Information regarding the type of the organized clinical trials will be provided, information about the localization of the organized clinical trial and also on how many of the reported clinical trials results are available, and if the results have positive or negative effects as a treatment of the treated disease.

Organizing this kind of clinical trials is beneficial for both the organizers of the clinical trials, and also for the patients that are receiving the treatment, and for the future patients that can receive treatment if the results of the clinical trials are showing some positive effects.

Also, some new data and information can be discovered, which shared can lead to some possible new discoveries that indeed can be beneficial.

The clinical trials that are involving cupping therapy as a main treatment are from interventional and from observational type. As known in the interventional type of clinical trials, the targeted patients are receiving some form of cupping therapy, it can be both dry or wet cupping and different type of cups can be used depending on the study protocol what is providing the main information how the clinical trial should be organized and conducted. The safety and efficacy of the cupping therapy is most researched in these types of clinical trials.

In the observational type, the patients are observed so some new not discovered information can be found and collected this can be beneficial for further usage of the observed treatment. Targeted population in this type of studies are healthy volunteers, people with certain disease, people that are in risk of developing some disease etc.

Most of the patients that are receiving this type of treatment are treated for different conditions, as mentioned in the abstract when the Greek civilization learned about this type of treatment, they tried to cure almost everything with some sort of cupping therapy.

Treatment with cupping have been tried for blood conditions, such is anemia and hemophilia, some rheumatic diseases such as arthritis and fibromyalgia, some skin problems as acne and eczemas, pain of patients body, most of the treated is back pain, however also pains on different localization of the human body is treated with cupping therapy. Some gynecological and fertility problems are treated with cupping therapy, some bronchial problems as asthma or allergies, high blood pressure, migraines, anxiety and depression, and a lot more conditions that are not mentioned in here.

The theory regarding pain in the patient's body is indicating that the cupping therapy is stimulating some nerve fibers, which leads to blocking the signals related to the pain to arrive in the patient's brain.

The cupping therapy can also be used in combination with acupuncture, the main idea of this combined treatment is that the acupuncture needles relieve the pain on the patient's body and the cupping therapy is loosening the muscles of the patient. [1]

Positive about this treatment is that it can be available, it is not expansive, and it can be easy to use if the practitioner is well educated about the relevant treatment.

There are couple of adverse events that can occur during this therapy, the most common is the skin discoloration on the human's body, some sort of scars, also burns and some infections, also there are some possibilities of eczemas or psoriasis.

Compared to the rest of alternative treatments available, and compared to treatments with Traditional Chinese Medicine, there are far less clinical trials organized on this topic.

The usage of cupping therapy is expanding in the past few years, however new relevant scientific information is available so the potential patients will have more knowledge if this treatment can be beneficial for them and for their conditions.

If the efficacy of this treatment can be proven in more clinical trials, the number of treated patients will become higher.

Materials and methods

The research of this study includes a data published on https://clinicaltrials.gov/ It is an online database with information about clinical research studies and the result of the privately and publicly funded clinical studies all around the world. The web page provides information about clinical research studies to the public, to health care professionals and to researchers. There is specialized search tool on the web page that is providing relevant information regarding clinical studies. [2]

Researchers are lately using more information from the database to get to research reporting practices, or to characterize the clinical research enterprise. [3]

The filters that were used to get the results are:

1. Intervention/ treatment used in the Clinical Trial is selected Cupping therapy,

The used filter will provide all the needed information regarding clinical trials in which cupping therapy is the main intervention.

After using this filter information regarding the number of organized clinical trials in which cupping therapy is the main intervention is available, information about the numbers of interventional and observational types of clinical trials, the date of the first reported clinical trial, how many of the clinical trials are accepting only children as potential patients, what was the main indication for the clinical trial, and also for some of the reported clinical trials, data regarding the study phase in which the clinical trial is conducted is available.

After collecting the data, some of the data will be sorted in diagrams for better visualization.

Result and discussion

According to the statistical analysis and the data reported on https://clinicaltrials.gov/, overall, there are 81 reported clinical trials in which the intervention is cupping therapy. The first reported clinical trial in which intervention is cupping therapy is dated from June 2008. On the first reported available clinical trial in which cupping therapy is the main intervention, indication was migraine.

The number of only 81 reported clinical trials in which the intervention is cupping therapy is low. Since it is well known treatment, higher number of organized clinical trials is expected which can lead to sharing some more knowledge regarding safety and efficacy of this kind of treatment. Also if the number of organized clinical trials is higher, more relevant intervention about the treated indication with this kind of therapy can be collected and shared with the scientists in the world, and that can be beneficial for everyone.

There is possibility that the number of organized clinical trials in which the intervention is cupping therapy is higher, due to the fact that a lot of researchers from different part of the world are using different platforms to share the collected data, however for this assumption further investigation should be made.

Also, the Covid 19 pandemia in the previous years for sure have some influence on organizing this kind of clinical trials, since we know that most of the medical staff was aimed on discovering treatment for the virus that cause the pandemia.

From the available data, we can see that from the 81 reported clinical trials in which the intervention is cupping therapy, the number of interventional clinical trials is 68 and the number of observational clinical trials is 13.

This numbers are expected, since well-known fact is that most of the organized clinical trials are from the interventional type, and the number of clinical trials from the observational type are lower compared to the interventional clinical trials.

Even though a lot of new information can be discovered during observational type, the number of organized interventional clinical trials is still a lot higher.

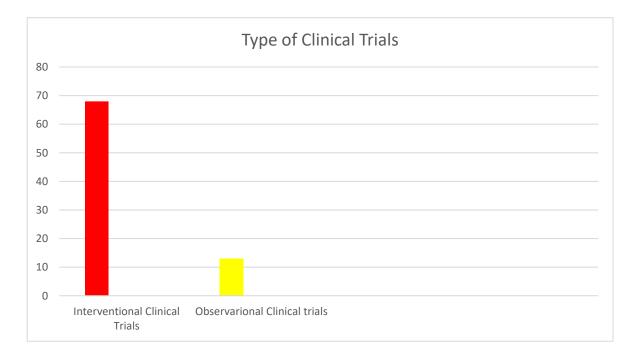


Chart 1. Type of clinical trials

Regarding the study phase in which the clinical trials are conducted, 1, clinical trial is in phase 1, 2 are in phase 2, 2 are in phase 3. There is 1 clinical trial in phase 4, and for the rest of the clinical trials the phase is not available at the moment.

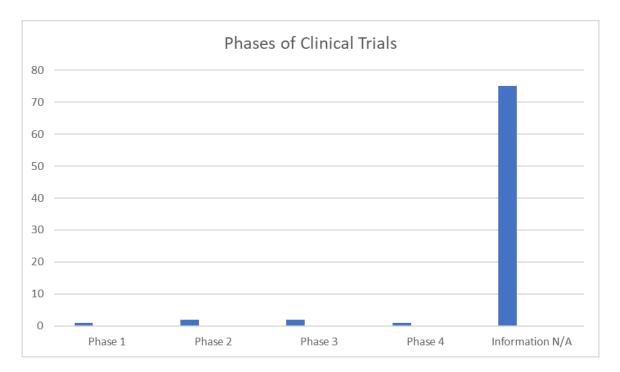


Chart 2. Phases of clinical trials

The reported numbers are showing that for most of the reported clinical trials, study phase information is not available, this can be due to the fact that it is hard to distinguish the study phase of this kind of clinical trials, however also fact that can cause this numbers are the low quality of the organized clinical trials, of the low quality of reporting this type of clinical trials.

Regarding countries in which clinical trials in which cupping therapy are conducted, the highest number of 10 clinical trials is in Republic of Korea, in People's Republic of China, Turkey and Pakistan there are up to 9 clinical trials reported in each of the countries, there are up to 5 clinical trials reported in USA, Germany and Egypt in each of the countries, there are up to 4 clinical trials reported in Brazil and Spain in each of the countries, there are 3 clinical trials reported in Saudi Arabia, there are 2 reported clinical trials in Portugal, and up to 1 clinical trial reported is in countries like: Israel, Cyprus, Poland, Chile, Iran, Iraq. For 10 of the reported clinical trials, information about the location of the clinical trials Is not available.

These numbers are showing that there is low quality in reporting of the conducted clinical trials, since the number of not available location of the clinical trials is same as the number of organized clinical trials in the country with highest number which is Republic of Korea. Regarding the other locations, it is expected that this will be the reported countries.

The number of organized clinical trials in People's Republic of China is low, since we all know that the scientists from People's Republic of China are working hard on proving a lot of new information regarding treatments that are considered part of the Traditional Chinese Medicine. However, like it is said before, this numbers can be low due to the usage of different platforms for reporting data like this one. Best approach will be the data to be shared in more and more different platforms so the results can become available for more people.



Chart 3. Countries in which Cupping therapy clinical trials are conducted.

Regarding the condition treated with cupping therapy in clinical trials, in most of the clinical trials, most common treated condition is pain in different parts of the patient's body. 24 of the reported clinical trials are with indication low back pain, 9 are related with indication neck pain, or conditions that can cause pain in the neck. 8 are related to non-

specific pain in the patient's body. 3 of the reported clinical trials are related to shoulder pain related to different etiology. 1 clinical trial is related to knee pain, 2 clinical trials are related to pain in the foot caused by plantar fasciitis.

Organized are 7 clinical trials in which the main indication is maintenance of the general health of the patients. There are 4 clinical trials in which the main indication is migraine, there are 2 clinical trials in which the main indication is hypertension, there are 2 clinical trials in which the main indication after covid 19, 2 clinical trials that have indication stroke, there are 2 clinical trials that have indication psoriasis, there are up to 1 organized clinical trials for conditions like: primary dysmenorrhea, complications after caesarean section, acne vulgaris, tennis elbow, fatty liver, anxiety, cognitive disfunctions, complications after Ankylosing Spondylitis, toxicities with heavy metals, Idiopathic Granulomatous Mastitis, primary open angle glaucoma, there is one clinical trial in which treated is whiplash syndrome and there is one clinical trial in which the main indication is navel herniation. Also 2 clinical trials are reported in which the targeted population are children, and the treated conditions are obesity and caries at children ages.

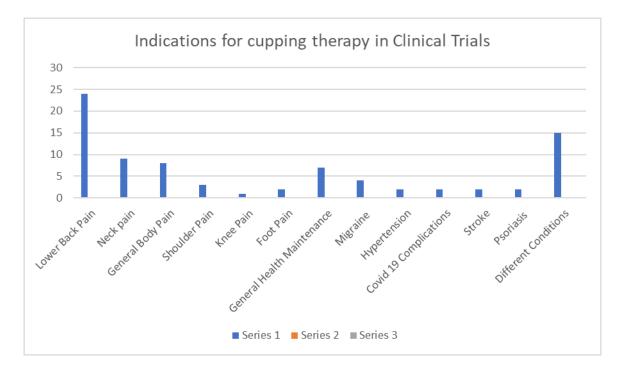


Chart 4. Indications for cupping therapy in Clinical Trials

Most of the indication reported are expected, since in most of the cases people are looking for cupping therapy for pain relief, however there are some interesting indications as fatty liver, anxiety, dysmenorrhea, hypertension and cognitive disfunction.

The fact that there are organized clinical trials in which targeted population are children is showing that the treatment can be safety used in treating both children and adults and it can be beneficial for almost everyone.

Reported Results of clinical trials

From the 81 reported clinical trials in which the main intervention is cupping therapy, results are available only for 1 of them.

This is showing the lack of quality in the organized clinical trials in which the main intervention is cupping therapy, however there is possibility that this can be due to the fact that the organizers and the investigators that are part of this type of clinical trials are using only domestic platforms for reporting the results of the clinical trials. This should be fixed, and the data should be reported on more platforms and the results should be available for everyone that has interest in these types of therapies. Future investigation should be made if there is some other relevant data available on other platforms.

One of the reported results after the clinical trial was conducted is regarding randomized clinical trial in which the efficacy of wet cupping in treatment of patients with hypertension was investigated, the conclusion of that clinical trial is that Wet-cupping therapy is effective for reducing systolic blood pressure in hypertensive patients for up to 4 weeks, without serious side effects. Wet cupping can be taken in consideration as a complementary treatment for hypertension and further researches are needed. [4]

Conclusion

The article is based on available data, reported 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 data, we can see that there are not a lot of clinical trials reported in which main intervention is cupping therapy. Also, from the available data we can see that most of the organized clinical trials are not with high quality. In almost every one of the reported clinical trials some data is missing or is not completely reported.

As mentioned above for only one of all the 81 reported clinical trials relevant result is reported. The result is promising and is showing good potential in using cupping therapy in treatment of hypertension at patients.

Overall, the number of organized clinical trials is low, organizing of new clinical trials in which the main intervention is cupping therapy are needed, in which if the results will be positive, it can be beneficial for everyone, both the patients and the practitioners of this therapeutical method.

As expected, the number of organized interventional clinical trials is significantly higher compared to the organized observational clinical trials. In most of the clinical trials new intervention that can be used for treatment of patients is investigated.

Regarding the countries in which the clinical trials have been organized, the number of the country in which most of the clinical trials have been organized and the number of not reported country in which the clinical trial is organized is showing the low quality of the reported data. As mentioned above this can be due to the fact that most of the clinical trials are organized in Asia, and the organizers and investigators are choosing some domestic platform for reporting the data.

This practice should be changed in future, and more platforms should be used.

Regarding the treated indications with cupping therapy, there are some expected indications, like pain in different locations of the patient's body, however there are some indications as fatty liver, anxiety, dysmenorrhea, hypertension and cognitive disfunction, that were not expected to be treated with cupping therapy. Overall, organizing more clinical trials with different indications can be beneficial for both the patients and the organizers of the clinical trials.

References

- Zhu J, Arsovska B, Kozovska K; The impact and role of the Traditional Chinese Medicine on human health; IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 17, Issue 10 Ver. 7 (October. 2018), PP 80-8
- Stojkovski K, Dameska-Stojkovska E, Stojkovski V, Petrov Mihaylov M, Clinical Trials in the Republic of Serbia after 2020, pp. 15-21 in Op. Acc. Inter. Jour. Acad. Res. UNIVERSES Volume 2, Issue 2
- 3. Tse T, Fain KM, Zarin DA. How to avoid common problems when using ClinicalTrials.gov in research: 10 issues to consider. *BMJ*. 2018;361:k1452
- Aleyeidi NA, Aseri KS, Matbouli SM, Sulaiamani AA, Kobeisy SA. Effects of wetcupping on blood pressure in hypertensive patients: a randomized controlled trial. J Integr Med. 2015 Nov;13(6):391-9. doi: 10.1016/S2095-4964(15)60197-2. PMID: 26559364.