São Paulo, Sep 6th 2017

Association of Acupuncture and Cupping in Advanced Knee Osteoarthritis
NCT 04168593

Informed Consent Form n 2.969.442
Approval on 9/6/2017

Research Title: Randomized controlled clinical trial of the use of Acupuncture and Cupping in patients awaiting Total Knee Arthroplasty (TKA) due to Osteoarthritis of the Knee.
Principal Investigator: Andre Wan Wen Tsai
Research advisor: Chin An Lin
Assistant researchers: Wu Tu Hsing, Raymundo Soares de Azevedo Neto, Marco Kawamura Demange, Ciro Blujus dos Santos Rohde, Liaw Wen Chao, Janini Chen, Marlene Yoko Hirano Ueda.

You are being invited to participate in this research, which aims to evaluate pain relief and improvement in your knee function through two Chinese Medicine techniques at the same time: Acupuncture combined with Cupping.
We are recruiting 120 (one hundred and twenty) volunteers who will be distributed into 4 (four) different groups by means of an electronic lottery (computer program).
Possible treatment groups are:
group A: acupuncture associated with cupping, both with minimal effects;
group B: minimal effects acupuncture associated with sliding cupping;
group C: classical acupuncture associated with minimal effects cupping;
group D: classical acupuncture and sliding cupping.
After determining which group you will belong to, there will be no possibility of changes. The treatment will be performed twice a week at the outpatient clinic of the Institute of Orthopedics and Traumatology, Hospital das Clínicas, Faculty of Medicine, University of São Paulo, for 5 sequential weeks, totaling 10 sessions.
There will be 2 moments in which the research team will apply 2 questionnaires that assess your pain, joint stiffness and quality of life. One before and one after the 10 sessions.
You are free to refuse to participate and still refuse to continue participating at any stage of the research, without any prejudice. Whenever you want, you can ask for more information about the research through the project researcher's telephone number and, if necessary, through the telephone number of the Research Ethics Committee.
It is very clear that by participating in this protocol, the volunteer will not have any damage in the progress of waiting for his prosthesis surgery at the Institute of Orthopedics and Traumatology of Hospital das Clínicas.
The treatments offered normally do not present complications to the patient, however, soreness and/or small bruises at the applied sites may occur.
In case of need, the participant can use paracetamol or dipyrone for pain relief, communicating the use to the researcher in the next session.

You will not incur any expenses to participate in this research, and nothing will be paid for your participation.
All information collected in this study is strictly confidential. Only the professionals involved in this project will have knowledge of the data. After these clarifications, we request your free consent to participate in this research. Therefore, please fill in the following items.

Note: Do not sign this term if you still have doubts about it.

Free and Informed Consent
In view of the items presented above, I freely and clearly express my consent to participate in the research. I declare that I have received a copy of this consent form, and I authorize the conduction of the research and the dissemination of the data obtained in this study.

_____
Research participant name

_____
Signature of the research participant

_____
Researcher Signature - Dr. André Wan Wen Tsai

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Other researchers: Ciro Rohde
Research Ethics Committee: CAPPesq
Committee Phone: 2661-6942