Tennis Elbow Acupuncture International Study  
China, Hong Kong, Australia and Italy (TEA-IS-CHAI)  
(UTS HREC REF NO. 2014000160A)

INFORMATION SHEET

WHO IS DOING THE RESEARCH?
The University of Technology, Sydney (UTS) is conducting a multi-site collaborative clinical trial research project with partners in China, Hong Kong and Italy. The Chief Australian investigator is A/Prof Christopher Zaslawski, Faculty of Science at UTS.

WHAT IS THIS RESEARCH ABOUT?
This research is to determine whether there are any health benefits using acupuncture or low level laser for people with lateral elbow pain.

IF YOU SAY YES, WHAT WILL IT INVOLVE?
You will be randomly allocated to one of two groups; either acupuncture or laser treatment three times per week for three weeks (treatments lasting approximately 45-60 minutes per session) to be conducted at the UTS TCM Clinic, Cnr Harris and Thomas Streets, Ultimo. The acupuncture will involve the insertion of sterile single use needles into two acupoints on the affected arm. Those receiving the laser will have low level laser light applied to the same acupoints as the acupuncture recipients. As the laser light is low intensity it is athermal (meaning no heat will be generated) and you may not experience any sensory feeling associated with its application.

A dynamometer (a device for measuring grip strength) and a Lafayette manual muscle tester (a device for measuring muscle tension) will be used before and after your treatment and at the three week follow-up (3 assessments). Participants will be asked to maintain a diary (monitoring medication, remedial exercise frequency and days off work due to the condition) and complete three different questionnaires at specially nominated times (Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, Pain questionnaire and a Sensation scale) pre and post treatment and at the three week follow-up.

ARE THERE ANY RISKS?
Yes, there are some risks. If you are randomised into the group receiving acupuncture, you are aware that acupuncture involves the insertion of fine needles into the skin. Side effects in acupuncture are infrequent and generally limited to bruising and spot bleeding. On rare occasions patients may feel faint and nauseous. A study (MacPherson et al, 2001) reported on adverse events and transient reactions associated with 34,407 prospective acupuncture treatments. No serious adverse events were reported, where these were defined as requiring hospital admission, prolonging hospital stays, permanently disabling, or resulting in death (95% CI: 0 to 1.1 per 10,000 treatments). A total of 43 significant minor adverse events were reported, a rate of 1.3 per 1,000 treatments. No adverse events have been published in the scientific literature associated with humans receiving low lever laser treatment.


WHY HAVE YOU BEEN ASKED?
You have been asked through a recruitment campaign because you:-
• Have chronic lateral elbow pain for a period greater than 3 months.
• The pain occurs on only one arm
• You are between 18-70 years of age

Unfortunately you will be excluded from the research project if you have:-
• Diseases of the central or peripheral nervous system
Inflammatory rheumatic diseases

Gout

Or have experienced a previous episode of lateral elbow pain that was treated surgically or have received:

- Acupuncture treatment or physiotherapy for tennis elbow within the previous 3 months
- Acupuncture treatment for any problems within the previous week
- Concurrent physiotherapy for tennis elbow

DO YOU HAVE TO SAY YES?
You don’t have to say yes.

WHAT WILL HAPPEN IF YOU SAY NO?
Nothing. I will thank you for your time so far and won’t contact you about this research again.

IF YOU SAY YES, CAN YOU CHANGE YOUR MIND LATER?
You can change your mind at any time and you don’t have to say why. You will be thanked for your time so far and you won’t be contacted about this research again.

WHAT IF YOU HAVE CONCERNS OR A COMPLAINT?
If you have concerns about the research, please feel free to contact the Recruitment Officer, Christine Berle on 0418 447 911 (email: Christine.Berle@uts.edu.au) or Chris Zaslawski on (9514 7856).

If you would like to talk to someone who is not connected with the research, you may contact the Research Ethics Officer on 02 9514 9615, and quote this number (UTS HREC REF NO. 201400160A).

IF YOU WANT TO KNOW MORE OR WANT TO APPLY?
Contact the Recruitment Officer, Christine Berle on 0418 447 911 or email Christine.Berle@uts.edu.au