

針灸治療網球肘國際多中心臨床研究

Tennis Elbow Acupuncture-International Study-China, Hong Kong, Australia and Italy (TEA-IS-CHAI)

研究背景：

網球肘是一種常見的痛症，以外側肘部肌肉疼痛為主要表現。常常由於附著在肱骨外上髁的肌腱發炎所引起，所以又叫肱骨外上髁炎。本病好發於經常需要前臂用力旋轉、反覆敲打或搬重物的人。患者用力握拳及或作前臂旋前伸肘動作（如絞毛巾、開門鎖及提取重物等），均會引起痛楚，影響日常生活。而現時的治療手段多數以藥物消炎止痛、注射類固醇，或物理治療方法以減少痛楚。可是這些治療未能完全解決網球肘的問題，易反覆發作，部分患者謂針灸治療能有助減輕病情。

研究機構：

本研究由香港浸會大學、長春中醫藥大學、雪梨科技大學和義大利 Instituto Paracelso 共同合作完成。香港浸會大學的項目領導者為中醫藥學院張世平博士。

地點：

研究將在香港浸會大學中醫藥學院開展。

第一階段：

第一階段的研究主要由香港浸會大學進行，目的為建立中醫針灸治療網球肘的中醫診斷標準。

現招募志願者參與，參加者須符合以下條件：

- 18 歲至 70 歲；
- 患有肘關節外側疼痛；

合適的參加者，將先接受第一階段的中醫診斷研究。過程包括以紅外線掃描紀錄疼痛部位的體溫及由中醫師作研究性診斷。全過程需時約 30 分鐘。如適合者將被邀請參與第二階段的針灸治療網球肘的臨床研究。

第二階段：

第二階段的研究由上述幾所機構同時開展，目的為確認特定的穴位刺激方法對於治療肘外側疼痛是否有利。

現招募志願者參與，參加者須符合以下條件：

- 18 歲至 70 歲；

- 患有長期肘外側疼痛 3 個月以上；
- 疼痛只出現在單側手臂。

合適的參加者，將會被隨機分配入針刺治療組或低強度激光治療組，並在香港浸會大學中醫藥學院接受為期 3 周，每週 3 次的針刺或激光治療（每次治療時間約為 45-60 分鐘）。針刺治療過程包含使用一次性無菌針灸針刺入患臂的兩個穴位，而激光治療組亦將會在相同的穴位接受低強度激光刺激。

在治療開始前，中段及所有治療結束後，我們將使用握力測量儀和拉斐特手動肌肉測試儀（測量手腕擴展力的裝置）分四次進行相關的機能測試。參與者也將被要求記錄自己的一些生活情況（用藥詳情、恢復性鍛煉的頻率和因網球肘疼痛不能工作的天數），並在指定的時間完成三種不同的問卷。

另外，在兩個治療組中，如果其中一組的治療效果沒有另外一組好，我們將會在所有研究完成後三至六個月的時間內，為效果較差的一組患者提供免費針灸治療肘外側疼痛九次。

有關第二階段研究的更多資料：

風險評估：參與此研究是否有風險？

是的，會有一些風險。如果您被隨機分配進入針刺組，您將會被細小針灸針紮入皮膚。針刺的副作用是罕見的，一般僅限於皮膚青紫和出血。極少數的病人可能會感到頭暈和噁心。一項針對 34407 次針灸治療的科研專案發現，有 43 例出現了輕微副作用，比例是千分之 1.3；但針灸不會導致嚴重的副作用（例如入院治療，長期住院，終生殘疾或者死亡）(MacPherson 等，2001 年)。在科學文獻中，尚未發現有關於人類接受低強度激光治療發生不良反應的報導。

參考文獻： MacPherson H, Thomas K, Walters S, Fitter M.(2001) A prospective survey of adverse events and treatment reactions following 34,000 consultations with professional acupuncturists. *Acupuncture in medicine*, 19, 2, p.93-101。

聯絡資料：

符合上述條件並有意參加本研究者，請致電 5488 8285 登記。如對本研究有任何疑問，請致電或電郵至 yimeng@hkbu.edu.hk。

本研究由香港浸會大學中醫藥學院撥款資助，參加者無需承擔針刺治療和與其相關的檢查費用。

研究組成員：

- 香港浸會大學中醫藥學院 張世平博士
- 香港浸會大學中醫藥學院 嚴韻詩醫師
- 香港浸會大學中醫藥學院 Marcus Gadau 先生
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Background:

Lateral epicondylitis, commonly known as tennis elbow, is a condition where there is pain found at the outer part of the elbow. This is usually due to the inflammation of the tendon attached to outer part of the humerus (upper bone that makes up the elbow). Tennis elbow is usually caused by repetitive wrist extension that leads to an overuse injury, followed by micro-tearing of the muscles involved. It might affect the daily activities (e.g. twisting a towel, opening a lock, or lifting an object) of people suffering from tennis elbow.

Conservative treatment of lateral epicondylitis is limited to taking pain killers, non-steroidal anti-inflammatory drugs (NSAIDs), injecting steroids, or physiotherapy treatment in order to minimize the pain. However, these treatments mostly do not fully relieve the condition. Patients suffering from tennis elbow oftentimes receive a series of different conservative treatments with little satisfying results.

Who is conducting the research?

The Hong Kong Baptist University is working on a multi-site, collaborative clinical on treating elbow pain with acupuncture with institutes in Australia, China and Italy. In Hong Kong the study is led by Dr. ZHANG Shi-ping, Associate Professor, School of Chinese Medicine, Hong Kong Baptist University.

Place:

The study to be conducted at School of Chinese Medicine, Hong Kong Baptist University.

PART ONE OF THE STUDY:

The first part of the study is conducted by The Hong Kong Baptist University alone. The aim is to set up a standardized tool for diagnosing the Chinese medicine pattern underlying tennis elbow.

The entry criteria are:

- Adults who are aged between 18-70

- Suffering from Tennis Elbow

Study Design:

Eligible participants will have their individual tennis elbow Chinese medicine pattern diagnosed with the help of a questionnaire, as well as have thermal images taken of their elbows. The whole process will take about 30 minutes. If eligible, the participants will be invited to participate in the second part of the study.

PART TWO OF THE STUDY:

The second part of the study is conducted by all above mentioned institutes. This research is to find out whether a particular type of stimulation at acupuncture points is of any health benefits in treatment of lateral elbow pain.

The entry criteria are:

- Adults who are aged between 18-70
- Have chronic lateral elbow pain for a period greater than 3 months.
- The pain occurs on only one side of your body

Study Design:

You will be randomly allocated to one of two groups to receive either acupuncture or low dose laser treatment three times per week for three weeks (treatments lasting approximately 45-60 minutes per session) to be conducted at School of Chinese Medicine, Hong Kong Baptist University. The acupuncture group will receive acupuncture needling at two acupoints at the affected elbow with disposable needles, whereas the laser treatment group will receive low intensity laser treatment.

A dynamometer (a device for measuring grip strength) and a Lafayette manual muscle tester (a device for measuring wrist extension force) will be used pre and post treatment, one week prior to commencing treatment and at a three week follow-up debriefing session (4 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.

In addition, if the results of this study show that the treatment effects of one group is inferior to the other group, we will provide make-up acupuncture treatments (9 in total) for the less-effective group free-of-charge 3-6 months after completion of the whole study.

More information about part two:

ARE THERE ANY RISKS?

Yes, there are some risks. If I am randomised into the group receiving acupuncture, I am 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. A total of 43 significant minor adverse events were reported, a rate of 1.3 per 1,000 treatments. No serious adverse events were reported, where these were defined as requiring hospital admission, prolonging hospital stays, permanently disabling, or resulting in death.

Reference: MacPherson H, Thomas K, Walters S, Fitter M.(2001) A prospective survey of adverse events and treatment reactions following 34,000 consultations with professional acupuncturists. *Acupuncture in medicine*, 19, 2, p.93-101.

CONTACT:

For those who meet the above criteria please call 5488 8285 and enroll in our study! If you have any questions in relation to the study, please also call our research team or email yimeng@hkbu.edu.hk.

Funding:

This study is funded by the Hong Kong Baptist University. Patients are not required to pay for participating.

Investigators:

- **Dr. ZHANG Shi Ping**, School of Chinese Medicine, HKBU
- **Ms. Wendy Yim**, School of Chinese Medicine, HKBU
- **Mr. Marcus Gadau**, School of Chinese Medicine, HKBU
- **Ms. Moment YUAN**, School of Chinese Medicine, HKBU