

2008 AACMA Research Grants Abstracts

The following abstracts comprise the successful applications for the 2008 AACMA Research Grants.

INVESTIGATION OF THE ANTICANCER EFFECTS AND THE MECHANISM OF ACTIONS OF EXTRACTS FROM CHINESE HERBAL MEDICINE FORMULAE ON PROLIFERATION OF HUMAN OVARIAN CANCER CELL LINES

Yuling Chen, Suilin Mo, Felix Wu Shun Wong and Daniel Man-yuen Sze
University of New South Wales
Award: \$2500

BACKGROUND

The use of traditional Chinese medicine (TCM) as a complementary therapy is getting more and more popular in cancer management. In addition, for many years, there have been demands for scientific evidence to support the professional use of Chinese herbal medicine (CHM) in oncology. Our previous study showed that some CHM formulae have an anti-proliferative effect on human ovarian cancer cell lines. However, it is important to provide further evidence to allow in-depth understanding of the probable mechanisms of action, which will provide a better understanding of how CHM may work clinically in cancer treatment and, in this particular context, targeting gynaecological ovarian cancer.

AIMS

The specific aims of the study are:

1. To evaluate NO1013 Formula, Modified NO1013 Formula, and Erzhu Decoction for their anti-tumour activities, as shown by their abilities to inhibit the proliferation of ovarian cancer cell lines, leading to the induction of cancer cell apoptosis;
2. To determine the related mechanisms underlying proliferative inhibition

and apoptotic actions of the CHM formulae.

METHODS

Effect of CHM formulae on proliferation of cancer cell lines

Drug-induced cell viability or proliferation effects will be measured by the commercially available CellTiter-Glo Luminescent Cell Viability Assay. By measuring cell ATP, this assay indicates the total 'live' cells in cancer cell lines.

Effect of CHM formulae inducing apoptosis of cancer cell line

After treatment with CHM formulae, a combination of Propidium Iodide staining and Annexin V binding (ANNEXIN V-FITC Apoptosis Detection Kit [BD Biosciences]) will be used to measure, by flow cytometry, for apoptotic cells versus cells dead by necrosis, following the manufacturer's instructions.

Effect of CHM formulae on the cell cycle arrest of ovarian cancer cell lines

After treatment with CHM formulae, cancer cells will be fixed with ethanol and stained with Propidium Iodide, then analysed by flow cytometry to determine the proportion of various fractions of cells in different cell cycle phases.

SIGNIFICANCE

This study will demonstrate the anti-cancer activity and the related mechanism of actions of the selected CHM formulae. With subsequent bioassay-guided fractionation and purification processes, we also aim at bioprospecting novel anti-cancer medicines derived from clinically used, evidence-based Chinese herbal medicine.

TRADITIONAL CHINESE MEDICINE DIAGNOSIS FOR PRE-DIABETES AND DEVELOPMENT OF A CHINESE MEDICINE ASSESSMENT MEASURE

Suzanne Grant and Emma Scully
University of Western Sydney
Award: \$2000

BACKGROUND

Central to the practice of traditional Chinese medicine (TCM) is a unique diagnostic framework. TCM diagnosis is not well integrated into research and few formal attempts have been made to evaluate its validity and reliability. The Harvard Medical School Division for Complementary and Integrative Medical Therapies and the New England School of Acupuncture (NESA) in the United States have developed a structured assessment instrument: the Traditional East Asian Medicine Structured Interview, TCM version (TEAMS1-TCM).

AIM

The hypothesis is that this instrument will increase the inter-rater reliability of TCM diagnosis when used in clinical trials. The testing phase of this instrument is currently underway. In Australia, the TEAMS1-TCM instrument will be tested as part of a clinical trial being conducted by the University of Western Sydney to evaluate the effectiveness of a Chinese herbal formula in the treatment of pre-diabetes.

METHOD

Thirty participants with pre-diabetes will be interviewed separately by two TCM practitioners. The results will be compared and inter-rater reliability

assessed. TCM patterns of pre-diabetes will be identified. The interview forms will be evaluated for their capacity to collect sufficient data, whether they do so in a naturalistic manner, and how the experience of using the form differs from the training and experience of practitioners.

SIGNIFICANCE

These results will contribute significantly to the refinement of a valid instrument to enable the use TCM diagnosis in clinical trials.

A RANDOMISED TRIAL OF ELECTOACUPUNCTURE VERSUS SHAM ACUPUNCTURE AND NO ACUPUNCTURE FOR THE CONTROL OF ACUTE AND DELAYED CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING

Christopher McKeon, Kerry Reed and Janet Hardy
Mater Adult Hospital
Award: \$2500

BACKGROUND

Chemotherapy-induced nausea and vomiting (CINV) continues to be a major concern for patients despite new and improved antiemetic therapy.¹ CINV can be described as acute, (in the first 24 hours) and/or delayed (from day 2 to day 5 post chemotherapy). In an observational study the incidence of post-chemotherapy nausea was 62% on days 1 to 5 post chemotherapy, 77% of patients suffered at least mild nausea.¹ Despite the advancements in antiemetic therapy, there still remain those who experience some form of CINV which impacts on their quality of life.¹

Streitberger et al.² identified that a growing number of studies have shown the benefit of electroacupuncture for CINV. A systematic review by Ezzo et al.³ as part of the Cochrane Collaborative Review recommended that, as most of the electroacupuncture (EA) studies did

not use modern antiemetics, further studies need to be done with concurrent use of modern antiemetics. The review also noted that very few of the studies addressed the benefit of EA on delayed CINV.

AIM

The aim of the trial is to determine whether real EA, in addition to standard treatment, gives greater relief from CINV over the 7-day study period than sham EA or no acupuncture as measured by the Functional Living Index Emesis score.

METHODS

Patients with cancer admitted to the haematology/oncology day unit for moderate- to high-dose chemotherapy for their first cycle of chemotherapy will be recruited and randomly assigned into one of the three arms.

1. Treatment arm. Standard EA applied to ST36 *Zusanli*, PC6 *Neiguan*, LR3 *Taichong* and LI4 *Hegu* bilaterally, and *deqi* will be obtained. The frequency of stimulation will be 10 Hz and intensity of stimulation will be adjusted according to the patient's tolerance (maximum 10 mA). Stimulation will commence 10 minutes prior to chemotherapy starting and continue for a total of 30 minutes on the first cycle. Treatment will be given on day 1 and day 3.

2. Sham EA arm. Each point will be defined by the corresponding acupuncture points and measurements, i.e. 1 cun lateral to PC6 *Neiguan*, midpoint between ST36 *Zusanli* and GB34 *Yanglingquan*, 1 cun medial to LI4 *Hegu* and 1 cun lateral to LR3 *Taichong*. Once inserted, the needle will not be manipulated. The circuit will be set up in the same way as for the treatment arm. A non-functioning electroacupuncture machine will be used. Sham stimulation will be given in a similar manner as the real EA treatment.

3. No-acupuncture group. Patients in this group will receive standard

antiemetic medication treatment without acupuncture.

Antiemetics

All patients will receive standard antiemetic therapy as per Mater Health Services protocols. All patients will receive rescue antiemetics, according to protocol if required.

Outcome measures

Instruments:

1. FLIE (Functional Living Index Emesis): The FLIE is a validated nausea- and vomiting-specific patient-reported outcome instrument that rates nausea and number of vomits and the impact of CINV on QoL (quality of life). QoL and the effects of CINV have been identified as impacting directly on the health care decision and continuation of treatment by patients.

2. Patient diary: Patients will be given a diary scoring daily nausea (using a 100 mm VAS scale), the number of vomits and use of rescue emetic medications for 7 days post chemotherapy.

Primary outcome measure:

- FLIE score at day 7 as compared to baseline.

Secondary outcome measures:

- FLIE score at day 3 compared to baseline;
- Number of vomits, days 1–6;
- Nausea score, days 1–6.

SIGNIFICANCE

CINV is still a major problem for cancer patients, even with the newer antiemetic regimes and drugs in use today. The significant aspects of the current study include:

- testing the benefit of EA as an adjuvant treatment for CINV;
- addressing the lack of evidence identified in the literature reviews; and
- providing support for the establishment of acupuncture as a service in the Mater Adult Hospital Cancer Service.

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3. Ezzo J, Vickers A, Richardson MA et al. Acupuncture-point stimulation for chemotherapy-induced nausea and vomiting. *J Clin Oncol* 2005;23:7188–98.

COLLECTION OF
DATA FROM A TCM
QUESTIONNAIRE,
PRACTITIONERS AND
MEDS DEVICE: A PILOT
TRIAL

**Michael Popplewell, Chris Zaslowski,
John Reizes and Narelle Smith**
University of Technology, Sydney
Award: \$1000

BACKGROUND

Many electrical devices have been purported to diagnose the condition of patients from a traditional Chinese medical (TCM) perspective with little published data to verify this assertion. Further, devices currently on the market have many flaws, thereby justifiably drawing criticism from the scientific community. The chief researcher, as part of his Master of Engineering Research (MER), constructed, validated and pilot-tested a device called the Meridian Electrical Data System (MEDS). This pilot study consisted of two-hourly data collections from 8 am to 6 pm from ten subjects. A particularly interesting observation was a diurnal variation in phase angle and impedance over time for each participant; unexpectedly, the subjects varied uniquely.

This pilot study and its interesting results led to a PhD at UTS. It was proposed that the diurnal variations observed in the Master's pilot may be the result of health disturbances in the subjects that could be identified by and correlated to TCM

patterns. In any case, this observation warranted further investigation.

As a first step towards this goal, a questionnaire called the Diagnostic System of Oriental Medicine (DSOM) was identified as a tool to objectively diagnose subjects from a TCM perspective. The DSOM was developed and validated by Professor Lee in Korea. It was translated into English and an attempt to validate it was performed with five practitioners each interviewing 34 subjects at the UTS clinic late last year. We will now take the next step and investigate possible correlations between MEDS, practitioner diagnoses and DSOM data.

AIM

We propose to undertake a clinical study to evaluate data collected from MEDS, the DSOM and two practitioners' TCM diagnoses and attempt to find any relationships.

METHODS

Subjects and treatment

Subjects will be tested in groups of three or four per data collection day. This is to determine whether the diurnal variations observed in earlier research are due to a collective influence that affects everyone or are unique to each individual and therefore possibly due to TCM diagnostic factors. Data will be collected at 10 am, midday and 2 pm from each subject with the same protocol that was used during previous data collections with MEDS. In between data collections, the subjects will complete the DSOM questionnaire and be diagnosed by two experienced practitioners. Lunch will be provided; fluid intake and environment conditions such as temperature and humidity will be controlled. No treatment intervention will be provided to any conditions diagnosed. As a pilot, it is proposed to test ten daily groups, with at least one group tested on two consecutive days.

Outcome measures

The primary outcome measures include:

correlation between datasets, which will indicate the agreement between practitioners, between practitioners and the DSOM, as well as between MEDS data and practitioners and DSOM; and using statistics such as Kappa statistics.

SIGNIFICANCE

The proposed pilot trial will be the first such project in the world in which objective and subjective TCM diagnoses are compared with a validated method of collection of electrical data from the meridian system of subjects. Should the results provide agreement between electrical data collected from the meridian system of a patient and TCM diagnoses, MEDS will then become a valuable diagnostic tool for TCM.

THE EFFECT OF
ACUPUNCTURE ON
OVARIAN BLOOD FLOW
AND FOLLICULAR
HEALTH AMONG 'IVF
POOR RESPONDERS': A
PILOT STUDY

Caroline Smith and Kelton Tremellen
University of Adelaide and
REPROMED
Award: \$5000

BACKGROUND

A poor response to ovarian stimulation is one complication of IVF, and is defined as failure of the development of sufficient number of mature follicles to proceed to oocyte retrieval, or the development of only a few oocytes following gonadotrophin stimulation. A poor response occurs in about 9–24% of women undergoing IVF.

According to Liang,¹ biomedical diagnoses of infertility can be viewed from TCM patterns. Poor follicle and/or egg quality can be viewed from a Kidney deficiency, with other Blood or Qi imbalances. Women who respond poorly to ovarian stimulation in an IVF cycle have been shown to have compromised blood flow to their ovarian follicles when compared to women with

normal ovarian responses. The levels of vasoactive protein vascular endothelial growth factor (VEGF) in the follicular fluid of poor responders is higher than that of normal responders, and levels are inversely related to the subsequent embryo quality.

Research suggests acupuncture may exert a sympatho-inhibitory effect reducing uterine artery impedance and thereby increase uterine and ovarian blood flow. Acupuncture may therefore improve circulation to the ovary. Acupuncture has also been shown to modulate the production of angiogenic factors such as VEGF.

AIM

This pilot study will examine whether acupuncture can improve ovarian blood flow and follicular health among women with a poor response to IVF treatment.

METHODS

Study design Clinical trial with subjects acting as their own self control.

Eligibility: Women who have a poor ovarian response in IVF cycles.

The study will involve before and after testing, with women acting as their own control. Phase 1 will establish baseline measurements for the study outcomes, and phase 2 will involve the acupuncture intervention, followed by measurement of outcomes at oocyte retrieval. The diagnosis and treatment will follow an agreed algorithm. Three acupuncture treatments will be administered.

Primary endpoints

The effects of acupuncture on the follicle will be assessed by changes from baseline to egg retrieval, as measured by:

- peri-follicular blood flow;
- levels of follicular fluid VEGF;
- level of follicular fluid anti-mullerian hormone (AMH).

We intend to recruit 20 subjects. This study will provide preliminary data

as to the effect of acupuncture on follicular health, and ovarian blood flow, and provide further evidence to the adjunctive role of acupuncture to assisted reproduction.

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BRAIN MAPPING OF CLINICAL ACUPUNCTURE EFFECTS WITH HIGH FIELD FUNCTIONAL MRI (fMRI)

Mark W Strudwick
Wesley Hospital
Award: \$3000

INTRODUCTION

Carpal tunnel syndrome (CTS) is a common entrapment neuropathy, with variable response to treatment, often seen in acupuncture practice.¹⁻³ The acupoint PC7 *Daling*, at the midpoint of the transverse crease of the wrist, is commonly listed in treatment of CTS.⁴⁻⁶ Conversely, another acupoint – ST 36 *Zusanli* – has no reported efficacy in the treatment of CTS.

Does PC7 have only the reported local effects, or are there effects within the central nervous system (CNS) accounting for its effectiveness?

In past studies, the insula has shown graded responses both to pain stimuli and acupoint stimulation. Is similar activity involved in the pain-relieving qualities of PC7? Is insula activation specific to the pain relieving qualities of an acupoint, or merely an epiphenomenon of stimulation?

METHODS

In a pilot project, nine subjects (six male) with documented CTS were

studied using fMRI to determine brain areas responding to point injection (PI) stimulation⁷ of PC7 with a comparison being made to areas affected by similar stimulation of ST 36 (used as a general analgesic point). Subjects were randomly allocated to one of two groups, one point being stimulated at the first session and the other four hours later. Subjective response was assessed by questionnaire before and after scanning; physiological response was measured immediately before and 20 minutes after stimulation, while continuous recordings were made of heart rate (HR) and intrapoint pressure at 2.5-second intervals throughout the experiment.

RESULTS

Repeated measures t-tests of mean heart rate (HR) and pressure-rate-product (PRP) before and after stimulation demonstrated a significant decrease in HR and PRP at PC7 and HR at ST36 – indicating an effect of stimulation (see Table 1). Results from the analysis of grouped imaging data with statistical parametric mapping ($p < 0.01$ uncorrected) are presented in Table 2. The results represent the signal positively correlated with the manometer pressure reading (increases) and negatively correlated with it (decreases). A decreased BOLD response was demonstrated in the insula cortex with increased response in the angular gyrus bilaterally with stimulation of PC7; while ST36 produced decreased response in the ipsilateral precuneus, supplementary motor area (SMA) and contralateral angular gyrus.

CONCLUSION

This pilot study demonstrated that an acupoint designated for the treatment of a specific disease induced a cerebral response pattern different from that of a non-treatment acupoint, measurable with fMRI. Further investigation of this is warranted on the basis that an increased understanding of these responses may lead to improved clinical outcomes.

TABLE 1 Physiological measurements: repeated measures t-tests, mean (SD)

Stimulation		N	Baseline	Endpoint	Paired difference	p (2-tailed)
PC7 <i>Daling</i>	HR*	9	78.1 (9.4)	73.0 (9.6)	5.1	<.001
	PRP#	9	10.39 (1.83)	9.61 (1.32)	0.78	.013
ST36 <i>Zusanli</i>	HR	9	75.4 (9.1)	70.4 (9.6)	5.0	.014
	PRP	9	9.72 (1.32)	9.26 (1.86)	0.46	NS

*HR = heart rate (beats/min); #PRP = pressure-rate-product

TABLE 2 Group activations

PC7 <i>Daling</i>				ST36 <i>Zusanli</i>			
Label	MNI co-ordinates (mm)	Z	Activity	Label	MNI co-ordinates (mm)	Z	Activity
(c)* insula	-30 12 9	4.79	↓	(i) precuneus	9 -54 57	4.16	↓
(i)# insula	36 27 6	3.68	↓	(i) SMA	12 6 54	3.88	↓
(i) angular	39 -72 54	3.94	↑	(c) angular	-63 -42 36	3.79	↓
(c) angular	-48 -57 42	3.72	↑	(c) post cingulum	-15 -45 21	3.65	↑
(i) inferofrontal operculum	36 6 27	3.68	↓				

*(c) = contralateral; #(i) = ipsilateral

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ACUPUNCTURE AND MAJOR DEPRESSIVE DISORDER: IS PATTERN DIFFERENTIATION NECESSARY?

Kirk Wilson, Peter Meier, Carole Rogers and Ashley Craig
University of Technology, Sydney
Award: \$1500

BACKGROUND

One in five Australians will experience depression at some time. This study tests the effectiveness of acupuncture as an adjunct therapy to Western medical drug therapy for depression. The study also aims to develop a more rigorous experimental design for acupuncture in depression trials than those noted in published literature.

METHOD

Subjects experiencing an episode of major depressive disorder according to the Diagnostic and Statistical Manual

for Mental Disorders IV (DSM IV), currently taking Serotonin Selective Reuptake Inhibitors (SSRI) and diagnosed as having Liver qi stagnation according to Chinese medical theory are randomly assigned into a treatment group or wait-list control group. The acupuncture prescription has been standardised and twelve treatments are administered over eight weeks. Control subjects receive the same intervention as the treatment group at the conclusion of the wait period. The Beck Depression Inventory II, Hamilton Rating Scale for Depression, State-Trait Anxiety Inventory for Adults and Symptomatic Checklist-90R are administered before and after intervention and at an eight week post-treatment follow-up.

RESULTS

Interim results suggest that acupuncture may be an effective adjunct treatment to SSRI therapy. Average BDI scores suggest subjects are entering the study classified as severely depressed (average BDI score of 29.95), and score as mild to moderately depressed (average BDI scores of 14.5) after the acupuncture intervention. The wait-list control group shows no statistically significant change in the severity of their depression.

THE EFFECT OF ACUPUNCTURE COMPARED TO USUAL CARE ON STOPPING SMOKING IN ADULTS: A SINGLE-BLIND, RANDOMISED, CONTROLLED STUDY
Chris Zaslowski, Deirdre Cobbin and Jenny Head
University of Technology, Sydney
Award: \$2500

INTRODUCTION

Smoking causes the deaths of approximately 19000 Australians per year. While Australian guidelines for smoking cessation advice recommend that, based on current evidence, acupuncture has little to offer, many

smokers continue to use complementary therapies such as acupuncture in their quest to quit smoking. The need for a well-designed controlled study is necessary to either confirm or refute the claim that acupuncture can significantly improve cessation rates in adults. This randomised, controlled, single-blind study uses established objective outcomes measures that include measurement of expired carbon monoxide and urine cotinine levels at 4, 8 and 26 weeks. In addition, it evaluates the participants' levels of cigarette craving, smoking urges, withdrawal symptoms, nicotine dependence and general wellbeing. The trial design has two parallel arms that uses an invasive sham acupuncture group (punctures the skin but not at acupoint sites) compared with a usual treatment group receiving counselling.

DESIGN

This is a single-blind, randomised, controlled trial on the effect of acupuncture in conjunction with advice on smoking cessation in adult smokers with three parallel arms ($n = 201$). Acupuncture (verum or invasive sham) will be given to two groups three times a week for four weeks and a continuous stimulation will be provided by use of a retained press needle on one of the ear acupoints. One group will receive 'Nicobate' nicotine replacement therapy patches. Smoking cessation advice (SCA) following Australian government guidelines will be given to all groups, as advice increases cessation and combining advice and other interventions improves outcomes.

The trial is applying the Russell standard at six months (RS6) for evaluating cessation by including biochemical measures of urine cotinine (a byproduct of nicotine excreted in the urine) and carbon monoxide readings (with the 'Smokerlyzer') as an independent confirmation of self reporting of smoking cessation at 6 months (RS6). Subjects who drop out are treated as intention-to-treat, and all subjects are followed up unless they die or become untraceable.

Outcome measures

The trial will use the 'Russell Standard' (RS), a gold standard for outcome criteria in smoking cessation trials.

Primary measure: Smoking cessation at week 26 as assessed by 'RS abstinence', defined as a self report of smoking not more than five cigarettes from the start of the abstinence period, supported by a negative biochemical test. Two biochemical tests will be used during the trial and at the endpoint of 26 weeks. At weeks 4, 8 and 26, the expired air carbon monoxide (CO) method will be used to detect recent smoking. A reading of 10 parts per million signifies smoking.

In addition, a urine cotinine analysis which is more sensitive and specific than CO will be taken at weeks 4, 8 and 26. A failed biochemical test classifies a participant as smoking, even when this is explained by the recent smoking of one to five cigarettes allowed throughout the follow-up period.

Secondary measures: A battery of questionnaires will be administered at baseline prior to the introduction of the intervention, and at weeks 4, 8 and 26. These instruments are:

- Fagerstrom nicotine dependence questionnaire;
- Shiffman-Jarvik smoking withdrawal questionnaire;
- Smoking Urges (brief) questionnaire;
- Post-treatment smoking cravings questionnaire;
- SF36 general wellbeing questionnaire.

EAR ACUPRESSURE FOR ALLERGIC RHINITIS: A RANDOMISED, SINGLE-BLINDED, SHAM-CONTROLLED, CLINICAL TRIAL

Claire Shuiqing Zhang, Angela Weihong Yang, Anthony Lin Zhang, Francis Thien, George Lewith, George Owe-Young and Charlie Changli Xue
RMIT University

Award: \$2000

BACKGROUND

Allergic Rhinitis (AR), including seasonal allergic rhinitis or perennial allergic rhinitis, is a common condition which affects 10–40% of the population globally, and the prevalence has increased in the last few decades.¹ In Australia, AR is one of the most common long-term conditions and it affects about 16% of the population. AR may cause impairment of physical, emotional and social functions, and poor quality of life. The common management of AR includes avoidance of exposure to allergens, medication and immunotherapy. In recent years, there are more and more AR sufferers seeking complementary and alternative medicine for treating AR.² Ear acupressure is a non-invasive technique using pellets attached to auricular points to achieve therapeutic effects. It has been proved to be effective and safe for the management of AR by a number of clinical studies.^{3–5} However, there is a lack of randomised controlled trials with rigorous methodology using ear acupressure to treat AR. This study is a randomised, single-blinded, sham-controlled, clinical trial to investigate the efficacy and safety of ear acupressure for the treatment of adults with AR.

METHODOLOGY

The trial will consist of a baseline period followed by a treatment period and a follow-up period. Participants will be randomly assigned into either real ear acupressure treatment or sham ear acupressure control group. The ear acupressure is achieved by using commercial stainless steel press-pellets. During the treatment, the participant will receive pellets taped on the real or sham ear points on one of the participant's ears. Outcome measures, including the severity of nasal symptoms and non-nasal symptoms, quality of life related to AR, participants' medication usage and medical expenses related to AR and participants' opinion about ear-acupressure, will be collected through participants' self-administered questionnaires.

SIGNIFICANCE OF THE STUDY

This study may provide evidence of ear-acupressure as an alternative therapy for the treatment of AR. It may contribute to the management of AR by providing data on symptomatic relief, improvement of AR sufferers' quality of life, and reduction of the use of Western drugs.

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EDITOR'S NOTE: Professor Xue has been researching Chinese medicine treatment for allergic rhinitis over the last 12 years. This year his research has received NHMRC support. An acupuncture trial for seasonal allergic rhinitis will be conducted in Melbourne in the coming three years.

COMBINED THERAPY OF
ELECTROACUPUNCTURE
AND COGNITIVE
BEHAVIOURAL THERAPY
FOR TENSION-
TYPE HEADACHE:
A RANDOMISED,
CONTROLLED PILOT
TRIAL

Zhen Zheng, Charlie Changli Xue and
Ken Greenwood
RMIT University
Award: \$3000

BACKGROUND

Tension-type headache (TTH) is

described as pressing pain or tightness on both sides of the head with mild to moderate intensity, and it affects up to three-quarters of the world's population and more than one-third of Australians. The majority of patients experience reduced quality of life and reduced effectiveness at work, school and home for up to one month each year. The causes of TTH include mental and physical stress and muscle tension on the scalp and around the neck. Commonly-used medications include simple pain killers and anti-depressants. They are either not effective for long-term management or not tolerated by patients due to side-effects. Nearly one-quarter of TTH patients develop medication-overuse headache or chronic daily headache over a 10-year period.

Acupuncture is effective for various types of headache, and relieves TTH by 50% within 4 to 12 weeks of treatment, as demonstrated by a few high quality clinical studies. However, it does not address mental stress, the main trigger for TTH, and its long-term effect is uncertain. Cognitive behavioural therapy (CBT) utilises various techniques and teaches patients how to cope with mental stress and correct unhelpful thoughts, beliefs and behaviour, and thus produces a long-term effect for TTH patients.

AIM

We propose to undertake a clinical study to evaluate the long-term efficacy and safety of the combined therapy of electroacupuncture (EA) and CBT for TTH.

METHODS

Subjects and treatment

Twenty TTH patients will be included and randomly allocated to (1) an individualised EA alone group, and (2) an individualised EA then CBT group. The first group will have up to 18 sessions of EA over 12 weeks, and the second group will have up to 12 sessions of EA over six weeks then six sessions of CBT over six weeks. Treatment will be

delivered by a registered acupuncturist and a registered psychologist.

Outcome measure

The primary outcome measures include: (1) number of days with headache per four weeks (with headache diaries); and (2) mean severity of average and worst headaches assessed with Visual Analogues Scales (VASs, 0 = no pain; 10 = worst pain possible) per four weeks (with headache diaries).

The secondary outcome measures include: (1) analgesics consumption for TTH per four weeks (with headache diaries); (2) any co-intervention for TTH per four weeks (with headache diaries); (3) mean duration of headaches per four weeks (with headache diaries); (4) Headache Impact Questionnaire (HIQ), which assesses pain as well as absence from work and reduced productivity; (5) Quality of life (QoL) assessed with SF-36; and (6) levels of stress experienced, assessed with Perceived Stress Scale-10 (PSS-10).

SIGNIFICANCE

The proposed pilot trial will be the first such project in the world in which acupuncture is combined with a well-received and practised intervention in pain management for TTH. The results will provide a rationale for a larger trial and be of significant value to patients and to clinicians in decision-making about the treatment of TTH.

EDITOR'S NOTE: A 2008 AACMA research grant was awarded to the pilot study. A study with a large sample size has received an NHMRC project grant in 2009 and will be conducted in Melbourne in the next three years.