Evaluation of the Effectiveness of Laser Acupuncture on Osteo-arthritic Knee Pain: A Randomised, Double-blind, Placebo-controlled Clinical Research Trial

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Certificate of Original Authorship

I certify that the work in this thesis has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree except as part of the collaborative doctoral degree and/or fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help that I have received in my research work and the preparation of the thesis itself has been acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

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Signature of Student

Mei-kin Li Rees

March 2017

Dedication & Acknowledgements

Dedication

This study is dedicated to the memory of:

- My proud parents, Lee Wing-wah and Yuen Sin-ching, and sister, Lee Chi-kin, each of whom encouraged the virtue of passion, dedication, determination and persistence – the very qualities that made completion of this study possible. Dad, Mum, Sister, you are forever in my thoughts; and

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Laser Technical Assistance

Dr Cedric Chaminade, Physicist, Raymax Applications Pty Ltd, Warriewood, New South Wales, Australia.

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Outcome Measures

Professor Nicholas Bellamy – Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Grant J. Devilly – Credibility/Expectancy Questionnaire (C/E)

Ronald Melzack – Short form McGill Pain Questionnaire (SF-MPQ)

Adam O. Horvath – Working Alliance Inventory Short Form – WAI (C)

Kenneth Wallston – Multi-dimensional Health Locus of Control Form C (MHLC-C)

Abstract

Background and Objectives

Worldwide, osteoarthritis (OA) is the major cause of musculoskeletal pain and mobility disability in elderly people. The objective of this randomised, double-blind, placebo-controlled clinical trial was to evaluate the effectiveness of laser acupuncture on osteoarthritis knee (OAK) pain. Traditional acupuncture philosophy, treatment principles and techniques were integrated with modern laser technology. The study tested the null hypothesis that laser acupuncture does not reduce pain and stiffness and improve physical function in OAK.

Study Design and Methods

Forty participants screened against Kellgren-Lawrence OA scale 2-3 and other inclusion/exclusion criteria were randomised equally into two groups – active and sham laser acupuncture – using computer-generated sequential numbers. Both the operator and participants were blinded to allocation.

An 810 nm 100mW Class 3B infra-red laser fitted with two identical probes – one active and one deactivated by the manufacturer – was used in the study. This type of laser provided a credible placebo arrangement because its invisible beam produces neither heat nor sensation when applied to the skin, thus eliminating potential bias.

At each treatment, the laser delivered 18J for two minutes to two sets of OAK-specific acupuncture points targeting Phlegm Retention and Blood Stasis and the underlying causes and symptoms according to the TCM paradigm. The 13 acupuncture points were aimed at reducing dampness and swelling, tonifying the Kidney, clearing blockages and stagnation of Qi and Blood, and soothing the Liver. In terms of Western science, laser is known to regenerate osteoblasts and cartilage, and produce analgesic effects through the release of serotonin and endorphins.

Treatments were administered three times a week over four weeks (i.e. a total of 12 treatments). Assessments occurred at four-week intervals with four time points over three months using a General Linear Model with repeated measures. Data were

analysed on an intention-to-treat basis. All data were carried forward, limiting bias for the six participants who dropped out. Participants experienced no adverse effects.

WOMAC (the gold standard for assessing OAK), VAS, McGill Pain Questionnaire, Credibility/Expectancy Questionnaire, Working Alliance Inventory and Multi-dimensional Health Locus of Control measured treatment outcomes, plus the psychometric and placebo effects of the practitioner-patient relationship and the power of others respectively.

Results

Study results rejected the null hypothesis, accepting the alternative hypothesis that the novel integration of laser with TCM methods safely reduces OAK pain and stiffness and improves physical function. All primary outcome measures scored $p < 0.05$. The vascular density of acupuncture points appears to amplify two energy-transporting systems – one based on TCM channel theory; the other cellular and peripheral nerve transduction signaling believed to occur in photo-biomodulation – thus magnifying and accelerating healing and metabolic processes. The study identified, for the first time, the importance of selecting optimum laser parameters, precise TCM diagnosis for OAK disease differentiation with specific acupuncture point formulae targeting the underlying causes and symptoms of OAK. Additionally, placebo assessment measured the importance of the patient-practitioner relationship, bonding, faith and task compliance in working towards mutual treatment goals.

Conclusion: The study indicates that irradiating specific acupuncture points according to the TCM paradigm offers a safe and effective treatment for OAK. Further studies are needed to confirm these findings.

List of Conference Presentations and Posters Arising from the Research

- Rees, L.M.K..; Meier, P.; late Rogers, C.; late Smith, N. Preliminary results of randomised, placebo-controlled clinical trial evaluating the effectiveness of laser acupuncture on osteoarthritic knee pain. Presented at Laser Helsinki 2012 World Congress Helsinki, Finland, August 2012.

- Rees, L.M.K.; Meier, P.; late Rogers, C.; late Smith, N. Preliminary results of randomised, placebo-controlled clinical trial evaluating the effectiveness of laser acupuncture on osteoarthritic knee pain. Presented at World Federation of Acupuncture/Moxibustion Societies 8th World Conference, Sydney, New South Wales, Australia, November 2013.

- Rees, L.M.K.; Meier, P.; late Rogers, C.; late Smith, N. Preliminary results of randomised, placebo-controlled clinical trial evaluating the effectiveness of laser acupuncture on osteoarthritic knee pain. Poster presentation Society of Acupuncture Research International Conference, Beijing, China, 30 May - 1 June 2014.

- Rees, L.M.K.; Meier, P.; Brown, J.; late Rogers, C.; late Smith, N. Abstract on results of randomised, placebo-controlled clinical trial evaluating the effectiveness of laser acupuncture on osteoarthritic knee pain at 37th American Society of Laser Medicine and Surgery Annual Conference on Energy-based Medicine and Science, San Diego, California USA, 5-9 April 2017.
  (Abstract Nominated for Best Basic Science and Translational Research)

- Rees, L.M.K.; Meier, P.; late Rogers, C.; late Smith, N. Abstract on results of randomised, placebo-controlled clinical trial evaluating the effectiveness of laser

acupuncture on osteoarthritic knee pain. Presented at Society for Acupuncture Research 2017: Advancing the Precision Medicine Initiative Through Acupuncture Research, San Francisco, California, USA, 27-29 April 2017.

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