Research Snapshots

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UTILIZATION OF GROUP-BASED, COMMUNITY ACUPUNCTURE CLINICS: A COMPARATIVE STUDY WITH A NATIONALLY REPRESENTATIVE SAMPLE OF ACUPUNCTURE USERS

BACKGROUND: Community acupuncture clinics in the United States of America (USA) provide treatments similar to the practice of group treatments in China. The arrangement of multi-beds or recliners in a room allows an acupuncturist to treat several patients concurrently. The treatment sessions are charged based on a sliding scale. This mode of treatment delivery is affordable, especially for uninsured people in the USA.

OBJECTIVES: To compare the demographic, health conditions and treatment frequency patterns of local community acupuncture users with national acupuncture users in the USA.

METHODS: Cross-sectional survey data of: a) two community acupuncture clinics in Portland, Oregon; b) the 2007 National Health Interview Survey (NHIS), which contains a sample of acupuncture users. The data of community-based treatment were obtained for six weeks from December 2009 to January 2010. Return patients visiting community acupuncture clinics were requested to complete a paper-based survey. The researchers aimed to collect 500 completed surveys for a margin error of ±4% at 95% confidence interval.

The NHIS is performed annually at a national level. The 2007 NHIS covers usage of Complementary and Alternative Medicine (CAM) and the intention of seeking CAM treatment. The data of 344 participants who have had acupuncture treatments in the past year were drawn out from the NHIS sample.

RESULTS: Although 478 surveys on community-based treatment were completed, only 463 participants were included for the analysis. The remaining 13 surveys were excluded, as they were either the same participant completing it for the second time or the participant was unsure if they had completed the survey before.

In comparison to the national sample of acupuncture users, local community acupuncture users consisted of more locally-born people (only 7.9% identified a foreign birthplace), with an education background of college level and above (72.3% compared to 56.5% of national acupuncture users), and had a lower annual household income (46% less than $35 000). Furthermore, all of them had acupuncture treatments at an average fee of $40. About 48% of community acupuncture users had more than ten treatments in the previous year, whereas only 15% of national acupuncture users had the same treatment frequency.

Similarly, acupuncture users in both settings were predominantly female, less heterogeneous racially (86.6% of community acupuncture users and 73.2% of national acupuncture users were non-Hispanic White), claimed self-health status as good and very good and suffered similar health conditions prompting them to seek acupuncture treatment. Back pain and joint pain were the top two health conditions for which acupuncture treatment was sought. Interestingly, 12.8% of community acupuncture users sought treatment for depression whereas <1% of national acupuncture users had treatment for the same condition.

CONCLUSION: The researcher concluded that community acupuncture users comprised of wider socioeconomic characteristics and tended to have more frequent treatments.

COMMENTS: As the researcher outlined, a limitation of a self-administered survey is the sample does not represent acupuncture users who are discontented with the treatment and do not return for subsequent treatment. Although the data on community acupuncture users and national acupuncture users were collected in 2009 and 2007 respectively, the researchers asserted that the difference in annual household income and acupuncture treatment fee is insignificant.

The findings suggest that with affordable treatment fees – as seen in community acupuncture clinics – acupuncture users tend to have more frequent treatments. As there is a higher proportion of community acupuncture users receiving

treatment for depression, it would be interesting to see if there is a relationship between treatment frequency and its effect in managing such chronic health conditions.

Chao MT, Tippens KM, Connelly E. Utilization of group-based, community acupuncture clinics: A comparative study with a nationally representative sample of acupuncture users. J Altern Complement Medicine, 2012;18(6);561–6.

Wan Najbah Nik Nabil

PROSPECTIVE SELF-CONTROLLED TRIAL OF THE EFFICACY AND TOLERABILITY OF A HERBAL SYRUP FOR YOUNG CHILDREN WITH ECZEMA

OBJECTIVE: To evaluate the clinical efficacy and tolerability of a five-herb Chinese herbal formula in syrup form in young children with eczema.

METHOD: The study consisted of a single-centre, open-label trial, involving children aged 4–7 years with moderate-to-severe atopic dermatitis (AD). Children with active concurrent disease (except allergic diseases such as asthma and allergic rhinitis) were excluded. The trial intervention used was a Chinese herbal formula consisting of the herbs *Flos Lonicerae* (*Jinyinhua*) 2 g, *Herba Menthae* (*Bohe*) 1 g, *Cortex Moutan* (*Mudanpi*) 2 g, *Rhizoma Atractylodis* (*Cangzhu*) 2 g and *Cortex Phellodendri* (*Huangbai*) 2 g. This formula improved quality of life and reduced corticosteroid use in children and adolescents when applied in capsular form in a previous study. As AD is commonly seen in children, who may have difficulty swallowing capsules, the formula was made into syrup form to test its efficacy and tolerability in young children. Participants were asked to take 20 ml of the herbal syrup every day for a period of 12 weeks. At baseline, details of dietary intake, emollient and topical corticosteroid use and disease severity were recorded. Participants were given an eczema diary for recording daily symptoms during the study period and were assessed at week two, seven, 12 and four weeks after treatment completion. Assessments were done using the Scoring Atopic Dermatitis (SCORAD) index as well as the Children's Dermatology Life Quality Index (CDLQI). Full blood count, serum IgE level, and renal and hepatic function tests were obtained before and at the end of the treatment period.

RESULTS: A total of 22 Chinese children (ten boys, 12 girls) participated in this study. There were significant improvements in objective SCORAD, pruritus and CDLQI scores four weeks after treatment period when compared to baseline. However, there were no changes in sleep score and use of topical corticosteroids. A total of six adverse events were reported: three participants developed rashes, one had increased bed-wetting, one complained of abdominal pains and one had suprapubic discomfort. Most adverse events resolved spontaneously, but two of the participants who developed rashes withdrew from the study.

CONCLUSION: It was concluded that the herbal syrup was palatable and well-tolerated by children and that the demonstrated palatability of the syrup enables its further evaluation and dosage studies in young children.

COMMENTS: The purpose of this study was to evaluate the clinical efficacy and tolerability of the herbal syrup. However, the conclusion was more focused on the palatability of the herbal syrup. It is assumed that there were no issues with palatability as there were no reports of compliance issues. Syrups are generally very sweet, and in Chinese medicine, sweet foods in excess are thought to generate dampness and phlegm, worsening conditions such as AD. It is therefore interesting that the syrup was able to reduce the severity of AD. However, more information is required on the production of the syrup – whether glucose, honey or other substances were used in addition to the herbs. The use of honey, for example might be an issue for children who are allergic to honey. Furthermore, the study stated that SCORAD was one of the primary outcomes but reported objective SCORAD (SCORAD score excluding pruritus and sleep score) and pruritus and sleep scores separately. As there was no significant improvement in sleep scores, it is unclear whether there was significant difference in SCORAD scores when the pruritus and sleep scores were included. It was reported that the herbal syrup was well-tolerated; however, there were no elaborations on the adverse events and their relation to the herbal syrup. It has always been an issue to find a proper, palatable form of medication for children, especially if, as is common in Chinese herbal medicine, the medication is strong and bitter. This is a good preliminary study to evaluate the applicability of herbal syrups to treat AD, which is commonly seen in children.

Hon KL, Lo W, Cheng WKF, Leung TF, Chow CM, Lau CBS, et al. Prospective self-controlled trial of the efficacy and tolerability of a herbal syrup for young children with eczema. J Dermatolog Treat. 2012;23(2): 116–21.

Hsiewe Ying (Amy) Tan

A CLINICAL STUDY ON THE EFFECT OF HWANGRYUNHAEDOCK-TANG ON ATOPIC DERMATITIS

OBJECTIVE: To evaluate the effects of *Hwangryunhaedock-tang* (HHDT, 黄連解毒湯, *Huang Lian Jie Du Tang*) in the treatment of atopic dermatitis (AD) by clinical trial questionnaire.

METHOD: This clinical study was conducted using a survey of patients with atopic dermatitis (AD) who visited the Department of Oriental Paediatrics at Daegu Haany University, South Korea. The study included those who received a single treatment by *Hwangryunhaedock-tang* (HHDT). Patients who took additional intervention(s) were excluded. The survey was conducted by contacting subjects via the telephone or administering the questionnaire in person.

Treatment by either decoction or powered HHDT was accepted. The basic ingredients of HHDT are *Huangbai* (*Cortex Phellodendri*), *Huangqin* (*Radix Scutellariae Baicalensis*), *Huanglian* (*Coptis Rhizome*) and *Zhizi* (*Fructus Gardeniae Jasminoidis*). However, treatment was usually a modified version of HHDT to suit individual conditions. Dosages were determined according to standard dosages for children. The treatment period varied from seven to 280 days. The questionnaire used was adapted from another study on the evaluation methods of symptomatic severity of AD. The subjects were asked about the severity of six main symptoms (erythema, papules/induration/oedema, abrasion, effusion/ furuncles, scaling and lichenification), and subjective symptoms at day and night, using a 4-points system.

RESULTS: During the study period, 93 patients were treated with HHDT and 71 were included in the survey. From the analysis of subjects, 45 patients were male and 26 were female. Five patients were aged 0–2 years; 48 patients aged 2–10 and 18 patients were more than 10 years old.

Overall there was significant improvement in the severity of the six main AD symptoms and subjective symptoms. The result analysis according to age group also showed clinical significance and there was a tendency of better results in the older age group.

CONCLUSION: It was concluded that HHDT is effective in the treatment of paediatric AD.

COMMENTS: This clinical study has significance in that the Korean herbal medicine HHDT could be a solitary and alternative therapeutic intervention in management and treatment of paediatric AD, as shown by the significant symptomatic improvement in all patients who received treatment by HHDT without other clinical intervention.

However, several questions arise concerning the study design. Firstly, as this study did not set a control or placebo group, it is difficult to estimate how effective HHDT is in treating AD when compared to a control or placebo treatment.

Secondly, from the methodological aspect, there were no fixed criteria concerning the standardisation of the formula ingredients, dosage, or period of administration. Furthermore, HHDT was modified on a case-to-case basis. Therefore, caution must be used when interpreting results as to whether the original formula itself has clinical significance. The varying period of administration from seven to 280 days makes it difficult to clarify the point of time when symptomatic improvement occurs. In addition, in cases of long-term administration of HHDT, the occurrence of side effects need to be reported, especially for children.

From the study, it was not stated if the questionnaire and the 4-points system used were validated instruments. Furthermore, the method of rating symptomatic severity from 0 to 3 is dependant on the subject's opinion, which could vary greatly.

Lastly, as the subjects were infants and young children the questionnaires were completed by the parents, which raises the issue of objectivity. There is also a lack of evaluation of quality of life, which is an important factor in paediatric clinical studies as well as in understanding HHDT's efficacy in treating AD.

Despite many methodological problems, it is a good preliminary study that prompts a controlled, randomised clinical study or pharmaceutical study in the future in order to establish the objective clinical efficacy of HHDD in a more rigorous manner.

Ko MJ, Baek JH. A clinical study on the effect of Hwangryunhaedock-tang on atopic dermatitis. J Korean Orient Paediat. 2012;26(4):51–60

Taein (Kay) Kim

A PILOT STUDY EXPLORING THE EFFECTS OF A 12-WEEK TAI CHI INTERVENTION ON SOMATIC SYMPTOMS OF DEPRESSION IN PATIENTS WITH HEART FAILURE

This was a two arm parallel (non-randomised) pilot study designed to explore the efficacy of 12 weeks of Tai Chi (TC) on the somatic symptoms of depression in patients with heart failure (HF). The authors state that HF is major medical disorder in North America and co-morbid depressive disorders are present in 40% of HF patients. In particular, HF patients who suffer from somatic depressive symptoms have an increased incidence of mortality over a three-year follow-up.[1] This research

may show TC as a potential therapeutic exercise for a broader range of patients, due to the less demanding nature of TC as well as previous studies where TC has been shown to have positive results in elderly participants.

The study involved 28 participants with a mean age of 67 years, who met the following criteria: suffering heart failure but clinically stable (defined by no hospitalisation in the past three months), on stable doses of neurohormonal blocking agents and diuretics for the past three months and had no cardiac surgeries within the last 6 months.

The participants were assigned to either a TC group (n = 16) or a usual care control group (n = 12) with both groups maintaining usual health care, including visits to cardiologists and other health specialists. The two outcome measures used were the Becks Depression Inventory which consists of a total score (BDI-t), subcategorised somatic (BDI-s) and cognitive scores (BDI-c), as well as the Multidimensional Fatigue Symptom Inventory – Short Form (MFS) for measuring fatigue. Despite the small number of participants the results were positive, showing a significant reduction in BDI-s scores pre- to post intervention when compared to the control ($p \leq 0.017$).

COMMENTS: While this study yielded positive results, there were several flaws in the study design. As it was a pilot study these issues are expected and will hopefully be resolved in future research.

The first issue was that the study was not a randomised trial and there were no indications as to how the participants were assigned to either of the two groups. This leads to issues of equity, expectancy and bias from both the participants as well as the researchers. This could explain the significant difference in baseline age between groups, as the TC group were significantly older (p = 0.04). Furthermore, there was a lack of explanation for the unbalanced assignment of participants to the two groups, with TC having more participants than the control group, making it very difficult to discern if this was a design flaw or an issue with reporting.

The nomenclature used to refer to the TC intervention lacked standardisation and could affect reproducibility of the study by other researchers. The intervention TC form used is referred to as 'Yang-style Tai Chi Chuan – Short Form'. This title, while stating the style of TC used, does not specify which form was actually used. Only after examining the move list can one infer that this is actually Yang Style 37 stance TC, which was made famous by the late Zheng Man Qing (Cheng Man-ch'ing) but never officially recognised by the Yang family. Secondly there was no justification why the Yang style short form was chosen or why only one third of the form was used in the study. As the mechanisms behind TC are still unknown, it would be difficult to correlate that the efficacy from using one third of a form is equivalent to an entire form, or even that all styles of TC are equal in their efficacy.

The total training time during the 12 weeks was 2640 minutes, provided the participants completed the 100 minutes (20 minutes of TC five times per week) of home practice additional to the 120 minutes of contact with the instructor. While the total is similar to the mean time of 2877 minutes in previous TC interventions (as reviewed by Sannes et al[2]), an additional method to quantify time spent on home exercises (such as a logbook) would further ensure compliance with the protocol. Furthermore, a breakdown of which components are involved in each class would have also been beneficial. For example, the authors have given the movement list for both TC movements and warm-up exercises, but it is unclear how long is spent on each.

The outcome measures used for this study were two self-reporting questionnaires and lack the objectivity of physiological measurements, which could have lent this study more credibility. Despite this, the authors were quite specific on the statistical tests conducted, and the results from this pilot study show great potential for further research into TC and somatic symptoms of depression in patients with HF.

Redwine, LS, Tsuang M. et al. (2012). A pilot study exploring the effects of a 12-week Tai Chi intervention on somatic symptoms of depression in patients with heart failure. J Altern Complement Med. 2012;18(8):744–8.

Shuai Zheng

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2. Sannes TS, Mansky PJ, Chesney MA. The need for attention to dose in mind-body interventions: lessons from Tai Chi clinical trials. J Altern Complement Med. 2008;14(6):645–53.

ELECTRONIC MEDICAL RECORD INFORMATION SYSTEM FOR PATIENT CONSULTATIONS IN CHINESE MEDICINE

BACKGROUND: Randomised controlled trials (RCT) have a high ranking in the hierarchy of evidence. Even so, conducting RCTs of traditional Chinese medicine (TCM) is difficult due to various reasons, such as the complexity of treatment and diagnosis. On the other hand, medical records that document the clinical data of daily practice are valuable in TCM research as disease or treatment pattern can be discovered from those records. There are, however, some difficulties when abstracting data from medical records. The difficulties may arise from the complexity of TCM treatment or some common difficulties faced by other researchers when using medical records as source of data.

Difficulties in abstracting and analysing TCM data	Examples of measures to address the difficulties
1 Structure of TCM clinical data	
• TCM encounters and managements are recorded as free-text data in medical records (even in some electronic medical record [EMR] systems). Before these clinical data can be utilised, these medical related notes need to be identified and retrieved from medical record, which is laborious.	• TCM encounters and managements need to be documented using structured data entry (SDE) and symptom-based clinical terminology systems, for instance International Classification of Primary Care-2. SDE may include usage of documentation template and structured field with values in EMR.
• Inadequate or non-standardised outcome-related data (clinical effectiveness) complicate the generation of useful knowledge related to TCM diagnosis and treatment. Clinical effectiveness of treatment is beneficial in establishing treatment guidelines, identifying effective herb–herb interaction, proposing reliable hypotheses for TCM clinical trials and practical clinical treatment.	• Introducing outcome-related data in medical records, for instance health related quality of life, disease-specific scales and patient-based measurements.
2 Quality of TCM clinical data	
• Missing data in medical records, such as undocumented abnormal value, may indicate negative or unknown condition of patients.	• TCM physician's name or code needs to be recorded to enable the identification of pattern of missing data entry and association with different TCM physicians.
• Data inaccuracy is often due to inconsistent use of clinical terminology.	• Using standardised terminologies, for example using Systematized Nomenclature of Medicine-Clinical Terms (SNOMED), can increase data accuracy and facilitate data mining.
3 Data management	
• The inconsistent management and storage of TCM and conventional medicine clinical data are often related to the attributes of TCM clinical data, such as patients' symptom differentiation and herb prescription.	• A large clinical data warehouse that can store, support and integrate clinical data of TCM and conventional medicine, including in- and out-patient, is needed.
	• Incorporating functions such as clinical reference information, extraction-transformation-loading tools, online analytical processing and data mining in electronic medical records facilitate data management, processing and evaluation.
4 Multi-relational nature of TCM data	
• TCM clinical data of patients' symptom, diagnosis, prescription are linked to each other in various ways. Multi-relational nature of the data complicates statistical analysis and data mining.	• Statistical methods such as probabilistic relational models, relational Markov models and author-topic models can be applied to examine the link between TCM clinical data.

OBJECTIVES: This review article discusses the difficulties in abstracting and analysing TCM clinical data for research purposes and suggests measures that can be applied. The listed measures are some examples from China.

CONCLUSION: In order to establish TCM clinical data for clinical and theoretical research, structured electronic medical records (EMR), standardised terminology, documentation of clinical effectiveness of treatment and design of a clinical data warehouse are needed.

COMMENTS: Medical records can be employed to study the effectiveness of TCM. However, there are some constraints in retrieving data from medical records due to their design, difference in documentation style of practitioners or even difference in policy and procedure across institutions. This article details the difficulties of using medical records as a source of data, as well as approaches to dealing with the difficulties. It is especially helpful to TCM researchers, as approaches in managing and analysing TCM data for research purposes are explained. Other studies have suggested combining medical record reviews with other data collection tools, such as interviews or survey questionnaires, as a means to address the constraints.

Even though literature has described many advantages of EMR over manual medical records, converting the latter to EMR alone is not sufficient, as even EMR can be a barrier to the conduct of TCM research. The key is taking into account the requirement of research when designing EMR and utilising uniform terminology and templates to record essential information. Uniform terminology is a step to removing uncertainty arising from the use of regional or colloquial terms.

Liu B, Zhou X, Wang Y, Hu J, He L, Zhang R, et al. Data processing and analysis in real-world traditional Chinese medicine clinical data: Challenges and approaches. Stat Med, 2012;31(7);653–60.

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