WORKSHOP

The role of acupuncture schools and individual practitioners in acupuncture research

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INTRODUCTION

Clinical research in Western biomedicine is usually conducted by biomedical practitioners in a medical school, medical research center, or hospital setting. The researchers are familiar with the disease they study and with the 'gold standard' scientific method that developed to evaluate new biomedical therapies. By contrast, most of the funded acupuncture/TCM research is not conducted in an acupuncture/TCM academic or research setting, but rather in biomedical settings, which are neither designed for acupuncture/TCM research, nor staffed with experienced acupuncture/TCM practitioners. In order to evaluate acupuncture/TCM effectively using Western research methodology, without losing the diagnostic and therapeutic characteristics of this traditional healing method, research efforts should involve TCM/acupuncture educators and practitioners.

The present article explores (1) how individual acupuncture practitioners or acupuncture schools can be involved in acupuncture research, (2) the role they can most appropriately play, (3) the types of research studies that can be conducted in these settings, and (4) the advantages and limitations of this approach. Realistic goals for practitioners and schools interested in research are put forward and discussed.

TYPES AND FORMATS OF ACUPUNCTURE RESEARCH

Considering that most acupuncture schools are relatively small with limited research funds, high-standard, randomized, controlled trials (RCTs) and basic science research may not be appropriate. However, individual acupuncture practitioners and educators often have extensive experience with patient care and acupuncture training. Therefore, their participation in research can contribute substantially and provide important information that may be used in future RCTs[1] or address questions that are rarely covered by a RCT.[2] There are several research formats that may be appropriate for these settings: case studies, case series, surveys, and outcome studies.

Case studies and case series

A *case study* usually documents in detail a successful treatment and the response of an individual patient.[3] Documenting a number of cases with the same condition treated by the same practitioner or same group of practitioners using the same style of treatment modality is a *case series* or clinical observation study.[2,4] The case study is most useful for difficult conditions such as cancer, AIDS, or renal failure, where the patient would not be expected to

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recover without treatment. The case study is also useful for difficult-to-treat chronic conditions such as fibromylagia or multiple sclerosis.

A well-described case study or case series often provides not only anecdotal practice experience that can be shared with other practitioners, but can also provide valuable information for designing a future clinical trial. It is a starting point for all clinical research, producing ideas and insights for further study. For example, observations from a case series of fibromyalgia patients informed the recommendations for future research in a recent systematic review.[5] A case study is also the basis for reflective practice, where an acupuncturist systematically looks over his/her experiences in order to improve understanding and performance and generate new ideas and insights.

Numerous classic texts of acupuncture/TCM have been based on case studies by ancient physicians and scholars. These texts have become the basis for the current acupuncture/TCM textbooks. A collection of contemporary case histories from Western acupuncturists is provided by MacPherson and Kaptchuk.[6] Other examples of case studies also exist.[7] The case study needs to describe the treatment process and procedure, and the condition and other medical information such as laboratory findings and conventional treatments of the patient. It also needs to include an adequate follow-up period to ensure that a remission of symptoms has not simply been part of the natural cycle of the disease.

The case study or case report is particularly suitable for an individual practitioner who is interested in participating in acupuncture research, and this should be encouraged and given practical support. It is also suitable for groups of practitioners, who could bring together case studies on a particular medical condition or TCM or other pattern, and compare and contrast them. Case study research requires no changes to normal clinical practice, no knowledge of research methodology, and no expense over and above the time for reflection and writing: but it must be done systematically and honestly. The internet now facilitates public airing and sharing of the practitioner's output. Publication of a number of similar cases, a case series, can provide persuasive evidence to potential funding bodies that you are worthy of support for further studies.

When writing a case study, practitioners should also be aware of potential biases and limitations of this method. One seldom-addressed aspect of the case study or case series report is how to minimize reporting practitioner's bias.[2] While acupuncture studies show that patients' subjective assessments can be far superior to objective findings,[8] these can reflect patient biases and thus, the use of objective improvements such as pulmonary function tests before and after treatment in an asthma patient are also recommended.

Surveys

Surveys are suitable for the individual practitioner as well as for an acupuncture school. The information obtained through a survey differs from the case study and differs from survey to survey depending on the sample selected. The results of a survey can provide valuable information about patients, such as satisfaction rate among patients who receive acupuncture[9] compared to conventional treatment. Surveys can also provide important information about practitioners, such as how they commonly diagnose and treat a complaint,[10] or how Western practitioners view alternative practices such as acupuncture.[11] Surveys also provide a means of gathering information on the safety of the therapy, both by questioning practitioners[12–14] and patients. Attitudes, understanding and expectations are important areas for future survey investigation. Such studies may involve patients (with reference to various aspects of their treatment, and why they came for care), practitioners (regarding their experiences of practice) and others such as doctors, health service managers, medical insurers and government.

Three important aspects of the survey should be planned carefully ahead of time to minimize bias and maximize the value of the information derived from the survey: (1) the selection of the survey sample; (2) the selection of the survey instrument; and (3) whether to include a qualitative 'in their own words' dimension.

The survey sample. Surveys can be population based or clinic based. Population-based surveys cannot interview every single person in the population of interest (e.g., the population of the United States); therefore, a sample that represents the entire population must be selected. Population-based surveys of alternative medicine utilization are very popular.[15] Methods for how to obtain a representative sample have been well described.[16] Clinic-based surveys[17] can be used to summarize basic patient information such as, 'What are the demographic characteristics of our patients?' 'What medical conditions do they have?' 'How many treatments over what period of time do they require?' It may be important in clinic-based surveys to minimize bias by having an independent third party, rather than the treating clinician, administer the survey. Also, patients may tend to be more honest if they know that their individual responses will not be seen by the treating clinician, but only reported as group statistics.

The survey instrument. The survey instrument must be carefully designed and validated, to ensure

that the questionnaire items measure what they say they are measuring. The questions should be clear and easily understood. A pilot test of a few people is very helpful to determine how clear the questions are. Also, a survey questionnaire should be no longer than necessary because long surveys may tend to reduce the response rate.

Qualitative dimension. Survey data can be quantitative or qualitative or a mixture of both. Recently, acupuncture and Oriental medicine survey research has expanded to include a qualitative dimension. The questions can be similar to those in a standard quantitative survey questionnaire except that the qualitative questions are open-ended. Cassidy surveyed patients at six acupuncture clinics in the US[9,18] Their satisfaction with treatment was quantified, but details of their expectations, insights, experiences were recorded qualitatively, providing a richer narrative than the standard quantitative survey could provide. The information obtained through qualitative questions are the 'stories' told by the patients rather than medical information from the practitioner's viewpoint.[9,18]

Outcome studies

An outcome study is simply an investigation that measures the health status of patients before and after an intervention (such as a treatment or course of treatments). Of all the above-mentioned types of study designs, the outcome study might be the most useful method to provide medical information regarding the patient's medical condition, treatment regimen and dose, patient progress, adverse effects, while controlling for other factors that might contribute to the patient's recovery other than the acupuncture treatment.[19–22]

Outcome studies are a particularly appropriate type of research for acupuncture schools because:

- Large numbers of patients and practitioners are available
- There is an experienced teaching faculty and/or faculty clinic
- The practitioners will tend to use similar styles
- The practitioners (e.g. students) will probably not need to be paid, so costs can be low
- There is already some administrative and clerical infrastructure in place
- There is often a standardized method of recording patient demographic and medical background as well as details of treatment established in acupuncture school clinics and these data can be utilized
- The study can form part of the students' training
- These studies are relatively straightforward to conduct.

Similarly outcome studies can be suitable for groups of individual practitioners, for example local professional study or discussion groups, who are interested in embarking on a research project. Outcome studies may be used to provide the foundations for subsequent controlled clinical trials[19] but equally important, they may be used for looking at aspects of current acupuncture practices with a view to improving them.[23] Outcome studies are immensely versatile and there are numerous possible questions to investigate:

(1) How do different conditions respond to acupuncture treatment?
(2) Do patients with different TCM patterns and a single biomedical condition respond differently to their TCM treatment?
(3) What is an optimal dose of an acupuncture treatment (frequency and number of treatments) for a given condition or TCM pattern of disharmony?
(4) What is the response rate of a given condition to different styles of acupuncture practice (e.g. TCM, Japanese, five element, etc.)?
(5) What treatments are most cost-effective in different clinical settings?
(6) What is the effectiveness of combination therapies, such as acupuncture combined with Chinese herbs, or with Western medicine?
(7) What is contraindicated among co-interventions?
(8) How important is a practitioner's Qi/energy level when a treatment is rendered?
(9) How important is the practitioner's level of training and experience?
(10) How important is a practitioner's personal profile (e.g., emotional state, health status) in influencing the effectiveness of the treatment?
(11) What influences do selected patient personal characteristics (e.g., demographic, medical history, beliefs, previous treatment used, motivation for coming to acupuncture, prior knowledge of acupuncture, emotional state, economic status of patient, previous experience with acupuncture, ethnic background of patient) have on patient outcomes?
(12) What are common side effects/adverse effects of acupuncture/TCM treatment?
(13) What aspects of the relationship between patient and practitioner have a significant effect on the treatment response?
(14) What are the effects of different needle depths/manipulation methods/retention times on outcomes?

Considerations for conducting an outcome study. Although it is appropriate to conduct an outcome study in a school clinic setting because of the large volume of patients, it is still very challenging to initiate such a study. Here is a guide through the process of setting up and running an outcome study (step-by-step details are also provided by White and Ernst[19]).

Determining the research question. The first step is to decide what question you wish to answer. Consultation with experienced researchers can be helpful for this process to ensure that the relevant information is collected in such a fashion that the question can actually be answered.

Establish a team. A qualified team leader (Principal Investigator) must be identified or hired. S/he then should form a research team for the study. It is crucial for the school administration and the board of directors to understand the importance of such research and fully support the effort.

Select the setting. The study could be conducted at a faculty clinical setting or a student clinical setting, or both. In either case, the school should develop a policy to encourage participation by the faculty and students. For example, participation can be made one of the promotional criteria for the faculty, or a mandatory requirement for a student research project.

Determine which patients are eligible for the study. The selection of inclusion and exclusion criteria allows one to clearly define the study population. It can vary from extremely broad (e.g., 'everyone with a particular symptom, such as back pain') to quite specific (e.g., 'stroke patients who have had paralysis for at least three months, live in a nursing home and no longer get standard rehabilitation'). The researchers need to think carefully about the implications of the inclusion and exclusion criteria as they will affect the types of patient outcomes they may see and the kinds of broad conclusions they can draw from their results.

Decide what the outcome measures will be and select an appropriate and previously validated questionnaire. To make the study valuable and the results reliable, a valid but not too complicated questionnaire is crucial. MYMOP, a patient-centered outcome measure,[21] has been used extensively in the UK in primary care settings – both by conventional and CAM practitioners, for example Chapman and Norton[20] have described its use by a local group of acupuncturists. MYMOP is rather quick and easy to use, a distinct advantage over the standard general health and well-being instrument, the SF-36. Of course the most appropriate tool will depend on the precise circumstances, and indeed many users have adapted standard questionnaires such as MYMOP by adding an extra question or two of their own. To develop a whole new measure, however, is best left to experts. If the study is to focus on a particular illness rather than the full range in general practice then a more disease-specific outcome measure will be needed (perhaps in addition to a general one). A large selection of these is described by Bowling[24] and McDowell and Newell.[25]

Plan for data collection, processing and analysis. There must be provision for collecting the data, storing completed questionnaires, entering the data into an appropriate computer database and analyzing it. Ideally, the data should be collected by an independent research coordinator who does not know the identity of the patient's practitioner. There must be secure storage of records, to maintain confidentiality. Specialist help may be needed for some aspects but for the most part simple descriptive statistics are sufficient.

Obtain approval from the appropriate ethics committee. Outcome studies tend to lie on the border line regarding the need for ethics committee approval. Advice should be sought locally, as there are national and regional variations, and the precise details of the study may be critical.

Conduct a small pilot study. A pilot study should last for a short period of time (e.g. 3–6 months). The data that are collected should be entered into a computer database and analyzed.

Conduct the larger study. Based on the results of the pilot study, the instrument and the data collection methods may require modification before the larger study is begun. The pilot results may also be used to determine the appropriate sample size for the full-scale project (though some studies use a defined cohort of subjects, e.g. the patients of all the students in a given class, and in those situations, sample size calculations are not performed). A timeline should be created showing expected completion dates for all stages of the study. In addition, sufficient resources (e.g. money, patients, practitioners, storage space, clerical help) need to be available to ensure that the study can be successfully completed.

Collaborate with an academic researcher. The experience that an academic researcher has in designing studies can ensure the study is of sufficient quality to provide interpretable results that are acceptable for publication. The most successful collaborations will involve researchers who have demonstrated an understanding of the nature of acupuncture practice and are willing to help strengthen the methodological rigor of the study without compromising the treatments and the patient–provider relationship. In an outcomes study, this should not be difficult given the 'black box' nature of such studies, even in the conventional medical world.

When practitioner groups are working together, the following recommendations will greatly increase the likelihood of successfully completing the study:[26]

(i) At least one person in the group must be knowledgeable in research
(ii) Methods should be standardized across the group
(iii) Regular meetings are needed – to keep the group together, keep up to date, and maintain momentum for the project
(iv) Some administrative/clerical help is needed for processing the questionnaires.

Other study design types

Educational research. Schools will be as, if not more, keen to carry out research into the development and performance of their teaching programs, students and graduates as into the clinical effectiveness of acupuncture and clinical practice issues[32] but that is beyond the scope of this article.

Reliability and validity of diagnostic clinical procedures. Traditional systems of acupuncture have their own diagnostic framework and methods. Practitioners may put together a large variety of information, derived by touch, sight, smell and listening to their patient's story, in order to make the diagnosis on which an individually tailored treatment program will be based. The effectiveness of the treatment is predicated on the accuracy of the diagnosis, but research in this area is just beginning.[27,28] The potential complexity of the TCM diagnostic process may make it hard to carry out clear tests of reliability and validity, but preliminary work has been done using simplified versions of a single diagnostic tool such as the radial pulse diagnosis.[29,30] Such research involves a number of practitioners each taking the pulse of a number of patients, and as such a school setting would be ideal. However, this is probably the most contentious and difficult of the several types of research discussed here and would need the most input from researchers and statisticians.

A simpler type of investigation concerns the accuracy of different methods of locating acupuncture points. Studies at the University of Technology, Sydney[31] have demonstrated the limitations of some procedures, and suggest a need for more standardization for research purposes.

LIMITATIONS AND RESISTANCE

(1) Unlike many conventional medical schools, the board and the administration of acupuncture/TCM schools are usually not formed by people who are familiar with clinical research, or who understand the importance and the nature of acupuncture/TCM research. Therefore, school authorities may be unwilling to hire persons capable of overseeing research projects or funding pilot studies, which are necessary to obtain additional funds.
(2) Acupuncture schools often lack research funding and administrative support to budget even a small amount of funds to support an outcome study.
(3) Unlike medical schools, acupuncture schools rarely require faculty research as a criterion for promotion. Therefore, motivation and support from faculty to participate in research are usually weak.
(4) Many acupuncture programs in the U.S. provide Master's degrees of acupuncture or traditional Chinese medicine, and some are also starting offering Doctoral degree in these programs. However, the design of these degree programs is not research based, but rather is focused almost exclusively on clinical training. Therefore, students are usually not motivated or encouraged to participate in clinical research.
(5) Although a major advantage of conducting a study in an acupuncture school clinic is the large number of patients available, administrative quality control and data management are crucial and often lacking.
(6) To carry out a research project often requires a prolonged struggle past innumerable obstacles. For the individual practitioner, these may be mostly within him/herself. For research in an acupuncture school, the problems may have to do more with resistance or indifference from others within the institution than with any inherent difficulties within the study. Gaining support and motivation from faculty and students is vitally important. Getting financial and administrative help may be a key factor. If ethics committees, outside funding bodies or universities are involved then negotiation and 'compromise' may be the order of the day.

CONCLUSIONS

Although the last few years have seen a marked increase in the funding of RCTs of acupuncture, many research questions related to the effectiveness of how acupuncture is practised on a daily basis remain unanswered and become more important to

examine. Practitioners, acupuncture/TCM schools and professional associations can play important roles in filling these gaps. Case studies, case series, surveys, and outcome studies are useful research designs that can be conducted by individual practitioners and schools. The information obtained from these studies can provide knowledge of acupuncture/TCM regarding daily clinical practice and is useful for treatment decision making and informing clinical judgment. Furthermore, the information obtained from these studies can be useful for designing future randomized controlled trials.

Most acupuncture schools are funded almost exclusively by student tuition and clinical income, and have few resources for developing high-quality research projects. Moreover, there is a lack of a supportive culture for research in most Western acupuncture schools. However, for the successful completion of research projects in a school setting, it is important that there be widespread support from the administration and faculty as well as the students if they are to be involved in the projects. In addition to general support, there must be adequate financial and material resources (e.g., computers and software) to complete any projects undertaken.

Though less rigorous, the study designs that can be conducted in an acupuncture school setting, especially outcome studies, are still challenging. It is hoped that a stepwise approach with carefully designed methods, as discussed in this paper, will encourage practitioners and professional schools to contribute to clinical research on this millennia-old medical practice.

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