PRELIMINARY DEVELOPMENT OF A STUDY PROTOCOL TO EVALUATE THE EFFICACY OF ACUPUNCTURE THERAPY FOR TREATMENT OF CHRONIC PAIN AND DEPRESSION

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The Community-University Health Care Center/Variety Club Children's Clinic (Clinic), a neighborhood-based, outreach clinic of The University of Minnesota Hospital and Clinic (UMHC) has, for the last seven years, run an acupuncture clinic in association with its Mental Health unit. Acupuncture is used to treat Southeast Asian (SEA) refugees, primarily the Hmong, Lao, Vietnamese, and Cambodian, for the chronic pain that is associated with depression from which so many of the adults suffer. Though medication may alleviate the depression, the chronic pain still leaves the patients dysfunctional (i.e., unable to go to work or school or to socialize). Acupuncture is a culturally acceptable method of treatment in the Asian culture; its availability draws patients into the Mental Health clinic, which, in turn, makes it possible to provide other services offered by the Mental Health unit as well as medical or dental services if the patient is found to be in need of more comprehensive treatment. For many patients, the Clinic may be their first contact with Western medicine, and acupuncture, along with a culturally sensitive mental health staff, seems to make the transition somewhat easier.

Southeast Asian mental health problems are difficult to treat for many reasons. A principal reason is reluctance of the patients to present themselves for treatment. As in most cultures, there is a stigma attached to mental illness. When mental illness, as a concept in the English language, is translated into most SEA languages, the implication is that the patient is "crazy." Thus, Southeast Asians are particularly reluctant to associate with a clinic or treatment that may cause this characterization to be attached to them or their family. Even if the patient or family members realize that there may indeed be a problem that needs to be dealt with, a professional mental health care system was non-existent in their country of origin and probably of little availability in the refugee camps. Over the centuries, the culture has called for such problems to be left to the family and immediate community to manage as best they could. This family support system is still in place in this country and continues to be very valuable to the SEA refugee population. However, it has had limited success in returning patients to a functional state.

When SEA patients do come to the Clinic for care, they tend to express their depression more in terms of somatic, unlocalized pain than in terms of their emotional state at the time. In fact, many do not realize that there may be a connection between their general state of ill health and the problems they may be having adjusting to a new culture or dealing with past emotional trauma. The Clinic's Mental Health staff has come to recognize this group's rather unique presentation of depression, and treats the patients accordingly. Acupuncture has helped to bridge some of the cultural gap by allowing patients many times to save face within their community, while enabling the Mental Health staff to help those who may otherwise have been alienated from the Western health care system. Not infrequently, patients request only acupuncture treatment.

Creating a blinded study that could examine the efficacy of acupuncture therapy in cases of chronic pain and depression is particularly difficult. First, while it is possible for physicians to be blinded to the treatment in a drug therapy study, it is impossible for a qualified acupuncturist to be unaware of whether true or placebo acupuncture is being performed, as it is he/she who places the needles. Hence, in any research project, it will be necessary for the acupuncturist to be conscious of ways in which he/she may influence a patient's perception of his/her therapy, and take precautions not to inadvertently reveal to the patient into which group he/she has been placed. It also complicates the study if the patient has previously received acupuncture and thus is able to distinguish between true and placebo points. For every condition, there are specific treatment points. To place the needles in other than those points would alert the patient to a sham procedure. Hence, if a control point could be established so close to the treatment point that the patient cannot distinguish the difference, research will be easier to design.

At every visit, the acupuncturist will ascertain each patient's progress by report of the patient and of the patient's spouse, child, or friend. These evaluations will be as objective as possible and will be based on measurement of muscle strength, tenderness at certain points as measured by a muscle/pain algometer (which measures the amount of pressure that can be applied before pain is felt), and functional level based on an evaluation of the patient's daily activities. It should be possible to quantitate these variables and so not introduce bias into the study. Separate evaluations by the psychiatrist and mental health counselors and staff will also be incorporated into the study to provide the most comprehensive data base. An independent evaluator, blinded to whether treatment or control points were used, will analyze the data to determine efficacy.

One method of differentiating true versus placebo acupuncture points is to use a galvonometer. Bullock and Culliton at Hennepin County Medical Center have published two studies on the use of acupuncture to treat chronic alcoholics. In these studies, they used the galvonometer to determine placebo ear acupuncture points. Treatment points gave a reading $\geq$50 uA, while nonspecific points always registered zero. From discussions with them, however, we decided that the use of a galvonometer may not be as accurate when the needles are placed on non-ear points. Acupuncture points over the rest of the body have a wider response range detectable by the galvonometer, perhaps because of increased conductivity of the skin. This might prevent the use of the galvonometer in determining needle placement during acupuncture therapy if non-ear points are used. It may not be possible, for example, to find an area of skin where conductance would be small enough, and consistent enough from patient to patient, that an adequate placebo acupuncture point could be localized. It will be possible to evaluate the effectiveness of the galvonometer for this study after

a group of patients has been identified and the patients' responsiveness measured at both therapeutic and placebo acupuncture points.

Hung Nguyen, the acupuncturist at the Clinic, feels that specific points can be isolated to treat a specific constellation of symptoms. For a given patient, Mr. Nguyen would choose, at his discretion, from a set of eight to ten acupuncture points. These points may be different from the points chosen at a previous session for that patient, and different from the ones chosen for another patient, but they will always be from the same set of eight to ten points. For example, if the diagnosis is lower back pain, Mr. Hung would choose from ten acupuncture points (SR3, UB62, UB40, GB30, DU26, K2, UB60, UB57, TW4, and GB41).

It is important that the patients who agree to participate in this study fully understand the purpose of this study and what their own involvement entails. The SEA refugee population already has a deep suspicion that the Western medical system wants only to experiment on them, and that, as a consequence, they are not given the same quality of care that other groups receive. The effect of living in a communist state for decades cannot be underestimated, and their reluctance to sign their name to any agreement, especially to participate in a medical study, is very real. Therefore, the consent form that is used must be constructed so that proper translation into their primary language is possible. Perhaps willingness to participate can be expressed with a handshake rather than a signature. It must be stressed that their participation in the study will not compromise their overall health care at the Clinic in any way and that they can withdraw from the study at any time without compromising their relationship with the Clinic or UMHC. The SEA staff will be available to explain the study and insure that patients fully understand what their participation will entail.

To evaluate better the effect acupuncture may have on a patient's overall use of health care resources, we examined the possibility of working with the Department of Human Services (DHS), Medical Assistance (MA) program, to examine how the SEA patients used the health care system before and after acupuncture treatments. Usage would be reflected in the charges paid by M.A. A partial list of procedures and diagnosis that may appear in a patient's medical record relating to the treatment of chronic pain and depression was compiled, and a preliminary search of the MA records at DHS of ten former acupuncture patients was attempted. Unfortunately, the codes we used produced such an overwhelming amount of information that an adequate analysis was impossible to do without narrowing or further defining the parameters of the search. DHS staff seem willing to work with us in the future in establishing a more efficient way of identifying and evaluating reimbursement data on patients for this study. Unfortunately, they are in the middle of converting their computer data base to a different system, and thus will be unable easily to access such records until late 1992.