Acupuncture for Chronic Pain in the Vermont Medicaid Population
Progress Report for the Legislature

Purpose and Funding: In seeking to address issues related to the opioid crisis, VT legislators noted that non-pharmacologic treatments have been recognized as an important strategy in the management of pain.[1,2] An advantage of this approach is the avoidance of serious adverse events.[3-5] The efficacy of acupuncture for the treatment of many common chronic pain conditions has been well documented in numerous high-quality randomized controlled explanatory trials.[6] The 2016 Vermont Legislature appropriated $200,000 to fund a pilot study to assess acupuncture as an adjunct therapy for the treatment of chronic pain in the Vermont Medicaid population.[7]

Timeline and Status: The pilot study described below is expected to begin recruiting participants in January of 2017 Data collection will continue through June 2017. A final reporting of results is expected to be available for the Legislature by September 30, 2017.

Research Design

Approach and Rationale: A pilot-level pragmatic research design was chosen as the most appropriate approach for this project after a thorough analysis of the legislative goals, resources, and timeline provided by Act 173, along with a review of the existing scientific literature. Several leading acupuncture trialists were consulted in order to confirm the soundness of this approach. To understand the design rationale, it is informative to review some differences in methodology and purpose between explanatory trials and pragmatic trials. Explanatory trials, such as those cited above, are designed to test whether the effects of a given therapy have a physiological basis beyond placebo effects. In order to draw firm conclusions, such trials use strict controls and designs that artificially maximize their internal validity. For example, most patients who see their health care providers for chronic pain would be excluded from a typical explanatory trial due to strict inclusion/exclusion criteria that provide the homogeneity necessary for definitive conclusions. Additionally, practitioners in explanatory trials are usually restricted by treatment protocols that inhibit replication of usual care. While explanatory trials serve a necessary gate-keeping function, they are not designed nor well-suited for making clinical and policy decisions.[8] Pragmatic trials, in contrast, are designed to answer questions useful to clinicians and policy makers because they aim to maximize external validity and generalizability to a real-world setting.[9,10] For example, most pragmatic trials study a therapy in the context it is actually practiced (rather than an artificially restricted or controlled setting) in a population that health providers actually see. Therefore, pragmatic trials deliberately include participants who reflect the heterogeneity and co-morbidities commonly seen in clinical practice. While these participants would confound the results of an explanatory trial; in a pragmatic trial, they provide evidence of the real-world impacts of a proposed therapy or policy decision.

This project has been designed as a pilot-level pragmatic trial optimized for generalizability within the healthcare ecosystem unique to Vermont. It will include a heterogeneous group of chronic pain patients that will be treated by Vermont-licensed acupuncturists who will provide treatment in their private clinics in line with their standard practice. This design is intended to reflect what would happen if acupuncture reimbursement were offered for local chronic pain patients by our local population of acupuncturists. As a Phase 1 uncontrolled pilot, this study is designed to provide qualitative and implementation data that, along with data from other trials (including high-quality, randomized, controlled explanatory trials), can help policy-makers make informed decisions.

Methods: Approximately 150 adult subjects will be recruited and offered up to 12 acupuncture treatments at no charge over a 60-day period at the offices of over a dozen participating Vermont-licensed acupuncturists in the Chittenden County, Montpelier, and White River Junction locales. After being screened and providing consent, each participant will receive pre-treatment questionnaires using several validated measures from the National Institute of Health's (NIH) Patient-Reported Outcome Measurement Information System (PROMIS) test library as well as an open-ended written questionnaire. Data collected is designed to address questions about the impact of acupuncture treatments on several areas of interest identified by the Legislature in Act 173: pain; as well as social, psychological, and occupational function. Questionnaires will collect data related to pain intensity and interference, physical function, depression, anxiety, sleep, fatigue, and medication use.

Participants will schedule treatments with the acupuncturist of their choice from a list of participating providers. After all visits have been completed, the NIH PROMIS questionnaires will be re-administered and results compared to the pre-treatment baseline. Participants will also be given the opportunity to discuss their experience with a research assistant if they wish. De-identified narratives may be used in order to assess the impact of the intervention.[11] The Department of Vermont Health Access (DVHA) will compare healthcare utilization data for participants for 60 days prior and 60 days after the first acupuncture treatment, as well as 60 days after the final acupuncture treatment.[12] Descriptive data will also be analyzed and reported, including number of participants referred, screened, and enrolled, average number of treatments completed per participant, common pain diagnoses, and co-morbidities, and demographic characteristics of participants.

Participants will be eligible for the study if they meet all of the following inclusion criteria:

- At least 18 years of age
- Qualifying Pain score for at least 15 out of the past 30 days and for at least the past 3 months.
- Enrolled for Vermont Medicaid services
- Able to read and understand English
- Able to understand and sign a consent form

Participants will be ineligible for the study if they meet any of the following exclusion criteria:

- Start of a new treatment for pain or any acupuncture treatment within the 4 weeks prior to the onset of treatment in this trial
- Concurrent participation in any other clinical trial
- Conditions that make treatment difficult: paralysis, psychosis, schizophrenia.
- Possible contraindications for acupuncture: pregnancy, untreated coagulation disorders, untreated seizure disorders

Participants will be offered $25 compensation for completing pre-treatment questionnaires and $25 compensation for completing post-treatment questionnaires.

Protection of Human Subjects – This project has been approved by the Agency of Human Services Institutional Review Board (IRB) in order to assure compliance with applicable standards protecting the safety and privacy of human subjects during research. No members of vulnerable populations (e.g. children, prisoners, institutionalized patients) will be included in this trial.

Summary and Limitations: This pilot will produce a report documenting changes that occurred amongst a group of adult Vermont Medicaid patients with chronic pain after receiving acupuncture treatment by Vermont's existing Licensed Acupuncturist workforce. Dimensions measured will include: pain, physical function, depression, anxiety, sleep disturbance, fatigue, medication use, and occupational function. We will also examine whether any changes in the utilization of other healthcare resources (e.g. visits to other providers, ER visits, prescription refills) can be detected. Finally, we will gain important descriptive information about the number and characteristics of patients who would choose to utilize this service were it to be available permanently (e.g. popularity and utilization of an acupuncture benefit, common diagnoses and co-morbidities, age and gender demographics of users). Due to the limitations of our design, we will not be able to make direct comparisons between the use of acupuncture and opioids for chronic pain. Additionally, based on data from this pilot alone, we will not be able to draw conclusions about causality between our acupuncture intervention and any changes observed. That is, we will not be able to rule out that observed changes could be due to non-acupuncture variables such as the natural course of disease. However, we can consider the data we will gain along with data from other acupuncture trials for pain that include rigorous controls in order to make the most well-rounded and informed decisions.

References

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