# Auricular Acupuncture for Pain and Anxiety During Hip Fracture Rehabilitation: A Pilot Study

By

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## ABSTRACT

More than 300,000 persons aged 65 and older are hospitalized annually in the United States because of hip fracture. Poorly controlled pain and anxiety during rehabilitation are associated with poor outcomes, including delayed functional recovery and long-term functional impairment. Medications to relieve these symptoms can themselves serve as barriers to successful rehabilitation, due to adverse effects such as nausea, drowsiness, and confusion. For these reasons, non-pharmacologic techniques for pain and anxiety relief are promising alternatives and adjuncts to standard pharmacologic approaches.

Auricular acupuncture is a safe and effective method of pain relief, especially during the acute phases of hip fracture. However, no studies have investigated if auricular acupuncture can be used to provide persistent relief of pain or anxiety during hip fracture rehabilitation. This pilot investigation will gather longitudinal data on 30 study participants recruited from two sites, thereby collecting the feasibility and preliminary outcome data needed to plan a randomized clinical trial of auricular acupuncture in patients undergoing rehabilitation after hip fracture. If effective in reducing the length of rehabilitation by as little as 5%, auricular acupuncture could reduce skilled nursing costs by an estimated $90 million and improve outcomes of rehabilitation for this common and devastating condition.

## SPECIFIC AIMS

More than 300,000 persons aged 65 and older are hospitalized annually in the United States because of hip fracture, with over 85% of hip fractures occurring in this age group. Poorly controlled pain and anxiety during hip fracture rehabilitation are associated with poor outcomes, including delayed functional recovery and long-term functional impairment. Medications to relieve these symptoms can themselves serve as barriers to successful rehabilitation due to adverse effects such as nausea, drowsiness, and confusion. For these reasons, non-pharmacologic techniques for pain and anxiety relief are promising adjuncts to standard pharmacologic approaches.

Auricular acupuncture is a safe and effective method of pain relief, and has been demonstrated in randomized trials to relieve hip fracture-related pain during the pre-hospital transport, intraoperative, and postoperative phases of care. However, no studies have investigated if auricular acupuncture can provide persistent pain relief during the rehabilitation phase of hip fracture recovery. Furthermore, no studies of auricular acupuncture have looked at the feasibility of long-term (i.e., four week) use of indwelling acupuncture needles, a relatively new technique that can easily and inexpensively be incorporated into rehabilitative care.

Therefore, we are proposing to gather pilot data to guide a subsequent randomized, controlled efficacy trial, with the ultimate goal of evaluating whether auricular acupuncture is an effective complementary strategy to standard pharmacological therapy to reduce pain, lower analgesic use, shorten the duration of inpatient rehabilitation, and improve functional recovery. To achieve this objective, we propose to randomly allocate 38 persons aged 65 and older who have recently undergone surgical hip fracture repair to one of two study groups: (1) auricular acupuncture standardized to five points specific for pain reduction; (2) sham acupressure control, with the goal of achieving or exceeding a target sample of 30 persons who complete the trial. Data collection will address the following specific aims:

**Specific Aim 1:** To estimate the eligibility, enrollment, dropout, adherence, and adverse event rates of a four-week auricular acupuncture intervention. Eligibility, enrollment and dropout rates will be determined by carefully identifying and tracking all patients at the study sites who have undergone surgical hip fracture repair. Treatment adherence will be measured by tracking refused treatments and dislodged needles between treatments, and by interviews and questionnaires designed to elucidate potential barriers to enrollment and protocol completion. Side effects and adverse events will be monitored at twice-weekly treatment and weekly data collection visits.

**Specific Aim 2:** To estimate mean scores, mean rates of change, and variances for measures of pain, anxiety, analgesic medication use, functional mobility, and fear of falling for the intervention and control groups. Pain will be measured using the Short Form McGill Pain Questionnaire (SF-MPQ); anxiety will be measured using the Spielberger State-Trait Anxiety Inventory (STAI); analgesic medication use will be measured using an analgesic burden scale; functional mobility will be measured with the Lower Extremity Gain Scale (LEGS); and fear of falling will be measured using the Falls Efficacy Scale (FES). Analyses will be run for each outcome using linear mixed models to estimate mean differences, rates of change, and their variances over the four-week intervention.

Participants will be recruited from the orthopedic services of the University of North Carolina Hospitals (Chapel Hill, NC) and Mission Hospitals (Asheville, NC).The intervention will begin at the onset of rehabilitation, and subjects will be followed until their discharge from rehabilitation or a maximum of four weeks. The research will be undertaken by an interdisciplinary team including a geriatrician, alternative medicine specialist, health services researcher, biostatistician, and research staff from the Cecil G. Sheps Center for Health Services Research, and will build upon the study team's successful feasibility study of auricular acupuncture

conducted in five post-fracture patients. Results of this proposed pilot study will be crucial to the design of a larger efficacy trial.

## BACKGROUND AND SIGNIFICANCE

### A. Hip Fracture in the United States: a major, growing public health problem.

In **2004, hospital discharges for hip fracture in the United States totaled about 329,000.**[1] This estimate represents a 20% increase in the number of hospitalizations for hip fracture since 1994, even though during the same time period the per capita fracture rate was declining.[2] With over 85% of hip fractures occurring in individuals age 65 and older, and the proportion of this population continuing to expand even further in the coming decades, the number of hip fractures is expected to continue to increase substantially.

**Hip fracture is associated with significant morbidity, mortality, and cost**. According to one estimate, at one year after fracture up to two thirds of patients will have reduced capability to perform one or more basic activities of daily living (ADLs) and 80% of will be unable to perform instrumental activities of daily living (IADLs) as well as they could prior to the fracture.[3] Additionally, one-year mortality after hip fracture is estimated to be almost 25%.[4] Some of this mortality is related to comorbid conditions that predated the fracture; however, hip fracture both functions as an independent risk factor and as a cofactor that increases the likelihood of dying from a comorbid condition.[5] Health care expenditures attributable to hip fractures in 1995 were estimated to be $8.7 billion, and the individual lifetime attributable cost approximately $80,000.[6] During the 12 months following fracture, one analysis estimated that individual yearly health care costs increased by an additional $17,000 (in 1993 dollars).[7]

### B. Physical Rehabilitation after Hip Fracture

**Physical rehabilitation following hip fracture repair is a key component to reducing post-fracture morbidity and mortality.** Mobilization is a primary component of post-operative hip fracture care and rehabilitation. Mobilization interventions include exercise, gait and balance training, and muscle stimulation, with the overall goal of minimizing functional impairments and

improving physical performance. Though optimal training protocols remain unknown, results from several studies suggest that intensive rehabilitation, especially for frail elders with persistent mobility and ADL impairments, can significantly improve physical performance and mobility, reduce disability, and improve quality of life.[8,9]

**Pain following hip fracture is a barrier to successful rehabilitation.** Poorly controlled pain following hip fracture repair increases hospital length of stay by 1.5 days, leads to a 26% decrease in ambulation by day three, and is associated with long-term functional impairment.[10] Furthermore, inadequate pain control during rehabilitation is associated with a nearly 60% increase in missed or shortened physical therapy sessions, as well as impaired long-term functional ability.[11] Despite these data indicating adverse outcomes from poorly treated post-operative pain, patients, particularly elderly patients, frequently suffer from inadequate pain relief.[12] Studies indicate that concern that opioid-related side effects may lead to confusion, falls, and other adverse outcomes[13] leads to a justifiable reluctance to prescribe opioid medications[14].

**Pain management after hip fracture repair most often includes narcotic medications whose adverse effects can be particularly deleterious for elderly patients.** Use of narcotic medications in older persons, especially those with dementia, is associated with at least double the frequency of adverse events compared to younger adults, and the frequency rises as the number of medications increases.[15] The most common adverse effects associated with opioids include sedation (number needed to harm [NNH] 5.3), nausea (NNH 5.0), vomiting (NNH 8.1), constipation (NNH 3.4), and pruritis (NNH 13), but respiratory depression, neurotoxicity, and urinary retention can also occur.[16,17,18]

Given the persistent pattern of inadequate analgesia and the high rate of adverse events associated with the use of narcotic medications, adjunctive strategies for pain reduction could play a significant role in post-operative hip fracture care. Auricular acupuncture as a

complementary pain reduction strategy may reduce the pain experienced during rehabilitation without the side effects associated with analgesic medications.

### C. Acupuncture – A Promising Complement to Medication for Pain after Hip Surgery

**Acupuncture is widely used in the U.S.** Since its first popular appearance in the U.S. in the 1970's[19], acupuncture has slowly made its way into Western scientific and clinical practice. In 1997, a National Institutes of Health consensus statement noted promising results for treating nausea, vomiting, and dental pain with acupuncture.[20] More recent studies support its use for facial pain[21], labor pain[22], knee osteoarthritis[23], and fibromyalgia[24]. It has become an increasingly popular form of complementary and alternative medicine (CAM); as of 2001, an estimated 8.2 million U.S. adults had used acupuncture, and 2.1 million U.S. adults had used it in the previous year.[25]

**Auricular acupuncture is a unique and advantageous acupuncture system.** Several distinct acupuncture microsystems have been developed, including hand, scalp, and auricular systems. Auricular acupuncture, which uses the ear exclusively as the treatment site, dates back to use in China as early as the 6$^{th}$ century B.C.E., but was first codified in the West by French physician Paul Nogier in the 1950's.[26] Dr. Nogier's system remains the most widely used system clinically, and much of the data that exist to support the efficacy of auricular acupuncture are based upon this system. In addition, auricular acupuncture provides several advantages over traditional full body acupuncture. Acupuncture points on the ear are generally easy to locate without the complex measurements required to find traditional body acupuncture points; patients can remain fully clothed and comfortably seated while receiving auricular treatments; needles can be placed with high accuracy with the assistance of a specialized applicator; and needles can easily and safely remain inserted for days for enhanced treatment exposure[27].

**Existing studies of auricular acupuncture have demonstrated beneficial effects on pain and anxiety,** including pain associated with cancer[28], knee arthroscopy[29], hip fracture, and hip arthroplasty[30]. Several recent small studies have suggested that auricular acupuncture alone can relieve pain and anxiety in the prehospital transport phase of hip fracture,[31,32] and it can reduce acute pain due to a variety of causes in the emergency department setting.[33] Table 1 (next page) summarizes randomized, controlled trials of auricular acupuncture published in English and indicates that, though results are mixed, the vast majority have demonstrated significant pain relief when auricular acupuncture was used. Additionally, several RCTs have shown auricular acupuncture can significantly reduce anxiety, especially anxiety related to surgical procedures.[34,35,36,37,38] However, while efficacy has been established across multiple studies and settings, no published studies have focused on efficacy during rehabilitation for hip fracture.

**Adverse events due to auricular acupuncture appear to be very rare.** There are currently no systematic reviews of adverse events for auricular acupuncture, and not all published studies of auricular acupuncture report on adverse events. However, a 2004 review of all acupuncture-related adverse events concluded that "the overall risk of acupuncture treatment is classified as 'very low'...below that of many common medical treatments."[27] This was based on an estimate of one serious adverse event (SAE) per 200,000 acupuncture treatments. The risk of SAEs due to auricular acupuncture appears to be very low as well. The only auricular acupuncture-specific SAE noted in this same review was auricular chondritis which represented just four percent of all primary case reports from that review (i.e. of the 1/200,000 estimated acupuncture-related SAEs, four percent were due to auricular chondritis). Further, a recent systematic review of studies using an auricular acupuncture intervention for pain revealed no reported infections and only minor adverse events in a very few subjects (e.g., minor local bleeding, headache, local pain, dizziness, nausea).[39]

**Table 1. A Summary of Published Randomized Controlled Trials of Auricular Acupuncture for Relief of Perioperative, Acute, and Chronic Pain**

| Author Country | Indication | Intervention Treatment | Control Treatment[a] | Primary Outcome Measure | Study size | Results | Quality Rating Applicability[b] | Year |
|---|---|---|---|---|---|---|---|---|
| **Perioperative Pain** | | | | | | | | |
| Li China | Post-operative pain (liver resection) | AA, Chinese herbs, epidural morphine | Placebo pill | VAS, pethidine use | 16 | Mixed | Poor Low | 1994 |
| Michalek-Sauberer Austria | 3rd molar tooth extraction | EA | AA + mock EA and no-needle mock EA | Tylenol use | 149 | Negative | Fair Moderate | 2007 |
| Sator-Katzenshlager Austria | Oocyte aspiration | EA | AA + mock EA and no-needle mock EA | VAS | 94 | Positive | Good Moderate | 2006 |
| Usichenko Germany | Post-operative pain (THA) | Indwelling AA | Indwelling AA at non-acupuncture points | Piritramide use | 61 | Positive | Fair Moderate | 2005 |
| Usichenko Germany | Post-operative pain (knee arthroscopy) | Indwelling AA | Indwelling AA at non-acupuncture points | Ibuprofen use | 18 | Positive | Fair Moderate | 2005 |
| Usichenko Germany | Intra-operative pain (THA) | Indwelling AA | Indwelling AA at non-acupuncture points | Fentanyl requirement | 64 | Positive | Good Moderate | 2006 |
| Usichenko Germany | Post-operative pain (knee arthroscopy) | Indwelling AA | Indwelling AA at non-acupuncture points | Ibuprofen use | 120 | Positive | Good Moderate | 2007 |
| Wigram U.K. | Post-operative pain (abdominal surgery) | EA | Standard medical care | VAS | 34 | Negative | Poor Low | 1996 |
| **Acute Pain** | | | | | | | | |
| Barker Austria | Hip fracture (prehospital transport) | AP | Sham AP (non-indicated points) | VAS | 38 | Positive | Good Moderate | 2006 |
| Goertz USA | Acute pain syndromes | Indwelling AA | Standard medical care | NRS | 100 | Mixed | Fair Moderate | 2006 |
| Gu China | Acute biliary colic | AA | IM atropine and phenergan | Pain relief or decrease | 48 | Positive | Poor Low | 1993 |
| Lewis USA | Acute burn | TENS | Placebo pill | VAS | 11 | Positive | Poor Moderate | 1990 |
| Xiang China | Dysmenorrhea | AA | Chinese herbal formula | Dysmenorrhea score | 67 | Positive | Poor Low | 2002 |
| **Chronic Pain** | | | | | | | | |
| Alimi France | Neuropathic pain | Indwelling AA | Indwelling AA & AP at non-conductance points | VAS | 90 | Positive | Good Moderate | 2003 |
| Longobardi USA | Distal extremity pain | TENS | Placebo pill | VAS, PRI | 15 | Mixed | Poor Low | 1989 |
| Mazzetto Brazil | TMJ pain | LAT | Mock LAT | VAS | 48 | Positive | Poor Low | 2007 |
| Sator-Katzenshlager Austria | Chronic neck pain | EA | AA + mock EA | VAS | 21 | Positive | Good Moderate | 2003 |
| Sator-Katzenshlager Austria | Chronic low back pain | EA | AA | VAS | 87 | Positive | Fair Moderate | 2004 |

AA - auricular acupuncture; Indwelling - AA using ASP needles or press tacks; EA - electro-acupuncture; AP - acupressure (most often performed with *vaccaria* seeds); TENS - transdermal electrical nerve stimulation; LAT - laser auriculotherapy; TMJ - temporo-mandibular joint; THA - total hip arthroplasty; VAS - visual analog scale; NRS - numerical rating scale; PRI - pain rating index (from McGill Pain Questionnaire); IM – intramuscular

[a] Acupoints for control and treatment groups were the same unless otherwise indicated. [b] Quality ratings and applicability scores were based on AHRQ guidelines.

## D. A promising therapy for improving hip fracture rehabilitation and outcomes

In summary, auricular acupuncture is a novel complementary approach to standard pain and anxiety relief during the rehabilitation phase of hip fracture repair. It is minimally invasive, simple to use, and relatively inexpensive to administer in that needles cost about $0.50 each and require only a few seconds to place. Non-pharmacologic reduction of pain and anxiety has several advantages over typical pharmacologic therapy, especially for elderly patients undergoing rehabilitation after hip fracture repair. Reducing pain, anxiety, and medication use associated with detrimental side effects for these patients may significantly improve their care and decrease the costs directly associated with hip fracture.

Of the 300,000 persons who annually undergo hip fracture repair in the United States, between 12% and 23% go to inpatient rehabilitation facilities (IRFs), between 56% and 62% go to nursing homes (NHs), and the remainder go directly home, die in hospital, or do not undergo rehabilitation. For patients in IRFs the mean length of stay is 16.2 days at a 1997 cost of $11,069; for patients in NHs the mean length of stay is 23.4 days at a 1997 cost of $7,210. Thus, without adjusting for increases since 1997, the combined annual cost of rehabilitation in IRFs and NHs is estimated at $1.87 billion.[6,40,41] If auricular acupuncture could reduce the length of time needed to undergo rehabilitation by as little as 5%, it would result in an estimated $94 million in Medicare savings annually.

## PRELIMINARY STUDIES

**A. Experience Conducting Research Involving Study Participants Who Are Aged, Disabled, and Residing in Long-Term Care Facilities.** The proposed study will be undertaken under the auspices of the Collaborative Studies of Long-Term Care (CS-LTC). Co-directed by Drs. Philip Sloane and Sheryl Zimmerman, the CS-LTC is one of the nation's most experienced long-term care research programs, with notable expertise in research related to aging, disability, and long-term care. Since 1996, 38 studies, including numerous clinical trials, have been funded under the auspices of the CS-LTC (the majority with federal funding), which have involved the participation of more than 700 long-term care facilities across 14 states.

The CS-LTC's approach to working with care providers and patients is one of partnership, and it is notable that only 3% of facilities (other than those which closed) have withdrawn their participation. More than 6,500 facility residents, family members and staff have participated in CS-LTC projects examining topics such as quality and outcomes of care, falls prevention, dementia care, end-of-life care, transitions across settings, and family involvement.

Two books have highlighted the CS-LTC findings[42,43] as have dozens of chapters, reports, peer-reviewed publications, and presentations. Completed clinical trials have included evaluations of bright light therapy as an alternative to medication for sleep, depression, and agitation[44,45,46], specialized bathing tubs for impaired populations[47], and techniques to improve bathing of persons with dementia[48,49,50]. Additional clinical trials in the field include a study of falls prevention in assisted living facilities and a study of family-staff partnerships to enhance long-term care outcomes.

**B. Feasibility Study of Auricular Acupuncture in Hip Fracture Patients.**

The CS-LTC study group has long been concerned about hip fracture because of its importance as a source of morbidity and mortality and its negative impact on the independence and well-being of older persons. Dr. Sheryl Zimmerman, a co-investigator on this proposed

project, directed the Baltimore Hip Studies in the 1990's and remains an investigator in that longstanding series of primarily epidemiological projects.[51,52,53,54,55,56,57,58,59,60,61] Dr. Philip Sloane, this study's co-PI, has through his prior work become very familiar with the heightened adverse effect profiles of pain and anxiety medications in frail elderly persons, particularly those with cognitive impairment.[62,63,64,65,66,67] Two years ago we became aware of intriguing preliminary trials (see Table 1) suggesting that auriculotherapy could significantly reduce pain and anxiety of patients with hip fracture during ambulance transport and in the emergency department. Since successful rehabilitation is critical to reducing long-term morbidity from hip fracture, we were interested in extending this work to that area. When, in late 2007, Gary Asher, MD, an alternative medicine specialist, acupuncturist, and postdoctoral fellow in an NCCAM research training program, began working with the CS-LTC, a strong team had assembled to study this topic.

**Methods.** This feasibility study was undertaken to determine the most appropriate treatment in terms of patient acceptance, tolerability, maintenance of needles in place, and side effects. Using internal funds, we planned and conducted a feasibility study of recruitment and treatment methods. The study proceeded as follows:

- Recruitment and informed consent. Patient participants were recruited from the University of North Carolina (UNC) Hospitals in Chapel Hill, NC, using inclusion criteria and methods that, with minor refinement, have been incorporated into our current research plan. Eligible and interested individuals provided written informed consent and signed a HIPAA waiver, in accordance with the protocol approved by the UNC IRB.

- Conduct of the intervention. After baseline data were collected, the physician acupuncturist (Dr. Asher) visited the patient at his/her site of rehabilitation (for four this was UNC's rehabilitation hospital; for the fifth it was her private home) twice a week. At the time of the visit, he observed and removed needles placed at his previous visit, inquired about side effects and

adverse events, and placed five sterile, nickel-free, gold-plated acupuncture needles unilaterally on the ear at the following acupuncture points: thalamus, cingulate gyrus, shen men, omega 2, and point zero points (these points are described later under research plan and illustrated in Figure 2a). After placement, the needles were covered with an adhesive patch and the date and place of placement were noted in the patient's treatment log.

- Study measures and data collection. The following measures were assessed at baseline, 1, and 2 weeks: the Lower Extremity Gain Scale (LEGS), the McGill Pain Questionnaire short form, the State-Trait Anxiety Inventory (STAI), the Falls Efficacy Scale (FES), medication use, and participant acceptance and satisfaction. Each has been incorporated into and will be described in more detail in our proposed research plan.

**Results.** This feasibility study was conducted between January and June, 2008. Results are summarized below:

- Participant recruitment and retention. Eligibility criteria included age 65 and older, English-speaking, post-unilateral hip repair, ability to ambulate pre-fracture, and ability to report pain; exclusion criteria included severe cognitive impairment, medical instability, metal allergy, and certain disease states associated with an increased susceptibility to infection or bleeding. Eleven patients were referred by hospital social workers for eligibility screening. Of these, 8 were eligible for participation (73%), 2 were ineligible (18%), and one (9%) was discharged before eligibility could be determined. Of the 8 eligible patients, 5 (63%) enrolled in the project and 3 (38%) refused participation. Of the 5 enrolled participants, 4 (80%) completed the three-week project period, and one individual (20%) discontinued participation before the first treatment was received.

- Participant characteristics. Age ranged from 73 to 98. All were female and white, had some education beyond high school, had good or very good health prior to the fracture but also multiple comorbidities, and were cognitively intact or borderline. While quite small, this sample

is largely reflective of the general population of individuals who undergo hip fracture repair annually (i.e., over the age of 65 and female).[68]

- Adherence. Of the 4 individuals who received the acupuncture treatment, all (100%) accepted the full 5-needle treatment during each treatment session. Of the approximately 20 needles inserted per participant (5 needles, twice a week for two weeks), on average, only 3 needles per participant fell out over the course of the entire study period. The majority of missing needles occurred during the treatment periods of the first two participants, when the intervention was new; subsequently the acupuncture protocol was modified to cover the sites with small adhesive bandages in order to better retain the needles in place.

- Side effects and symptoms. None of the four participants exhibited signs of infection or tissue damage. One participant asked the acupuncturist to remove one needle during one treatment session due to mild itching around the acupuncture site. In addition each participant was asked weekly if she had experienced any side effects or symptoms, regardless of attribution. One participant reported each of the following symptoms, all of which were rated as "mild": itching, dizziness, and localized pain/discomfort around the acupuncture site. The individual who reported mild dizziness reported that it was a long-standing problem that occurred only when suddenly sitting or standing, and the participant who reported nausea reported that it was a side effect of a pain medication she was receiving. Thus, the side effects of the acupuncture treatment have been minimal.

- Adverse events. Each participant was monitored for hospitalizations, falls, seizures, death, and any other catastrophic event. None were experienced.

- Outcome measures. Table 2 presents data related to change in the outcome measures over the two-week study period. It should be noted that the proposed project involves a longer treatment period and a control group, and thus these data are intended only to show that the

measures can be accurately and feasibly administered and scored, and that they appear to be sensitive to change in this population.

| Table 2: Mean (SD) Ratings on Key Outcome Measures Among the Four Feasibility Study Respondents | | | |
|---|---|---|---|
| **Measure** | **Baseline** | **Week 1** | **Week 2** |
| Pain (McGill) | 1.71 (0.63) | 1.38 (0.67) | 0.95 (1.03) |
| Physical Function (LEGS) | 11.00 (10.74) | 20.00 (6.27) | 17.00 (14.80) |
| Fear of Falling | 52.25 (22.56) | 53.75 (25.79) | 42.75 (22.50) |
| Anxiety (STAI) | 34.25 (9.14) | 30.75 (10.78) | 29.25 (10.24) |

- Data quality. A secondary aim of this feasibility study was to assess the suitability of the proposed study measures, as well as the feasibility of their proposed administration and scheduling. Overall, participants were able to address all study questions, suggesting that the questions were suitable for this population. Further, data quality was high, with very little missing data.

- Participant satisfaction. At the end of the study period, all participants were asked questions to assess the acceptance of the study procedures. All reported that they were not bothered by the study procedures, including the questionnaires and the acupuncture treatment, nor the time required by the study. Further, when asked if they would be willing to participate in a longer version of the study, all participants reported that they would be willing to continue their participation in an identical study for two additional weeks.

**Implications for the proposed pilot study.** This feasibility study field tested and refined the acupuncture intervention, and demonstrated that it was feasible to administer in this population. It also allowed us to gain experience in use of the proposed outcome measures and to gain confidence in their ability to measure change. This experience is reflected in the research design presented in the next section, and in the draft instruments that are included in the appendix.

## RESEARCH DESIGN AND METHODS

### A. Overview

The long-term objective of this research is to determine the extent to which auricular acupuncture can improve rehabilitation outcomes for elderly patients after hip fracture by relieving pain and anxiety. In this pilot randomized, sham controlled trial we will compare pain, anxiety, medication use, functional mobility, and fear of falling between groups receiving either auricular acupuncture or sham. Additionally, we plan to investigate barriers to enrollment and continued participation to maximize future study participation. In order to achieve these aims, we plan to enroll 38 patients aged 65 or older with recent hip fracture repair and follow them for up to four weeks during their post-fracture rehabilitation, to achieve the goal of having complete data on a minimum of 30 study participants.

### B. Project Organization and Management

Project team. To carry out the proposed study, we have assembled an interdisciplinary team with expertise in geriatric medicine, acupuncture, health services research, biostatistics, and project management. Key personnel include:

- Philip D. Sloane, MD, MPH, Elizabeth and Oscar Goodwin Distinguished Professor of Family Medicine and co-director of the Program on Aging, Disability, and Long-Term Care at the Cecil G. Sheps Center for Health Services Research (Sheps Center) at the University of North Carolina at Chapel Hill (UNC-CH). A senior investigator with expertise in geriatric medicine and health services research involving old and disabled persons, Dr. Sloane will serve as co-principal investigator, providing oversight of all aspects of study design.
- Gary Asher, MD, Postdoctoral Research Fellow in Complementary and Alternative Medicine at UNC-CH, who will be joining the faculty of the Department of Family Medicine at UNC-CH in July, 2009 (see letter of support from Warren Newton, MD in Section 16). A junior investigator with expertise in acupuncture, who developed and piloted the study intervention, Dr.

Asher will serve as co-principal investigator, working in tandem with Dr. Sloane to oversee all aspects of study design.

- Sheryl Zimmerman, PhD, Professor of Social Work and Public Health at UNC-CH and co-director of the Program on Aging, Disability, and Long-Term Care at the Sheps Center at UNC-CH. A senior gerontological researcher, Dr. Zimmerman is an expert on hip fracture recovery and has co-developed the study's primary functional outcome measure, the Lower Extremity Gain Scale (LEGS). She will contribute her expertise to all aspects of study design and implementation, and to interpretation of the study results.

- John Preisser, PhD, Professor of Biostatistics at UNC-CH, has worked with the Program on Aging, Disability, and Long-Term Care at the Sheps Center on numerous studies, and as such is familiar not only with research design and statistics but also with the methodological issues unique to conducting clinical trials in frail older persons with multiple comorbid conditions. He will serve as project biostatistician.

- Doug Dirschl, MD, Frank C. Wilson Distinguished Professor and Chair of Orthopedics at UNC-CH, will advise the study on accounting for severity of fracture and type of surgical repair in analyses.

- Lauren Cohen, MA, Research Associate at the Sheps Center, has coordinated multiple studies in long-term care facilities, including several multi-site and multi-state studies. She will serve as overall project coordinator.

- Lourdes Lorenz, RN, MSN, Research Coordinator at Mission Hospitals in Asheville, NC, will serve as project coordinator at the Asheville site. Ms. Lorenz has coordinated clinical studies for Mission Hospitals for several years and is highly familiar with project coordination, research assistant supervision, and protocol adherence.

A biosketch for each of the above key personnel is included in this application.

Acupuncturists. The study will use licensed, experienced acupuncturists as interventionists, who will conduct the study interventions under the direction of Dr. Asher.

- In Chapel Hill the acupuncturist will be Wunian Chen, MD. Co-founder and principal acupuncturist at the UNC-CH Department of Family Medicine's acupuncture clinic, Dr. Chen has experience serving as the acupuncturist in controlled clinical trials. His biographical sketch is included in this application.
- In Asheville, where there are 30 practicing acupuncturists, the study acupuncturist will be selected after funding based on his/her ability to guarantee availability during the proposed intervention period. The two most likely candidates, both of whom have expressed interest in the project, are Mary Cissy Majebe, O.M.D., L.Ac., and James Whittle M.S., L.Ac. Ms. Majebe is Academic Dean of Daoist Traditions, College of Chinese Medical Arts in Asheville, N.C., has practiced in Asheville since 1985, and was the first chair of the North Carolina Acupuncture Licensing Board. Mr. Whittle completed a four year clinical Masters of Science (M.S.) degree in Acupuncture at Bastyr University in 2001, received a certificate in Chinese herbal medicine in 2002 and completed an 8-month internship at the Shanghai University of Traditional Chinese Medicine before coming to Asheville to found the Blue Ridge Acupuncture Clinic.

Project coordination. Study coordination in Chapel Hill will be done through the Cecil G. Sheps Center for Health Services Research and in Asheville through the Mission Hospitals Research Institute. Each site will have a team that includes a research coordinator (Chapel Hill – Lauren Cohen, MA; Asheville – Lourdes Lorenz, RN, MSN) to identify and enroll eligible patients; a licensed acupuncturist to provide treatments to both the experimental and control groups; and a data collector who will collect all baseline and follow-up data, and who will be blinded to study aims and participant intervention/control group status. Overall study coordination and oversight in both study locations will be provided by the principal investigators, who are located in Chapel Hill.

Consistency of reporting, supervision, and methods will be assured by: a) joint training of coordinators and data collectors; b) use of common protocols and forms for providing information, obtaining informed consent, tracking participants, and data gathering; c) use of standardized intervention protocols and training to the acupuncturists regarding treatment protocols; d) monthly project team meetings (with Ms. Lorenz participating by conference call, supplemented by weekly or biweekly project conference calls between the two project coordinators; e) data checking and editing by one coordinator (Ms. Cohen); and f) monthly in-person spot checks by the investigators and the study coordinators of the interventionists and data collectors.

Data Safety and Monitoring Board (DSMB). The project will have a DSMB, consisting of 3 scientists with expertise relevant to the study design who will meet every six months by conference call to review the study protocol and progress. Dr. Preisser, the study statistician, will serve as the liaison to the DSMB; he is experienced in clinical trials research and has served previously on DSMBs.

**C. Study Sites**

Two sites will be used to enroll patients: UNC Hospitals in Chapel Hill, NC and Mission Hospitals in Asheville, NC. Study participants will be recruited from the orthopedic units at UNC and Mission Hospitals. See Section 16 for letters of support from the Department of Orthopedics at each site. Both sites have sufficiently high volumes of patients with hip fractures to ensure a steady and reliable pool for enrollment. Data for the years 2005 – 2007 show that approximately 130 patients per year with hip fracture and repair (ICD-9 codes 820 for hip fracture, and codes 79 or 81 for repair) were seen at UNC Hospital and about 380 similar patients per year were seen at Mission Hospitals.

## D. Participant Enrollment and Randomization

All patients meeting study criteria will be approached for participation and randomized if enrolled. The goal of the study will be to enroll 5-6 persons per month over a 7-month enrollment period (totaling 10 participants at UNC Hospitals and 28 at Mission Hospitals). Previous studies of auricular acupuncture and our feasibility study (described above under preliminary studies) reported dropout rates between 15-25%.[79] Projecting a dropout rate of 20% would leave 30 patients for our final analyses. Table 3 provides site-specific estimates of eligible patients, enrollment, and completion during the study period. Our study timeline (figure 8) allots 10 months for enrollment to accommodate unanticipated problems in subject accrual.

**Table 3: Estimated capacity of the proposed study to recruit participants over a 7 month period**

| | UNC | Asheville[b] | Combined |
|---|---|---|---|
| Patients with hip fracture repair ≥65yrs old [a] | 76 | 222 | 298 |
| Estimated number of eligible patients [c] | 53 | 155 | 208 |
| Target number of enrolled participants [c] | 10 | 28 | 38 |
| Subjects who will complete study [c] | 8 | 22 | 30 |

[a] Estimates based on patients with ICD-9 codes 820 AND 79 or 81 for each hospital during the years 2005-2007.
[b] Asheville estimates are based on preliminary data from UNC.
[c] Based on an eligibility rate of 50%, enrollment rate of 25%, and dropout rate of 20%.

Note from Table 3 that the estimated number of eligible patients is between 5 (at UNC) and 7 (at Asheville) times the number of enrollees required. Based on our feasibility study, we have projected a refusal rate of approximately 50%. Therefore, during project months 1-3 we will revisit these estimates with our statistician to develop a strategy to assure that the final sample will be as representative as possible of the population of eligible patients.

Study participants. Eligible patients will be adults aged 65 and over that have experienced unilateral hip fracture (intertrochanteric, femoral neck, or subtrochanteric) with surgical repair (fixation, partial, or total replacement) and anticipate discharge to a rehabilitation facility (i.e., rehabilitation hospital or nursing home) with daily physical and/or occupational therapy. Table 4

details the full list of inclusion and exclusion criteria. We have selected age 65 as a cut point because most hip fractures occur in patients over this age.

**Table 4. Inclusion and Exclusion Criteria for Study Participants.**

Inclusion Criteria:
- ✓ ≥65 years of age
- ✓ English-speaking
- ✓ Unilateral hip fracture with surgical repair
- ✓ Self-reported pre-fracture ability to walk from room-to-room within their residence independently of other persons, with or without a cane or walker
- ✓ Ability to answer questions
- ✓ Anticipated discharge from the hospital to a rehabilitation center with daily rehabilitation within Orange or Buncombe counties

Exclusion Criteria:
- × Hip fracture or replacement within the past 12 months
- × Complicated or problematic surgical or post-surgical experience
- × Medically unstable (at discretion of project physician)
- × Current problem with, or anticipated, severe skin or wound infection
- × Prosthetic cardiac valve
- × Hemophilia[1]
- × Diabetes with severe peripheral neuropathy or poor control (FBS >200 or HbA1C>9)
- × Compromised immune system due to conditions including HIV/AIDS, Hepatitis B or C
- × Morbid obesity (BMI >40)
- × Moderate or severe cognitive impairment (St. Louis University Mental Status Examination score ≤15)
- × Acute psychiatric disease with psychotic features
- × Current alcohol or substance abuse
- × Major ear deformation[2]
- × Allergy to metals or adhesives
- × Conditions posing severe limitation to ability to participate in physical therapy, such as New York Heart Association Class 4 congestive heart failure or severe $O_2$-dependent chronic obstructive pulmonary disease

[1] Though minor bleeding and hematoma formation have been reported in 3% - 38% of patients receiving acupuncture, no reports have been associated with the use of aspirin or coumadin.[23,69]

[2] Keloid formation is not a contraindication, as no reports of keloid formation after acupuncture were identified in our review of the literature and acupuncture has been reportedly used to treat keloids.[70]

Patient recruitment and informed consent. To accommodate the local hospital environment, recruitment procedures will be slightly different between the two sites. In Chapel Hill, surgical residents will alert the study coordinator of all potentially eligible patients they plan to bring to the operating room for surgical repair that day. In Asheville, the study coordinator will access electronically the daily operating room schedule to identify all potentially eligible patients. Similar methods have been used by Dr. Zimmerman in prior hip fracture recovery studies.

Once a potential participant is identified, the study coordinator will call the social worker to determine if inclusion criteria are met (age ≥65, English-speaking, unilateral repair, prior

ambulation, ability to answer questions, and anticipated discharge in the county). Determination of which patients are to be approached for consent and which will be approached through a family/guardian will be determined using the "Evaluation to Sign Consent" measure developed by Resnick, et al.[71]

Each patient meeting the eligibility criteria (and/or his family/guardian) will be approached by the study coordinator to discuss the study and potential participation, in accordance with procedures approved by the IRB. This assumes that, as in the past, we obtain a HIPAA waiver to do so; if not, then orthopedic service social workers will do this, as was done in our feasibility study. This initial contact will include an explanation of the study, provision of a study brochure, a medical record review, and a brief interview to determine eligibility (see Table 4 above). Potential participants will be approached in this manner until 38 individuals who meet eligibility criteria agree to enroll in the study. As part of the informed consent process (and using IRB-approved methods) all participants will be invited to sign a HIPAA waiver and informed consent form. A letter indicating that the patient has agreed to participate in the study will be placed in the patient medical record.

These visits should occur within 48 hours of identification, while the patient is still in the hospital. In some cases, however, it may be necessary to visit the patient after arrival at the place of rehabilitation to explain the study and invite participation; if so, we will endeavor to make these visits within 24 hours of admission.

Post-enrollment procedure. Enrollment will occur while the patient is in the hospital. After enrollment, the study coordinator will remain in daily contact with the orthopedic service social worker and with the participant and/or guardian/proxy to monitor discharge plans. Randomization, baseline data collection and initiation of the intervention protocol will begin on the day of discharge to a rehabilitation setting.

Contact with the rehabilitation site. Although the rehabilitation facility will not be actively involved in the study protocol, care will be taken to assure that all rehabilitation facilities are informed about the study protocol and have someone to contact with questions or concerns. This procedure is standard for all of our subject contacts in prior hip fracture studies. Our process for working with facilities will be as follows:

a) Prior to initiation of the study, the administrator, medical director, and rehabilitation director at each of five facilities that receive the most referrals from our two study hospitals will receive a personal site visit. During that visit the study coordinator at that site will explain the study and discuss the possibility that one or more study participants may be placed in that facility;
b) When a study participant enters a facility, the administrator, attending physician, and rehabilitation director will receive a fax explaining the study;
c) On the first visit to the facility, the data collector will introduce him/herself to key facility staff and leave an explanatory note and copy of the signed consent form for insertion into the participant's medical record; and
d) Facility staff will be provided with the cell phone number of the study coordinator and invited to call if they have any questions or concerns.

Randomization. Stratified randomization by site will be performed using a computer-generated blocked randomization scheme developed by the study biostatistician, with randomly arranged blocks of four such that there are two assignments to control and two to treatment per block. Since the Chapel Hill site will randomize 10 subjects, the final block will consist of only two assignments: one treatment and one control. Consecutively numbered sealed opaque envelopes containing the randomization sheets will be created by our statistician, who will remain blinded to participant intervention status. Separate randomization sheets will be generated for the two sites and kept locally by the study coordinator at each site. Group

assignment will be determined by selecting the next numbered envelope at the time the patient is discharged from the hospital. Both the numbered envelope and the randomization sheet will be entered into the database for the selected patient by the study coordinator. Following randomization, the study coordinator will contact the acupuncturist and the data collector to coordinate the collection of the baseline measures and the first treatment.

### E. Characteristics and Implementation of the Study Intervention

All participants in the study will have access to standard physical therapy and rehabilitation methods provided by their facility as well as pharmacological pain and anxiety control as prescribed by their physicians.

#### 1. Experimental Group

Auricular acupuncture. All study participants in the experimental group will receive auricular acupuncture by a licensed acupuncturist using sterile nickel-free, gold-plated needles (Aiguille Semi-Permanente [ASP], Sedatelec, Irigny, France). The acupuncturist will meet with participants twice weekly at their rehabilitation facility to remove existing needles and place new needles. During the initial treatment, needles will be placed in the ipsilateral ear to the site of the fracture; needle placement during follow-up treatments will alternate between the contralateral and ipsilateral ears. The initial treatment will occur within 48 hours of baseline data collection. Participants will continue to have auricular needles placed until they are discharged from their rehabilitation facility or for a maximum of four weeks.

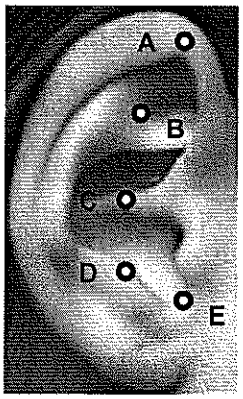
Acupuncture needles. Needles are 3.4 mm long and have a cylindrical head measuring 1.2 mm in diameter and height (see figure 1). Each needle is prepackaged in a sterile applicator that requires minimal pressure at the application site to place the needle intradermally. After placement, needles

**Figure 1: Photograph of applicator and needles**

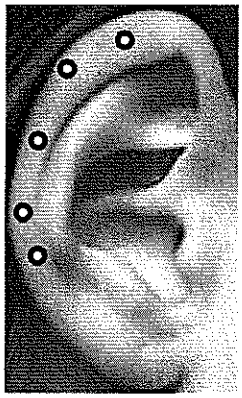
will be covered with a small adhesive patch to keep them in place. In this manner, needles typically stay in place for 5-7 days but have been reported to remain in place for up to 25 days.[28]

Point selection. Participants randomized into the true acupuncture group will have needles placed unilaterally at five predefined points associated with treatment for pain (figure 2a): omega 2 (point A), shen men (point B), point zero (point C), cingulate gyrus (point D), and thalamus (point E). Point selection was based on the following information sources: (1) successful use of points in prior studies of ear acupuncture and acupressure,[72,73,74] (2) clinical reports (Col. Richard Niemtzow, MD, PhD, MPH, Malcolm Grow Medical Center, Andrews Air Force Base, personal communication), and (3) experts' opinion for the treatment of pain.[75]

**Figure 2: Location of Acupuncture Points**




2a: Intervention acupuncture points.



2b: Control (sham) acupressure points.

Adherence. All participants will have a notification placed in their medical chart indicating that they are enrolled in a study and to report any missing needles or adverse events, such as possible infection, to the study coordinator. The acupuncturist will visit each participant two times per week. At each visit, a record will be kept of which needles have fallen out prior to that visit, as well as any adverse events related to the needle placements that might have occurred. During each weekly visit by the data collector, additional information concerning potential adverse events including type, severity, and duration of symptoms experienced will be gathered and entered into a logbook.

## 2. Control Group

Selection of an acupuncture control procedure. The definition of an appropriate control procedure in clinical trials of acupuncture remains controversial. Many types of controls exist, including penetrating and non-penetrating sham acupuncture located at either indicated or non-indicated acupuncture points or at non-acupuncture points. Additionally, some studies have used waiting list, placebo pill, or other non-acupuncture treatments as control procedures. Consensus recommendations by the International Acupuncture Research Forum suggest that the choice of controls should be guided by the effect to be measured;[76] however, there is a considerable lack of agreement among acupuncture researchers concerning the best applications of placebo acupuncture for control groups. Other issues related to the choice of control procedures include attempts to blind participants, practitioners, and data collectors.

There are thought to be three potential sources of "beneficial effects" from acupuncture: (1) placebo effects (e.g., patient suggestibility and expectancy, treatment environment, relationship with practitioner), (2) non-specific effects (e.g., needle sensation, local tissue irritation or damage, distal neurological changes), and (3) specific effects due to the acupuncture itself. Many researchers in the acupuncture field consider placebo effects to be a subset of non-specific effects that are difficult to cleanly partition into a separate category. For this study, it is important to have a control procedure that will have minimal potential for therapeutic effect yet be believable by both participants and care providers as a true treatment. The use of *vaccaria* seeds for auricular acupressure has a long history of use by acupuncturists as a credible method of acupuncture stimulation. The seeds are often affixed to auricular points with an adhesive tape, and patients are usually instructed to stimulate the points by applying manual pressure to the seeds throughout the day. To minimize the potential effect of the seeds, we will make two changes to the usual procedure for their use: a) seeds will be placed at non-acupuncture points along the helix of the ear, and b) participants will be instructed not to apply

pressure to the seeds. In this way, the procedure will provide a credible control with minimal therapeutic effect. Patients, data collectors, and non-acupuncturist care providers can be masked with this type of control procedure; masking of acupuncture practitioners will be unlikely since the use of non-acupuncture points may be noted by experienced acupuncturists.

Procedure. Control participants will receive *vaccaria* seeds at five non-acupuncture points (Figure 2b), as defined by Margolin,[77,78] and used in several recent trials of auricular acupuncture.[29,30,79,80] Control participants will be visited by the acupuncturist and data collector in the same way as participants in the true acupuncture group; the only differences in therapy will be the location of the auricular points and the use of seeds instead of indwelling needles.

### 3. Timing of Intervention Administration

After all baseline data have been collected, the licensed acupuncturist will visit the participant to administer the initial treatment (as described above for the intervention and control groups). After placement, a digital photograph will be taken to confirm placement, the needles or ear seeds will be covered with the supplied adhesive patch, and the date and ear treated (i.e., right or left) noted in the participant's treatment log. The day that the acupuncture needles or seeds are placed will be called 'Intervention Day 1'. Treatments will occur two times per week (i.e., every 3 to 4 days), with existing needles or seeds being removed and a new treatment placed at the appropriate points on the contralateral ear. All treatment visits will be performed at the participant's place of rehabilitation.

## F. Variables and Measures

Methods Feasibility

1) Eligibility and enrollment

We will track all hip fracture cases using a case identification tracking form and screening and recruitment tracking form. From these data, we will determine the number and proportion of

individuals who: a) have hip fractures repaired at the participating hospitals; b) are approached for screening; c) meet screening criteria; d) meet full eligibility criteria; e) agree to participate; f) are enrolled in the study; g) have baseline data collected; and h) complete the study. For individuals not meeting criteria, declining to participate, and withdrawing from the study, the reasons will be recorded and summarized.

2) Dropout

Subjects will be followed until they are either discharged from their rehabilitation facility or for a maximum of four weeks. The number of subjects dropping out of the study and their reasons for dropout will be summarized, particularly whether or not dropout is related to treatment.

3) Adherence

On each occasion of needle placement, we will record if, to what extent (i.e. how many), when (if available from the participant), and from which point(s) needles have become dislodged since the previous insertion. It is possible that some subjects may refuse placement of some or all needles. If so, reasons for refusal of needle placement will be documented.

4) Adverse events

Study participants will be monitored for adverse events on a regular basis. The acupuncturist will monitor for infection, noting and photographing each site immediately after needle or seed removal. The research assistant will monitor for other adverse effects (e.g., itching at the site, pain at needle insertion, unusual tiredness) by administering a standardized series of questions weekly. Section 18 [Appendix] contains a draft of the adverse events reporting form (embedded within the weekly interview). In addition the medical record will be checked for the following adverse events: hospitalizations, falls, death. All reports of adverse events will be reviewed by the Data and Safety Monitoring Committee, and provided to the University of North Carolina Institutional Review Board.

Outcome measures

1) Pain: McGill Pain Questionnaire Short Form (SF-MPQ)[81]

The short form of the McGill Pain Questionnaire consists of 15 sensory and affective descriptors that are rated on a 0-3 intensity scale, yielding a summary measure with a range from 0 to 45. Typical sensory descriptors include: throbbing, shooting, heavy; affective descriptors include: sickening, fearful, punishing. Pain scores are derived for the sensory, affective, and total descriptors. Additionally, the Present Pain Intensity (PPI) index (a six point Likert scale for current pain anchored at 'no pain' and 'excruciating pain') and a visual analog scale (VAS) – a 10 centimeter line anchored with 'no pain' at the left end and 'worst possible pain' at the right end – are also included to provide overall intensity scores.

SF-MPQ scores obtained from post-surgical and physiotherapy patients correlate highly with the full MPQ but can be gathered more quickly.[81] Two studies have demonstrated that the concurrent criterion validity of the SF-MPQ with the standard MPQ is good.[81,82] Estimates for the intraclass correlation coefficients for the sensory, affective, and total scores (with 95% confidence intervals) for the SF-MPQ are 0.95 (0.92-0.97), 0.88 (0.81-0.93), and 0.96 (0.94-0.98) respectively indicating good test-retest reliability. The coefficient of repeatability (CoR) was 5.2 for the total score representing the amount of change in the total score necessary to be detected as a clinical change. These data were derived from a cohort of patients with a mean age of 65 years.[83] Sensitivity to change has been demonstrated as well.

2) Anxiety: State-Trait Anxiety Inventory (STAI)[84]

The STAI has been used extensively in clinical practice and the research environment. It consists of 40 statements that measure current (state) and general (trait) feelings of anxiety.[84] Because we will be looking for changes in current anxiety only, we plan to administer the State portion of the STAI. Representative statements include: I feel calm, I am tense, I feel upset, I

am worried. Each item is rated on a four-point Likert scale anchored at 'not at all' and 'very much so'. Respondents are also scored for refused items and 'don't know' responses. Data from community and psychiatric samples of older adults indicate adequate internal consistency and convergent validity. Cronbach's alpha for healthy and psychiatric subjects range from 0.85-0.94 for the state portion of the test and 0.79-0.90 for the trait portion. Test-retest coefficients for the state and trait portions are 0.62 and 0.84 respectively.[85,86,87]

3) Pain medication use (analgesic medications received)

There is no "gold standard" method of determining the total amount of analgesic medication being received by a given individual. Therefore, we will use two different methods and instruments in the proposed study: the analgesic load of all medications received (primary measure), and the morphine equivalent daily dose of narcotics received (secondary measure). Analyses will be run using both measures so as to maximize validity of findings.

a. Analgesic load. We will measure analgesic load using the method developed by Sloane et al.[88] Each medication will be assigned a category and potency based on an expert consensus panel: opioids for the treatment of moderate to severe pain (potency = 9); opioids for the treatment of mild to moderate pain (potency = 6); non-opioid analgesics (potency = 3); adjuvant (co-analgesic) medications (potency = 1); or non-analgesic agents (potency = 0). For all medications assigned a non-zero value, resident medication administration will be abstracted to produce a daily record of the amount received of each drug. For each resident for each day, the sedative load ($SL_{ij}$, for resident *i* on day *j*) will be computed according to the following formula:

$$SL_{ij} = \sum_{k=1}^{m} \frac{Dose_{ijk} \times SR_k}{ADMD_k}$$ , where

- $m$ is the number of analgesic medications for resident $i$ on day $j$
- $Dose_{ijk}$ is the quantity of medication $k$ received by resident $i$ on day $j$ (in same units as $ADMD_k$)
- $SR_k$ is the potency rating (1, 3, 6, 9) for analgesic medication $k$
- $ADMD_k$ is the average daily maintenance dose for medication $k$ (determined based on standard pharmacy references)

This results in a single continuous variable for each study participant and each data collection period. This variable can then be used in longitudinal analyses to control for changes in medications at the resident level across the data collection period.

b. Morphine equivalent daily dose (for narcotics only). Comparative potency ratings of narcotics have been used for several decades. Initially the term 'defined daily dose' was used, then 'defined daily dose for statistical purposes', and most recently the 'morphine equivalent daily dose'.[89,90] For each study participant day, we will calculated the morphine equivalent received by multiplying and summing the potency by the number of milligrams received of narcotics.

4) Fear of falling: Falls Efficacy Scale (FES)[91]

The FES is designed to assess the degree of perceived efficacy at avoiding a fall during the performance each of ten ADL's (bathing, reaching into closet, meal preparation, walking around the house, getting in and out of bed, answering the door or phone, getting in and out of a chair, getting dressed and undressed, light housekeeping, simple shopping). This is useful in assessing the independent contribution of fear of falling to functional decline among the elderly.[91] The FES demonstrates good reliability (Cronbach's alpha = 0.94, test-retest coefficient (r) = 0.71), construct validity, and responsiveness as measured in a variety of studies, including a study conducted by Dr. Sloane and colleagues involving older patients with chronic dizziness.[92,93]

5) Functional recovery: Lower Extremity Gain Scale (LEGS)[94]

The LEGS is a performance-based measurement designed specifically to assess recovery after hip fracture. It consists of timed scores for nine tasks (reaching for an item, putting on a shoe and sock, rising from a chair, walking ten feet, walking up and down stairs, and getting on and off a toilet). The summed total score has demonstrated sufficient sensitivity to change to be both clinically relevant and useful in the research environment. Cronbach's alpha for baseline to 2-month measurements is 0.98, and ICC for all of the nine tasks ranges from 0.63 – 0.96. These data were developed and validated in a cohort of patients aged 65 years and older.[94,95] Clinically significant change is indicated by a change in score of two or more.

Other variables

In addition to data collection for the previously mentioned outcome measures, a variety of other data will be collected during the baseline examination, some of which will be repeated at each treatment and/or data collection visit (detailed below).

Additional baseline information collected by interview will include age, highest level of education, race, ethnicity, gender, marital status, self-reported health status, and cognitive status (using the St. Louis University Mental Status Examination, which is superior to the Mini-Mental State Examination for differentiation between levels of mild impairment).[96] In addition, we will administer the 4-item treatment expectancy scale developed by Mao, et al, which measures the expectation of improvement of illness, enhanced coping, increased vitality, and symptom alleviation as a result of acupuncture therapy, yielding a 20-item continuous measure that has a Cronbach's alpha of 0.82 and positive correlations with other measures of perceived efficacy.[97]

A hospital and nursing home chart review will confirm date and type of fracture, type of surgical repair, discharge date from hospital, height, weight, and physical therapy regimen.

Missed and shortened physical therapy sessions will be recorded, and a descriptive account of therapy progress will be abstracted from the physical therapists' notes.

**G. Data Collection**

As soon as rehabilitation begins (usually after discharge to a skilled nursing facility or rehabilitation hospital), the data collector will visit the participant at his/her place of rehabilitation to complete the baseline measures (i.e., the demographic and medical history questionnaire, SF-MPQ, LEGS, STAI, and the FES.) To assure good relationships with nursing homes or rehabilitation facilities to which each study participant is placed, study staff will distribute materials to and meet with each facility as part of this entry process (see Section 18 [Appendix] for examples of materials). Initial intervention (acupuncture or sham) will begin within 48 hours after baseline measures have been collected.

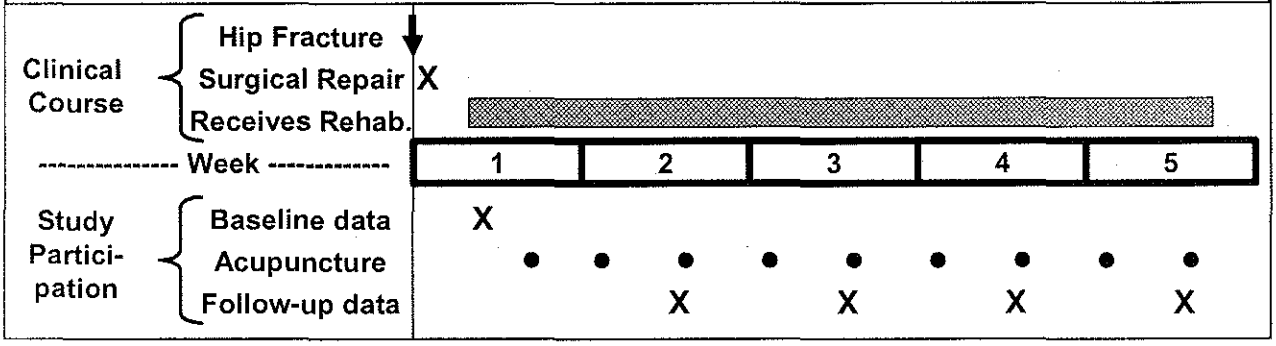
The data collector will conduct return visits 8, 15, 22, and 29 days after baseline data collection (if the participant was discharged within 3 days prior to the scheduled visit, this final assessment will be made in the participant's home; otherwise the scores on the prior visit will be the final values obtained. Each visit will be scheduled for a time in the morning, preferably prior to any scheduled therapy sessions for that day. Questions concerning adverse events and symptoms will be asked at each visit.

Data collection and study participation will end after four weeks if the participant has not yet been discharged from their rehabilitation facility. In addition, early termination will be considered for any patients experiencing adverse side effects from the treatment (e.g., reaction to metals, intolerance to needle placement, infection or inflammatory response at needle placement sites) or at the request of the participant.

Figure 3 graphically displays the timeline of one participant's study involvement. We expect most patients to undergo surgical repair within 1-2 days after hip fracture, and we plan to begin

baseline data collection within 4-5 days after hip fracture. Following baseline data collection, the four-week clock for inpatient rehabilitation will begin with weekly follow-up data collection and twice-weekly acupuncture visits.

**Figure 3: Graphic Representation of One Participant's Study Involvement Timeline**




## H. Quality Control

To ensure that the intervention is implemented across sites and participants in accordance with protocol, significant time will be spent on acupuncturist training and fidelity assessments. The selected acupuncturists are both certified in medical acupuncture and have many years experience in acupuncture treatment. In Year 1, Dr. Asher (the project PI and a certified and experienced medical acupuncturist) will train each of the acupuncturists in the protocol requirements. Over a period of two days, Dr. Asher will meet with these individuals and demonstrate correct needle placement and technique for both intervention and control visits. The acupuncturists will then be asked to independently place the needles and will work with Dr. Asher until acceptable reliability and validity is achieved between and within the two individuals. In addition to this initial training session, Dr. Asher will accompany the acupuncturists on approximately 5% of treatment visits to monitor technique and adherence to protocol. Finally, once in the field, the acupuncturists will use digital cameras to document all needle and seed placements; these digital files will be sent to the project office on a weekly basis and reviewed for accuracy and consistency.

The data collectors (one a previously trained and highly experienced data collector) will be trained in the project protocol by the project manager (Ms. Cohen). Prior to the initiation of the project, the data collectors from both sites will receive training in enrollment and consent procedures, interviewing techniques, monitoring for signs of infection, and data reporting. After data collectors have received training, the project manager will separately accompany both individuals in their respective first rounds of data collection to ensure accuracy and consistency. Also, throughout the data collection period, the project manager will accompany the data collectors on approximately 5% of the data collection visits to ensure continued adherence to protocol. All members of the project team will meet twice monthly (by phone or in-person) to discuss any questions or concerns, and the project manager will be available at all times by phone to answer questions and provide consultation.

**I. Data Management**

All data forms will be edited twice, once by the data collector on the same day collection occurs, and once again upon return to the project office by a different member of the study team. The forms will be edited for accuracy, clarity, skipped questions, and outlying and impossible values. Data will be double entered into Microsoft Access databases by two members of the project team, and the project coordinator will periodically compare these data-entry and double-data entry databases to identify and correct typographical errors. Additionally, frequency and logic checks will be periodically performed to identify implausible values (such as those out of range) as well as suspicious values (such as outliers) and correct mistakes. These actions will be conducted throughout and at the end of the project and will help ensure high data quality.

No names will appear on data collection forms; instead, all participants will be assigned a numeric ID. The list linking names and IDs will be kept separate from data collection forms and in a locked filing cabinet at all times. All data will be entered into databases maintained on a

secure, password-protected server, and only designated members of the project staff will have access to the database.

**J. Sample size**

A recruitment sample size of 38 participants has been chosen based on the feasibility aims of this proposal with the goal of having at least 30 participants complete the study. Previous studies of auricular acupuncture have reported dropout rates between 15-25%.[79] Projecting a dropout rate of 20% would leave 30 patients for our final analyses. A sample size of 30 permits the estimation of proportions in Aim 1 (e.g., proportion of enrollment, dropout, and adverse events) with precision given by plus or minus 0.05 (e.g., a dropout rate of 20% will correspond to a completion rate of 80% with corresponding 95% confidence interval of 75%, 85%.)

For Aim 2, Table 5 below shows estimates of the rate of change of the outcomes, and their standard errors, from the preliminary data based upon n = 4 individuals (see preliminary studies) and as projected for the proposed study planned to have within-group sample sizes of 15. Table 5 does not include the McGill Pain Score since our preliminary feasibility study used a modification of this score; thus we do not have preliminary data for it. The projected standard errors (last two columns of the table) were determined by simulating data from a random intercept repeated measures model whose parameters (intercept, slope, subject level variance, and within-subject error) were fixed at values estimated from the preliminary data. The table suggests that, while none of the measures had a statistically significantly decrease over time in

**Table 5. Estimated precision of slope estimates for linear trend in outcome from a repeated measures model for the preliminary data and for simulated data based upon larger planned sample size**

| | Preliminary Data Estimates (n=4) | | Proposed Study Estimate (n=15) |
|---|---|---|---|
| Outcome Measure | Estimated slope (rate of weekly change) | Standard error | Standard error |
| LEGS | 3.568 | 2.483 | 1.221 |
| Falls Efficacy Scale | -4.750 | 2.302 | 1.127 |
| STAI | -2.500 | 1.600 | 0.787 |

the preliminary data set (n=4), increasing the sample size to 15 per group for the proposed study would provide ample data to detect changes at levels observed in the preliminary data. For example, a simulated data set of 15 subjects resulted in a 95% confidence interval for change in the LEGS scale of 1.175 to 4.789 (3.568 +/- 1.96*1.221).

**K. Data Analysis**

Demographic information (e.g., age, race/ethnicity, gender, marital status, educational level) will be summarized overall and by treatment group. Other covariates including BMI, dementia, fracture type, and expectancy, will be summarized overall and by treatment group. Means and standard deviations will be used for continuous variables and frequencies for categorical variables. For the former, ANOVA adjusting for study site will be used to assess baseline balance, and for the latter, Mantel-Haenszel Chi-square tests will be used. Finally, the extent of differences in summary measures of baseline data by study site will be determined.

**Specific Aim 1: Estimation of eligibility, enrollment, dropout, adherence, and adverse event rates**

Eligibility and enrollment. We will determine the number and proportion of individuals who: a) have hip fractures repaired at the participating hospitals; b) are approached for screening; c) meet screening criteria; d) meet full eligibility criteria; e) agree to participate; f) are enrolled in the study; g) have baseline data collected; and h) complete the study. In addition, we will perform bivariate analyses to identify whether and to what extent patient factors (e.g., age, gender, race, degree of disability), site factors (e.g., Asheville vs. Chapel Hill), and other factors (e.g. type of surgery, day of week) are associated with non-enrollment and non-completion of the study. Individuals declining to participate will be asked the reason for refusal, and these reasons will be listed and summarized. Enrollment will also be summarized by age, type of hip fracture, pre-fracture ability to independently ambulate, and cognitive function. While a seven-month period is anticipated to enroll 38 study participants, it will be important in the planning of a

future larger study to document the actual monthly rate of enrollment in the two sites participating in this pilot study.

Concomitant therapies. As every participant in the trial will have access to standard physical therapy and rehabilitation methods, it will be important to record the timing of these sessions and whether any were missed or shortened. Providing summarizations of the length and amount of sessions and the proportion of such sessions that were missed or shortened will reveal the subject-to-subject variability of attendance to physical therapy sessions and whether the extent of attendance would be an important covariate in the assessment of the efficacy of auricular acupuncture. Besides physical therapy, the use of pharmacological pain and anxiety control will be a critical factor in ascertaining the efficacy of acupuncture in the rehabilitative process. Therefore, the use of drugs to combat pain will be documented, coded, and summarized on a weekly basis in terms of average daily dose. Comparison will be made between the two treatment groups in terms of our summary variables, the analgesic load, and the morphine equivalent daily dose.

Dropout. Subjects will be followed from the time of entry into an inpatient rehabilitation facility until they are discharged from inpatient rehabilitation for up to a maximum of four weeks. The number of subjects dropping out of the study and their reasons for dropout will be summarized, particularly whether or not dropout is related to treatment. Dropouts will be summarized by treatment group.

Adherence. Adherence to needle placement will be summarized for the nineteen subjects receiving acupuncture by study visit, number of needles placed, needle placement site, and participant characteristics. At each study visit point (i.e., 1, 2, 3, and 4 weeks after entering the study), an overall estimate of adherence (total adherence by a subject) with 95% confidence intervals will be computed in the usual way for proportions. A second measure of adherence is whether the participant has all five needles in place at the beginning of a needle placement

session. A third measure, if able to determine, is the proportion of time a subject has each needle in place; this captures information between visits. A related measure will be the proportion of needles remaining in place between visits will be calculated for each of the five auricular points.

Adverse events. All adverse events will be described and characterized by severity, relation to treatment, length of occurrence, and resolution.

**Specific Aim 2: Outcome estimation**

The means and standard deviations of outcome measures will be computed at baseline and for each follow-up data collection visit by treatment group. Pain will be measured using the Short Form McGill Pain Questionnaire (SF-MPQ); anxiety will be measured using the Spielberger State-Trait Anxiety Inventory (STAI); analgesic use will be measured using a morphine equivalent daily dose formulation as well as a scale designed to measure total analgesic load, functional mobility will be measured with the Lower Extremity Gain Scale (LEGS); and fear of falling will be measured using the Falls Efficacy Scale (FES). Additionally, the mean within-subject change (standard deviation) of each measure with respect to baseline will be computed by visit for the acupuncture intervention and sham control. Psychometric properties of the measures (e.g., Cronbach's alpha) will be established for these measures in this study population.

Preliminary analyses will be run for each scale using linear mixed models to estimate mean outcomes, rates of change, and their variances over the four-week intervention. Intra-subject correlation due to repeated measures will be accounted for by either subject-level random effects or through direct modeling of the covariance structure of a subject's random errors. Due to the small sample size, the Kenward-Roger correction will be used.[98] We will explore models that consider weekly visits as a categorical variable or a linear factor. Models will adjust for baseline factors such as analgesic use, dementia and fracture type. Further exploratory

analysis will adjust for differences in concomitant therapy use (physical therapy or drug use) during the trial. These analyses will be exploratory. The main purpose is to identify a modeling approach for use in a future larger study, as well as to obtain preliminary point estimates and measures of intra-subject correlation and variances to be used in the sample size calculations of a future confirmatory clinical trial.

## L. Limitations and Potential Challenges

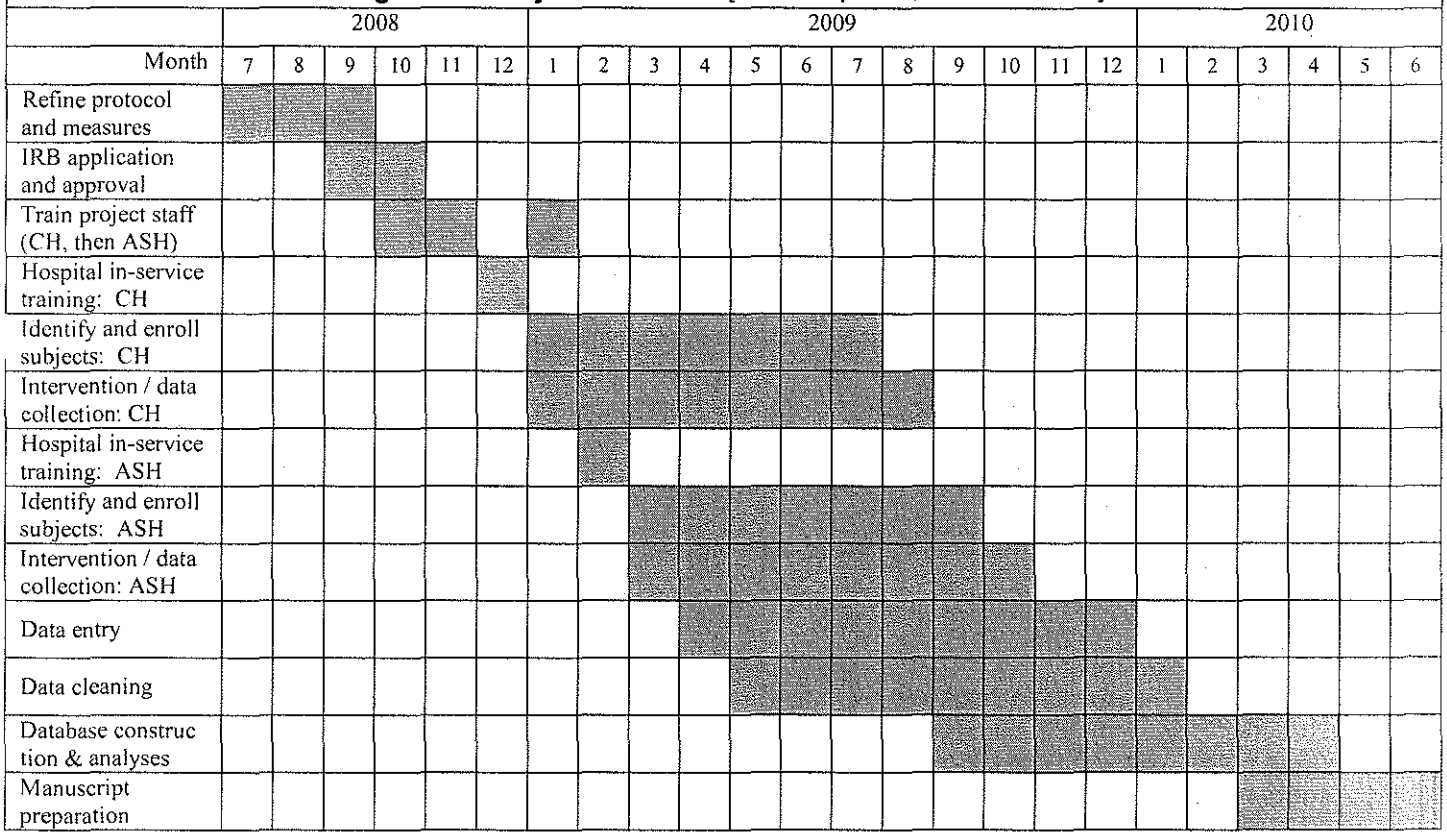
This pilot study is not intended to provide a definitive assessment of the efficacy of auricular acupuncture in hip fracture patients, but rather to gather feasibility and preliminary data needed to design a more definitive efficacy trial. As such, the study has inherent limitations related to its small size and relatively low power to detect small differences. Another limitation of the design is that there are only two arms: the acupuncture arm and a control arm involving sham acupressure at non-acupuncture points. As such, it is impossible to blind interventionists. However this is a limitation insofar as one would want to compare treatments, and not with respect to establishing the feasibility of a larger trial. The future larger trial will improve blinding by incorporating a sham treatment characterized by the placement of needles in non-acupuncture sites.

There are several potential challenges that we have attempted to address, but that could nevertheless pose problems. One is participant recruitment, which may suggest that a minority of potential subjects agree to participate in the project. Based on prior experience, we will maximize potential patient identification by simplifying the identification process for key personnel and by reviewing the daily operating room schedule. Another is the maintenance of consistency of the two interventionists and of the data collectors; here we will draw upon the experience of the CS-LTC project team, using established methods to monitor through a variety of modalities (use of photography and logs, spot checks in person and by telephone, and careful data review).

## M. Project Timeline

The project will be conducted over a 24-month period, according to the timeline graphically represented in Figure 4 below. Note that intervention and data collection activities will last 8 months at each of the two study sites, with these activities being staggered so that they are begun 2 months earlier in Chapel Hill than in Asheville. This will allow us to work out final logistics near our project headquarters and to have the Asheville staff and acupuncturist come for training and observation after the project is up and running.

**Figure 4: Project Timeline** [CH = Chapel Hill; ASH = Asheville]



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# Appendix

**Participant Name:** _____
(Black out or erase after completion, ID check)

# Collaborative Studies of Long-Term Care:

# Auricular Acupuncture for Pain and Anxiety Following Hip Fracture Repair: A Pilot Study

## A. Baseline Participant Interview

Date completed: | | | | | | | | | (M M D D Y Y Y Y)

Participant ID: | | | |

Proxy Respondent Sections I & II: ☐0 No ☐1 Yes

Interviewer ID: | |

Section VIII Data from non-Chart source: ☐0 No ☐1 Yes

Period: Baseline ☐0
(check one)

# I. Demographics

**I'd like to start by asking you a few questions about yourself.**

**1. In what year were you born?** ____ ____ ____ ____

**2. What is your highest level of education completed?**

- ☐1 Junior high or middle school
- ☐2 Some high school
- ☐3 High school grad or GED
- ☐3 2-year college or associate's degree
- ☐4 Some college (no degree)
- ☐5 4-year college degree or higher

**3. Are you Hispanic or Latino/Latina?**

*[code 7 for don't know; 8 for refusal]*

☐0 No ☐1 Yes

**4. What is your race? Please select one or more?**

*[record all that the respondent identifies with; Code 6 for other; 7 for don't know; 8 for refusal]*

- ☐1 American Indian or Alaska Native
- ☐2 Asian
- ☐3 Native Hawaiian or Other Pacific Islander
- ☐4 Black or African American
- ☐5 White

**5. What is your gender? (*DO NOT ASK*)**

- ☐1 Male
- ☐2 Female

**6. What is your marital status?**

*[code 7 for don't know; 8 for refusal]*

- ☐1 Never Married
- ☐2 Married
- ☐3 Widowed
- ☐4 Separated
- ☐5 Divorced

# II. Health

**Now I'd like to ask you about your health and any medical conditions you may have experienced.**

**1. In general, would you say your health is:**

- ☐ 1 Excellent
- ☐ 2 Very Good
- ☐ 3 Good
- ☐ 4 Fair
- ☐ 5 Poor

**2. Has a doctor every told you that you have any of the following diagnoses?**

| | | No | Yes |
|---|---|---|---|
| a. | Heart disease | ☐ 0 | ☐ 1 |
| b. | High blood pressure | ☐ 0 | ☐ 1 |
| c. | Chronic lung disease | ☐ 0 | ☐ 1 |
| d. | Stroke | ☐ 0 | ☐ 1 |
| | **d2.** If Yes, year of last stroke: ____ | | |
| e. | Depression | ☐ 0 | ☐ 1 |
| f. | Orthostatic hypotension | ☐ 0 | ☐ 1 |
| g. | Chronic back pain | ☐ 0 | ☐ 1 |
| h. | Cancer, other than skin cancer | ☐ 0 | ☐ 1 |
| i. | Diabetes | ☐ 0 | ☐ 1 |
| j. | Arthritis, or other musculoskeletal disorders | ☐ 0 | ☐ 1 |
| k. | Osteoporosis | ☐ 0 | ☐ 1 |
| l. | Dementia or Alzheimer's Disease (includes Vascular, Binswanger's disease, Pick's disease, Lewy Body disease, Creutzfeldt-Jakob disease, Huntington's Chorea, Alcoholic dementia, Organic Brain Syndrome, Chronic Confusion, Senile Dementia) | ☐ 0 | ☐ 1 |
| m. | Parkinson's disease | ☐ 0 | ☐ 1 |
| n. | Altered mobility or gait | ☐ 0 | ☐ 1 |
| o. | Visual impairment | ☐ 0 | ☐ 1 |
| p. | Hearing impairment | ☐ 0 | ☐ 1 |
| q. | Dizziness | ☐ 0 | ☐ 1 |
| r. | Dehydration | ☐ 0 | ☐ 1 |
| s. | Blackouts | ☐ 0 | ☐ 1 |
| t. | Seizures | ☐ 0 | ☐ 1 |
| u. | Headaches | ☐ 0 | ☐ 1 |

## III. St. Louis University Mental Status Examination

Now I will ask you some questions that use your memory and concentration. Please listen carefully to each complete question until I have finished reading the whole question before you respond. I would like you to try to answer each question even if you are not positive of your answer. Do you have any questions?

| | Record Answer | Correct | Incorrect |
|---|---|---|---|
| 1. What day of the week is it? | | 1 | 0 |
| 2. What is the year? | | 1 | 0 |
| 3. What state are we in? | | 1 | 0 |
| 4. Please remember these five objects. I will ask you what they are later. *(Read List)* Apple Pen Tie House Car | | | |
| 5. You have $100 and you go to the store and buy a dozen apples for $3. You also buy a tricycle for $20. | | | |
| 6. How much did you spend? *($23)* | | 1 | 0 |
| 7. How much do you have left? *($77)* | | 2 | 0 |

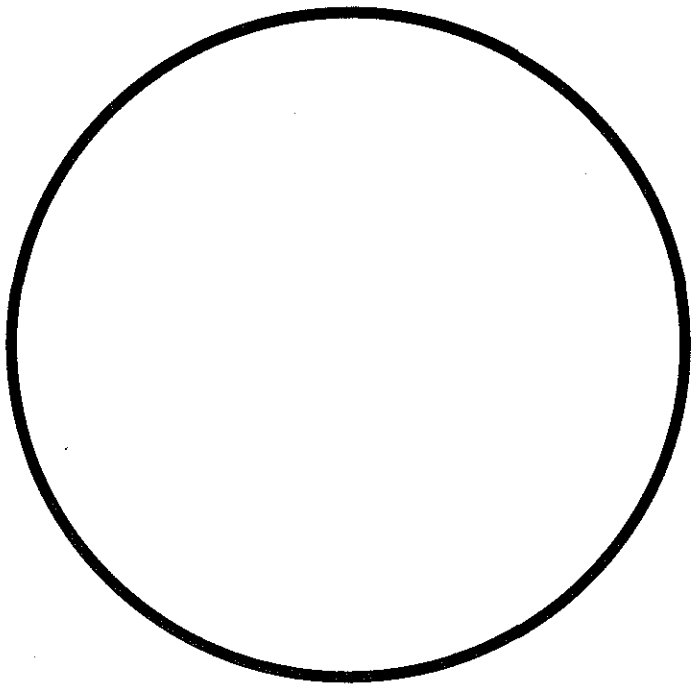
| | 15+ animals | 10-14 animals | 5-9 animals | 0-4 animals |
|---|---|---|---|---|
| 8. Please name as many animals as you can in one minute. *(Repeated animals should be counted only once)* | 3 | 2 | 1 | 0 |

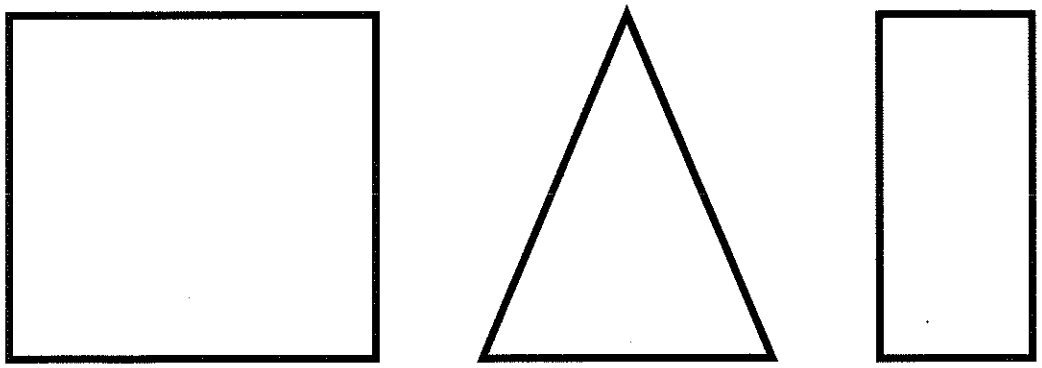
| 9. What were the five objects that I asked you to remember earlier? | | Correct | Incorrect |
|---|---|---|---|
| | A. APPLE | 1 | 0 |
| | B. PEN | 1 | 0 |
| | C. TIE | 1 | 0 |
| | D. HOUSE | 1 | 0 |
| | E. CAR | 1 | 0 |

| | | Correct | Incorrect |
|---|---|---|---|
| 10. I am going to give you a series of numbers and I would like for you to repeat them to me, backwards. For example, if I say 42, you would say 24. | A. 87 *(78)* | | |
| | B. 649 *(946)* | 1 | 0 |
| | C. 8537 *(7358)* | 1 | 0 |
| 11. *Fold the next page in half so that only the clock face is showing.* This is a clock face. Please put in the hour markers and the time at ten minutes to eleven o'clock. *Do not score if physically unable.* | A. Hour markers okay | 2 | 0 |
| | B. Time correct | 2 | 0 |
| 12. Show the bottom half of the folded paper – the half with the geometric shapes. Please place an 'X' in the triangle. Which of these shapes is the largest? *Do not score if physically unable to do A* | A. Places X in triangle | 1 | 0 |
| | B. Selects the square | 1 | 0 |

| 13. I am going to tell you a story. Please listen carefully because afterwards, I'm going to ask you some questions about it. *(Read story)* Jill was a very successful stockbroker. She made a lot of money on the stock market. She then met Jack, a devastatingly handsome man. She married him and had three children. They lived in Chicago. She then stopped work and stayed at home to bring up her children. When they were teenagers, she went back to work. She and Jack lived happily ever after. | | Correct | Incorrect |
|---|---|---|---|
| | A. What was the woman's name? *(Jill)* | 2 | 0 |
| | B. What work did she do? *(stockbroker)* | 2 | 0 |
| | C. When did she go back to work? *(when her children were teenagers)* | 2 | 0 |
| | D. What state did she live in? *(Illinois)* | 2 | 0 |

**SCORE (sum)** _____ / 30





## IV. Spielberger State Anxiety Inventory (STAI-Y1)

READ ALOUD TO SUBJECT: I am going to read you a number of statements that people have used to describe themselves. For each, please indicate how you feel right now, at this very moment, using the responses listed on this card. Do not spend too much time on any one statement, but give the answer that seems to describe your present feelings best. *Show Card A and read options.*

| | Not at all | Somewhat | Moderately so | Very much so | Refused | Don't know |
|---|---|---|---|---|---|---|
| 1. I feel calm. | 1 | 2 | 3 | 4 | 7 | 8 |
| 2. I feel secure. | 1 | 2 | 3 | 4 | 7 | 8 |
| 3. I am tense. | 1 | 2 | 3 | 4 | 7 | 8 |
| 4. I feel strained. | 1 | 2 | 3 | 4 | 7 | 8 |
| 5. I feel at ease. | 1 | 2 | 3 | 4 | 7 | 8 |
| 6. I feel upset | 1 | 2 | 3 | 4 | 7 | 8 |
| 7. I am presently worrying over possible misfortunes. | 1 | 2 | 3 | 4 | 7 | 8 |
| 8. I feel satisfied. | 1 | 2 | 3 | 4 | 7 | 8 |
| 9. I feel frightened. | 1 | 2 | 3 | 4 | 7 | 8 |
| 10. I feel comfortable. | 1 | 2 | 3 | 4 | 7 | 8 |
| 11. I feel self-confident. | 1 | 2 | 3 | 4 | 7 | 8 |
| 12. I feel nervous. | 1 | 2 | 3 | 4 | 7 | 8 |
| 13. I am jittery. | 1 | 2 | 3 | 4 | 7 | 8 |
| 14. I feel indecisive. | 1 | 2 | 3 | 4 | 7 | 8 |
| 15. I am relaxed. | 1 | 2 | 3 | 4 | 7 | 8 |
| 16. I feel content. | 1 | 2 | 3 | 4 | 7 | 8 |
| 17. I am worried. | 1 | 2 | 3 | 4 | 7 | 8 |
| 18. I feel confused. | 1 | 2 | 3 | 4 | 7 | 8 |
| 19. I feel steady. | 1 | 2 | 3 | 4 | 7 | 8 |
| 20. I feel pleasant. | 1 | 2 | 3 | 4 | 7 | 8 |

## V. Falls Efficacy Scale

READ ALOUD TO SUBJECT: On a scale of 1 to 10, where 1 is extremely confident and 10 is not confident at all, how confident are you at.....
*(Show Card B)*

| Question | | Circle best answer<br>Most confident ----- Least confident |
|---|---|---|
| **1.** | Taking a bath or shower? | 1 2 3 4 5 6 7 8 9 10 |
| **2.** | Reaching into cupboards? | 1 2 3 4 5 6 7 8 9 10 |
| **3.** | Preparing a meal (not requiring carrying heavy or hot objects? | 1 2 3 4 5 6 7 8 9 10 |
| **4.** | Walking around the house? | 1 2 3 4 5 6 7 8 9 10 |
| **5.** | Getting in and out of bed? | 1 2 3 4 5 6 7 8 9 10 |
| **6.** | Answering the door or telephone? | 1 2 3 4 5 6 7 8 9 10 |
| **7.** | Getting in and out of a chair? | 1 2 3 4 5 6 7 8 9 10 |
| **8.** | Getting dressed or undressed? | 1 2 3 4 5 6 7 8 9 10 |
| **9.** | Doing light housekeeping? | 1 2 3 4 5 6 7 8 9 10 |
| **10.** | Doing simple shopping? | 1 2 3 4 5 6 7 8 9 10 |

| | |
|---|---|
| **Score** (10-100) | |

## VI. Short Form McGill Pain Scale

READ ALOUD TO SUBJECT: Now, I will ask about how you are feeling today. I am going to read a list of words to you that people often use to describe pain. For each descriptor, please tell me the extent to which it describes your type of pain. Please respond by saying 'None', 'Mild', 'Moderate', or 'Severe'. *(Show Card C)*

| | | None | Mild | Moderate | Severe |
|---|---|---|---|---|---|
| 1. | Throbbing | **0** | **1** | **2** | **3** |
| 2. | Shooting | **0** | **1** | **2** | **3** |
| 3. | Stabbing | **0** | **1** | **2** | **3** |
| 4. | Sharp | **0** | **1** | **2** | **3** |
| 5. | Cramping | **0** | **1** | **2** | **3** |
| 6. | Gnawing | **0** | **1** | **2** | **3** |
| 7. | Hot – Burning | **0** | **1** | **2** | **3** |
| 8. | Aching | **0** | **1** | **2** | **3** |
| 9. | Heavy | **0** | **1** | **2** | **3** |
| 10. | Tender | **0** | **1** | **2** | **3** |
| 11. | Splitting | **0** | **1** | **2** | **3** |
| 12. | Tiring – Exhausting | **0** | **1** | **2** | **3** |
| 13. | Sickening | **0** | **1** | **2** | **3** |
| 14. | Fearful | **0** | **1** | **2** | **3** |
| 15. | Punishing – Cruel | **0** | **1** | **2** | **3** |

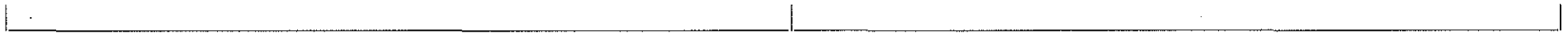
16. Please look at this line *(Show page 9)*
This line goes from No Pain at one end to the Worst Pain possible at the other end.
Point to the place on the line that shows how much physical pain or discomfort you have had in the past week.

*(Enter the corresponding number as the score.)*

**Score:** ___ ___ ___
***(00-100)***

17. Which of the following words best describes your pain <u>overall</u>?

- ☐$_0$ No pain
- ☐$_2$ Mild
- ☐$_3$ Discomforting
- ☐$_1$ Distressing
- ☐$_2$ Horrible
- ☐$_3$ Excruciating


0
No Pain
100
Worst Pain
Imaginable

# VII. LEGS

## LOWER EXTREMITY GAIN SCALE (LEGS): A MEASURE TO ASSESS RECOVERY FOLLOWING HIP FRACTURE

**Zimmerman, Hawkes, Hebel, Fox, Lydick, Magaziner**

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Directions: For each of nine activities, ask the patient to perform the activity, record the time it took to do the activity, indicate the type of assistance used, and record how accurately the activity was performed. Have all assistive devices available before beginning.

**Perform each activity as accurately, completely, and quickly as it safe for you to do. I will be timing you. If someone usually assists you, I will assist you. If you usually use something special to help you, such as a cane, or anything else, please use it here. Although these are everyday activities, if you should become dizzy or have any problems, tell me and we will stop.**

| a. Time | b. Assistance Used | | c. Manner Performed |
|---|---|---|---|
| 999.2=Never done | 00=No assist | 06=Sock donner | 1=Correctly |
| 999.3=Health | 01=Cane | 07=Furniture | 2=Incorrectly |
| 999.4=Technical | 02=Walker | 08=Grab bar | 3=Incompletely |
| 999.5=Attempted | 03=Dressing stick | 09=Handrail | |
| 999.8=Refused | 04=Reacher/grabber | 10=Crutch | |
| | 05=Shoe horn | 11=Human | |

| ACTIVITY | a. TIME | b. ASSISTANCE | c. MANNER |
|---|---|---|---|
| 1. Reach for an item on the ground from a sitting position | ___ ___ ___.___ | ___ ___ | ___ |
| 2. Put sock on fractured side | ___ ___ ___.___ | ___ ___ | ___ |
| 3. Put shoe on fractured side | ___ ___ ___.___ | ___ ___ | ___ |
| 4. Chair rise | ___ ___ ___.___ | ___ ___ | ___ |
| 5. Three-meter walk | ___ ___ ___.___ | ___ ___ | ___ |
| 6. Step up four steps | ___ ___ ___.___ | ___ ___ | ___ |
| 7. Step down four steps | ___ ___ ___.___ | ___ ___ | ___ |
| 8. Get on the toilet | ___ ___ ___.___ | ___ ___ | ___ |
| 9. Get off the toilet | ___ ___ ___.___ | ___ ___ | ___ |

# VIII. Expectancy Scale

| **I believe that acupuncture will …** | Completely disagree | Mostly disagree | Mostly agree | Completely agree |
|---|---|---|---|---|
| 1. Improve my illness/condition a lot. | 1 | 2 | 3 | 4 |
| 2. Help me better able to cope with my illness/condition. | 1 | 2 | 3 | 4 |
| 3. Help the symptoms of my illness/condition disappear. | 1 | 2 | 3 | 4 |
| 4. Increase my energy level. | 1 | 2 | 3 | 4 |

# IX. Chart Review

Review the participant's medical chart to answer the following questions as thoroughly as possible.

1. Date of fracture: __ __ / __ __ / __ __ __ __

2a. Fracture type:
- ☐ 1 Displaced intertrochanteric
- ☐ 2 Displaced femoral neck
- ☐ 3 Non-displaced intertrochanteric

2b. Side of fracture:
- ☐ 1 Left
- ☐ 2 Right

3. Date of fracture repair: __ __ / __ __ / __ __ __ __

4. Date of hospital discharge: __ __ / __ __ / __ __ __ __

4. Weight (ask patient if unknown): _____ pounds

5. Height (ask patient if unknown): _____ feet and _____ inches *(convert to inches for data entry)*

Record all medications administered in the last week.

| Medication | Medication Name | Dose | Administration | | |
|---|---|---|---|---|---|
| | | | | PRN Only | |
| (Circle if no medications) 0 | | If a range for a PRN, be certain to specify the dose in the PRN Dose column | If given regularly, number times/day | Number of times/past week | Dose (if range given) |
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |
| 8 | | | | | |
| 9 | | | | | |
| 10 | | | | | |
| 11 | | | | | |
| 12 | | | | | |
| 13 | | | | | |
| 14 | | | | | |
| 15 | | | | | |
| 16 | | | | | |

**Participant Name:** _____
(Black out or erase after completion, ID check)

# Collaborative Studies of Long-Term Care:

# Auricular Acupuncture for Pain and Anxiety Following Hip Fracture Repair: A Pilot Study

## B. Weekly Participant Interview

Date completed: | | | | | | | | | (M M D D Y Y Y Y)

Participant ID: | | | |

Proxy Respondent Section I: ☐0 No ☐1 Yes

Interviewer ID: | |

Section V Data from non-Chart source: ☐0 No ☐1 Yes

Period: *(check one)*
- Week 1 ☐1
- Week 2 ☐2
- Week 3 ☐3
- Week 4 ☐4

# I. Adverse Event and Symptom Checklist

READ ALOUD TO SUBJECT OR THEIR GUARDIAN/REPRESENTATIVE: I am going to read you of symptoms or events. Please tell me whether or not you have experienced any of these symptoms or events in the past week, and if so, if this is unusual for you, and whether or not you attribute the event to the acupuncture.

**During the past week, have you seen or experienced any signs or symptoms of:**

| | No | Yes | Symptom Severity | | | **Explain** (did you have these symptoms prior to acupuncture, how long did it last, did you attribute it to the acupuncture?): |
|---|---|---|---|---|---|---|
| | | | Mild | Moderate | Severe | |
| 1. Infection to the outer ear | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |
| 2. Infection to the inner ear | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |
| 3. Abcesses, sores, or lesions on or near the ear | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |
| 4. Inflammation or redness on or around the acupuncture site | | | | | | |
| 4. Persistent pain on or around the ear | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |
| 5. Dizziness | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |
| 6. Nausea | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |
| 7. Difficulty staying awake | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |
| 8. Unusual joint pain | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |
| 9. Persistent headache | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |
| 10. Strange tingling or numbness in the arms, legs, neck, or other areas of the body | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |
| 11. Bleeding at the acupuncture site | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |
| 12. Other symptom you attribute to the acupuncture _____ (specify) | ☐0 | ☐1 | ☐1 | ☐2 | ☐3 | |

**During the past week have you experienced any of the following events? If any, please describe the details.**

| | | | |
|---|---|---|---|
| 1. Hospitalization? | ☐0 | ☐1 | |
| 2. Seizure? | ☐0 | ☐1 | |
| 3. A fall? | ☐0 | ☐1 | |
| 4. Death (do not ask) | ☐0 | ☐1 | |
| 5. Transfer? | ☐0 | ☐1 | Specify date and place to and from: |

## II. Spielberger State Anxiety Inventory (STAI-Y1)

READ ALOUD TO SUBJECT: I am going to read you a number of statements that people have used to describe themselves. For each, please indicate how you feel right now, at this very moment, using the responses listed on this card. Do not spend too much time on any one statement, but give the answer that seems to describe your present feelings best. *Show Card A and read options.*

| | Not at all | Somewhat | Moderately so | Very much so | Refused | Don't know |
|---|---|---|---|---|---|---|
| 1. I feel calm. | 1 | 2 | 3 | 4 | 7 | 8 |
| 2. I feel secure. | 1 | 2 | 3 | 4 | 7 | 8 |
| 3. I am tense. | 1 | 2 | 3 | 4 | 7 | 8 |
| 4. I feel strained. | 1 | 2 | 3 | 4 | 7 | 8 |
| 5. I feel at ease. | 1 | 2 | 3 | 4 | 7 | 8 |
| 6. I feel upset | 1 | 2 | 3 | 4 | 7 | 8 |
| 7. I am presently worrying over possible misfortunes. | 1 | 2 | 3 | 4 | 7 | 8 |
| 8. I feel satisfied. | 1 | 2 | 3 | 4 | 7 | 8 |
| 9. I feel frightened. | 1 | 2 | 3 | 4 | 7 | 8 |
| 10. I feel comfortable. | 1 | 2 | 3 | 4 | 7 | 8 |
| 11. I feel self-confident. | 1 | 2 | 3 | 4 | 7 | 8 |
| 12. I feel nervous. | 1 | 2 | 3 | 4 | 7 | 8 |
| 13. I am jittery. | 1 | 2 | 3 | 4 | 7 | 8 |
| 14. I feel indecisive. | 1 | 2 | 3 | 4 | 7 | 8 |
| 15. I am relaxed. | 1 | 2 | 3 | 4 | 7 | 8 |
| 16. I feel content. | 1 | 2 | 3 | 4 | 7 | 8 |
| 17. I am worried. | 1 | 2 | 3 | 4 | 7 | 8 |
| 18. I feel confused. | 1 | 2 | 3 | 4 | 7 | 8 |
| 19. I feel steady. | 1 | 2 | 3 | 4 | 7 | 8 |
| 20. I feel pleasant. | 1 | 2 | 3 | 4 | 7 | 8 |

## III. Falls Efficacy Scale

READ ALOUD TO SUBJECT: On a scale of 1 to 10, where 1 is extremely confident and 10 is not confident at all, how confident are you at.....
*Show card B and read options.*

| Question | | Circle best answer<br>Most confident ----- Least confident |
|---|---|---|
| **1.** | Taking a bath or shower? | 1 2 3 4 5 6 7 8 9 10 |
| **2.** | Reaching into cupboards? | 1 2 3 4 5 6 7 8 9 10 |
| **3.** | Preparing a meal (not requiring carrying heavy or hot objects? | 1 2 3 4 5 6 7 8 9 10 |
| **4.** | Walking around the house? | 1 2 3 4 5 6 7 8 9 10 |
| **5.** | Getting in and out of bed? | 1 2 3 4 5 6 7 8 9 10 |
| **6.** | Answering the door or telephone? | 1 2 3 4 5 6 7 8 9 10 |
| **7.** | Getting in and out of a chair? | 1 2 3 4 5 6 7 8 9 10 |
| **8.** | Getting dressed or undressed? | 1 2 3 4 5 6 7 8 9 10 |
| **9.** | Doing light housekeeping? | 1 2 3 4 5 6 7 8 9 10 |
| **10.** | Doing simple shopping? | 1 2 3 4 5 6 7 8 9 10 |

| | |
|---|---|
| **Score** (10-100) | |

## IV. Short Form McGill Pain Scale

READ ALOUD TO SUBJECT: Now, I will ask about how you are feeling today. I am going to read a list of words to you that people often use to describe pain. For each descriptor, please tell me the extent to which it describes your type of pain. Please respond by saying 'None', 'Mild', 'Moderate', or 'Severe'. *(Show Card C)*

| | | None | Mild | Moderate | Severe |
|---|---|---|---|---|---|
| 1. | Throbbing | **0** | **1** | **2** | **3** |
| 2. | Shooting | **0** | **1** | **2** | **3** |
| 3. | Stabbing | **0** | **1** | **2** | **3** |
| 4. | Sharp | **0** | **1** | **2** | **3** |
| 5. | Cramping | **0** | **1** | **2** | **3** |
| 6. | Gnawing | **0** | **1** | **2** | **3** |
| 7. | Hot – Burning | **0** | **1** | **2** | **3** |
| 8. | Aching | **0** | **1** | **2** | **3** |
| 9. | Heavy | **0** | **1** | **2** | **3** |
| 10. | Tender | **0** | **1** | **2** | **3** |
| 11. | Splitting | **0** | **1** | **2** | **3** |
| 12. | Tiring – Exhausting | **0** | **1** | **2** | **3** |
| 13. | Sickening | **0** | **1** | **2** | **3** |
| 14. | Fearful | **0** | **1** | **2** | **3** |
| 15. | Punishing – Cruel | **0** | **1** | **2** | **3** |

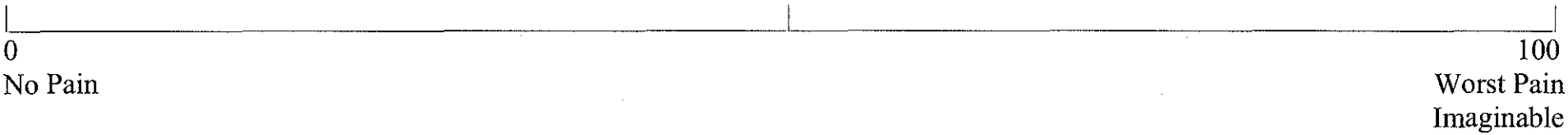
16. Please look at this line *(Show next page)*
This line goes from No Pain at one end to the Worst Pain possible at the other end.
Point to the place on the line that shows how much physical pain or discomfort you have had in the past week.

*(Enter the corresponding number as the score.)*

**Score:** ___ ___ ___
***(00-100)***

17. Which of the following words best describes your pain overall?

- ☐$_0$ No pain
- ☐$_2$ Mild
- ☐$_3$ Discomforting
- ☐$_1$ Distressing
- ☐$_2$ Horrible
- ☐$_3$ Excruciating


0
No Pain
100
Worst Pain
Imaginable

# V. LEGS

## LOWER EXTREMITY GAIN SCALE (LEGS): A MEASURE TO ASSESS RECOVERY FOLLOWING HIP FRACTURE

**Zimmerman, Hawkes, Hebel, Fox, Lydick, Magaziner**

Directions: For each of nine activities, ask the patient to perform the activity, record the time it took to do the activity, indicate the type of assistance used, and record how accurately the activity was performed. Have all assistive devices available before beginning.

**Perform each activity as accurately, completely, and quickly as it safe for you to do. I will be timing you. If someone usually assists you, I will assist you. If you usually use something special to help you, such as a cane, or anything else, please use it here. Although these are everyday activities, if you should become dizzy or have any problems, tell me and we will stop.**

| a. Time | b. Assistance Used | | c. Manner Performed |
|---|---|---|---|
| 999.2=Never done | 00=No assist | 06=Sock donner | 1=Correctly |
| 999.3=Health | 01=Cane | 07=Furniture | 2=Incorrectly |
| 999.4=Technical | 02=Walker | 08=Grab bar | 3=Incompletely |
| 999.5=Attempted | 03=Dressing stick | 09=Handrail | |
| 999.8=Refused | 04=Reacher/grabber | 10=Crutch | |
| | 05=Shoe horn | 11=Human | |

| ACTIVITY | a. TIME | b. ASSISTANCE | c. MANNER |
|---|---|---|---|
| 1. Reach for an item on the ground from a sitting position | ___ ___ ___.___ | ___ ___ | ___ |
| 2. Put sock on fractured side | ___ ___ ___.___ | ___ ___ | ___ |
| 3. Put shoe on fractured side | ___ ___ ___.___ | ___ ___ | ___ |
| 4. Chair rise | ___ ___ ___.___ | ___ ___ | ___ |
| 5. Three-meter walk | ___ ___ ___.___ | ___ ___ | ___ |
| 6. Step up four steps | ___ ___ ___.___ | ___ ___ | ___ |
| 7. Step down four steps | ___ ___ ___.___ | ___ ___ | ___ |
| 8. Get on the toilet | ___ ___ ___.___ | ___ ___ | ___ |
| 9. Get off the toilet | ___ ___ ___.___ | ___ ___ | ___ |

# VI. Chart Review

Review the participant's medical chart to answer the following questions as thoroughly as possible.

1. During the past week (7 days) during how many days did the patient have physical therapy appointments: _____ days scheduled _____ days attended

1b. Were any appointments missed? No ☐$_0$ Yes ☐$_1$ → If yes, why?

2. During the past week (7 days) during how many hours did the patient have physical therapy appointments: _____ hours scheduled _____ hours attended

2b. Were any appointments shortened? No ☐$_0$ Yes ☐$_1$ → If yes, why?

3. Please note any major deviation from the physical therapy regimen in the last week.

Record all medications administered in the last week.

| Medication | Medication Name | Dose | Administration | | |
|---|---|---|---|---|---|
| | | | | PRN Only | |
| (Circle if no medications) 0 | | If a range for a PRN, be certain to specify the dose in the PRN Dose column | If given regularly, number times/day | Number of times/past week | Dose (if range given) |
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |
| 8 | | | | | |
| 9 | | | | | |
| 10 | | | | | |
| 11 | | | | | |
| 12 | | | | | |
| 13 | | | | | |
| 14 | | | | | |
| 15 | | | | | |
| 16 | | | | | |

**Participant Name:** _____
(Black out or erase after completion, ID check)

# Collaborative Studies of Long-Term Care:

# Auricular Acupuncture for Pain and Anxiety Following Hip Fracture Repair: A Pilot Study

## C. Participant Acceptance & Satisfaction

| Date completed: | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | M | M | D | D | Y | Y | Y | Y |

| Participant ID: | | | |
|---|---|---|---|

| Interviewer ID: | |
|---|---|

# I. Participant Acceptance and Satisfaction

**I am going to ask you a few questions about the study that you participated in. Your honest responses will help us refine this treatment and study.**

| *(Show Card A )* | Not at all | A little | Moderately | Quite a bit | Extremely |
|---|---|---|---|---|---|
| 1. In general, how much did the acupuncture needles bother you while they were in your ear? | 0 | 1 | 2 | 3 | 4 |
| 2. How much did the needles cause you pain while they were in your ear? | 0 | 1 | 2 | 3 | 4 |
| 3. How much did the needles cause you pain while they were being removed or inserted? | 0 | 1 | 2 | 3 | 4 |
| 4. How much did the questions that we asked you each week bother you? | 0 | 1 | 2 | 3 | 4 |

5. Do you feel that the study required too much of your time? No ☐$_0$ Yes ☐$_1$
6. Given everything, would you participate in a study like this again? No ☐$_0$ Yes ☐$_1$
7. Given the opportunity, would you be willing to continue your participation in this study for an <u>additional</u> two weeks? No ☐$_0$ Yes ☐$_1$

| 8. On a scale of 1-5, where 1 is very satisfied and 5 is very dissatisfied, how satisfied are you with the study overall? *(Show Card E)* | **Very satisfied** | **Somewhat satisfied** | **Neither satisfied nor dissatisfied** | **Somewhat dissatisfied** | **Very dissatisfied** |
|---|---|---|---|---|---|
| | **1** | **2** | **3** | **4** | **5** |

9. How could this treatment and study be improved?

**Participant Name:** _____
(Black out or erase after completion, ID check)

# Collaborative Studies of Long-Term Care:

# Auricular Acupuncture for Pain and Anxiety Following Hip Fracture Repair: A Pilot Study

## D. Treatment Log

Date completed:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| M | M | D | D | Y | Y | Y | Y |

Participant ID:

| | | |
|---|---|---|
| | | |

Interviewer ID:

| |
|---|
| |

# I. Acupuncture Needle Log

| Treatment Day | Date | Ear | Needle Log | | |
|---|---|---|---|---|---|
| | | | **Needles Removed** | **Needles Missing** | **Needles inserted** |
| *Example* | 1/1/1960 | L | O, T, G, Z | S | |
| | | R | | | O, S, T, G, Z |
| *In the above example, needles were removed from the omega, thalamus, cingulate gyrus, and point zero sites on the left ear. However, the needle in the shen men left ear site was missing and presumably fell out and was lost. New needles were inserted into all five sites on the right ear.* | | | | | |
| **1** | | **L** | | | |
| | | **R** | | | |
| **2** | | **L** | | | |
| | | **R** | | | |
| **3** | | **L** | | | |
| | | **R** | | | |
| **4** | | **L** | | | |
| | | **R** | | | |
| **5** | | **L** | | | |
| | | **R** | | | |
| **6** | | **L** | | | |
| | | **R** | | | |
| **7** | | **L** | | | |
| | | **R** | | | |
| **8** | | **L** | | | |
| | | **R** | | | |
| **9** | | **L** | | | |
| | | **R** | | | |
| **10** | | **L** | | | |
| | | **R** | | | |
| **11** | | **L** | | | |
| | | **R** | | | |
| **12** | | **L** | | | |
| | | **R** | | | |
| **13** | | **L** | | | |
| | | **R** | | | |
| **14** | | **L** | | | |
| | | **R** | | | |
| **15** | | **L** | | | |
| | | **R** | | | |
| **16** | | **L** | | | |
| | | **R** | | | |
| **17** | | **L** | | | |
| | | **R** | | | |
| **18** | | **L** | | | |
| | | **R** | | | |

**Location codes:**

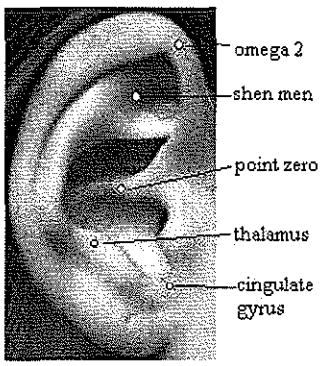
Omega 2 = **O**

Shen Men = **S**

Point Zero = **Z**

Thalamus = **T**

Cingulate Gyrus = **G**



**This patient is participating in a study about acupuncture. Five acupuncture needles have been placed in this patient's ear. Please help us monitor for signs of infection.**

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# Signs of infection include:

- **Redness**
- **Swelling**
- **Inflammation**
- **Increasing pain at acupuncture site**
- **Discharge from acupuncture site**

Although these symptoms may be normal, we would like to check—just to be safe. If you notice any of these symptoms, please call (919) 843-8874 to report them. Thank you for your help.

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FOR HEALTH SERVICES RESEARCH