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A PILOT STUDY OF THE EFFECTIVENESS OF COMPLEMENTARY THERAPIES TO REDUCE PAIN IN SPINAL FUSION PATIENTS

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Title of Project: A Pilot Study of the Effectiveness of Complementary Therapies to Reduce Pain in Spinal Fusion Patients

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DESCRIPTION. Please state the application's broad, long-term objectives and specific aims. Describe concisely the research design and methods for achieving these goals. This description is meant to serve as a succinct and accurate description of the proposed work when separated from the application. **Please complete within space below.**

INTRODUCTION:
The use of complementary and alternative medicine (CAM) is common and increasing among children. Often our most vulnerable pediatric populations, particularly those with chronic, recurrent, or incurable conditions, turn to CAM. Rates vary depending on how CAM is defined and how sampling is done, with some rates reaching > 75%. Furthermore, it is not uncommon for children to be given >1 type of CAM at a time. A 2003 study found that of the 64% of children attending a Rheumatology clinic in Toronto who were currently using CAM, 50% were using >1 type. Concurrent use of CAM with conventional medications is also common. For example, 20%of pediatric patients in a Canadian emergency department used conventional medicines and CAM concurrently.

In children with chronic pain, multiple studies have documented efficacy of CAM therapy, yet difficulties in studying pediatric CAM use have been identified and include variation in definitions of both CAM as well as lack of reporting of period of assessment, costs, insurance coverage, occurrence of adverse events, source of CAM information, and discussion of CAM use. Overall, few randomized control trials have utilized CAM therapy as an additional treatment modality versus the standard of care. Additionally, in children undergoing surgery and experiencing acute postoperative pain, little information is available regarding use of CAM therapy versus standard of care. One systematic review reported use of acupuncture did not significantly affect postoperative pain in adults experiencing arthroscopic knee surgery; however, a reduction in Ibuprofen use in postoperative pain was demonstrated in two of the studies cited. A limitation of the systematic review was that few studies have been performed in understanding the effect of CAM therapy on acute post-surgical pain. Little is known, therefore, regarding the potential effectiveness of CAM therapies as treatment modalities to decrease narcotic use in the postoperative setting. In this pilot study, our central hypothesis is that two CAM therapies, Hypnosis and Healing Touch as adjunct therapies to the standard of care, will improve analgesia use for postoperative pain. In this pilot study we will randomize 45 adolescents undergoing spinal fusion for idiopathic scoliosis to two test groups: Hypnosis with Standard of Care for Post-op Pain, Healing Touch with Standard of Care for Post-op Pain, and a control group (Standard of Care only).

AIMS:
Specific Aim One: To demonstrate the effectiveness of the addition of Hypnosis to decrease pain versus the standard of care. Hypothesis: We anticipate there will favorable changes in reported anxiety and pain scores, cortisol levels, a mean decrease in mean arterial pressure and heart rate variability and less narcotic use with the addition of Hypnosis.
Specific Aim Two: To demonstrate the effectiveness of the addition of Healing Touch to decrease pain versus the standard of care. Hypothesis: We anticipate there will favorable changes in reported anxiety and pain scores, cortisol levels, a mean decrease in mean arterial pressure and heart rate variability and less narcotic use with the addition of Healing Touch.

METHODS: (Please see attached Flow Chart for Process o f the study)
Statistical Analysis: Descriptive Statistics: Standard Descriptive Statistics will be used to describe the outcomes, demographic and independent variables of interest pre- and post-intervention, overall and by intervention group. Changes in outcomes will also be calculated and descried. For continuous variables

means, medians and ranges will be produced, while frequencies and percentages will be produced for categorical variables. Means, standard deviations, medians and ranges will be computed for measured continuous variables; marginal distributions will be used for categorical factors. Graphical methods including histograms, scatterplots, and boxplots, will be used in order to understand aspects of data quantity and examine assumptions (such as normality) underlying statistical models.
Aim 1 and Aim 2: The primary outcome is decrease in reported pain and narcotic use. We will compare difference in pain pre- to post- between the two intervention and control groups, using ANOVA. Since data will be collected at multiple points pre- and post-intervention, and some randomly missing data expected, the primary analysis will employ generalized estimating equations (GEEs). The GEEs models will be adjusted for baseline characteristics, such as age, race and any important clinical characteristics. GEEs will also be used to compare the changes in reported pain and analgesic use between the three groups.

PARTICIPANTS/SAMPLE GROUP

Approximately 45 adolescents with the diagnosis of idiopathic scoliosis requiring surgery will be approaches to participate in the study. Participants will be called prior to their pre-op visit from the weekly surgical list to inquire their interest in participating. Adolescents will be female patients, ages 12-17, undergoing Posterior Spinal Fusion. Exclusion criteria include those with any other diagnosis requiring spinal fusion; adolescents with profound mental disabilities not allowing them to voluntarily assent to participate, male adolescents with diagnosis of Idiopathic Scoliosis.

Random assignation (Microsoft Excel to generate a random group assignment table) of patients to one of the following groups Randomization will be done at time of presurgical visit

- Control Group – 15 female patients (Stand Pain Management)
- Healing Touch Modality – 15 female patients (Standard Pain Management + Healing Touch Protocol)
- Hypnosis - 15 female patients (Standard Pain Management + Hypnosis Protocol)

PARTICIPATING NEMOURS ASSOCIATES IN STUDY

Healing Touch Practitioner: Three co-investigators (Gerdts, Russell, Dituri) who have successfully completed at least Level 2 of the ANCC approved curriculum Observation and Approval to be noted by the subject matter expert, the Healing Touch Certified Practitioner/Instructor and Program Coordinator of the Healing Touch Program at Nemours/AIDHC.

Certified Health Care Hypnosis Practitioner: Principal Investigator and one co-investigator are certified for Hypnosis, and will implement for this study (Sacks and Floyd). Each has successfully completed Hypnotherapy training and certified by the Pennsylvania Center for Hypnosis.

HEALING TOUCH GROUP

Preoperative Protocol
Day of Surgery in Pre-op Holding Area:

Patient waiting in a quiet, calm space, lights low and gentle music playing.
HT Provider offers the following HT techniques to prepare the body and energy field for the surgery.

Chakra Connection (10 min) - 30 second held positions to connect, open, and balance the energy centers to the energy field. At each location the practitioner will hold the intention to balance the flow of energy between the palms and the body area which the hands are held.

Magnetic Clearing (10 min) – Ten 30 second slow sweeps down each side of the body (total of 20 passes) to clear the energy field of any discomfort/anxiety/stress prior to surgery, creating a clean template for the procedure.

Intra-operative Protocol
HT Provider will pause at designated time on the hour to send one minute of intentional healing and decreased pain experience upon completion of procedure to the patient while in surgery.

Postoperative Protocol
Post-Op PACU Area:
HT student Provider to offer following techniques once patient is settled in bay and stable:

Open Spiral Meditation(6 min) – 30 second hand positions held at each location to open the energy field for deeper healing and to re-balance body to the field post-surgery.

Magnetic Clearing (10 min) – Ten 30 second slow sweeps down each side of the body (total of 20 passes) to clear the energy field of completed anesthesia, stress, pain.

Pain Drain (5 minutes) – A hands still polarity technique offered to "energetically drain" the discomfort from a specific area. Left hand positioned over incision site. Patient may be prone or supine during this technique.

Recovery on Inpatient Unit: Day One and Back Techniques
Within 24 hours of patient arrival to floor, the HT student Provider will provide:

Chakra Connection (10 min) - 30 second held positions to connect, open, and balance the energy centers to the energy field. At each location the practitioner will hold the intention to balance the flow of energy between the palms and the body area in which the hands are held.

Back Energy Flow Assessment and the following techniques to re-establish/and/or to increase vibrancy of energetic flow along spinal column (patient may be supine or prone for this therapy):

Lower Body Connection (4 min) - 30 second held positions, connecting lower body energy centers to the hips.

Opening Energy Flow from Neck to Sacrum (1 min) – Hands held in designated locations for one minute to establish flow along the spinal column.

Vertebral Spiral Technique (5 min) – Small rotational spirals of both hands directed on either side of the spinal column and along each vertebrae, with intention to release energetic congestion and relax the small ligaments/muscles along the spine, allowing for more effective healing, comfort and energetic flow.

Re-Assessment of Spinal Column – Should the HT student Provider find that the energy flow is still compromised, then the above **Vertebral Spiral Technique** will be performed again and re-assessment will follow. Should assessment indicate the energy flow is still impeded, the HT student provider will encourage flow with the **Hands Still** technique for 2 minutes. (Palm of one hand placed at the base of the neck and the other palm at the sacral area, with the intention held to open the flow of energy and to re-establish the spinal energy connection.)

Energetic Sweep down Spinal Column (1 min) - Completes back techniques with gentle brushing motions down the back to the waist. Random patterning from neck to waist.

Daily on Inpatient Unit (after above noted Back Techniques post op Day One:

Assessment of Spinal Energy Flow, energy centers flow, and pain level(s) to be determined by the HT Provider. Protocol for findings are as follows:

If pain is noted by patient, Pain Drain to be offered. (see Post-op PACU area), followed by Magnetic Clearing.

Magnetic Clearing (10 min) – Ten 30 second slow sweeps down each side of the body (total of 20 passes) to clear the energy field of completed narcotics, stress, pain.

If energy centers are found to be compromised, (but the spinal energy flow is open), then a Chakra Connection will be offered.

Chakra Connection (10 min) - 30 second held positions to connect, open, and balance the energy centers to the energy field. At each location the practitioner will hold the intention to balance the flow of energy between the palms and the body area in which the hands are held.

If spinal energy flow is found to be compromised, Back Techniques to be offered.(see Inpatient Unit Day One protocol)

(This continues as a daily offering until patient is discharged from the hospital.)

HYPNOSIS GROUP

Preoperative Protocol

Day of Surgery in Pre-op Holding Area

Prior to preoperative dose of midazolam and gabapentin

Hypnosis practitioner will provide Wakeful hypnosis using a standardized script of suggestions (15 minutes) to achieve a state of focused attention with heightened receptivity for acceptable suggestions targeting relaxation, comfort and healing.

Intra-operative Protocol

Patient will listen to the tape recorded voice of the preoperative hypnosis practitioner using a standardized script of suggestions during anesthesia encouraging:

- increased feelings of relaxation
- increased feelings of security
- minimal discomfort
- decrease in nauseas and vomiting
- return to normal appetite
- increase in physical endurance
- quick recovery
- total body wellness

Postoperative Protocol

The same hypnosis practitioner will provide Wakeful hypnosis using standardized script of suggestions during the wake-up period in the Post-Anesthesia Care Unit (PACU) suggesting:

- continued physical healing

- decrease in side effects
- quick recovery

Patient will be seen daily by the same hypnosis practitioner until discharge to provide Wakeful hypnosis using standardized script of suggestions to continue to achieve continued healing and recovery.

A Randomized Controlled Trial Piloting the Effectiveness of Complementary Therapies to Reduce Pain (decrease morphine use) in Spinal Fusion Patients

Purpose of Study: To describe the effectiveness of complementary alternative therapies in improving pain outcomes in patients undergoing spinal fusion. Hypothesis One: We propose that CAM therapies will decrease pain in this pediatric population by decreased morphine usage, stable VS, less anxiety compared to the standard of care.

SAMPLE: Ages 12-17 years, N = 45, (15 in each group)

AFTER CONSENT/ASSENT MEASUREMENTS OBTAINED: Anxiety Scale, Pain Scale, Blood Pressure, Heart Rate, Temperature, CBC, Cortisol level.

EXCLUSION CRITERIA: Non-idiopathic scoliosis; unable to read/write English (add others); Hearing Impaired; Admitted to PICU post procedure.

HYPNOSIS & HEALING TOUCH: Hypnosis and Healing Touch will be delivered to patients per protocol. For example: patients will receive therapy in a quiet area, i.e. placing patients in PACU South (glass enclosed room).

RANDOMIZE

Hypnosis	Healing Touch	Standard of Care
Pre-Op VS, Anxiety Scale, Pain Scale, CBC, Cortisol level Hypnosis Therapy	**Pre-Op** VS, Anxiety Scale, Pain Scale, CBC, Cortisol level Hypnosis Therapy	**Pre-Op** VS, Anxiety Scale, Pain Scale, CBC, Cortisol level
Intra-Op Taped suggestions (iPod, ear buds) VS, Cortisol level	**Intra-Op** Mentally send one minute of healing VS, Cortisol level	**Intra-Op** VS, Cortisol level
Post-op PACU VS, Pain Scale, Opioid requirement Hypnosis therapy	**Post-op PACU** VS, Pain Scale, Opioid requirement Healing Touch therapy	**Post-Op PACU** VS, Pain Scale, Opioid requirement
Post-op Day #0-4 (patient room) VS, Pain Score, Opioid requirement Hypnosis therapy **POD #2** – CBC, Cortisol level, Anxiety scale	**Post-op Day #0-4 (patient room)** VS, Pain Score, Opioid requirement Healing Touch therapy **POD #2** – CBC, Cortisol level, Anxiety scale	**Post-op Day #0-4 (patient room)** VS, Pain Score, Opioid requirement **POD #2** – CBC, Cortisol level, Anxiety scale
Follow-up Orthopedic visit (4weeks) VS, Pain scale, Anxiety scale, Cortisol level, opioid requirement	**Follow-up Ortho visit (4 weeks)** VS, Pain scale, Anxiety scale, Cortisol level, opioid requirement	**Follow-up Ortho visit (4 weeks)** VS, Pain scale, Anxiety scale, Cortisol level, opioid requirement