SUMMARY STATEMENT

PROGRAM CONTACT: (Privileged Communication)  Release Date: 05/13/2020

Revised Date:

Application Number: 1I21 RX003611-01

Principal Investigator
HERROLD, AMY

Applicant Organization: EDWARD HINES JR VA HOSPITAL

Review Group: RRDS
Rehabilitation Research and Development SPiRE Program

Meeting Date: 04/23/2020  RFA/PA: RX20-009
Council: AUG 2020
Requested Start: 10/01/2020

Project Title: Feasibility of a Combined Neuromodulation and Yoga Intervention for Veterans with Mild Traumatic Brain Injury and Chronic Pain
SRG Action: Impact Score:233

Human Subjects: 30-Human subjects involved - Certified, no SRG concerns
Animal Subjects: 10-No live vertebrate animals involved for competing appl.
Gender: 1A-Both genders, scientifically acceptable
Minority: 1A-Minorities and non-minorities, scientifically acceptable
Age: 1A-Children, Adults, Older Adults, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial

| Project Year | Direct Costs Requested |
|--------------|------------------------|
| 1            | 100,000                |
| 2            | 100,000                |
| TOTAL        | 200,000                |
CONDITIONS:
• In order to minimize confounds associated with inconsistent timeline of interventions, clarify how much time will lapse between iTBS and start of yoga intervention for each participant.
• Indicate the yoga instructor’s qualifications/training to perform the yoga sessions.
• Describe how administration of an analgesic before and/or after intervention will be controlled and accounted for in any outcomes measured. Provide the protocol for analgesic administration.

ADMINISTRATIVE NOTE:
The presence of a condition(s) is not an indication that the application has been selected for funding. If a notice of intent to award is issued, then the condition(s) will need to be addressed as part of Just-in-Time (JIT).

DESCRIPTION (provided by applicant):
Over 340,000 people have incurred a mild traumatic brain injury (mTBI) as a result of the military conflicts in Iraq and Afghanistan. mTBI leads to a host of poor rehabilitation outcomes including impairments in cognition, physical health, and psychological health. These impairments among people with TBI lead to poor quality of life (QOL). Worsening this clinical picture, the prevalence of chronic pain is estimated to be 51.5% among civilians with TBI and 43.1-70% among Veterans with TBI. Opioids are used for treating chronic pain including among people with TBI. Thus, given the ongoing opioid epidemic in the United States, it is very timely to develop alternative, non-pharmacologic treatments for chronic pain among Veterans with mTBI. Yoga is a promising activity-based intervention for TBI and chronic pain. Yoga is an activity generally comprised of breathing exercises, gentle stretching, and meditation. Neuromodulation through transcranial magnetic stimulation (TMS) is a promising non-invasive, non-pharmacological treatment for TBI and chronic pain. Intermittent theta burst stimulation (iTBS) is a type of patterned, excitatory TMS. iTBS can induce a window of neuroplasticity, making it ideally suited to boost the effects of treatments provided after it. Thus, iTBS shows promise to prime the brain for combined interventions and may magnify the impacts that these interventions would have when used alone, in order to boost outcomes. The purpose of this SPIRE project is to develop a novel, combined neuromodulation and yoga neurorehabilitation intervention for Veterans with mTBI and chronic pain, and to examine the intervention’s feasibility and acceptability. Using an existing, evidence-based, yoga program created specifically for people with TBI (LoveYourBrain Yoga), we will first develop a neurorehabilitation intervention that combines iTBS with yoga (iTBS+yoga), and then collect pilot data about its feasibility and acceptability. Aim 1 will develop a novel, combined iTBS+yoga neurorehabilitation intervention for Veterans with mTBI and chronic pain. Aim 2 will examine the feasibility and acceptability of the iTBS+yoga intervention for Veterans with mTBI and chronic pain. Aim 3 will gather preliminary data to provide the foundation for sample size and power considerations for a future clinical trial to examine the effectiveness of iTBS+yoga on Veterans’ quality of life, function and pain outcomes. The combined intervention will be provided in small group settings once a week for 6 weeks. iTBS will be administered immediately prior to the LoveYourBrain Yoga session. Emphasizing National Institute of Neurological Disorders and Stroke (NINDS) Traumatic Brain Injury Common Data Elements (TBI CDEs), we will collect preliminary outcome data related to quality of life, function and pain to inform a future Merit application, should the intervention prove feasible. This SPIRE project will directly benefit Veterans and VA Services by developing a new, non-pharmacological neurorehabilitation treatment for Veterans with mTBI and chronic pain in need of non-opioid treatment options. TMS is now offered at 30 VA hospitals nationwide for treatment-resistant depression, and yoga is among the complementary and integrative health programs being rolled out as a part of VAs nationwide Whole Health implementation efforts, with classes offered through VA service lines such as recreational therapy. Therefore, should iTBS+yoga ultimately prove to be efficacious and effective, VA facilities will be well-poised to offer this treatment. A novel, activity-based, non-pharmacological
treatment for Veterans with mTBI and chronic pain is of great need given the high prevalence of chronic pain, increased risk of opioid therapy, and increased risk of developing opioid use disorders.

PUBLIC HEALTH RELEVANCE:
The objectives of this VA SPIRE application are to develop a combined neuromodulation and yoga (iTBS+yoga) intervention for Veterans with mild traumatic brain injury (mTBI) and chronic pain, assess the intervention's feasibility and acceptability, and to gather preliminary clinical outcome data on quality of life, function and pain that will guide future studies. This SPIRE project will directly benefit Veterans and VA Services by developing a new, non-pharmacological neurorehabilitation treatment for Veterans with mTBI and chronic pain in need of non-opioid treatment options. Neuromodulation is now offered at 30 VA hospitals and yoga is among the complementary and integrative health programs being rolled out as a part of VAs Whole Health implementation efforts. Thus, should iTBS+yoga ultimately prove to be efficacious, VA facilities will be well-poised to offer this treatment. A novel, activity-based, non-pharmacological treatment for Veterans with mTBI and chronic pain is of great need given the high prevalence of chronic pain.

CRITIQUE 1

Significance:
• Highly significant in context of improving non-opioid pain management options for Veterans.
• With extant research supporting use of yoga for management of pain, concept of creating an intervention that magnifies impact of yoga intervention is novel and interesting.
• A successful intervention of this type would likely be very significant in terms of increasing VA treatment options for common medical concerns experienced by the Veteran population; could have cost-effectiveness outcomes for VA healthcare systems as a whole.
• If the combined model seems feasible, acceptable, and beneficial, it can be tested later with other well-established interventions for different (and potentially hard-to-treat) medical issues.

Approach:
• Aim 1: Develop a novel, combined intervention (iTBS + Yoga) for Vets with TBI and Chronic Pain.
  o Aim 1 seems well-developed; the iTBS and the LoveYourBrain Yoga protocols are well-established on their own. The researchers are proposing to combine them. One question is will all participants in each group be given the iTBS at the same time? In the proposal as written it is unclear if the timeline for application of iTBS prior to starting yoga will vary between participants. In order to minimize confounds associated with inconsistent timeline of interventions, please clarify how much time will lapse between iTBS and start of yoga intervention for each participant.
• Aim 2: Examine feasibility and acceptability of the novel intervention.
  o Aim 2 seems like an important step for future research. Researchers seem to have an a priori hypotheses that the intervention will be feasible and acceptable to the population based on extant research utilizing iTBS and LoveYourBrain yoga with populations of patients with TBI.
  o It will be important to consider potential barriers (e.g., psychosocial, physiological, psychological) to sustaining attendance at a yoga class for 6 weeks. There exists some research surrounding such barriers.
  o Per the protocol, “acceptability will be assessed using…semi-structured interviews with a sub-sample of 10 Veterans.” Why not do the interview with all Veterans who completed the study given that the study proposes recruiting only 20 Veterans. If there is a reason for assessed acceptability/feasibility via only half of the study population, please provide this rationale.
HERROLD, A

- It is very impressive that the research team has already conducted preliminary acceptability outreach and has incorporated Veteran feedback where appropriate.

- **Aim 3:** Gather preliminary data about QOL and pain outcomes to inform future research.
  - Patients with TBI may struggle with sustaining attention. Individuals with chronic pain are also prone to concentration difficulties. Thus, the battery of screeners and assessments may require an ability to sustain attention for a period that may exceed the capacity of the typical TBI/chronic pain patient. It is recommended that the battery of screeners proposed to assess outcomes be pared down as much as possible to reduce participant burden. In addition, may be important to consider burden & feasibility of keeping “weekly diaries” in this population.

**Innovation:**
- The proposed study appears to combine two increasingly available interventions (TMS offered at 30 VA hospitals; yoga with Whole Health at VA’s) in a very creative way. The proposal seems quite innovative and, if results suggest the proposed combined intervention could be beneficial for Vets with TBI + Chronic Pain, the innovation will likely have a significant and far-reaching impact.
- Per the proposal, the impact of LoveYourBrain yoga nor the impact of iTBS has ever been tested on pain outcomes in a population of patients with TBI.

**Investigator Qualifications:**
- Dr. Herrold and her team members appear highly qualified to engage in the proposed study.
- Need to clarify who will be leading the LoveYourBrain yoga: does this person have training/qualifications in yoga instruction? Medical/anatomy training? It may be helpful to provide more information about the actual postures involved in this yoga protocol as well to ensure that it is a protocol that can be implemented by an adequately trained instructor.

**Environment:**
- All aspects of proposed environment seem adequate for supporting this research; the investigators have access to all needed equipment, software, consultants, etc.
- Collaboration between Hines VA and Northwestern University seems ideal and likely to provide all necessary resources.

**Design/Scope:**
- **Recruitment:** Procedures seem acceptable and in accordance with VA guidelines.
- **Screening Visit:** Likely too long/too much burden associated with number of screeners/assessments. May need to break this session into two to reduce burden and assist patients in sustaining attention and effort.
- **MRI visit:** No concerns.
- **iTBS & Yoga Intervention:**
  - Need to ensure that time lapse between iTBS application and start of yoga session is equal for all patients or is statistically controlled for in outcomes.
  - Need to clarify who is leading the yoga session and what the training of this individual will be. Whereas many individuals may be able to lead a meditation and psychoeducation session, there are aspects of leading a 45-min gentle yoga session that will require an instructor to have adequate training if it is to be done safely in this population.
  - Also, will it be the same set of participants in each intervention group each time? Or will the participants be allowed to switch group days/times each week? If group attendees are not the same in each group each week there will need to be a discussion as to why this is allowed (e.g., making up a missed session) and a plan to account for social influence differences (e.g., outcomes during a yoga session may be very different in different groups of people).
Protocol suggests that participants will be “given acetaminophen before each iTBS session to reduce any potential discomfort.” Will acetaminophen be given at every iTBS session for every participant? What about those for whom a dose of acetaminophen is contraindicated? Will there be an alternative NSAID option? What happens when someone does not take the NSAID offered? The protocol states that patients may also be allowed to take a 2nd dose of the medication if needed. In any population – and in a chronic pain population especially -the application of a pain medication before engaging in the yoga intervention is likely to play a role in the person’s ability to engage in the yoga practice. The application of this medication after the yoga practice is also likely to influence someone’s perception/satisfaction associated with said intervention. The application of an NSAID before and/or after intervention should be controlled and accounted for in any outcomes measured.

- Qualitative analysis: Procedures are appropriate; however, need rationale for using only half of sample for this piece.
- Quantitative analysis:
  - If missing data is noted and cannot be inputted, what will happen with those missing data points? Please elaborate on this statistical plan.
  - In addition, please clarify plan for accounting for inflated Type 1 error in light of the proposed plan to perform a series of t-tests.

Human Subjects:
- The study proposes to enroll 20 Veterans >22 years of age (assuming that individuals under that age will not yet qualify as a Veteran?) who have both mild TBI and chronic pain.
- Would strongly recommend having some form of medical clearance required for each participant.
- Inclusion & Exclusion criteria listed seem generally appropriate.
- Additional criteria to consider include pre-existing experience with yoga/meditation and current use of opioid (or like) pain medications. If individuals with previous yoga experience will not be excluded, please consider controlling for impact of said previous experience and pre-existing positive views on the potential benefit of yoga may have. In addition, individuals who are vs. are not taking pain medications at the time of this study are likely to have very different experiences. This should be accounted for.

Inclusion of Women, Minorities and Children:
- Participants will be age 22 or older.
- Women and minorities will not be excluded, though pregnant or nursing women will be excluded.

Critique of Vertebrate Animals Section: Not applicable.

| Research with vertebrate animals? | Yes | No |
|----------------------------------|-----|----|
|                                  |     | X  |

Biohazards and Radioisotopes: No concerns.

Budget: Please clarify where the $190 that participants are "eligible to receive" will come from, when/how this will be awarded, and if participants are aware of this potential at onset of study.

Data Management and Access Plan (for data sharing, unscored):
- Data de-identification and confidentiality procedures seem appropriate.
- Data sharing between VA researchers and Northwestern University seems appropriately planned.
**Overall Strengths:**
- Novel intervention idea with potential for broad significant impact in a population that needs alternative interventions for these common medical comorbidities.
- Creative collaboration between many medical/research personnel at two sites.
- Important steps to take to move forward with research for alternative pain management interventions.
- Assists in legitimizing the utilization of yoga-based interventions in medical populations.

**Overall Weaknesses:** Some concerns surrounding procedure and protocol that need to be controlled for/accounted for before data can be accurately interpreted.

**CRITIQUE 2**

**Significance:** This proposal is appropriate for the SPIRE funding mechanism due to the potential clinical utility of the intervention. Chronic pain is highly prevalent among Veterans and there is a critical need for effective, nonpharmacological interventions to improve functional outcomes.

**Approach:** The approach is to combine two interventions to reduce chronic pain and improve quality of life in Veterans with MTBI, so the proposal has clear relevance to clinical care. However, the small sample size, lack of any control subjects, the relatively high burden on participants (all of whom have chronic pain) and the combination of three interventions (iTBS, yoga and a cognitive/psychosocial intervention) will make it difficult to determine which aspects of the treatment are effective. For this funding mechanism, it might be more effective to simplify the approach and increase the number of subjects rather than attempting to understand the effects of multiple interventions with such a small group of subjects. Given the required participation (initial assessment, MRI, 6 weekly 2 hour sessions and keeping a diary, plus multiple post-assessments) there is a risk of drop outs or partial participation given the nature of chronic pain. Enrolling a greater number of subjects will help account for the possibility of treatment drop-out. The iTBS appears to have a sham setting which would be very helpful if you used a randomized design (with and without iTBS) and all subjects could complete the yoga and psychosocial intervention, making the results very useful in determining if the iTBS has added benefit to the yoga. This is important because yoga is a relatively low-cost intervention which can be provided across the VA, while iTBS requires significant investments in equipment, neuroimaging resources and time of the subject.

**Innovation:** This study is attempting to validate several non-pharmacological interventions by assessing pre and post-measures of clinical and functional status in Veterans with chronic pain and MTBI. By studying a novel way (iTBS) to potentiate the effects of a behavioral intervention, this study is innovative. Improving our understanding of the clinical utility of iTBS as an adjunctive to behavioral interventions is exciting and potentially very valuable. This is a non-invasive treatment which combined with yoga could have a high impact on treatment options for chronic pain.

**Investigator Qualifications:** This investigator has excellent experience and appears very well qualified for this study. She has a number of good collaborators on her study and she is well positioned within the institution to obtain necessary support and expertise to accomplish this study.

**Environment:** Not applicable.

**Design/Scope:** The design of the study is a limiting factor as written. The study design will not allow the investigator to determine if any effects are due to the iTBS, the physical intervention or the
psychosocial intervention. Improving the study design to examine the yoga using a small sample or increasing the sample size and using a randomized control of a sham iTBS intervention with the yoga+psychosocial intervention would greatly improve the strength of the study and determine if the iTBS has added value in improving quality of life, function and reducing chronic pain in Veterans.

**Human Subjects:** The safeguards and recruiting of participants is well described and subjects will be compensated, but the time commitment and number of appointments involved in this study will be a limiting factor for recruitment efforts. Even if appointments are offered at various times during the day, this will also add a potential bias because working Veterans will likely be unable to participate in the study. The added burden of a pretreatment assessment, MRI and tracking their activities in diaries also adds to the burden on the participants. This also will increase the potential for drop-out or partial treatment in the subjects which will threaten the ability to interpret the results with such a small sample size.

**Inclusion of Women, Minorities and Children:** Addressed in the proposal although no specific strategies are discussed to ensure that representative numbers of women and minorities are recruited. This could be a potential source of bias if women and minorities are not adequately represented in the sample.

**Critique of Vertebrate Animals Section:** Not applicable.

| Research with vertebrate animals? | Yes | No  |
|----------------------------------|-----|-----|
|                                  |     | X   |

**Biohazards and Radioisotopes:** Not applicable.

**Budget:** The budget is detailed and seems appropriate for the study.

**Data Management and Access Plan** (for data sharing, unscored): Well described including monitoring security of data and procedures to maintain confidentiality.

**Overall Strengths:** This is a very relevant proposal for the funding mechanism because it is focused on validating a non-pharmacological intervention for chronic pain in Veterans and it has the potential to directly impact clinical care options available to providers within the VA. It is also very innovative by combining whole health interventions (yoga and a psychosocial intervention) with a novel method which appears to increase the efficacy of behavioral intervention (iTBS).

**Overall Weaknesses:** The study design is the major weakness because it does not allow the investigator the ability to understand if the iTBS has any added value above the Yoga/psychosocial intervention. This is important to establish given the costs of time and equipment in adding the iTBS as a standard of care. Although a manualized yoga intervention was selected, the reality is that it also is a combination of interventions (physical-yoga, psychosocial-cognitive). Although this intervention was selected because it was developed for use with TBI patients in rehabilitation settings, it may not be the ideal intervention for patients with MTBI who will not have significant functional impairments due to their MTBI. This intervention may not be challenging enough for MTBI patients if it was designed for patients with moderate to severe TBI. In addition, the number of weeks of treatment (6 weeks) seems very brief to have a significant impact on the multiple pain and functional measures included in the study. Consideration to the “dose” of treatment should be examined to see if this treatment is sufficient to
result in change in functioning (most physical therapists would not consider six sessions adequate for chronic pain). Examination of other yoga programs might be helpful.

**CRITIQUE 3**

**Significance:** Proposal seeks to develop a novel, combined neuromodulation and yoga neurorehabilitation intervention for Veterans with mTBI and chronic pain, and to examine the intervention’s feasibility and acceptability. This program has the potential to be highly significant, as Veterans with mTBI have increased pain and compromise to quality of life. Additionally, the development of this program of rehabilitation has the potential to offer this vulnerable group of Veterans a treatment option for pain that does not involve opioids.

**Approach:** The Principal Investigator (PI) proposes a prospective, within-subject pilot study to develop a six week, six sessions combined iTBS+yoga treatment for TBI and comorbid pain. Twenty Veterans will be recruited who are over 22 years of age who have comorbid mTBI and chronic pain.

- **There are concerns about the heterogeneity of the sample.** Veterans over the age of 22 could encompass several war epochs and could result in groups that are wildly diverse with regard to age. Group exercise mixing generations of Veterans would not result in good group dynamics and could affect acceptability and feasibility. This reviewer would suggest a more targeted study population that is more homogenous and would not confound results with age.
- **There are tests contained in the screening visit that do not address eligibility and are not outcomes (e.g., CVLT, NSI).** What is the rationale for including these assessments? Table 2 indicates that they will be used to assess memory but that is not an outcome of this feasibility study. NSI and its purpose are not listed in Table 2. There are concerns that the NSI will be influenced by comorbidities in this Veteran sample.
- **MRI will be conducted at the Center for Translational Imaging at Northwestern University.** No offsite waiver to conduct these scans was included and the Director’s letter specified that the work would be completed at the Hines VA Hospital. This may not be problem but without this information it is not possible to determine whether the critical MRI is feasible.
- **The feasibility of the proposed treatment will be defined by enrollment and the number of sessions completed by each participant.** Acceptability will be quantitatively assessed using satisfaction ratings (using a previously published tool relevant to this treatment/population) and with semi-structured clinical interviews with a subset of 10 Veterans. Why only 10? How will that subset of 10 be identified? The analysis of the qualitative interviews is complex, and there is concern whether the study team has any prior experience in this process.
- **No concerns with the actual intervention.**

**General concerns:** They do not have evidence that repeated iTBS will result in greater improvement over single session. Is there any plan to evaluate this hypothesis? Not demonstrated that iTBS (single or repeated) can be used safely with individuals with TBI (single case study reported to support this is insufficient). Alcohol use and alcohol use disorder is a common comorbidity in Veterans with mTBI and pain. The investigators may consider an assessment of alcohol to determine if use impact’s their outcomes.

**Innovation:** The innovation of the study is in the novel combination of iTBS with yoga as a treatment for TBI and pain. Evidence suggests that the neural plasticity invoked by iTBS can last for up to 60 minutes following administration, which makes it ideal to precede a yoga session and potentially influence yoga’s beneficial effects.
**Investigator Qualifications:** The investigative team is strong and has the expertise to carry out the proposed research.

**Environment:** The research environment appears excellent. Dr. Herrold and her team are well equipped with the necessary equipment/laboratory space.

**Design/Scope:** Design noted above. The timeline of the study is well delineated and seems feasible. Subject recruitment will proceed across a number of avenues that have been used in the past by these investigators, so there are no concerns.

**Human Subjects:** As mentioned, there is concern that the study population will be “Veterans over 22 years of age”. This is potentially problematic, confounding age with feasibility/acceptability. The human subject section includes a paragraph about venipuncture (not relevant to this proposal). The biggest concern with iTBS is seizure induction. Will a physician be available in the event of an adverse effect?

**Inclusion of Women, Minorities and Children:** It is noted that both males and females will be included but it is not clear whether there will be equal representation.

**Critique of Vertebrate Animals Section:**

| Research with vertebrate animals? | Yes | No |
|-----------------------------------|-----|----|
|                                   |     | X  |

**Biohazards and Radioisotopes:** Not applicable.

**Budget:** Appropriate.

**Data Management and Access Plan** (for data sharing, unscored): Appropriate.

**Overall Strengths:** The major strengths of this proposal include the investigative team, resources and the proposed novel therapy combining iTBS and yoga. While the components of the study are not particularly innovative, combining them as a therapy to increase QOL in Veterans with mTBI and chronic pain is innovative.

**Overall Weaknesses:** The weaknesses have to do with the age of the proposed participants and the lack of detail in some of the study characteristics.
MEETING ROSTER

Rehabilitation Research and Development SPIRE Program
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04/23/2020

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