MEMORANDUM FOR CHIEF, DEPARTMENT OF CLINICAL INVESTIGATION (DCI), KELLER ARMY COMMUNITY HOSPITAL AT WEST POINT, NEW YORK

SUBJECT: Application and Request for Approval of Clinical Investigation Study Proposal

Check all the sites where subjects will be enrolled: **STUDY SITE(s): __X__KACH, ____WRNMMC, ____MGMC, ____USUHS; Other, please specify: _____**

1. GENERAL INFORMATION

1.1 Protocol Title:
Effectiveness of Trigger Point Dry Needling and Physical Therapy versus Physical Therapy Alone Following Shoulder Stabilization Repair: A Randomized Controlled Trial
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1.4 Collaborators: N/A

1.5 Research Monitor N/A

2. ABSTRACT

2.1 Purpose

The purpose of this single-blinded, randomized clinical trial is to determine the effectiveness of dry needling compared to a standard shoulder rehabilitation program on

range of motion, functional movement, and pain in patients who have undergone shoulder stabilization surgery. Measurements of the aforementioned dependent variables will be taken at time intervals of four weeks, eight weeks, 12 weeks, and six months post-operatively. It is hypothesized that the inclusion of dry needling will result in an increase in range of motion, increase in functional movement, and decrease in pain at an accelerated rate when compared to rehabilitation alone. Findings will potentially lead to insights as to the benefit of applying this intervention to additional body regions.

2.2 Research Design

The research design will be a single-blinded randomized controlled trial.

2.3 Methodology /Technical Approach

30-50 subjects at least four weeks after shoulder stabilization surgery will be randomized into two groups (one experimental group and one control group). Subjects in the experimental group will receive Trigger Point Dry Needling (TDN) intervention with standard rehabilitation protocol (Appendix A) while subjects in the control group will receive the same standard rehabilitation protocol without TDN. The experimental group will receive trigger point dry needling one time per week for four to six weeks in addition to the standard rehabilitation protocol. The control group will receive only the standard rehabilitation protocol. Baseline measurements will be taken at approximately four weeks post operatively, and subsequent measurements will be recorded at eight weeks, 12 weeks, and six months.

All patients who have undergone a shoulder stabilization procedure will be invited to participate. Description of the study and informed consent will take place prior to randomization. Concealed randomization will take place 0-7 days post-operatively.

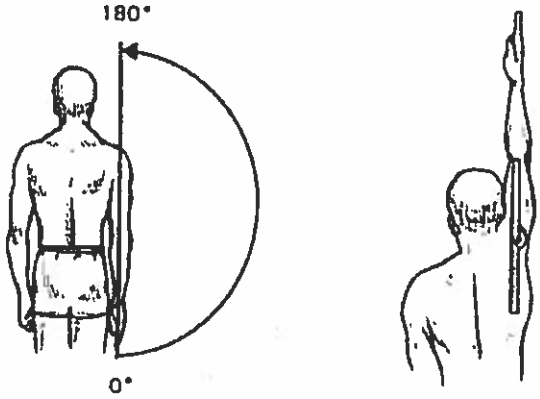
At 4 weeks post-operatively, the following assessment tests will be undertaken: supine shoulder flexion, supine shoulder external rotation, supine shoulder internal rotation, functional movement testing, functional outcome measures, and the numeric pain rating scale. [1,2,3] Those subjects in the 'experimental group' will receive manual palpation of all upper quarter muscles, including the cervical and thoracic spine region, to detect the presence of myofascial trigger points (TPs). Dry needling will be performed to all detected TPs by a provider trained and experienced in TDN.

In addition to the TDN intervention, the experimental group subjects will undergo a rehabilitation program in accordance with a shoulder stabilization repair protocol which is the standard of care for this surgical procedure. Per the shoulder stabilization protocol, subjects will be instructed in a home exercise plan (HEP) that will reinforce the clinical treatment, will be provided with a handout of instructions, and will be required to demonstrate all exercises correctly.

Subjects in the 'control group' will undergo a rehabilitation program as described above for the 'experimental group', except that they will not receive a TDN intervention.

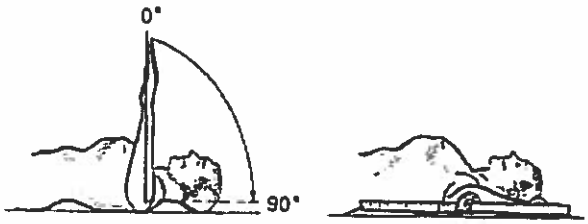
Objective Measures with Brief Descriptions

Passive Range of Motion (PROM) Shoulder Flexion



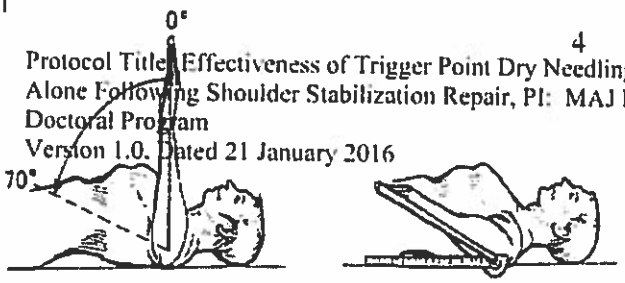
Subject is supine with hips and knees flexed for stabilization. Elbow will be extended, forearm relaxed, and wrist in neutral position. Subjects' arm will be raised into forward flexion by the practitioner. The stationary arm of the goniometer will be placed parallel to the spine but at the lateral aspect of the body. The moving arm of the goniometer will be placed along the midline of the humerus. Goniometric measurement is a valid and reliable measure of glenohumeral joint range of motion. [1,2,4]

PROM Shoulder External Rotation



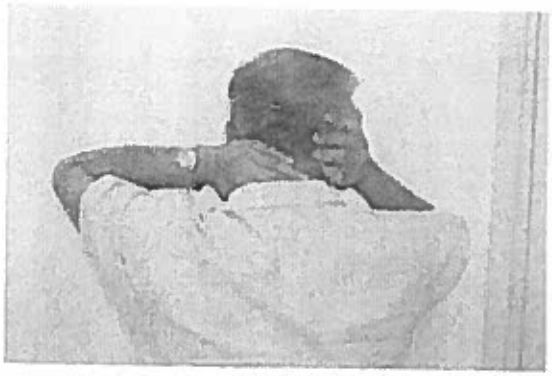
Subject is supine on the plinth with hips and knees flexed for stabilization. Tested arm abducted to 90 degrees; elbow flexed to 90 degrees; forearm in the midposition between supination and pronation and perpendicular to the plinth. Subjects' arm will be externally rotated by the practitioner. The stationary arm of the goniometer will be horizontal to the plinth with the pivot of the protractor on the olecranon process. The moving arm of the goniometer will be in line with the styloid process of the ulna. [1,2,4]

PROM Shoulder Internal Rotation



Subject is supine on the plinth with hips and knees flexed for stabilization. Tested arm abducted to 90 degrees; elbow flexed to 90 degrees; forearm in the midposition between supination and pronation and perpendicular to the plinth. Subjects' arm will be internally rotated by the practitioner. The stationary arm of the goniometer will be horizontal to the plinth with the pivot of the protractor on the olecranon process. The moving arm of the goniometer will be in line with the styloid process of the ulna. [1,2]

Functional Shoulder Tests



Hand to neck (shoulder flexion and external rotation)
Measurement scale (0-4)

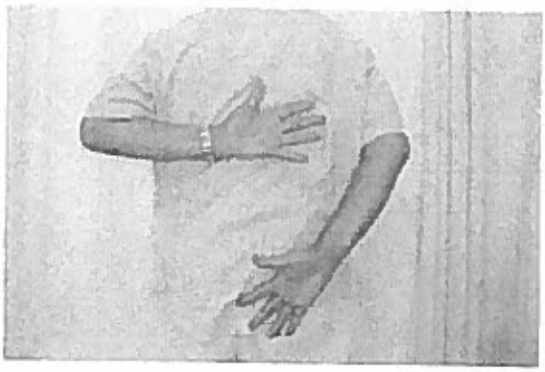
0-The fingers reach the posterior median line of the neck with the shoulder in full abduction and external rotation without wrist extension

1-The fingers reach the median line of the neck but do not have full abduction and/or external rotation

2-The fingers reach the median line of the neck, but with compensation by adduction in the horizontal plane or by shoulder elevation

3-The fingers touch the neck

4-The fingers do not reach the neck [3]



Hand to scapula (shoulder extension and internal rotation)
Measurement scale (0-4)

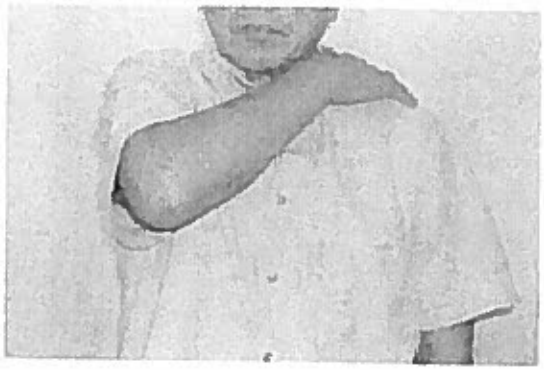
0-The hand reaches behind the trunk to the opposite scapula or 5 cm beneath it in full internal rotation. The wrist is not laterally deviated

1-The hand almost reaches the opposite scapula, 6-15 cm beneath it

2-The hand reaches the opposite iliac crest

3-The hand reaches the buttock

4-Subject cannot move the hand behind the trunk [3]



Hand to opposite scapula (shoulder horizontal adduction)
Measurement scale (0-4)

0-The hand reaches to the spine of opposite scapula in full adduction without wrist flexion

1-The hand reaches to the spine of the opposite scapula in full adduction

2-The hand passes the midline of the trunk

3-The hand cannot pass the midline of the trunk [3]

Numeric Pain Rating Scale (NPRS): Subjects self-report pain at rest and with activity on a scale from 0-10. The Minimum Important Difference (MID) for the NPRS (on a scale from 0 to 10) ranged from -1.5 (small change) to -3.0 (medium change) to -3.5 (large change). The NPRS is a valid and reliable tool in patients with shoulder pain. [5,6]

Global Rating of Change (GROC): score is rated from -7 (very great deal worse) to +7 (very great deal better) where subjects will check an answer that best describes their current perceived status since injury onset to time of follow up. Meaningful patient improvement/ deterioration (on a 15 point scale) is considered to be >5 or <-5. [7,23] See Appendix A

Patient Specific Functional Scale (PSFS): The PSFS is a self-report questionnaire assessing pain, instability and activities of daily living (ADLs). The MID for the PSFS (on a scale from 0 to 10) ranged from 1.3 (small change) to 2.3 (medium change) to 2.7 (large change). The PSFS is a reliable and valid tool for assessing outcome in Shoulder Injuries. [6] See Appendix A

Shoulder Pain and Disability Index (SPADI): The SPADI is a self-report questionnaire assessing pain and disability. The MID for the SPADI (on a 100 point scale) is 13.2. The SPADI is a reliable and valid tool for assessing outcome in shoulder injuries.[48,49] See Appendix A

3. OBJECTIVES AND SPECIFIC AIMS

Objectives:

1.) To determine if the addition of upper quarter TDN to a rehabilitation protocol is more effective in improving range of motion and functional movement when compared to a rehabilitation protocol alone after shoulder stabilization surgery.
2.) To determine if the addition of upper quarter TDN to a rehabilitation protocol is more effective in decreasing pain than a rehabilitation protocol alone after shoulder stabilization surgery.

4. MEDICAL APPLICATION/ MILITARY RELEVANCE

TDN is becoming an increasingly common intervention and is widely used among military musculoskeletal providers. Providers claim many benefits from this intervention to include myofascial pain relief and myofascial tension release resulting in improved joint dynamics, range of motion, and flexibility. There are many studies available showing the benefits of this intervention treating myofascial pain. [24, 25, 26, 27] By contrast, there is a relatively small amount of literature examining the claim of improved range of motion, and to date, only one study has been done to evaluate the benefit of TDN in a postoperative setting. [8] In case studies by Mason et al, and Dembowski et al, patients receiving TDN demonstrated good improvement in range of motion and demonstrated improved functional movement patterns.[26, 28]

Movements such as push-ups, pullups, climbing, and throwing are functional movement patterns required by soldiers in training and combat environments. Range of motion of the glenohumeral joint is significantly involved in these movements. Decreased range of motion to the glenohumeral joint may lead to decreased physical performance as well as increased risk of injury.[9] Additional studies such as this randomized controlled trial are needed to identify if relationships exist between TDN and improved muscle flexibility/tension and ultimately improved functional movement capacity to further support as well as improve the utilization of this treatment modality.

5. BACKGROUND AND SIGNIFICANCE

5.1 Literature Review and Preliminary Data and/or Findings.

Search terms: dry needling, trigger point, shoulder stabilization repair, shoulder range of motion, labral repair, shoulder range of motion measures, functional movement, functional outcome scores, global rating of change

Search engines: Pubmed, Medline, CINAHL, Google Scholar

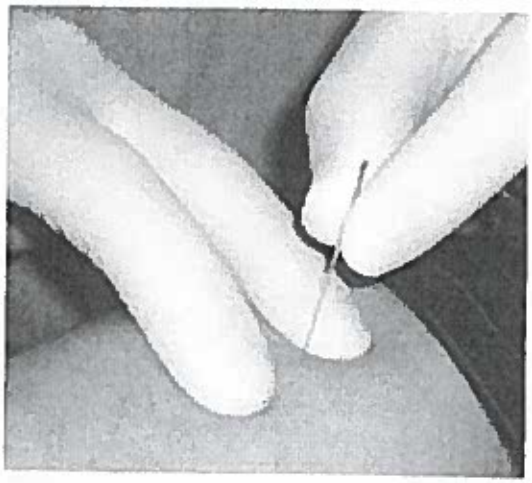
Post-operatively, patients often have limited range of motion following their immobilization period. Di Silvestro noted that increased stiffness and loss of range of motion may lead to slower recovery times, decreased performance, and even early degeneration of the glenohumeral joint. Loss of glenohumeral range of motion after shoulder stabilization may be the result of a decreased length of glenohumeral ligaments and increased tightness of the joint capsule.[10, 11] Recently, Bailey et al has proposed that another possible cause of decreased glenohumeral range of motion may be linked to muscle tension and trigger points (TPs) within the musculature of the shoulder girdle.[12] Trigger Points are described as localized hyperirritable areas associated with hypersensitive palpable taut bands located in muscle tissue, and are suggested to contribute to joint range of motion restrictions as well as adversely affect muscle activation.[24, 28, 31, 32, 33] TPs are further described in the literature as either active or latent.[34] Active TPs can be responsible for local pain as well as referred pain or paresthesia [13] and may contribute to spontaneous pain at rest.[34] Latent TPs are focal areas of tenderness and tightness in muscle that may not be directly responsible for referred or local pain unless stimulated; however, latent TPs are believed to alter muscle activation patterns which may consequently result in limited range of motion or weakness of the muscles involved.[13,30, 34] TPs may also develop secondary to an excessive release of acetylcholine from motor endplates which has been associated with increased motor endplate noise and resulting muscle fiber knots.[31]

Recently, TDN has emerged as a popular treatment for muscular pain and muscle tension. The execution of TDN involves identifying target TPs through manual palpation. Upon identification of a TP a solid monofilament acupuncture needle is inserted into the skin directed towards the target TP. The needle is then repeatedly pistoned (inserted and withdrawn rapidly from each TP) without being fully withdrawn from the skin with the goal of eliciting a local twitch response. A local twitch response is an involuntary spinal cord reflex contraction of muscle fibers following needling of the involved fibers.[40,41] Treatment is repeated to produce several local twitch responses and continued until all identified areas of dysfunction have been addressed.[26]

While there are several studies detailing the benefits of this intervention for pain, few studies exist examining the effects on range of motion, muscle tension and stiffness and only one study exists examining it use in a post-operative population.[8, 14, 15] A recent case study by Mason et al demonstrated immediate improvements in range of motion after 2 treatment sessions of TDN to the calf region that were retained at a 3 month follow up.[26] Dembowksi et al demonstrated immediate improvements in hamstring flexibility retained at 1 week follow up intervals after TDN to the hamstring muscle group.[28] In a population of healthy adults with confirmed presence of latent TPs and abnormal muscle activation patterns of the scapulohumeral muscles, TDN directed at the latent TPs showed normalization of muscle activation patterns by EMG post treatment.[30] The duration of these effects were not measured.

While the exact mechanisms of TDN are still largely unknown, TDN has been shown to alter the biochemical environment surrounding a TP as well as reduce spontaneous

electrical activity within a TP.[36, 37, 38] Mechanically, TDN could disrupt the integrity of dysfunctional motor endplates related to shortened muscle fibers.[25] TDN may evoke a neurophysiological reset[25] as well as mechanically disrupt taut bands of muscle tissue found in areas of muscle dysfunction, allowing for normalized range of motion of the targeted muscle fibers favorably affecting pain and tension in the affected regions.[35, 39] These effects appear to be most effective when a local twitch response is elicited.[38]



This picture is an example of the needles that would be used for the intervention. Please note the actual needle placement and size will differ between participants.

5.2 Scientific Justification.

This study will address the potential benefits of TDN and rehabilitation against rehabilitation alone to improve range of motion of the shoulder, assess improvements in functional movement, and patient reported changes in pain in a population of post-operative shoulder stabilization repair patients. Findings may lead to insights as to the benefit of applying this intervention to additional regions of the body. If there is an increase of ROM and functional movement or decrease in pain, TDN may be used as an adjunct to current methods to ultimately provide better patient outcomes. Finding better and more effective interventions may help rehabilitation providers be more effective at preserving the fighting force and improving combat effectiveness.

Military musculoskeletal providers as well as soldiers and athletes are constantly seeking the fastest most effective treatment strategies to improve performance on the battlefield or the playing field. TDN has become a popular intervention with these populations, however, there is a paucity of evidence to explain or support the intended benefit.[16] The results of this study will add to the limited body of research on this topic as well as assist musculoskeletal providers in making evidence based decisions justifying the use of this treatment modality.

5.3 Human Use Justification.

This study is designed with human subjects because that is the population of interest, and the surgical procedures for shoulder stabilization are performed on humans. Additionally, the results of this study will be used to further treatment with humans, therefore human participants will yield the most applicable and generalizable results.

Dry needling has been shown to have minimal risk to subjects with reported frequency of significant adverse effects occurring in less than 1% of sessions.[17, 43] The most common adverse effects are post needling soreness, hematoma at needling site and pain.[17, 43, 44] The application of dry needling to the protocol and conducting on human subjects is reasonable and risks to the subjects are minimal.

6. PLAN

6.1 New Investigational Drugs/Investigational Devices Exemption Status

N/A

6.2 Selection of Subjects

6.2.1 Type of the Subject Population

Participants for this study will be Department of Defense (DOD) healthcare beneficiaries at West Point and Keller Army Community Hospital age 18 years to 40 presenting status post shoulder stabilization repair surgery. In the event that an emancipated, 17 year old cadet meets inclusion criteria for the study, they will also be allowed to participate.

6.2.2 Inclusion and Exclusion Criteria

Inclusion	Exclusion
Age 18-40 DOD beneficiaries (17 if Cadet)	Self-Reported Pregnancy
Status post shoulder stabilization repair surgery	History of blood borne pathogens/infectious disease/active infection/metal allergy
	Bleeding disorders or currently taking anti-coagulant medications
	Participants who are not fluent in English

The PI is not fluent in languages other than English and is unable to have study materials translated and certified in other languages. For this reason, we are not able to accommodate participants who speak languages other than English.

6.2.3 Recruitment

a. Subject selection must be equitable.

There is a high feasibility of recruiting 30-50 subjects for this study within an eight month timeframe. This is based on the number of shoulder stabilization procedures performed at Keller Army Hospital that average 8 per month. To our knowledge, the other studies that involve this population do not include subjects status post shoulder stabilization repair and are not receiving TDN. There is a low likelihood that subjects able to participate in our study will already be participating in another injury study of this nature.

Given the inclusion and exclusion criteria, any subject that presents status post shoulder stabilization repair has the possibility of being recruited into the study. We have selected the age ranges based on the general accessible population. Selection of age ranges 18-40 (17 if cadet) are to include the typical ages of Cadets and other personnel at West Point. There is no exclusion criteria that would specifically exclude any gender, race or ethnicity. The study population will reflect that of the corps with regards to race, ethnicity, and gender.

a. **Describe from when, where and how the study subjects will be recruited.**
Subjects will be recruited from the population of patients thatpresent to the Arvin and Keller Physical Therapy clinics status post shoulder stabilization repair surgery. When potential subjects present to physical therapy, they will be screened by the PI in accordance with the standard of care following shoulder stabilization surgery. Upon meeting the inclusion criteria, all subjects will be oriented to the need and purpose of the research, invited to participate, and if willing, provided with informed consent. After obtaining consent, the subject will be randomly assigned to treatment groups using a random number generator. All subjects will be evaluated by the PI or designated provider using a normal physical therapy evaluation as part of the standard of care that patients would receive regardless of study participation or not. Subjects that decline to participate in the study or do not meet inclusion criteria will be provided care for their injury as would normally occur.

b. **Compensation for participation.**
Participants will receive no compensation.

6.2.4 Consent Process

a. Participants will be consented by the PI or other study staff designated by the PI. The PI will provide copies of the IRB approved consent form to each participant and provide a verbal outline of the study as described in the consent form. Participants will then be encouraged to read the consent form and will be allowed up to 24 hours if requested before signing to appropriately weigh the risks and benefits to them. Throughout the consent process, participants will be instructed that participation is voluntary and that their decision to participate or withdraw will have no bearing on their career, educational status, or overall medical care.

b. The consent form will be written in layman's terms at an eighth grade reading level.

Participants will be given up to 24 hours if requested to read the consent form and ask questions prior to signing the consent form. In the event that participants do not wish to take the whole 24 hours, they may consent immediately. In this case, the PI will review the consent form prior to participant signature.

6.3 Study Design and Methodology

6.3.1 Study Design

This study will be a single-blinded, randomized controlled trial with repeated measures design. Outcome assessors will remain blinded from group assignment and perform measurements related to the study protocol at 4 weeks post-intervention, 8 weeks, 12 weeks, and 6 months. The PI or an AI will consent each subject and open a sealed envelope to reveal the subjects intervention group. Concealed allocation to treatment group will be performed by an individual not involved in subject recruitment or treatment, using a computer generated randomized table of numbers created for each participating site prior to the beginning of the study. The group assignment will be recorded on an index card. This card will be folded in half such that the label with the patient's group assignment is on the inside of the fold. The folded index card will be placed inside the envelope, and the envelope will be sealed. The PI or an AI, trained in TDN, will perform dry needling interventions and will not participate in outcome measurements related to the study protocol. Blinded outcome assessors will repeat all study related measurements at a follow up at 8 weeks, 12 weeks, and 6 months. Group assignment will not be combined with subject data until all measurements have been completed at the final six month follow up. Over the course of rehabilitation, subjects will engage in a standard protocol as described previously. This will include frequent re-assessment, measurement, and progression of rehabilitation that is the standard of care for this procedure.

6.3.2 Study Methodology/Procedures

GROUPS

Group assignment will be recorded with individual subject identifier and secured in a separate folder until completion of all data collection through the final follow up.

-Experimental Group: Upper Quarter TDN with shoulder stabilization protocol
-Control Group: Shoulder stabilization protocol alone

All TDN will be performed by the PI or AI's who are trained and experienced in TDN, to all detected TPs in the examined musculature. The TDN technique will be standardized. The subject will continue to receive care in accordance with the post-operative protocol between follow-ups.

Experimental Group: Manual palpation of the upper quarter will be performed to detect the presence of TPs. Any combination of the following criteria will be used to determine the presence of trigger points and will be used to determine the location of needle placement[31]:

The presence of a palpable taut band in examined muscles, the presence of a hypersensitive spot within the taut band, a palpable or visible local twitch on snapping palpation, and/or the reproduction of local or referred pain elicited by palpation of the sensitive spot. These criteria have good inter-examiner reliability (k = 0.84-0.84) when performed by experienced clinicians. [46] A previous review[47] found that reliability was based on determining the presence or absence of a TP without distinction between active or latent status. TDN will be performed to all detected active and/or latent TPs. Subjects in this group will also receive rehabilitation and will be asked to perform a home exercise program in accordance with the post-operative protocol. Subjects will record compliance on an exercise log. Handouts will be provided to each subject.

Control Group: Subjects in this group will receive rehabilitation and will perform a home exercise program in accordance with the post-operative protocol. Subjects will be asked to record compliance on an exercise log. Handouts will be provided to each subject.

Repeat measurement of glenohumeral internal rotation, external rotation, flexion, and functional movement testing will be performed. Each subject will record pain with each measurement on the NPRS. The AI will record all data as at initial data collection.

Over the course of rehabilitation, all subjects will engage in a standard protocol as described previously (Appendix A).This will include frequent re-assessment, measurement, and progression of rehabilitation. The measurements and assessment included in this process will not be included in data collection for the purposes of the study and will not be subject to blinding.

BASELINE DEMOGRAPHIC COLLECTION AND EVALUATION – POST OP DAY ~7

Subject recruitment

Subjects will be screened for inclusion/exclusion criteria.

Subjects will be given a random numeric identifier.

All data will be recorded and stored by individual numeric identifier. Group assignment will be kept separate and will only be known by PI or AI`.

Subjects meeting all entrance criteria, to include standardized physical exam, will be consented, numeric identifier given, and group assignment provided. Demographic information will be recorded to include age, gender, duration and location of symptoms. The physical exam will be in accordance with the post-operative protocol and is standard of care after these procedures. Elements may include evaluation of neurological status, neurovascular integrity, wound healing, and assessment of joint mobility. Data from the initial physical exam is only used for clinical purposes. Both the experimental and control groups will receive physical therapy in accordance with the post-operative protocol until their 4 week follow up. No TDN will be performed at this time post-operatively, baseline demographics only.

4 WEEKS POST-OPERATIVE:

Initial Data Collection

The outcome assessor performing data collection and measurements will remain blinded to group assignment. In both the experimental and control groups, they will test and record ROM of glenohumeral internal rotation, external rotation, flexion, and functional movement of the shoulder. Each subject will complete the Global Rating of Change survey (GROC), Patient Specific Functional Scale (PSFS), and Shoulder Pain and Disability Index (SPADI). Subjects will be asked to report compliance with home exercise program by presenting his or her exercise log. Pain level will be recorded using the NPRS. No TDN will be performed at this time post-operatively, data collection only.

EXPERIMENTAL GROUP TDN TREATMENTS #1-4, 4-8 WEEKS POST-OPERATIVE

TDN will be performed to all detected TPs in experimental group only by PI or AI's. As part of the standard course of treatment, both the experimental and control groups will participate in supervised rehabilitation in accordance with the post-operative rehabilitation protocol throughout this time period.

8 WEEKS POST-OPERATIVE

Follow Up Data Collection

Outcome assessors will remain blinded to group assignment. Both the experimental and control groups will be re-evaluated by an outcome assessor, who will test and record ROM of glenohumeral internal rotation, external rotation, flexion, and functional movement of the shoulder. Each subject will complete the Global Rating of Change survey (GROC), Patient Specific Functional Scale (PSFS), and Shoulder Pain and Disability Index (SPADI). Subjects will be asked to report compliance with home exercise program by presenting his or her exercise log. Pain level will be recorded using the NPRS. No TDN will be performed at this time post-operatively, data collection only.

12 WEEKS POST-OPERATIVE

Follow Up Data Collection

Outcome assessors will remain blinded to group assignment. Both the experimental and control groups will be re-evaluated an outcome assessor, who will test and record ROM of glenohumeral internal rotation, external rotation, flexion, and functional movement of the shoulder. Each subject will complete the Global Rating of Change survey (GROC), Patient Specific Functional Scale (PSFS), and Shoulder Pain and Disability Index (SPADI). Subjects will be asked to report compliance with home exercise program by presenting his or her exercise log to the AI #1. Pain level will be recorded using the NPRS. No TDN will be performed at this time post-operatively; only data collected.

6 MONTHS POST-OPERATIVE

Follow Up Data Collection

Outcome assessors will remain blinded to group assignment. Both the experimental and

control groups will be re-evaluated by an outcome assessor, who will test and record ROM of glenohumeral internal rotation, external rotation, flexion, and functional movement of the shoulder. Each subject will complete the Global Rating of Change survey (GROC), Patient Specific Functional Scale (PSFS), and Shoulder Pain and Disability Index (SPADI). Pain level will be recorded using the NPRS. No TDN will be performed at this time post-operatively, data collection only.

6.3.3 Collection of the Human Biological Specimens

No biological specimens will be collected during this study.

6.3.4 Data Collection – Describe what and how the data will be collected including the measurement time points. List all study variables, instruments/questionnaires to be administered, if any. As appropriate, include the validity and reliability of the instruments. For subject's confidentiality protection, outline the procedure for coding, recording, storing and protecting the data. Provide a copy of data collection sheets, case report forms, survey forms/questionnaires/instruments, and/or a copy of the author's permission granting the use of the instruments in the *Appendix Section 20*.

All data will be collected through survey questions and direct researcher measurements.

Data collected and Time Points

SURVEY DATA	OBJECTIVE MEASUREMENTS
Age -baseline demographic questionnaire	Glenohumeral Internal Rotation - initial data collection, at each follow u
Gender -baseline demographic questionnaire	Glenohumeral External Rotation - initial data collection, at each follow u
Duration of symptoms -baseline demographic questionnaire	Glenohumeral Flexion - initial data collection, at each follow u
Numeric Pain Rating Scale (NPRS) for shoulder pain -baseline demographic questionnaire - initial data collection, at each follow up	Functional Range of Motion Test - initial data collection, at each follow u
	Global Rating of Change (GROC) -at each follow up
	PSFS -initial data collection, at each follow up
	SPADI -initial data collection, at each follow up

Study Variables

INDEPENDENT VARIABLES	DEPENDENT VARIABLE
Group Assignment (2 Levels) - Experimental - Control	Shoulder Range of Motion -Internal Rotation (degrees) - External Rotation (degrees) - Flexion (degrees) -Functional Movement Test
Time (4 Levels) - Week Four - Week Eight - Week 12 - Month Six	Shoulder pain (NPRS) -with internal rotation - with external rotation - with flexion - with functional movement test
	GROC
	PSFS
	SPADI

Data Collection/Confidentiality

Subjects will sign the consent forms but no identifiable information will be on data collection forms. Each of the subjects will be randomly assigned a subject identification number from 1-38 upon entrance into the study and subsequently given consent forms and survey/data collection forms with the corresponding number. Each number assigned will only be used once.

All subject information and data collection forms will be kept behind double locks: in a locked filing cabinet, behind a locked door. Signed consent forms, group assignment, and data collection forms will all be kept in separate folders and filing cabinet drawers. All electronic study databases will be secured on password protected computers and stored on a server with restricted access requiring CAC authenitication. Subject data will only be identified by each subject's identification code.

6.3.5 Study Time Line

Demographic/ Data Collection and Intervention Timeline

	Baseline	4 weeks	Tx 1-4; Experimental Group Only	8 weeks	12 weeks	6 months
Informed Consent, Discuss Plan, etc	x					
Screening, Demographics	x					
Randomization	x					

History and Physical		x		x	x	x
TDN to Experimental group			x			
HEP Instruction	x	x		x	x	x
ROM Measurement		x		x	x	x
GROC	x	x		x	x	x
PSFS	x	x		x	x	x
NPRS	x	x		x	x	x
SPADI	x	x		x	x	x

615
616
617 **6.4 Statistical Consideration**

618 Descriptive statistics will be provided. Data analysis will be performed with statistical
619 analysis software R version 3.1.2. A 2x4 repeated measures ANOVA with Sidak's post hoc
620 testing will be used with time as the within-subjects factor and group (control or TDN) as the
621 between-subjects factor.

622
623 **6.4.1 The primary endpoints (i.e., primary outcome variables) and the secondary**
624 **endpoints, if any**. Clearly define primary and secondary outcome variables of the research
625 study.
626 Outcome variables for this study are as follows:
627 Primary Outcomes:
628 1. Passive Range of Motion: Changes in range of motion of the shoulder, as
629 measured by glenohumeral range of motion during passive shoulder flexion,
630 external rotation, and internal rotation, and are necessary outcome variables to
631 determine the effectiveness of dry needling of shoulder TPs in a post-operative
632 population. [8]
633 2. Shoulder Functional Movement Test: To assess overall change in movement
634 mechanics of the shoulder. Functional Movement patterns are needed to perform
635 complex tasks such as pull-ups and pushups.[3]
636 3. Numeric Pain Rating Scale (NPRS): Severity of pain in the shoulder with
637 functional activities at each visit will be assessed using a scale from 0-10. The
638 subject will report their level of pain with the instruction that "0 is no pain, 10 is
639 the worst pain imaginable".[6, 18]
640 Secondary Outcomes:
641 1. Global Rating of Change score: To assess overall change from initial presentation,
642 the GROC will be recorded at each follow up visit. This score is rated from -7 to
643 +7 where subjects will select an answer that best describes their current perceived
644 status since injury onset.[23, 45]
645 2. PSFS: The PSFS is a self-report questionnaire assessing pain, instability and
646 activities of daily living (ADLs).[6]
647 3. SPADI: The SPADI is a self-report questionnaire assessing pain and

disability.[48,49]

4.

6.4.2 Data analysis

Descriptive statistics will be provided. Data analysis will be performed with statistical analysis software R version 3.1.2. A 2x4 repeated measures ANOVA with Sidak's post hoc testing will be used with time as the within-subjects factor and group (control or TDN) as the between-subjects factor. Alpha will be = .05.

6.4.3 Safety Monitoring and Analysis Plan.

For this study, continuous assessment of participant's response to treatment will be performed, especially their response to dry needling techniques. If the participant experiences soreness greater than expected or has hematoma develop increasing in size then needling techniques will be discontinued. At any time the subject can elect to discontinue participation in the study and will continue with standard of care treatment.

6.4.4 Sample Size Estimation

30-50 status post shoulder stabilization surgery meeting inclusion and exclusion criteria will be recruited for this study. A priori sample size calculation using G Power 3.1.2 was performed and it was determined the required sample size would be 34 subjects. This sample size provides 80% power to detect an effect size of 1.0 at the eight week follow-up with an alpha level of .05. To account for a potential 10-15% of subjects lost to follow-up, 38 subjects is the goal for recruitment.[19] Multiple prior studies on TDN of upper quarter musculoskeletal disorders have reported very large changes (effect sizes > 1.5) in range of motion after TDN.[20,27]

6.5 Reporting Adverse Events

6.5.1 Expected Adverse Events from Research Risks and Reporting Describe the expected adverse events from research risks using the following categories (the event rates may be derived from your clinical experience or literature).

- Rare but serious (Event Rate < 1%):
  - Pneumothorax is possible when needling the muscles of the thorax and shoulder. This can be a potentially life threatening event and may limit participation in the study if it occurs. Likelihood of pneumothorax when needling in this region has been estimated at 1/10,000. [21]
- Less Likely (1% ≤ Event Rate < 5%)
  - Vasovagal syncope is possible when needling and has been shown to be more common when needling the thorax and shoulder.[22] This will not limit subject participation in the study and typically resolves within 1-2 minutes. Likely (5% ≤ Event Rate < 10%)

- Bruising at insertion site: visual inspection

- Likely (5% ≤ Event Rate < 10%):
  - It is common with dry needling techniques for subjects to develop a hematoma or ecchymosis at the needled site if a small vessel is needled inadvertently. This will not limit subject participation in the study and typically resolves within 2-3 days.[43,44]
- More likely (Event Rate ≥ 10%):
  - Likely event to occur within this study is muscle soreness following dry needling techniques. This soreness typically resolves within 2-3 days and is not a limiting factor to continued participation.[43,44]

Expected adverse events which are not serious are reported on the Annual Progress Report (APR) during the continuing review of the protocol. APR is mostly due in a 12-month cycle, the anniversary month of the protocol's initial approval or due in lesser than 12-month cycle as determined by the IRB for continuing review and approval.

6.5.2 Reporting Serious and Unexpected Adverse Events to the IRB

Serious Adverse Events: The PI, within two working day, must report all serious adverse events (SAE) occurring in subjects enrolled at KACH. This is accomplished by submitting an adverse event report memorandum to the IRB via DCI. For protocols involving investigational drugs or devices, the investigator must also report a serious adverse event to the sponsor of the IND or IDE immediately (within 24 hours). Serious adverse events must be reported even if the PI believes that the adverse events are unrelated to the protocol.

Unexpected (but not serious) adverse events occurring in subjects enrolled at KACH which, in the opinion of the PI, are possibly related to participation in the protocol must be reported by the PI within 10 (ten) working days to the IRB using the same procedure.

For all serious and/or unexpected adverse events, the PI must forward a copy of the adverse event report to the Research Monitor for the protocol.

For multi-center studies, unexpected or serious adverse events occurring in subjects enrolled at other medical facilities must be reported to the KACH IRB within 10 working days after the PI receives notification of such events.

A summary of all serious or unexpected side effects also must be included in the APR.

6.7 Subject Confidentiality Protection

Each of the subjects will be randomly assigned a number from 1-38 upon entrance into the study and subsequently given consent forms and survey/data collection forms with the corresponding number. Each number assigned will only be used once. All consent and data

collection forms will be kept behind double locks: in a locked filing cabinet, behind a locked door. Signed consent forms, group assignment, and data collection forms will all be kept in separate folders and filing cabinet drawers.

6.7.1 Certificate of Confidentiality

N/A

6.7.2 HIPAA

Authorization

Your answers to the following questions will assist compliance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA). The DOD HIPAA regulations 6025.LL-R and other guidance can be found on the DCI website.

If your research will collect Protected Health Information (PHI) such as, physical, clinical, psychological well-being, behavioral and genetic data (e.g., blood pressure, type of cancer, disease stage, ADL, PSA, urine protein, use of alcohol, depression, etc.) **along** with any of the following 18 personal identifiers, a HIPAA authorization is required. The research data collected in such format is referred to as "Identifiable Protected Health Information"

i. Are you intending to collect subject's Protected Health Information (PHI) and any of the following 18 personal identifiers?

___ No – HIPAA does not apply – go to question #iv

_X_ Yes – please check which ones:

_X__ 1. Names

___ 2. Street address, city, county, 5-digit zip code

___ 3. Months and dates (years are OK) and ages >89 (unless all persons over 89 years are aggregated into a single category)

___ 4. Telephone numbers

___ 5. Fax numbers

___ 6. E-mail addresses

___ 7. Social security number

___ 8. Medical record number

___ 9. Health plan beneficiary number

___ 10. Account number

___ 11. Certificate/license number

___ 12. Vehicle identification number (VIN) and/or license plate number

___ 13. Device identifiers and serial numbers

___ 14. URLs (Uniform Resource Locators)

___ 15. Internet protocol address number

___ 16. Biometric identifiers, such as finger and voice prints

___ 17. Full face photographic images or any comparable images

_X_ 18. Any other unique identifying number, characteristic, or code such as patient initials

ii. Can you limit your collection of personal identifiers to just dates, city/state/zip, and/or "other unique identifier" (#18 of the above)?

___ Yes – then your dataset may qualify as a Limited Data Set – please complete a Data Use Agreement and attach to your protocol. Then go to question #iv.

__x_ No – Go to question #iii.

iii. Is obtaining patient Authorization "impracticable"?

___ Yes – Authorization may qualify to be waived by the IRB. Go to *Section 6.7.3* HIPAA Authorization Waiver for the application.

_x__ No – Research subjects will need to sign a HIPAA Authorization. Complete the HIPAA Authorization template on the joint NCA website and attach to this protocol.

iv. What precautions will you take to protect the confidentiality of research source documents (Case Report Forms, questionnaires, etc.), the research data file, and the master code (if any)?

To protect the confidentiality of research source data, these forms will only be labeled with the subjects' identification number for the study. All de-identified information will be stored in a locked cabinet in a locked room separate from master code list, consent forms, etc. which will be also be secured in a locked cabinet in a separate locked room. All electronic data will be de-identified information and will be secured on a restricted access server and in a password protected file.

v. When will you destroy the research source documents, data file, and the master code?

De-identified information will not be destroyed, however, the master code list will be destroyed three years after completion of the study.

vi. Will research data including Identifiable Protected Health Information be sent outside of KACH?

___ Yes – Please explain assurances you have received from the outside party that they will appropriately follow confidentiality protections, follow the HIPAA requirements, and abide by the provisions of your Authorization.

_X_ No

6.7.3 HIPAA Authorization Waiver

If you wish to obtain and use identifiable protected health information for a study without obtaining written approval ("HIPAA Authorization") from the subject, please complete the HIPAA Authorization Waiver Form to provide justification for IRB review and approval.

6.8 Reporting Protocol Deviations

Any protocol deviations during the course of the study will be promptly reported to DCI/IRB and sponsor if applicable, through the research monitor of the protocol if applicable. Examples of deviations include but are not limited to variances from the treatment schedule for an individual patient, failure to use the most current consent form, and/or incomplete or lost records.

Reporting protocol deviation is accomplished by submitting a protocol deviation memorandum to the IRB via DCI. See the protocol deviations report template on the DCI web under "Deviations" and filename *deviation.doc*.

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8. FACILITIES/ORGANIZATIONS TO BE USED

Arvin Cadet Physical Therapy Clinic
DPE and ODIA Athletic Facilities
Arvin Cadet Physical Development Center

9. ROLE AND RESPONSIBILITIES OF EACH INVESTIGATOR AND COLLABORATOR

Researcher	Role	Responsibilities
MAJ Halle	Primary Investigator	Identify subjects, TDN, randomization, data collection, consent, home exercise instruction, recording of measurements, maintain study records, statistical analysis
MAJ Szymanek	Associate Investigator	Data collection, consent, back up TDN and home exercise instruction, group assignments/randomization and maintaining this data, maintain study records
CPT Helton	Associate Investigator	Data collection, consent, back up TDN and home exercise instruction, group assignments/randomization and maintaining this data, maintain study records
CPT Stoltenberg	Associate Investigator	Data collection, consent, back up TDN and home exercise instruction, group assignments/randomization and maintaining this data, maintain study records
MAJ Watson	Associate Investigator	Data collection, consent, back up TDN and home exercise instruction, group assignments/randomization and maintaining this data, maintain study records
LT Riebel	Associate Investigator	Data collection, consent, back up TDN and home exercise instruction, group assignments/randomization and maintaining this data, maintain study records
LTC Goss	Associate Investigator	Maintain study records, statistical analysis, recording measurements
MAJ Crowell	Associate Investigator	Maintain study records, statistical analysis, recording measurements, back up TDN, randomization and home exercise instruction

10. TIME REQUIRED TO COMPLETE THE RESEARCH (INCLUDING DATA ANALYSIS)

Anticipated start date – March 2016
Expected completion date – June 2018

11. BUDGET

Will any outside organization provide funding or other resources? Yes ( ) No (X)

Protocols that are funded through grants, congressionally-approved funding, or CRADAs are not eligible for supplemental intramural funding. A ***conflict of Interest Disclosure Memorandum*** must be submitted for each investigator and included in the APPENDIX for all protocols that receive funding from an outside source—this memo can be found on DCI web site.

DCI Budget Request for Intramural Protocols Only:

	Current FY	Next FY	TOTAL
Consumable Supplies (Itemize each supply)	$0	$0	$0
Other*	$0	$0	$0
Travel**	$0	$0	$0
TOTAL ***	$0	$0	$0

12. ENVIRONMENTAL IMPACT STATEMENT (***May be revised IAW future DCI SOP)

Does any part of this protocol generate any of the following regulated waste?

a. Hazardous chemical waste Yes ( ) No (X)
b. Regulated Medical Waste Yes ( ) No (X)
c. Radioactive Waste Yes ( ) No (X)

If yes to any questions, please indicate at what stage and how much, and how it will be safely disposed to protect the environment and provide an Environmental Impact Statement signed by the appropriate official. If any or part of the protocol will be executed at the DCI Research Laboratories, an Environmental Impact Statement signed by the DCI Laboratory Chief will be required.

If the study will involve radiation exposure beyond the standard of care, DCI coordinator will forward your protocol to the Radiation Safety Committee for review.

13. INVESTIGATOR COMPLIANCE STATEMENT (May be revised IAW DCI SOP)

a. I have read and understand the provisions of The Belmont Report, Ethical Principal

and Guidelines for the Protection of Human Subjects of Research, April 18, 1979.

b. I have read and will comply with KACH DOD Assurance for the protections of human subjects from research risks.

c. I have read and will comply with the institutional policies and guidelines as outlined in the Standard Operating Procedures (SOP) of the Department of Clinical Investigation and the Principal Investigator Guide.

d. I have read and will comply with the "Potential Conflict of Interest in Clinical Research at KACH as outlined in the DCI SOP.

e. I certify that any outside funds and/or other resources (other than requested from DCI) being provided for this study are listed above in this application under *Section 11*- Budget.

14. RESPONSIBILITIES OF THE PRINCIPAL/ASSOCIATE INVESTIGATOR IN HUMAN SUBJECTS RESEARCH

The principal investigator is the individual who is primarily responsible for the actual execution of the clinical investigation. He/she is responsible for the conduct of the study, obtaining subjects' consent, providing necessary reports, and maintaining study documents. The Associate Investigator will assist the Principal Investigator for the responsibilities stated below.

As the Principal Investigator or Associate Investigator:

a. I will not enroll a subject into a study until the study has been approved by the appropriate authority and, when appropriate, the subject's primary care physician has granted approval for him/her to enter a study.

b. By signing this protocol, I warrant that any use of Protected Health Information (PHI) for reviews preparatory to research met the following requirements:

- **i. The review of PHI was done solely to prepare a research protocol, or for similar purposes preparatory to research;**
- **ii. No PHI was taken outside the Military Health Care System; and**
- **iii. This review of PHI was necessary for research purposes**

c. I am responsible for assuring that the prospective volunteer is not participating as a subject in other research that will significantly increase the research risks to the subject.

d. I am responsible for assuring the quality of each subject's consent in accordance with

current federal regulations. This will include ensuring that any "designee" that obtains consent on my behalf is completely conversant with the protocol and is qualified to perform this responsibility.

e. I will obtain the KACH IRB approval for advertisements used to recruit research subjects.

f. I will not accept any outside personal remuneration for implementation of a study.

g. I will take all necessary precautions to ensure that the study does not generate hazardous chemical waste.

h. I will obtain the proper KACH clearance prior to all presentations, abstracts, and publications. The following require KACH approval:

- **i. Reports involving KACH subjects and/or patients.**
- **ii. Reports that cite KACH in the title or byline.**
- **iii. Reports of KACH approved clinical investigation or research.**
- **iv. Reports of research performed at KACH.**
- **v. Reports of research conducted by KACH assigned personnel.**

i. I must <u>submit</u> to the Department of Clinical Investigation (DCI):

- **i. Any source of outside funding.**
- **ii. An APR, due in the anniversary month of the protocol's initial approval or due in the month as determined by the IRB for <u>continuing review</u> and approval.**
- **iii. Reports of adverse effects occurring in subjects as a result of study participation or of any protocol deviations and submit these reports to Research Monitor if there is one for the study.**
- **iv. An Addendum, prior to any changes made to the study or a change in the funding status.**
- **v. A Final Report within 30 days following termination of a study.**
- **vi. Listing of presentations, abstracts, and publications arising from the study for inclusion in the APR.**

j. I will maintain a Study File that must be kept for three years following completion of the study if no IND/IDE used (32 CFR 219.115(b). If IND medication or IDE appliances are used, the file must be kept for 2 years after FDA approval and can then be destroyed; or if no application is filed or approved, until 2 years after the study is discontinued and FDA notified (21CFR 312.62(c). The records should be kept in the Department/Service where the research took place (AR 40-38). If I am scheduled to PCS or ETS, these records will be given to a new KACH PI or the Department/Service Chief. If research is being conducted at NNMC research files are to be kept indefinitely. At the conclusion of the study the files may be submitted to the Responsible Conduct of Research Service.

This file may be inspected at any time by DCI, (future 2nd tier office), Department of the Defense (DOD), the Food and Drug Administration (FDA), and/or other regulatory agencies responsible for the oversight of research. This file will include:**

i. **The approved protocol and applicable addenda.**
ii. **The KACH Scientific Review Board and IRB minutes (as appropriate) and the DCI memorandum granting approval to begin the study.**
iii. **Other applicable committee minutes [e.g., Radioactive Drug Research Committee (RDRC); the Surgeon General's Human Subjects Research Review Board].**
iv. **Each Volunteer Agreement Affidavit (i.e., consent form) signed by the subject.**
v. **APR or Final Report.**
vi. **Reports of adverse effects occurring in subjects as a result of study participation.**
vii. **Reports of any significant new findings found during the course of the study.**
viii. **All study documents generated from study date, e.g., subject enrollment log research records, data collection sheets, etc.**
ix. **Publications/abstracts/Presentations Clearance documents, and reprints from study data**
x. **All information pertaining to an investigational drug or device.**
xi. **For HIV research studies, approval of the Chief, Infectious Disease Service.**

k. I will be familiar with all applicable regulations governing research, and will adhere to all of the requirements outlined in the KACH's DOD Assurance and Federal-Wide Assurance granted by the Office for Human Research Protections, Department of Health and Human Services.

15. RESEARCH MONITOR RESPONSIBILITIES

Duties as the Research Monitor include:

1) **Monitoring the conduct of the protocol per the approval plan and ensuring protection of human subjects. This may involve periodic review of medical records of enrolled subjects and the research files being maintained by the PI.**
2) **Reviewing and keeping abreast of adverse events and protocol deviations that occur during the research; (all adverse events, including deaths and serious or unexpected side effects, are reported to the Research Monitor via the PI).**
3) **If there is concern about the welfare of enrolled subjects, the Research Monitor has the authority to stop a research study in progress, remove individual subjects from a study, and take whatever steps necessary to protect the safety and well being of research subjects until the IRB can assess the Research Monitor's report. Notification of such actions must be forwarded to the DCI within one (1) working day of receipt of knowledge of actions prompting human subject welfare concerns.**

4) **Research Monitors will be required to co-sign all adverse event reports, protocol deviation memoranda, APR, and addendum.**
5) **The Research Monitor must keep current the KACH required research ethics Human Subjects Training every 3 years.**
6) **If the Research Monitor is expected to be away for more than 14 days but less than 30, the PI or Research Monitor must designate an acting Research Monitor and document such action.**
7) **If a Research Monitor leaves KACH for greater than 30 days then the PI must be informed to designate a new Research Monitor and report such change to the IRB via a memorandum for a change of Research Monitor.**

16. PRINCIPAL INVESTIGATOR ACKNOWLEDGEMENT

I acknowledge that I have read and am accountable for the responsibilities under *Section 13* and *Section 14*. I understand that if I fail to comply with any of these responsibilities, all projects for which I am an investigator may be suspended. I also acknowledge the above Application for Clinical Investigation Project; Request for Approval of Clinical Investigation Study Proposal; Environmental Impact Statement; Investigator Compliance Statement; and Responsibilities of the Principal/Associate Investigator in Human Subject Research.

HALLE.ROBERT.J.1164855941 Digitally signed by HALLE.ROBERT.J.1164855941 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USA, cn=HALLE.ROBERT.J.1164855941 Date: 2016.01.19 14:33:49 -05'00'

MAJ Rob Halle, SP Date

17. ASSOCIATE INVESTIGATOR (s) ACKNOWLEDGEMENT (PROVIDE SIGNATURE ELECTRONICALLY)(*Add as many associate signatures as necessary.)

I acknowledge that I have read the responsibilities under *Section 13* and *Section 14* and will comply with them.

SZYMANEK.ELIZA.BLACKFORD.1250889417 Digitally signed by SZYMANEK.ELIZA.BLACKFORD.1250889417 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USA, cn=SZYMANEK.ELIZA.BLACKFORD.1250889417 Date: 2016.01.19 14:40:58 -05'00'

MAJ Eliza Szymanek Date

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CPT Brian Stoltenberg Date

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CPT Gary Helton Date

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LT Mark Riebel Date

Daniel J Watson Digitally signed by WATSON.DANIEL.J.1297863335 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=WATSON.DANIEL.J.1297863335 Date: 2016.01.20 09:41:27 -05'00'

Maj Daniel Watson Date

1/20/16

MAJ Michael Crowell Date

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LTC Donald Goss Date

Note: If the Service/Department Chief is an investigator on the study, a higher level signature is required.

18. RESEARCH MONITOR ACKNOWLEDGEMENT

N/A

19. DEPARTMENT CHIEF AND SERVICE CHIEF ACKNOWLEDGEMENTS

I concur with the submission of this proposal to the Department of Clinical Investigation for review and approval.

1/22/16

Chad A. Haley Date
COL, MC
Chief, Department of Surgery

POSNER.MATTHEW.ADAM.1020319980 Digitally signed by POSNER.MATTHEW.ADAM.1020319980 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USA, cn=POSNER.MATTHEW.ADAM.1020319980 Date: 2016.01.25 14:07:40 -05'00'

Matthew A. Posner
LTC, MC
Chief, Department of Orthopedics

20. APPENDICES

As appropriate include all relevant documents in the following sequences:

APPENDIX A - Data collection sheets / Post-Surgical Protocol / Home Exercise Program / Exercise Log

APPENDIX B – Signed Conflict of Interest Statement

APPENDIX C - Consent Form(s)

APPENDIX D - HIPAA Authorization Form

For more information, Contact DCI at (845) 938-4821

(Version 1 - KACH 4 Jan 2010)

DEPARTMENT OF THE ARMY
U.S ARMY MEDICAL DEPARTMENT ACTIVITY
REPLY TO ATTENTION OF West Point, New York 10996-1197

MCUD-ORTHO

Date: 14 January 2016

RE: SCIENTIFIC REVIEW OF RESEARCH PROTOCOL
Effectiveness of Trigger Point Dry Needling and Physical Therapy versus Physical Therapy Alone Following Shoulder Stabilization Repair: A Randomized Controlled Trial
PI: MAJ Rob Halle, SP

1. **Description:** The purpose of this single-blinded, randomized clinical trial is to determine the effectiveness of dry needling compared to a standard shoulder rehabilitation program on range of motion, functional movement, and pain in patients who have undergone shoulder stabilization surgery. Measurements of the these dependent variables will be taken at time intervals of four weeks, eight weeks, twelve weeks, and six months post-operatively. It is hypothesized that the inclusion of dry needling will result in an increase in range of motion, increase in functional movement, and decrease in pain when compared to rehabilitation alone at similar time points. Findings will potentially lead to insights as to the benefit of applying this intervention to additional body regions.

2. **Standard Review Criteria:**

Significance: Dry needling is a relatively new technique that is commonly utilized among military physical therapists in a rehabilitative setting. The evidence to support this technique is recent and emerging. It is imperative that clinicians in this setting continue to pursue quality research to support the benefits and identify the limitations of this tool so that it is most effectively implemented.

Approach: Given the existing literature, the next logical step is to execute randomized controlled trials in order to assess the efficacy of this treatment. MAJ Halle's methods are well developed with randomized group assignments and the blinded assessor.

Investigator: MAJ Halle and the associate investigators are experienced clinicians who are trained to utilize dry needling in the physical therapy clinic. MAJ Halle's work to prepare for this research combined with his status in the fellowship program puts him in an ideal position and setting to execute this research project.

Environment: This controlled environment is ideal for a study of this nature. Patients who are candidates for this study will make up a homogenous group that is healthy and active. All patients will be treated by a team of surgeons who use similar surgical techniques and follow the same post-surgical protocols. All eligible subjects receive their healthcare from the same providers and at the same facilities so the follow-up schedules and procedures will be similar.

3. **Overall Evaluation:**

Synopsis: MAJ Halle has thoroughly reviewed the literature and has appropriately formulated a research question that is the next logical step in this line of research. He will address a population that has not been well-studied and the information from this study has potential to improve treatment for future soldiers recovering from surgical procedures.

Strengths: There are two strengths of this study that immediately stand out: 1) the controlled setting and 2) the experienced clinicians who will administer the treatment. This setting will provide a homogenous group of subjects who have surgical and rehabilitation experiences that are more similar than you would see with a pool of subjects in a civilian setting. All of the physical therapists who will administer both the experimental treatment and the standard of care rehabilitation have extensive training in both and will follow standardized protocols.

Weaknesses: The biggest challenge with this study will be the time limit under which MAJ Halle is operating, given the timeline to complete the fellowship program. However, I believe with the systems in place and the team that he has assembled, he will be able to recruit the requisite number of subjects and complete this research in the timeline allotted.

Impact: The dry needling treatment is used throughout the military in physical therapy settings. The information gained from this study has the potential to improve outcomes for soldiers who require surgical interventions. Additionally, this knowledge can be applicable for civilian athletes who undergo similar procedures and hope to return to high demand sports and activities.

Military Relevancy: Soldiers are expected to engage in a variety of high demand physical activities. When they become injured, it is important that quickly and safely return to their previous levels or participation. If dry needling can be shown to hasten a soldiers' return to activity and to decrease pain, this tool could improve outcomes for soldiers who sustain serious injuries.

Literature Review: MAJ Halle has done an excellent job summarizing the literature related to dry needling. His thorough literature review has identified a need for RCTs in patients who are recovering from surgical procedures which leads to his research question.

Human Use Issues: Dry needling is performed on a regular basis in physical therapy settings so the risk to patients is minimal. Protocols are in place to deal with the relatively rare side effects that can occur with this procedure. Subjects can withdraw at any time from this study. This study should be considered no more than minimal risk.

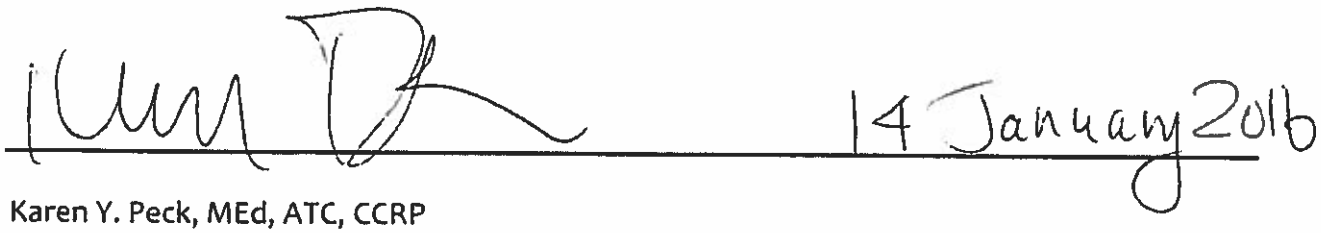
Specific recommendations for improvement: I have no specific recommendations for improvement.

4. Make one of the following 5 recommendations for the protocol:

Approve without modification

CONFLICT OF INTEREST

There is no financial or professional interest or personal circumstance that will impair my ability to provide an objective review. I understand the confidential nature of the protocol and agree to destroy or return all review-related materials and to not discuss these materials or review proceedings with any individual except the Scientific Review Committee Chairperson.



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