Frequency Specific Microcurrent for the Treatment of Diastasis Recti

NCT04060563

Doc Date: 3/2/2021

EIRB Protocol Template (Version 1.14)

1.0 General Information

***Please enter the full title of your study:**

Frequency Specific Microcurrent for the treatment of diastasis recti

***Please enter the Protocol Number you would like to use to reference the protocol:**

FWH20190124H
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

Is this a multi-site study (i.e. Each site has their own Principal Investigator)?

No

Does this protocol involve the use of animals?

○ Yes ◉ No

2.0 Add Site(s)

2.1 List sites associated with this study:

Primary Dept?	Department Name
◆	**USAF** - 99 MDG/MOFMC

3.0 Assign project personnel access to the project

3.1 *Please add a Principal Investigator for the study:

Trang, Diana T, DO, BS

Select if applicable

☐ Student ☐ Site Chair
☑ Resident ☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Adams, Shalease S
Associate Investigator
Crawford, Paul F
Associate Investigator

Hughes, Pamela Rae, MD
Associate Investigator
Moss, David
Associate Investigator

B) Research Support Staff

Bogdanovich, Tracy Lee
Research Coordinator
Clark, Jill Marie, MBA/HCM
Research Coordinator
Crawford, Amanda J
Participating Clinician
Crawford, Kristy J, BSN
Team Member
Huffman, Sandra G
Research Coordinator
Moss, Jennie B
Research Coordinator
Shaffer, Daniel WILLIAM
Research Coordinator

3.3 *Please add a Protocol Contact:

Clark, Jill Marie, MBA/HCM
Huffman, Sandra G
Trang, Diana T, DO, BS

The Protocol Contact(s) will receive all important system notifications along with the Principal Investigator. (i.e. The protocol contact(s) are typically either the Protocol Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Site Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Site (e.g. the Site Chair).

4.0 Project Information

4.1 * Has another IRB/HRPP reviewed this study or will another IRB/HRPP be reviewing this study? If Yes, answer the questions according to the IRB/HRPP Determination.

○ Yes ◉ No

IRB Name	Review Date	Determination
No records have been added		

4.2 * Is this a research study or a Compassionate Use/Emergency Use/HUD project?

◉ Yes ○ No

4.3 What type of research is this?

- [x] Biomedical Research
- [ ] Clinical trial (FDA regulated)
- [ ] Behavioral Research
- [ ] Educational Research
- [ ] Psychosocial Research
- [ ] Oral History
- [ ] Other

4.4 Are you conducting this project in pursuit of a personal degree?

- ( ) Yes
- (•) No

4.6 * Is this human subjects research? (As defined by 32 CFR 219)

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

- (•) Yes
- ( ) No

4.7 * Do you believe this human subjects research is exempt from IRB review?

- ( ) Yes
- (•) No

5.0 Personnel Details

5.1 List any Research Team members without EIRB access that are not previously entered in the protocol:

Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:
Tate, Rachel Role on Protocol: Research Technician	(702) 653-3298	r.tate.ota@gmail.com	99 MDG/Nellis AFB
Name: (Last, First, M.I.) Estrada, Jonica Role on Protocol: Research Coordinator	Phone Number: (702) 653-2975	Email Address: jonica.estrada.ctr@mail.mil	Associated Institution: 99 MDG/Nellis AFB
Name: (Last, First, M.I.) Haney, Thomas	Phone Number: (702) 653-3902	Email Address: thaney@axiom-rm.	Associated Institution: 99 MDG/Nellis AFB

Role on Protocol: Research Coordinator		com	

5.2 Will you have a Research Monitor for this study?

- ○ Yes
- ○ No
- ◉ N/A

6.0 Data/Specimens

6.1 Does the study involve the use of existing data or specimens only (no interaction with human subjects)?

○ Yes ◉ No

7.0 Funding and Disclosures

7.1 Source of Funding:

Funding Source	Funding Type	Amount
: Other Air Force Medical Support Agency	: Research Development Testing and Evaluation (RDT&E) funds	595000

Total amount of funding:

595000

7.2 Do you or any other Investigator(s) have a disclosure of a personal interest or financial nature significant with sponsor(s), product(s), instrument(s) and/or company(ies) involved in this study?

○ Yes ◉ No

If Yes, complete and attach Conflict of Interest forms for all key personnel

8.0 Study Locations

8.1 Is this a collaborative or multi-site study? (e.g., are there any other institutions involved?)

○ Yes ◉ No

8.2 Study Facilities and Locations:

Institution	Site Name	Site Role	FWA or DoD Assurance Number	Assurance Expiration Date	Is there an agreement?	IRB Reviewing for Site
Air Force	99MDG	Performance site	F50417	10/31/2020	: IAIR	: WHASC IRB Protocol Office

Other:

Other Institution Site	Site Role	FWA or DoD Assurance Number	FWA or DoD Expiration Date	Is there an agreement?	IRB Reviewing for Site
No records have been added					

8.3 Are there international sites?

Attach international approval documents, if applicable, when prompted. Note: Ensure local research context has been considered

○ Yes ◉ No

8.4 Is this an OCONUS (Outside Continental United States) study?

○ Yes ◉ No

Select the area of responsibility:

Have you obtained permission from that area of responsibility? (This is a requirement prior to study approval)

○ Yes ○ No

9.0 Study Details

9.1 Key Words:

Provide up to 5 key words that identify the broad topic(s) of your study

Family Medicine Residency, Family Medicine

9.2 Background and Significance:

Include a literature review that describes in detail the rationale for conducting the study. Include descriptions of any preliminary studies and findings that led to the development of the protocol. The background section should clearly support the choice of study variables and explain the basis for the research questions and/or study hypotheses. This section establishes the relevance of the study and explains the applicability of its findings

Diastasis rectus abdominus (DRA) is a common finding among pregnant and postpartum women (3,6). A small number of studies have shown a correlation between DRA and reduced abdominal wall functioning and poor overall body image (5, 6); some studies have shown DRA to be associated with lumbopelvic pain (3). A study evaluating natural recovery of DRA after pregnancy showed some improvement in DRA and abdominal wall function compared to baseline, but did not return to baseline levels (6). DRA-specific exercise protocols have not been consistently effective in improving associated lumbopelvic pain and it is

unclear if abdominal functionality is improved (1, 2, 6). Ultrasound can be used to noninvasively and accurately measure DRA (3, 4, 5, 7). With general therapy, microcurrent treatments have been shown to improve muscle function and may reduce pain associated with muscular dysfunction, however no studies that we are aware of are using microcurrent to treat DRA. We wish to determine if frequency specific microcurrent treatment is an effective treatment for DRA. Secondarily we will assess lumbar and/or pelvic pain levels, urogynecologic symptoms, and overall body image after having microcurrent therapy. The significance of improving DRA in the postpartum military population may be that the service member can return to exercise sooner without pain and have improved strength, thereby allowing her to return to duty and meet military fitness standards

9.3 Objectives/Specific Aims/Research Questions:

Describe the purpose and objective(s) of the study, specific aims, and/or research questions/hypotheses

Determine if frequency specific microcurrent therapy improves pain management of DRA by 30% or greater

9.4 Study Design:

Describe study design in one to two sentences (e.g., prospective, use of existing records/data /specimens, observational, cross-sectional, interventional, randomized, placebo-controlled, cohort, etc.). Specify the phase – Phase I, II, III, or IV – for FDA-regulated investigational drug research

Active duty or DoD beneficiary post-partum females aged 18 years or older who have met inclusion /exclusion criteria and are willing to participate in a randomized double-blind study assessing a microcurrent therapy treatment vs placebo (a microcurrent faux (fake) treatment) over a 12-week period post-partum. They will be recruited from the post-partum unit at 99MDG (see section 13.1).

9.5 Target Population:

Describe the population to whom the study findings will be generalized

Active duty or DoD beneficiary females aged 18 years or older who are postpartum from a singleton gestation status post vaginal, who meet the inclusion and exclusion criteria will be recruited. No special populations (i.e. pregnant women, children, military basic trainees, prisoners, detainees) will be recruited.

9.6 Benefit to the DoD:

State how this study will impact or be of benefit to the Department of Defense

Improving pain management of DRA after microcurrent therapy in post-partum females may allow a faster, more effective return to activity, the return-to-duty transition and establishing personal readiness by meeting military fitness standards

10.0 Study Procedures, Data Management, and Privacy

10.1 Study Procedures:

Describe step-by-step how the study will be conducted from beginning to end

Female Active duty members or DoD beneficiaries, aged 18 years or older, meeting the inclusion /exclusion criteria will be offered an opportunity to participate. They will be recruited from the postpartum unit at 99MDG (see Protocol Section 13.1). All of the below items are research-related unless marked as 'standard of care':

Pre-Eligibility review: Subjects who responded to advertisements or have given their permission to be contacted will be approached by a study staff member to discuss the subject's interest in the research study and to receive a pre-eligibility screening for study participation. The attached "Pre-Eligibility Review Script" will be used and response will be recorded. If the subject is interested in participating in the study, the study staff member will schedule a screening visit while the subject waits on the phone or in-person, in order to confirm the schedule appointment with the subject. Following the pre-screening procedure, the script will be shredded.

Screening visit (within 3 months postpartum):
-Obtain and document signed Informed Consent and HIPAA authorization.
-Review past medical and pregnancy history to verify inclusion and exclusion criteria.
-Collect demographic information to include age, weight (pounds), height (inches), BMI, DoD ID#, current email address (for scheduling), phone number, race, ethnicity.

Randomization: Subjects will be randomized into one of two research treatment groups with approximately 58 subjects in each arm:
-Group 1: Sham (fake) microcurrent therapy (placing the microcurrent pads on the patient and turning the microcurrent box on placebo mode), for one treatment lasting a total of 7 hours and 10 minutes the device will worn at home and returned.
Group 2: Frequency specific microcurrent therapy (100-300μA microccurrent amps) with Diastasis Recti Repair protocol (8), for one treatment lasting a total of 7 hours and 10 minutes the device will be worn at home and returned.

Blinding: Amanda Crawford will be responsible for managing the excel spreadsheet that randomly assigns the patient to Group 1 or Group 2. She will place the randomization code into a sealed envelope and deliver it to the Research Technicians who will program the microcurrent boxes to either Group 1 (Sham microcurrent therapy) or Group 2 (microcurrent therapy). The blinded microcurrent boxes will them be provided to the study staff to apply the microcurrent treatment. The remaining study staff will be blinded to the study treatment. If at any time a patient experiences and adverse event that requires breaking of the blind, Amanda can provide the randomization assignment. At the conclusion of the study, and once all the subjects have completed treatment and follow up, Amanda will provide the randomization assignments to the study staff to be included in the data analysis.

Visit 1 (may be the same day as screening visit):

- We will apply ultrasound gel and measure inter-rectus distance (IRD), 2 cm above and 2 cm below the umbilical ring, via ultrasound or if unable via ultrasound, via palpation and measuring tape.

-Begin treatment according to randomization group, patients will be instructed to leave microcurrent in place until treatment is over. Subjects will return to the clinic the day after visit 1 so that Reserch personnel can retrieve the microcurrent box. We will apply ultrasound gel and measure inter-rectus distance (IRD), 2 cm above and 2 cm below the umbilical ring, via ultrasound or palpation with tape measure (measurement will be the same technique as the original measurement.

Visit 2/week 2 (between 2 weeks and 4 weeks):

- We will apply ultrasound gel and measure inter-rectus distance (IRD), 2 cm above and 2 cm below the umbilical ring, via ultrasound or palpation with tape measure (measurement will be same technique as original measurement)

Visit 3/week 4-12 (between week 4 and 12):

- We will apply ultrasound gel and measure inter-rectus distance (IRD), 2 cm above and 2 cm below the umbilical ring, via ultrasound or palpation with tape measure (measurement will be same technique as original measurement)

-Administer Body Image States Scale (BISS) (5 minutes)

-Administer Pelvic Floor Impact Questionnaire- short form 7 (PFIQ-7) (5 minutes)

-Obtain Defense and Veterans Pain Rating Scale for lumbar pain and pelvic pain (DVPRS) (5 minutes)

Microcurrent Device: We will be using the Inspirstar microcurrent stimulator TENS device. It is an FDA 510k approved portable hand-held device used for the symptomatic relief of chronic pain. It generates low current intensity pulses in the ranges of 20μA to 400μA.For this study, we will use a treatment range of 100-300μA.

10.2 Data Collection:

Describe all the data variables, information to be collected, the source of the data, and how the data will be operationally measured.

-Variables: Age, parity, pregnancy weight-gain (from medical record), BMI
-Information to be collected: Demographics (age, weight, height, BMI, parity, medical and pregnancy history, assessments (pain, body image, strength, urogynecologic symptoms)
-Source of data: Patient

10.3 At any point in the study, will you request, use, or access health information in any form, including verbal, hard copy and electronic?

○ Yes ◉ No

11.0 Statistical/Data Analysis Plan

11.1 Statistical Considerations:

List the statistical methods to be used to address the primary and secondary objectives, specific aims, and/or research hypotheses. Explain how missing data and outliers will be handled in the analysis. The analysis plan should be consistent with the study objectives. Include any sub-group analyses (e.g., gender or age group). Specify statistical methods and variables for each analysis. Describe how confounding variables will be controlled in the data analysis

The primary outcome measures are inter-rectus distances (IRD) taken 2 cm above and 2 cm below the umbilical ring. Secondary outcome measures taken once at the final postpartum visit between weeks 4 and 12 are Body Image States Scale (BISS); Pelvic Floor Impact Questionnaire- short form 7 (PFIQ-7); and Defense and Veterans Pain Rating Scale for lumbar pain and pelvic pain (DVPRS). Employing these outcome measures, the statistical null hypotheses are as follows:

H01 — there are no differences in IRD means between times, locations and treatment groups
H02 — there are no differences in BISS means between treatment groups
H03 — there are no differences in PFIQ-7 means between treatment groups
H04 — there are no differences in DVPRS means between treatment groups

11.2 Sample Size:

Planned to Enroll: 116
Planned to Complete: 98

11.3 Total number of subjects requested (including records and specimens):

116

11.4 If you are recruiting by study arm, please identify the arms of the study and how many subjects will be enrolled in each arm

Randomization: Subjects will be randomized into one of two research treatment groups with approximately 58 subjects in each arm:
-Group 1: Sham (fake) microcurrent therapy (placing the microcurrent pads on the patient and turning the microcurrent box on placebo mode), for one treatment lasting a total of 7 hours and 10 minutes the device will be worn at home and returned. Group 2: Frequency specific microcurrent therapy (100-300μA microccurrent amps) with Diastasis Recti Repair protocol (8), for one treatment lasting a total of 7 hours and 10 minutes the device will be worn at home and returned.

11.5 Please provide a justification for your sample size

Subjects will be a random sample of patients meeting the inclusion criteria. Subjects are presumed to be a random representation of the population of patients obtaining similar care at this and other Air Force medical treatment facilities. The main treatment effect is treatment using microcurrent electrical neuromuscular stimulation. Group 1 will receive a placebo effect and Group 2 will receive the treatment effect.

The study is organized as a mixed effects, randomized complete block design with repeated measures. Subject is a random effect as subjects will have been randomly subject to DRA from the population of patients obtaining similar care at these Air Force medical treatment facilities, randomly enrolled from this population of patients, and randomly assigned to treatment groups at the time of enrollment. Fixed effects are treatment group, time of repeated measure, and IRD location as these effects cannot be generalized to other treatments, times or locations.

A priori power was assessed using G*Power Version 3.1.9.3. (9) The researchers wish to detect at least a 30% difference in IRD between the treatment groups. The mean (SD) IRD at the four locations at 7 weeks postpartum has been estimated to be 1.97 (0.71) cm, 2.39 (0.59) cm, 1.99 (0.65) cm, and 1.30 (0.77) cm respectively, and the minimally detectable changes at a 95% confidence level to be 0.45 cm, 0.47 cm, 0.55 cm and 0.36 cm respectively. (10) These are smaller differences, but near the stated research objective; therefore, these will be used as a conservative effect size to estimate a priori power. The results indicate 98 subjects with 3 repeated measures will have a power of 0.801 at $\alpha = 0.05$ to detect these minimally detectable differences between the treatment groups.

11.6 Data Analysis Plan: Complete description: Background, Objectives, Design, Step by Step how the project is going to be done, Data analysis plan:

Means, standard deviations, medians, interquartile ranges (IQR) and ranges will be calculated for interval variables. These variables include patient characteristics and physiological measurements such as age, weight, height, BMI, and pregnancy weight gain. Frequency distributions will be calculated for nominal variables that include race/ethnicity, and parity.

Null hypothesis H01 will be tested by a mixed effects repeated measures analysis of variance (rANOVA) controlling for location and treatment group. In the event the null hypothesis is rejected, contrasts will be used to investigate sub-group differences. The significance level of multiple comparison tests will be corrected to α = .05 by the Holm method. (11) Null hypotheses H02 to H04 will be tested with a two sample t-test or Mann-Whitney U test depending on whether the data is distributed normally or non-normally.

Mr. Danny Sharon, Senior Research Biostatistician Subject Matter Expert for Clinical Research Management under contracts OMNI 0004 3-82 and OMNI 0005 3-126, is the statistical consultant supporting this study. Statistical analysis will be performed with R Version 3.5.1. (12)

12.0 Participant Information

12.1 Subject Population:

Active duty or DoD beneficiary post-partum females aged 18 or older, meeting the inclusion and exclusion criteria will be recruited. No special populations be recruited.

12.2 Age Range:

Check all the boxes that apply. if the age range of potential subjects (specimens, records) does not match the range(s) selected, please specify in the text box.

- [ ] 0-17
- [x] 18-24
- [x] 25-34
- [x] 35-44
- [x] 45-54
- [x] 55-64
- [x] 65-74
- [x] 75+

12.3 Gender:

- [ ] Male
- [x] Female
- [ ] Other

12.4 Special categories, check all that apply

- [ ] Minors /Children
- [ ] Students
- [ ] Employees - Civilian
- [ ] Employees - Contractor
- [ ] Resident/trainee
- [ ] Cadets /Midshipmen
- [x] Active Duty Military Personnel
- [ ] Wounded Warriors
- [ ] Economically Disadvantaged Persons
- [ ] Educationally Disadvantaged Persons
- [ ] Physically Challenged (Physical challenges include visual and/or auditory impairment)
- [ ] Persons with Impaired Decisional Capacity
- [ ] Prisoners

☐ Pregnant Women, Fetuses, and Neonates
☐ Non-English Speakers
☐ International Research involving Foreign Nationals - Headquarters Review is necessary

You must also consider the requirements of DoDI 3216.02, Enclosure 3, paragraph 7.e.

12.5 Inclusion Criteria:

Order Number	Criteria
1	-Active Duty and DoD beneficiary Postpartum Females (within 3 months postpartum) with Diastasis Rectus Abdominus (DRA) pain -IRD greater than or equal to 2.5 cm -Aged 18 years or older -Singleton gestation/delivered (one baby carried and born) -Vaginal delivery -Nulliparous (first pregnancy) or multiparous (more than one pregnancy in the past)

12.6 Exclusion Criteria:

Order Number	Criteria
1	-less than 18 years of age -females greater than 3 months post-partum -Medical history to include pacemaker -History of arrhythmia -Transplant status -Insulin pump -Pain pump -Active cancer -IRD less than 2.5 cm -Inability to measure IRD -Delivery via caesarean section -Operative vaginal delivery (vacuum or forceps) -3rd or 4th degree vaginal laceration - Inability to return the microcurrent device

13.0 Recruitment and Consent

13.1 Please describe the recruitment process, including how subjects will be identified and selected for the study.

All potentially eligible patients will be offered an opportunity to participate. Labor and Delivery staff referrals, with the patient's oral or written authorization, will be utilized for recruiting subjects to the study. Some patients may be patients of the PI or AI; however, they will have another study staff recruit their patients to prevent any misconception of coercion or undue influence. When a potential subject is identified by the Labor and Delivery staff , the patient will either be provided a contact number to the Research Staff, the Research Staff will be given the potential subjects' contact information by the Labor and Delivery staff, or the Research Staff will speak with the patients directly. The patients will then be given a copy of the advertisement and told that they will be contacted at a later date to see if they are still interested in participating.

13.2 Compensation for Participation:

Subjects will not be paid for their participation.

13.3 Please describe the pre-screening process. If no pre-screening, enter Not Applicable in the text editor

Pre-Eligibility review: Subjects who have given their permission to be contacted will be approached by a study staff member to discuss the subjects' interest in the research study and to receive a pre-eligibility screening for study participation. The attached "Pre-Eligibility Review Script" will be used and response will be recorded. If the subject is interested in participating in the study, the study staff member will schedule a screening visit while the subject waits on the phone or in-person, in order to confirm the schedule appointment with the subject. Following the pre-screening procedure, the script will be shredded.

13.4 Consent Process:

Revised Common Rule, Section 219.116: General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

Are you requesting a waiver or alteration of informed consent?

○ Yes ◉ No

Please explain the consent process:

Informed Consent and HIPAA authorization will be sought in advance of any screening and study-related procedures from each prospective study subject and appropriately documented in accordance with 32 CFR 219.117. Potential candidates will be notified about the study by their healthcare provider and will be given the opportunity to consent by one of the referred study coordinators. The study coordinator will provide a written copy of the Informed Consent Document (ICD). The subject may decline to consent without prejudice. At the subjects' discretion, they may take the ICD home to discuss further with family members or another physician prior to making a decision. If they decide they are interested in participating in the study, they can contact the research department. If the subject consents, a copy of the signed ICD and HIPAA Authorization Document will be given to the subject. No vulnerable populations are included in this research study. Subjects who cannot provide Informed Consent will not be allowed to participate. No Legally Authorized Representatives (LAR) will be utilized. Each subject will be asked to place their de-identified research data into the "Mike O'Callaghan Military Medical Center General Research Data Repository" (FWH20180064H) for future research. If the subject does not give their authorization, then the de-identified research data will be destroyed no later than at 3 years after closure of the study.

13.5 DoDI 3216.02 requires an ombudsman to be present during recruitment briefings when research involves greater than minimal risk and recruitment of Service members occurs in a group setting. If applicable, you may nominate an individual to serve as the ombudsman.

◉ N/A
○ Propose ombudsman

13.6 Withdrawal from Study Participation:

Explain the process for withdrawal and specify whether or not the subjects will be given the opportunity to withdraw their data their data/specimens in the event they wish to withdraw from the study

If a participant first agrees to participate and then changes their mind, they are free to withdraw consent and discontinue participation at any time. Their decision will not affect their ability to receive medical care and will not be penalized or lose any benefits to which they would otherwise be entitled. There are no risks from withdrawing. They will be advised in the Informed Consent process that if they decide to withdraw from the study early, we will ask them to discuss their decision with the study staff. The researcher may withdraw them from the study prior to the study's end without their consent for one or more of the following reasons: Failure to follow the instructions of the researchers and study staff. The researcher decides that continuing their participation is not in their best interests. The study is cancelled. Other administrative reasons. Unanticipated circumstances. They become Pregnant. If they lose their status as a military health care beneficiary, they can no longer be included in the study.

14.0 Risks and Benefits

14.1 Risks of Harm:

Identify all research-related risks of harm to which the subject will be exposed for each research procedure or intervention as a result of participation in this study. Consider the risks of breach of confidentiality, psychological, legal, social, and economic risks as well as physical risks. Do not describe risks from standard care procedures; only describe risks from procedures done for research purposes

There may be a risk of an accidental breach of confidentiality. The potential risks to participate in this study are minimal, although there may be risks currently unknown. The risks associated with participating in this research study include:

Less Likely and Not Serious:

Ultrasound:

-Skin sensitivity or allergic reaction to gel
-Discomfort with ultrasound exam

Microcurrent:
-Discomfort with microcurrent treatment
-Skin sensitivity after treatment
-Skin damage
-Conditions may worsen
-Nausea

-If the device malfunctions, it could give an inadvertent electrical shock similar to a mosquito bite

14.2 Measures to Minimize Risks of Harm (Precautions, safeguards):

For each research procedure or intervention, describe all measures to minimize and/or eliminate risk of harms to subjects and study personnel

Safeguards are in place for protecting subjects and their health data. The research consents and HIPAA Authorization Documents will be stored in a locked cabinet in a locked room. Safeguards are in place for protecting subjects. Risks related to the microcurrent will be minimized by proper use of the microcurrent device. Proper use includes software and firmware updates, cleaning pads after each patient, and daily inspection of cables. Subjects do not have to participate or answer any question that they do not want to

complete. If at any time the patient reports a side effect, they will be referred to one of the Investigators for care.

14.3 Confidentiality Protections (for research records, data and/or specimens):

Describe in detail the plan to maintain confidentiality of the research data, specimens, and records throughout the study and at its conclusion (e.g., destruction, long term storage, or banking). Explain the plan for securing the data (e.g., use of passwords, encryption, secure servers, firewalls, and other appropriate methods). If data will be shared electronically with other team members/collaborators outside the institution, describe the method of transmission and safeguards to maintain confidentiality. Explain whether this study may collect information that State or Federal law requires to be reported to other officials or ethically requires action, e.g., child or spouse abuse

Safeguards for Protecting Information: The research consents and HIPAA Authorization Documents will be stored in a locked cabinet in a locked room with restricted access. All identifiable research data including patient demographics will be kept in an electronic database separate from the coded research data, which will be encrypted, double password protected and the access will be restricted. Based on AFI 33-332, "The Air Force Privacy and Civil Liberties Program" and the National Institute of Standards and Technology Special Publication (NIST SP 800-88) which outlines the approved methods to destroy PII: The research data will be coded and any links to identifiable data (i.e., Master Key) will be destroyed as soon as all data mergers have occurred or no later than at the closure of the study. The anonymized research data will not be utilized for further research activity beyond the protocol stipulations without additional IRB approval. At the conclusion of the study, the data will be de-identified prior to review and analysis. Paper data, including completed consent forms: The research consents and HIPAA Authorization Documents will be stored in a locked cabinet in a locked room with restricted access.
Electronic data: Medical records will be annotated with ICD-10 code Z00.6 to reflect the subjects' participation in a research study, in which they are receiving a research-related treatment intervention. All research data that includes the Master Key of identifiable patient demographics and PHI/PII will be kept in an electronic database, separate from the coded research data, which will be encrypted, password protected and the access will be restricted.
Long-term storage (following completion of the study and inactivation of IRB approval): The research data will be coded and any links to identifiable data will be destroyed (in approved shredding bin) as soon as possible or no later than at the closure of the study, with the exception of those study subjects that consent to place their de-identified research data into the "Mike O'Callaghan Military Medical Center General Research Data Repository" (FWH20180064H) for future research. The anonymized research data will not be utilized for further research activity beyond the protocol stipulations without additional IRB approval. All de-identified research data will be maintained for 3 years following study closure. No data transfers to the repository will occur until the protocol has been officially closed and the Master Key of identifiable PHI/PII and codes has been destroyed.

14.4 Potential Benefits:

Describe any real and potential benefits of the research to the subject and any potential benefits to a specific community or society

If the individuals in the research are considered experimental subjects (per 10 USC 980), and they cannot provide their own consent, the protocol must describe the intent to directly benefit all subjects

Subjects may experience an improvement in diastasis rectus abdominus (DRA), improvement in abdominal wall functionality, reduction of pain, improvement in body image, improvement in urogynecologic symptoms; however, this is not a guarantee.

14.5 Privacy for Subjects:

Describe the measures to protect subject's privacy during recruitment, the consent process, and all research activities, etc.

Records of participation in this study may only be disclosed in accordance with Federal law, including the Federal Privacy Act, 5 U.S.C. § 552a, the Health Insurance Portability & Accountability Act of 1996, Public Law 104-109 (also known as HIPAA), and their implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records. The Informed Consent gives permission for information gained from participants in this study to be published in medical literature, discussed for educational purposes, and used generally to further the generalizable knowledge of the medical science community. They will not be personally identified; all information will be presented as anonymous data. We will annotate their medical record to reflect their participation in a research study for each visit because this study involves an intervention that is for research purposes only. A copy of this consent will be stored by the investigator in a locked cabinet in a locked room, as part of the research record. All research data will be kept in an electronic database, which will be double password protected, firewall-protected, encrypted, and access-restricted to people involved in this study. The research data will be coded. As soon as possible, any link between identity and the research information will be destroyed which means research information about the participant will be permanently de-identified. Personal identifying information will be destroyed no later than at the closure of the study. The research information collected for this study will not be used for any additional research activity beyond what was approved in the signed consent. In the unlikely event that a loss of confidentiality occurs, the study staff will advise the subjects to contact their local privacy office for assistance. Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.

14.6 Incidental or Unexpected Findings:

Describe the plan to address incidental findings and unexpected findings about individuals from screening to the end of the subject's participation in the research. In cases where the subject could possibly benefit medically or otherwise from the information, state whether or not the results of screening, research participation, research tests, etc., will be shared with subjects or their primary care provider. State whether the researcher is obligated or mandated to report results to appropriate military or civilian authorities and explain the potential impact on the subject

If significant new findings develop during the course of this study that may relate to subjects' decision to continue to participate in the study, they will be informed

15.0 Study Monitoring

15.1 Your study requires either Data and Safety Monitoring Plan (DSMP) or a Data and Safety Monitoring Board (DSMB).

- ○ DSMP
- ○ DSMB
- ○ Both
- ◉ Not Applicable

16.0 Reportable Events

16.1 Reportable Events: Consult with the research office at your institution to ensure requirements are met. Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event.

Consult with the research office at your institution to ensure requirements are met

• Describe plans for reporting expected adverse events. Identify what the expected adverse events will be for this study, describe the likelihood (frequency, severity, reversibility, short-term management and any long-term implications of each expected event)

• Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the research protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event

Events will be reported in accordance with 59MDW IRB policies and procedures.

17.0 Equipment/non-FDA Regulated Devices

17.1 Does the study involve the use of any unique non-medical devices/equipment?

○ Yes ◉ No

18.0 FDA-Regulated Products

18.1 Will any drugs, dietary supplements, biologics, or devices be utilized in this study?

- ☐ Drugs
- ☐ Dietary Supplements
- ☐ Biologics
- ☑ Devices
- ☐ N/A

18.3 Device Details:

- ☑ Are device(s) in this research being used in accordance to the approved labeling?
- ☐ Are device(s) in this research being used in a manner other than its approved labeling?

When adding a device indicate in the details section of the device if the use is either used in accordance to the approved labeling or in a manner other than it's approved labeling

View Details	Device Name
⊟	INSPIRSTAR IS02 MICROCURRENT STIMULATOR

Manufacturer/Supplier of Device	INSPIRSTAR, INC.
Where will the Devices Be Stored	Stored in the clinic with all the other supplies.
Will Devices be supplied at no Cost	Yes
Is this a HUD (HDE)	No
HDE Number	
Who holds the IDE	N/A
IDE details	The device is lawfully marketed in the U.S. The device has been published in the federal register under 510k# K060368. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K060368

18.4 Reporting Requirements for FDA-regulated research under IND and IDE:

Describe the process for complying with FDA regulatory requirements for adverse event reporting and adverse device effects reporting to the sponsor

N/A

18.5 Sponsor (organization/institution/company):

☑ N/A

If applicable, provide sponsor contact information:

19.0 Research Registration Requirements

19.1 ClinicalTrials.gov Registration:

- ○ Registration is not required
- ◉ Registration pending
- ○ Registration complete

19.2 Defense Technical Information Center Registration (Optional):

- ◉ Registration is not required
- ○ Registration pending
- ○ Registration complete

20.0 References and Glossary

20.1 References:

1. Benjamin, D., van de Water, A., & Peiris, C. (2014). Effects of exercise on diastasis of the rectus abdominis muscle in the antenatal and postnatal periods: a systematic review. Physiotherapy, 1-8.
2. Chiarello, C., McAuley, J., & Hartigan, E. (2016). Immediate Effect of Active Abdominal Contraction on Inter-recti Distance. Journal of Orthopedics Sports Physical Therapy, 177-183.
3. Fernandes da Mota, P., Pascoal, A., Cartia, A., & Bo, K. (2015). Prevalence and risk factors of diastasis recti abdominis from late pregnancy to 6 months postpartum, and relationship with lumbo-pelvic pain. Manual Therapy, 200-205.
4. Keshwani, N., Mathur, S., & McLean, L. (2015). Validity of Inter-rectus Distance Measurement in Postpartum Women Using Extended Field-of-View Ultrasound Imaging Techniques. Journal of Orthpedic Sports Physical Therapy, 808-813.
5. Keshwani, N., Mathur, S., & McLean, L. (2018). Relationship Between Interrectus Distance and Symptom Severity in Women With Diastasis Recti Abdominis in the Early Postpartum Period. Journal of Physical Therapy, 182-190.
6. Liaw, L., Hsu, M., Liao, C., & Hsu, A. (2011). The relationships between inter-recti distance measured by ultrasound imaging and abdominal muscle function in postpartum women: a 6-month follow-up study. Journal of Orthopedic Sports Physical Therapy, 435-443.
7. Sancho, M., Pascoal, A., Mota, P., & Bo, K. (2015). Abdominal exercises affect inter-rectus distance in postpartum women: a two-dimensional ultrasound study. Physiotherapy, 286-291.

8. Goossen, S., Demitry, P. (2018) Frequencies for Physical Therapy.

9. Faul F, Erdfelder E, Lang A-G, Buchner A. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior Research Methods. 2007; 39 (2): 175-191.

10. Liaw LJ, Hsu MJ, Liao CF, Liu MF, Hsu AT. The Relationships Between Inter-recti Distance Measured by Ultrasound Imaging and Abdominal Muscle Function in Postpartum Women: A 6-Month Follow-up Study. J of Ortho & Sports Phy Ther. 2011; 41(6):435-443.

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12. R Core Team (2014). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL Caution-http://www.R- < Caution-http://www.R- > project. org/ < Caution-http://project.org/ > .

20.2 Abbreviations and Acronyms:

-diastasis rectus abdominus (DRA), inter-rectus distance (IRA), centimeter (CM), body mass index (BMI)