Cover Page

# Positional Release Therapy and Therapeutic Massage Reduce Muscle Trigger and Tender Points

NCT #: Not yet assigned

Todays date: 1/14/2021

Study protocol and statistical analysis plan

# Consent to be a Research Subject

**Introduction**

This research study is being conducted by Amber Hancock Bethers, BS ATC, a graduate student in the Exercise Science (ExSc) department at Brigham Young University (BYU). She will be assisted by David Draper PhD, ATC, Wayne Johnson PT PhD, Brent Feland PT, PhD (all of whom are in the Exercise Science Department at BYU), and Dennis Eggett, PhD in the Statistical Department at BYU.

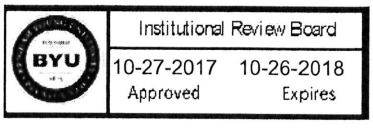
The purpose of this study is to determine if positional release therapy (a treatment for muscle pain used in physical therapy and athletic training that positions the body in a comfortable and supported position which allows the painful muscle to relax ) or massage is more effective at decreasing muscle pain and tightness. You were invited to participate because you are 18+ years of age, experience upper trapezius pain and tightness, and can also lie on your stomach for 30 minutes.

**Procedures**

If you agree to participate in this research study you will report to the Human Performance Research Center in room 292 of the Smith Fieldhouse on your assigned day and time. A female researcher will be available to help female participants. In the event of an injury to your trapezius, such as a strain or bruise, you will be dropped from the study and directed toward further treatment. Any absence from study sessions will also result in your being dropped from the study. **You will be asked to participate in 2 sessions in one week. Total time commitment is about 1.5 hours.**

During your first session, the following will occur:

- You will complete the consent process and fill out the pre-participation questionnaire.
- You will have your height and weight measured in a private area.
- You may wear whatever you'd like to the study. You will remove your shirt and be covered by a towel in order to access the treatment area but also maintain modesty.
- You will lay on your stomach on the treatment table as both trapezii are examined for tightness and tenderness. You will report to the researcher which one is more painful. The area will be marked with a sharpie.
- You will fill out a visual analog scale, marking what point on the line represents your current pain.
- Using an ultrasound machine in the elastography mode (a program that measures muscle tightness/stiffness), your muscle will be imaged and tightness measured. Ultrasound gel or a gel pad placed on your skin will be used to improve the image quality. You will be asked to relax while the measurements are being taken.
- A pressure algometer (device that measures pressure) will be pressed against your skin over the area of muscle tightness and you will report when pain is present. We will measure the pressure amount at the moment of pain and record it.
- After measurements are taken, you will receive a predetermined treatment (positional release therapy or therapeutic massage). It is important that you stay relaxed during the approximate 6-minute treatment.



- After treatment is administered, you will do the same measurements mentioned above.
- You will be encouraged to increase your water intake to minimize any potential soreness from the treatment
- You will reschedule a time to come back 48 hours later.
- You will provide your cell phone number so that reminders can be sent to you for the following session.
- You will be given a voucher of $5 to redeem at the Exercise Science office in the SFH.
- You will spend approximately 60 min in this session.

During your second session, the following will occur:

- You will undergo the same measurements as before.
- You will fill out an activity log to record how many hours you exercised between sessions.
- You will be given a voucher of $20 to redeem at the Exercise Science office in the SFH.
- You will spend approximately 30 min in this session.

**Risks/Discomforts**

- You may experience slight soreness or more pain after the massage or positional release treatment. We will minimize this by ensuring your treatment is applied by an ATC and your symptoms will be monitored. If your pain is getting worse, you will be referred to a doctor or PT at your own cost.
- You may be at an unlikely risk of an allergic reaction to the ultrasound gel. We will respond to this rare event by wiping off the gel, withdraw you from the study, and, if necessary, assist you in finding medical help.
- You may experience discomfort during the pain pressure threshold test, due to its nature.
- You may not want to know or are sensitive to your body weight, especially if you are female, and especially if you are experiencing the female athlete triad (issues with body weight/appearance, eating disorder, and over exercising). Your weight will be taken by a female athletic trainer in a private area and your information will not be associated with your name in any way, just a subject number. If you experience stress about your weight, you will be referred to the appropriate counseling and medical care as needed.

**Benefits**

You may experience direct benefits from the study. Both treatments in the study are used clinically to treat musculoskeletal conditions; therefore you may experience relief of pain and improved function.

**Compensation**

Your compensation will be prorated. This means that you will receive a piece of the total compensation at each session of the study. At the end of the first session you will receive a voucher to redeem at the Exercise Science office in the SFH of $5. At your second session you will receive one for $20.

**Confidentiality**

All forms and data will be stored in the modalities lab in a locked filing cabinet during the study and then will be locked in Dr. Draper's office in a filing cabinet for three years, after which hard copies of data will be destroyed. Cell phone information will be locked in the modalities lab and then destroyed after research is complete. Data will be coded to a study subject number and saved in a spreadsheet for statistical analysis. Images from the ultrasound portion of the study will be stored under the research subject study number and transferred to an external hard drive and/or password protected server. Once all data is collected, it will be statistically analyzed, used in the researcher's thesis presentation and eventually published in a scientific journal.

**Participation**

Participation in this research study is voluntary. You have the right to withdraw at any time or refuse to participate entirely without jeopardy to your class status, grade, or status in campus organizations.

**Questions about the Research**

If you have questions regarding this study, you may contact Amber at 801-710-5883 or prtstudy4trap@gmail.com or Dr. Draper at david_draper@byu.edu for further information.

**Questions about Your Rights as Research Participants**

If you have questions regarding your rights as a research participant contact IRB Administrator at (801) 422-1461; A-285 ASB, Brigham Young University, Provo, UT 84602; irb@byu.edu.

**Statement of Consent**

I have read, understood, and received a copy of the above consent and desire of my own free will to participate in this study.

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Research Subject's Name (please print)

_____ _____

Research Subject's Signature Date