

**PROTOCOL TITLE:** *Effects of a Metronome on Functional Outcomes in Aquatic Therapy*

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**1.0 BACKGROUND INFORMATION AND RATIONALE**

○ Introduction

Physical therapy patients experiencing musculoskeletal pain often lack effort and consistency when performing aquatic exercises. Studies have shown that the use of acoustic stimuli, such as music and the beeps of a metronome, improve performance and efficiency in runners. However, it has not been determined if the use of a metronome can improve the outcomes of patients participating in aquatic physical therapy.

○ Relevant Literature and Data

In 2012, one of two adults in the United States were diagnosed with musculoskeletal conditions. In the same year, 25.5 million people lost an average of 11.4 days of work due to back and neck pain. (1)

The benefits of aquatic therapy make it well suited for the treatment of musculoskeletal conditions. These benefits include decreased weight bearing, the thermal and compressive effects of water on the body, and less cardiovascular stress during exercise. (2)

In a 2008 study it was demonstrated that the use of acoustic pacing device can improve consistency and performance during and between exercise sessions in an aquatic environment among runners(3) Studies have also shown that an aquatic exercise program can improve strength and function among varied age groups.(4,5) However, what isn't known is if the use of an acoustic pacing device, such as a metronome, can improve the outcomes of patients in an aquatic therapy program.

**STUDY OBJECTIVES**

○ Primary Objective

To determine if the use of a metronome improves measures of functional outcome in aquatic therapy.

**2.0 INVESTIGATION PLAN**

○ General Schema of Study Design

Quasi-experimental

- Study Duration, Enrollment and Number of Sites
  - 2.○ .1 Date Range of Study  
(January 3, 2019 - December 1st, 2019)
  - 2.○ .2 Total Number of Study Sites  
*Aultman Tusc Therapy*
  - 2.○ .3 Total Number of Subjects Projected 120  
The statistician projected the study would require 102 participants. I will recruit up to 120 to allow for unforeseen issues. The 120 participants will be divided into a control group of approximately 60 and the metronome group of approximately 60.
- Study Population
  - 2.○ .1 Inclusion/Exclusion Criteria  
All patients over the age of 18 will be included in the study except for those that have identified themselves as being pregnant on intake, and those that are unable to hear the metronome or unable to hear it when their hearing aide is removed during treatment.

## **STUDY PROCEDURES**

### ○ Procedures Involved

During their initial evaluations and again at re-evaluation or discharge, patients will be assessed using a 30 second sit to stand. The patient will be asked to rate their progress using the global rating of change scale at re-evaluation or discharge. The patients will be asked to rate their pain using a numerical pain scale. Their reported pain level will be recorded before and after each treatment. The number reported on initial evaluation and at discharge will be used in the study. The above numbers will be recorded in the patient's electronic chart and on the de-identified flow sheet. All patients will be educated on proper performance of aquatic exercises following normal physical therapy procedures. The patients will be randomly placed into two groups: a control group and a group exercising with the pacing of a metronome. (The metronome does not appear in the FDA's product classification database as a medical device.) The patient's will be randomized by placing 20 poker chips in a bag. There will be 10 white pieces with the letter C and 10 red pieces with the letter M. When a patient is chosen for the study a piece of paper will be drawn out of the bag and they will be assigned to a group by the letter chosen. The bag will be refilled and the process repeated until the study groups are filled.

The two groups will follow exercise protocols based on their diagnosis. Each session will last approximately 30 to 45 minutes. The length of each treatment will be recorded on the flow sheet. The BORG scale (a valid, subjective measure of perceived exertion) will be used as a monitoring device to ensure that a desired level of exercise intensity is reached. The desired level is a score between 12 and 16. The patients will be asked to rate their level of exertion at the end of each session. Intensity of the exercises will be adjusted the next session if the patient's reported level of exertion does not fall within the desired range. The pain rating, noted above, and the BORG number will be recorded for both groups in the chart and flow

sheet as will be the metronome beats per minute for the study group. The beats per minute of the metronome will be adjusted to the patient's pain free exertion level. Patients in both groups will start with 10-20 repetitions of the exercises depending on their physical ability. The repetitions will be progressed as the patient's strength and endurance improve and noted in the chart and the flow sheet.

The patients in the metronome group will have the metronome synchronized as previously noted on their second aquatic therapy treatment. The beats per minute (BPM) will be increased on the metronome during the series of treatments until the patient can no longer maintain proper technique with the exercises. The patient will be cued to keep pace with the beat of the metronome during the duration of the exercise.

- Visit Schedule  
Each individual will participate in the study for the duration of their physical therapy plan of care, typically 10 to 12 visits. Enrollment will be on going during the study period in order to recruit the needed number of participants. Estimated completion date will be May 1st, 2019.
- Recruitment Procedures  
Participants will be recruited during their initial physical therapy evaluations. The study will be explained to them and the consent forms will be signed during their first aquatic therapy treatment.
- Data Collection and Management
  - 2.○ .1 Data sources  
Participant's initial evaluation will be used to determine age, gender and diagnosis.
  - 2.○ .2 Data Elements to be Abstracted
    - *Numerical pain scale rating*
    - *30 second sit to stand*
    - *BORG (perceived rating of exertion)*
    - *Global Rating of Change (GRoC)*

### **3.0 STUDY ADMINISTRATION**

- Data Quality. Data collection in the pool will be limited to two Physical Therapist Assistants. There will be 1- 4 Physical Therapist collecting data during the initial evaluation and re-evaluation depending on which PT is referring the patient for aquatic therapy.

#### Privacy and Confidentiality

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- All laws ensuring privacy and confidentiality governed through HIPPA will continue to be practiced.
- Data with patient identifiers will be de-identified by me.
- All files will be stored in a secured and locked location at Aultman Tusc Therapy.

- Confidentiality  
See above
- Regulatory and Ethical Considerations
  - 3.○ .1 Risk Assessment  
The participants in the study will face no additional risk than those not in the study. As normal physical therapy procedures will be followed for patients receiving aquatic therapy.
  - 3.○ .2 Potential Benefits of Study Participation  
Anticipated benefits of participation in the study will be a decrease in the number of visits needed to improve strength and function.
  - 3.○ .3 Informed Consent/Assent and HIPAA Authorization  
Informed consent will be obtained by the primary/secondary investigators during the patient's first aquatic therapy treatment. No data will be collected until that point.
    - 3.○ .3.1 Waiver or Alteration of Consent (requesting a waiver)  
  
N/A
    - 3.○ .3.2 Waiver of HIPAA Authorization  
N/A

#### **4.0 SAFETY MANAGEMENT**

- Adverse Events Collection/Reporting  
Non-invasive use of a metronome
- Data Safety Monitoring Plan  
Physical therapy guidelines are already in place to ensure data safety of the patient participating in physical therapy treatment.

#### **5.0 STATISTICAL CONSIDERATIONS**

- Primary and Secondary Endpoints  
To determine if the use of a metronome increases intensity of exercise performance as measured by an increase in the BORG scale.  
To determine if the use of a metronome improves self-reported and objective measures of functional outcome performance by using the GROC and the 30 second sit to stand and noting an improvement in scores.
- Measures to Avoid Bias

Study participants will be randomized as previously noted.

#### Statistical Methods, Sample Size and Power

A minimum of 102 participants will be needed for a medium effect, a power of 0.8 and a level of significance of 0.05. The data analysis plan will be an Analysis of Covariance (ANCOVA), with the baseline data as the covariate.

### **6.0 PUBLICATION**

Yes

### **7.0 REFERENCES**

1. Bone and Joint Initiative USA 2016. The Impact of Musculoskeletal Disorders on Americans - Opportunities for Action.  
<http://www.Boneandjointburden.org/docs/BMUSExecutiveSummary2016.pdf>
2. Becker BE, Aquatic therapy: Scientific Foundations and Clinical Rehabilitation Applications. PM R. 2009 Sept; 1(9): 859-72
3. Colado JC, Tella V, Triplett NT, A Method for Monitoring Intensity During Aquatic Exercises. J Strength Cond Res. 2008 Nov;22(6):2045-9
4. Kieffer HS, Lehman MA, Veacock D, Korkuch L, The Effects of a Short-Term Aquatic Exercise Program on Functional Strength and Performance of Older Adults. Int J Exerc Sci 2012, Oct 15; 5(4): 321-333, Ecollection 2012
5. Poyhonen T, Sipila S, Keskinen K, Hautala A, Savolainen J, Malkia E, Effects of Aquatic Resistance Training on Neuromuscular Performance in Healthy Women. Med Sci Sport Exerc 2002 Dec; 34(12) 2103-9