Cover Page Study Protocol

Date: 4/28/2022

All the information contained in this document including the Study Protocol and Statistical Analysis Plan are directly related to the study entitled:

Effects of Physical Therapy on Isometric Neck Retraction Strength and Pain in Patients with Neck Disability

NCT04334655

The primary researcher Frank Tudini changed positions from Campbell University to The University of Tennessee at Chattanooga in August 2020. Campbell University provided oversight of this project until August 14th, 2020 and after August 14th 2020 the study was covered under the IRB of The University of Tennessee at Chattanooga (IRB # 20-082). Other than changing the name on the top of the consent form from Campbell University to The University of Tennessee at Chattanooga, no other changes were made to the methods or procedures.

Study Protocol

Four physical therapists (PT) from four different outpatient clinics will collect demographic, anthropomorphic, and isometric neck retraction strength data with an Hand Held Dynamometer (HHD) in patients with primary complaints of neck pain at the time of the initial evaluation, regular follow-ups, and at discharge. The PT will also include a shortlist of the primary interventions used during the course of treatment. A short video explaining how to test isometric neck retraction strength will be provided to each clinic and the description can also be found in the investigator's previous article entitled "Reliability and validity of measurements of cervical retraction strength obtained with a hand-held dynamometer." Basically, the patient will lay on their back with the HHD under the external occipital protuberance. The patient will then perform a practice isometric contraction at 50% maximum force followed by two maximum effort trials with 1-minute in-between.

A follow-up phone call will be made to each clinic to assure that the units arrived and to answer any additional questions regarding the procedure or data to be collected. Follow up phone calls will then be performed monthly to assess progress. At the end of three months, a preliminary analysis, based on the total number of documented patients will be made. A power analysis indicates that 40 patients will be sufficient to answer our research question. This is based on a 2007 article by Cagnie, B. in the Archives of Physical Medicine Rehabilitation entitled "Differences in isometric neck muscle strength between healthy controls and women with chronic neck pain: the use of a reliable measurement." To account for drop-outs the investigators raised this to an n=60.

Data will be collected over a secure Qualtrics server to which each participating PT will have an individual access code. No identifiable patient information will be given to the investigators. Data analysis will include Pearson or Spearman correlation coefficients to examine the relationship between isometric neck strength with patient-reported outcome measures including the Numeric Pain Rating Scale (NPRS) and Neck Disability Index (NDI). Repeat Measure ANOVA will be used to compare the variables including strength over different time frames throughout the episode of care. An intention to treat analysis will be used for patients who do not complete the study or their Physical Therapy (PT) care.

Data will be collected on 60 consecutive patients with neck pain. Inclusion criteria include patients over the age of 18 years that are receiving physical therapy with

primary complaints of neck pain. Exclusion criteria include individuals with a history of cervical neck surgery as well as those with neurologic diseases or Chronic Obstructive Pulmonary Disease (COPD).

Day 1: Patient with a primary complaint of neck pain is seen in one of the four physical therapy clinics participating in the study. The patient is recruited by the PT in the clinic. The study will be explained to the patient and written consent obtained and filed in the clinic. A copy of the consent will also be given to the participant.

The PT conducts their initial evaluation and treatment as they normally would with the addition of a test for isometric neck strength. Measuring neck strength is a normal procedure for a PT to perform and is well within the scope of practice for physical therapists. Many clinics do not have hand-held dynamometers (HHD) so we will be providing the dynamometers and mailing them to each clinic. The MicroFET2 hand-held dynamometer is FDA approved (Regulation number: 21 CFR 888.1240) and will be used only in the manner for which it was attended, i.e. to measure isometric strength. The hand-held dynamometer is placed in a cradle behind the patient's head in supine. Instructions are given to retract the chin and head into the dynamometer three times. 1 practice trial at 50% and 2 maximum effort trials with 1 minute between attempts. This is outlined in the investigator's 2019 study (Reliability and validity of measurements of cervical retraction strength obtained with a hand-held dynamometer. Journal of Manual and Manipulative Therapy. 2019;27(4): 222-228.) The entire procedure will take approximately 5 minutes. This information is recorded along with anthropomorphic data, pain levels, neck disability index, and treatment performed. All information is coded and sent to the primary researchers over a secure Qualtrics connection.

4. The patient will receive regular Physical Therapy care. The neck strength, pain, and neck disability index are recorded at re-assessments (usually monthly) and at discharge. The use of this assessment will in no way impact the quality or quantity of PT received by the patient

Statistical Analysis Plan (SAP)

The primary measure of interest in this study is neck retraction force. The average of 2 trials will be used in all strength analysis. Secondary measures such as the Numerical Pain Rating Scale and the Neck Disability Index will be used to characterize the neck pain. Paired t-tests and standardized response mean will be used to describe the responsiveness of neck retraction forces in patients receiving therapy for neck pain. Convergent validity will be examined by calculating spearman correlations between baseline neck retraction force, numerical pain rating scale scores, and neck disability index scores (expressed as percentages).