
Examining the effects of a posterolateral mobilization with movement compared to a posterolateral self-mobilization with movement and dynamic stretching on hip internal rotation limitations: A randomized control trial

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Study Title: Examining the effects of a posterolateral mobilization with movement compared to a posterolateral self-mobilization with movement and dynamic stretching on hip internal rotation limitations: A randomized control trial

Principal Investigator Name: Cathy Arnot

Faculty Mentor Name (if applicable): Cathy Arnot

- 1) *If there is a written grant proposal, dissertation, or thesis, or your professor has provided you with a template, you are not required to use this template. However, this template should be used as a reference so that you are aware of the issues that should be addressed.*
- 2) *Texts in italics are instructions, which should be deleted. Modify as appropriate to your study.*
- 3) *Once protocol is complete, save it as a Word document. Go back to the IRB application and upload the protocol.*

A. SPECIFIC AIMS

List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

The goal of this study is to compare the efficacy of three clinical interventions intended to treat hip dysfunctions such as hip osteoarthritis. Physical therapists utilize mobilization with movement clinically to increase range of motion that has been limited by hip pathology. This study will compare mobilization with movement administered by a physical therapist, self-administered mobilization with movement, in which patients are instructed in the maneuver and then perform it at home, and dynamic stretching as instructed by a physical therapist. Efficacy will be judged through changes in hip internal rotation range of motion, a motion which is typically limited in patients with hip pathology.

Our objectives are to quantify the effects of two different modalities of hip mobilization with movement and dynamic stretching in terms of hip internal rotation increases, and to inform current physical therapy practice by filling gaps in the literature surrounding the therapeutic effects of hip mobilization with movement. This study is intended to better equip physical therapists to select the most appropriate evidence-based interventions, thereby increasing the quality of patient care.

B. BACKGROUND AND SIGNIFICANCE

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. If the aims of the study are achieved, state how scientific knowledge or clinical practice will be advanced.

Minimal evidence exists comparing the therapeutic effects of variations of mobilization with movement on the hip, but the evidence that does exist shows promising results, with participants gaining increases in functional range of motion from the interventions. There is a significant amount of research regarding mobilization with movement at joints throughout the body, but little that specifically examines internal rotation at the hip. Studies exist that evaluate and compare physical therapist-directed mobilization with movement and self-administered mobilization with movement, with only a single study comparing these two interventions specifically for hip internal rotation, and none which include a dynamic stretching

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control group. Stretching is a commonly used physical therapy intervention for range of motion limitations and provides an appropriate foundation and context with which to compare mobilization with movement interventions.

This study will improve physical therapy practice by addressing the nonexistent literature comparing the effects of physical therapist-administered mobilization with movement, self-administered mobilization with movement, and dynamic stretching. Achieving this study's goals and objectives will provide physical therapists with greater evidence to select the most effective treatment interventions to administer to patients, making physical therapy more conducive to functional range of motion gains for the patient.

C. PRELIMINARY STUDIES

Provide an account of the principal investigator's preliminary studies pertinent to this protocol and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project.

PUBLICATIONS

Dunning JR, Cleland JA, Waldrop MA, Arnot CF, Young I, Turner M, Sigurdsson G. Upper Cervical and Upper Thoracic Thrust Manipulation Versus Nonthrust Mobilization in Patients With Mechanical Neck Pain: A Multicenter Randomized Clinical Trial. *Journal of Orthopedics and Sports Physical Therapy*. 2012; 42: 5-18.

Beattie PF, Arnot CF, Donley JW, Noda H, Bailey L. The Immediate Reduction in Low Back Pain Intensity Following Lumbar Joint Mobilization and Prone Press-Ups is Associated with Increased Diffusion of Water in the L5-S1 Intervertebral Disc. *Journal of Orthopedics and Sports Physical Therapy*. 2010;40:256-264.

Beattie PF, Donley J, Arnot C, Miller R The Immediate Change in the Diffusion of Water in Lumbar Intervertebral Discs Following a Single Session of Lumbar Joint Mobilization Compared to a Single Session of Prone Lying. *Journal of Orthopedics and Sports Physical Therapy*. January 26, 2009.

CERTIFICATION-CREDENTIALING

2005 – present Fellow, AAOMPT, FAAOMPT, Am Academy Ortho Manual PT

2003 Manual Therapy Certification, MTC, University of St. Augustine, Written, Oral, Practical Cert.

2001 – present Orthopedic Clinical Specialist, OCS APTA Board Certified Specialist

PROFESSIONAL EXPERIENCE

2006- present Clinical Assistant Professor University of South Carolina, Columbia, SC Clinical Assistant Professor. Teaching doctoral physical therapy students, including: spinal and extremity mobilization/manipulation, range of motion assessment, manual muscle testing, gait training, postural assessment, emergency procedures, practice management, documentation and ethics.

2002-2003 Doctoral Fellow SportsMedicine of Atlanta, Snellville, GA Fellowship in Manual Therapy under the mentorship of Dr. Robert DuVall, PT, DHSc, OCS, MTC, PCC, FAAOMPT. Specializing in the manual therapy techniques of Stanley Paris. Supervising Duke University and Washington University PT students

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D. RESEARCH DESIGN AND METHODS AND DATA ANALYSIS

Describe the research design and the procedures to be used to accomplish the specific aims of the project, including the following:

Location: University of South Carolina, Blatt Physical Education Building, 1st floor

Surveys/Instruments, Devices, or Other Measures: Baseline bubble inclinometer to measure each participant's hip internal rotation will be used throughout the data collection. A Mulligan mobilization belt will also be used for two of the treatment groups in order to apply the mobilization at the hip required for the mobilization with movement technique.

Groups will be randomized using a random number generator with a proposed number of approximately 15-20 participants in each of the three groups. Participants will also be grouped by level of severity of the limitation in ROM, ranging from severe limitations to mild limitations. The mild limitation group will have from 25-30 degrees of IR at the hip, moderate will be 20-24 degrees, and severe will be <20 degrees. To ensure that participants are evenly spread out between the three treatment groups in regards to the severity of their limitation, they will roll a die which will determine in which of the three treatment groups they will be placed in. Only the therapist will know how the participants are grouped based on the die roll to make sure the researchers are blinded to the groups.

Data Analysis: Statistical analysis will be performed using SPSS with a Repeated Measures Analysis of Variance (ANOVA) in order to determine significance between the three groups while also using time as an outcome pre-and-post-test. Significance will be set at $p < .05$ which establishes a 95% confidence interval. A one-way ANOVA will be performed first to determine whether the groups are different at baseline, followed by a repeated measure ANOVA with a within factor and a between group factor. This will reveal the main effects of time, group, and a time by group interaction. ANOVA tests are used to determine whether there are significant measures between two or more groups and allows for comparison of multiple sample means to assess whether there is a significant difference between groups and within the same group from pre and post intervention. F values will be calculated using SPSS software to assess for any significant differences. Post-Hoc testing will be conducted if a significant F value is found in order to determine where the differences exist using three Paired t-tests, one for each group.

E. PROTECTION OF HUMAN SUBJECTS

1. TARGET POPULATION:

Participants will be recruited through in person interview from the University of South Carolina Doctor of Physical Therapy program graduate students and Wingate Doctor of Physical Therapy program. The targeted population is college-aged individuals. Inclusion criteria will be that participants must have less than 30 degrees of hip internal rotation (HIR) in at least one hip. Previous studies have suggested that HIR of less than 30 degrees has been correlated with an increase in injuries to the lower back and lower extremities.^{21,22} Exclusion criteria will include any traumatic injury within the last six months, any known skeletal deformities limiting activity such as femoro-acetabular impingement or fractures, surgeries within the last 6 months, positive findings in the Flexion, Adduction, Internal Rotation (FADDIR) or Flexion, Abduction, External Rotation (FABER) tests for hip impingement pathology depicted in figures 3 and 4 below, and any presence of OA, rheumatoid arthritis, or neurological

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conditions which could negatively impact findings. Anticipated sample size is between 45-60 participants.

2. RECRUITMENT PLANS:

Participants will be recruited through in-person interview and conversation during the Fall Seminar class for DPT students. The study will be described through verbal presentation and a sign-up sheet will be passed around for interested participants where they will be asked to provide their name and email address for further communication pertaining to the study in terms of location and scheduled dates. Only interested participants that fill out the sign-up sheet will be contacted regarding participation in the study.

3. EXISTING DATA/SAMPLES:

If the investigator plans to utilize data or samples that are in existence (the investigator will not be recruiting/consenting subjects), describe where the data/samples are housed, how the investigator will gain access to the data/samples, whether the data/samples contain any direct identifiers (e.g., names, address, telephone numbers) or are coded and who will have access to the key to the code (i.e., will the USC investigator have access to key), whether the investigator will sign any data use agreement, and how data will be recorded by USC investigator.

4. CONSENT/ASSENT:

All participants will have to sign an informed consent form in order to participate in the study which outlines the expected timeline of the study, the requirements of participation, and the option to opt out of the study at any time if someone chooses to do so. The informed consent form has been uploaded onto the eIRB at this time for review.

5. POTENTIAL RISKS:

There are minimal risks that can occur during the study as we are only performing a mobilization with movement at the hip joint using external measures such as a Mulligan mobilization belt. The only side effects that can occur from performing the technique is increased range of motion at the hip or possible discomfort from increased range of motion at the hip. If any participants experiences any pain or discomfort during the interventions provided, the technique will be stopped and will be re-assessed before continuing with that specific participant to limit any source of discomfort.

6. POTENTIAL BENEFITS:

The potential benefits for participants is increased range of motion at the hip, specifically for hip internal rotation. The benefit to others includes the potential that clinicians may be able to assign a self-mobilization with movement for patients at home if it proves to be just as effective as the therapist-performed-mobilization with movement. This would allow clinicians to focus on other interventions while patients are in the clinic and hopefully have better long-term outcomes.

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7. CONFIDENTIALITY

The data will be confidential and all recorded data will be stored on a password protected computer within a locked office with the only access to the office being through the lead investigator's keys. No names of participants will be used as each participant will be assigned a numerical value to correspond with their data in order to maintain participant confidentiality.

8. COMPENSATION:

There will be no compensation provided to participants.

9. WITHDRAWAL:

Each participant will be required to sign an informed consent form and will be allowed to opt out of future data collection or to be a part of the study at any time without any negative consequences to the participant as they will not be receiving any compensation for participation.

F. REFERENCES/LITERATURE CITATIONS

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G. APPENDIX

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Mulligan mobilization belt:



Baseline Instruments Bubble Inclinometer: