Informed Consent for Participation in Proposed Research Study

Name of Participant: _____

Title of Protocol: Clinical Relationship between a Hypertonic Psoas Muscle & Hamstring Flexibility

Protocol Number: 2

Principle Investigator:

Anita K. Davidson PT, DPT, CAFS
CREAT
Creative Research Education and Training
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Introduction

You are being asked to participate in a research study. Before you decide whether to participate, it is important that you know certain things related to the study. These will be explained by a member of the research team and written in this form. This process is called "informed consent". If you desire any further explanations or information, please ask and it will be provided to you to the best of our ability.

Important Information about This Research Study

What is the purpose of this research study? To determine the relationship between muscle tone and flexibility.

How long will I be expected to participate? 5-10 minutes during your initial physical therapy evaluation as part of the normal evaluation process at Creative Rehab.

What is going to happen? You will be asked to complete a brief survey related to your general health and medical history. During your initial evaluation with your physical therapist your flexibility will be tested. As part of the study, when you are lying on your back, the therapist will lift your leg from the heel to see how far your leg will stretch comfortably just to the point of tightness, not pain. The angle of your hip will be measured by a second staff member and your leg will be lowered to the table. The therapist will then press on your stomach to the side of your belly button to locate your hip flexor muscle to determine at what depth the muscle is present. This depth will be measured and recorded. While the therapist maintains pressure on your hip flexor, the leg is raised a second time to the point of a stretch, not pain and a measurement is taken. The angle of your hip will again be measured and recorded.

What parts are "experimental" and what does that mean? Although the entire research project is considered the experiment, the parts that are sometimes called "experimental are the procedure or things that are being evaluated or tested to see what happens". In this research project, the "experimental" parts of the study include the measurement of the hamstring stretch with and without pressure on the hip flexor muscle.

What are the potential risks or discomforts? The leg raise with you knee straight may be uncomfortable at the end, but the therapist will only lift to the point of tightness/tension not pain. In addition, pressure on the hip flexor muscle is often tender or painful during the pressure but does not continue to be painful after the pressure is relieved. You will be informed about any significant new information that may be important to you concerning your decision whether or not to continue participating in this research. ***Please inform the evaluators if you have abdominal mesh. Presence of abdominal mesh used for a hernia repair surgery will eliminate you from the study.***

Are there any benefits to participating in this research study? By participating in this study, you will be assisting the research and documentation of patterns related to tight hamstrings and tight hip flexors. Your participation will assist the staff at Creative Rehab to document our observations related to this issue. Following completion of this study, our goal is to publish our findings to assist other physical therapists in providing treatment related to tight hamstrings.

What alternative procedures are there? Performance of hamstring stretches for hamstring tightness is the standard of care and is an alternative to this study. As described in detail later in this form, participation in this research is voluntary, which means you do not have to participate at all.

How will records be kept confidential and private? The records related to this study will be maintained following the laws and ethics for medical document storage. The documentation will be secured in a private location and locked when not in use for the purposes of the study. Information related to study participants and personal information will not be shared, published or distributed following HIPAA requirements. The measurements will be included in your medical record as part of your evaluation for physical therapy.

What happens if an injury occurs? While a study related injury is highly unlikely, if an injury occurs, CREAT, Creative Research Education and Training a subsidiary of Creative Rehab assumes liability for appropriate medical care and follow-up management.

In the event of a research-related injury, please contact: Anita Davidson PT, 847-599-9171 immediately.

Is there any money involved for participants, whether received in or paid out? Participant's data collection will be completed as a normal part of the physical therapy evaluation at Creative Rehab. There is no money involved in the study. If the study exceeds the time allowed for the initial evaluation, your insurance will not be billed for the additional time.

Who will answer questions that may arise in the future? If you have any question, concerns, or complaints about the research, please contact Anita Davidson PT at Creative Rehab 847-599-9171.

Is this voluntary or mandatory? Participation is voluntary. You do not have to participate. If you decide not to participate, there is no penalty and you will not lose any benefits that you already have. Even if you now decide you want to participate but later change your mind, you may discontinue your participation at any time without any penalty or loss of benefits to which you are otherwise entitled. Sometimes even when you want to participate, the Principal Investigator may decide not to allow you to participate or decide to stop your participation in the future. This might happen when you have a recent injury or illness that might make you at risk for an injury during testing.

Certification of Informed Consent and Authorization

By signing this form, you are stating that you have read this document and understand it. In addition, by signing this form, you are stating that you voluntarily desire to participate in this research study. You do not have to volunteer or give this permission.

_____ _____

Printed Name of Participant | Signature of Participant

_____

Date Signed

[For Use by Research Team]

I have explained the information contained in this form and answered questions to the best of my ability to the participant. I have given a copy of this form to the participant.

_____ _____

Printed Name and Title of Member of Research Team Soliciting Content | Signature

_____

Date Signed

Adapted from Rosalind Franklin University of Medicine and Science Informed Consent Document