

Study Participants Needed for a Research Study

Ultrasound Assessment of the Thoracolumbar Fascia in Individuals with and without Low Back Pain, and Treatment Response with OMT or Hydrodissection (IRB# 2023-154)

This research attempts to better understand how the thoracolumbar fascia (a soft-tissue covering over the top of your muscles) in your low back may be a cause of low back pain. The goal is to develop reliable image analysis approaches to distinguish individuals with or without acute or chronic low back pain. Secondly, we hope to assess the preliminary beneficial effect of either Osteopathic Manipulative Therapy (OMT – a form of hands-on manual therapy) or hydrodissection (an injection of fluid used to gently “powerwash” restricted soft-tissue) of the thoracolumbar fascia as a novel and simple treatment for chronic low back pain.

All Individuals who meet inclusion and agree to participate will undergo an initial history, physical exam and ultrasound imaging assessment, with an estimated time of 120 minutes. Chronic low back pain individuals (pain greater than 3 months) with certain ultrasound findings may go on to 3 treatment sessions (30 minutes each) and 5 post-treatment re-evaluation sessions lasting approximately 120 minutes each.

To participate in this study: We are looking for individuals between the ages of 18 and 50, including:

- 50 individuals without low back pain
- 50 individuals with acute low back pain (less than 3 months)
- 100 individuals with chronic low back pain (greater than 3 months)

Exclusions to the study include anyone that cannot lie on their stomach for 30 minutes at a time; have a BMI over 30; history of lower thoracic or lumbar spinal surgery within the past year; any older spinal surgical procedure involving *more than* a single level of hardware in these regions (prior multilevel microdiscectomy, laminectomy, or fusion); corticosteroid injections into the low back or oral corticosteroid medication within the last 3 months; physical therapy or spinal manipulation in the last 90 days; current or remote (within the past 6 months) pregnancy or breastfeeding.

For the duration of the study, participants must be able to cease taking blood thinners other than aspirin (your PCP or specialist must approve this) or muscle relaxants; forgo other physical treatments anywhere to their body, including injections (acupuncture, trigger points, soft-tissue, spinal), corticosteroid medication, spinal manipulation, or any other bodywork treatment.

Study location: All study encounters will occur at:
VCOM Sports and Osteopathic Medicine (VSOM)
1691 Innovation Dr., Suite 2100, Blacksburg VA, 24060

Benefits of participation: While there are no assurances of direct benefits, some participants may see improvement in pain relief, range of motion, and general body function if in a treatment group. Participants will be helping the advancement of new diagnostic and treatment approaches for low back pain, especially for military personnel as these treatments are transferable to the battlefield.

Funding: this study is funded by the United States Department of Defense (DoD) and the American Osteopathic Association (AOA). Some compensation will be provided to participants at study completion.

Contact Information:

If you are interested in participating, or would like more information, please contact

Albert J Kozar, DO Office: **540-232-8405** Email: **akozar@vcom.edu**
Nicole Fremarek, DO Office: **540-232-8405** Email: **nfremarek@vcom.edu**

*This research is being conducted under the direction of **Albert J Kozar DO** and **Gunnar Brolinson DO**, at the Edward Via College of Osteopathic Medicine, in collaboration with **Vincent Wang, PhD**, Biomedical Engineering Virginia Tech Polytechnic University. This flyer has been reviewed and approved by the VCOM Institutional Review Board (**VCOM IRB #2023-154**). Approved 10/24/2023*