



Research Study:

Augmentation of Immune Response to COVID-19 mRNA Vaccination Through Osteopathic Manipulative Treatment Including Lymphatic Pump



FIRST TIME COVID-19 VACCINE PATIENTS NEEDED

If you or someone you know is planning to receive your first COVID-19 vaccine, we invite you to participate in our research study. Please contact us if you are:

- Between the ages of 18 and 65 years
- No previous Covid-19 Vaccination



Participants in this study will be compensated for their time in the form of \$200 in gift cards (Target or Amazon)

If you are interested in participating, please e-mail us at:

covid-omtstudy@westernu.edu

Western University IRB Protocol #: FB21/IRB/026

Invitation to Participate:

You are invited to participate in a study using osteopathic manipulative treatment (OMT) looking to improve immune (antibody) response to COVID-19 vaccination. This study is being conducted by Jesus Sanchez, D.O. who is a Professor of Neuromuscular Medicine/Osteopathic Manipulative Medicine (NMM/OMM) and Family Medicine at Western University of Health Sciences. COVID-19 has had a devastating impact on so many people around the world. The introduction of vaccines has given us some much needed support in combating the virus. With large numbers of people having received the COVID-19 vaccine and many more taking it in the near future, this is an opportune time to explore methods that may make the vaccine even more effective. Studies have shown that OMT used in conjunction with vaccines against other diseases -- pneumonia and hepatitis B -- significantly increases patients' immune response. It is our hope that if you are eligible you will decide to participate in this study to see if we can improve the immune response provided by the COVID-19 vaccine with the use of OMT. If you are a student at WesternU, participation and whether or not you complete the study will have no impact on your academic progression or standing.

[SEE IF YOU QUALIFY FOR THE STUDY HERE](#)

If you qualify at the above link and you would like to schedule an appointment to come in to begin the study please provide your name and the best way to contact you [HERE](#)

What is the purpose of this study?

The purpose of this study is to determine if Osteopathic Manipulative Medicine lymphatic techniques will increase the antibody production in response to the COVID-19 vaccine.

What is involved with participation in this study?

If you qualify and decide to participate in the study:

- Each participant will randomly be assigned to either the control group or the osteopathic manipulative treatment (OMT) intervention group.

The following data will be collected at the start of the study:

- All participants will be asked to fill out a medical screening form that should take no longer than one minute to fill out.
- All participants will also undergo a blood draw before they receive their vaccination.

Throughout the course of the study the following data will be collected:

- All participants will be asked about any reactions they have to the vaccine or to the OMT.
- All participants will also be asked to tell us of any medications they may use during the clinical trial and for what reason.
- Blood draws will be tested for antibody levels in each participant's blood.

Participants in the OMT intervention group will received an additional 4 rounds of OMT including: Myofascial release of the thoracic inlet, pectoral traction, diaphragm release MFR, splenic pump, and thoracic pump.

The following appointments will be required:

INTERVENTION GROUP

Day 0	<ul style="list-style-type: none">• Medical screening• Informed consent• Baseline blood draw• First vaccination• First OMT session
Day 1	<ul style="list-style-type: none">• Second OMT session
Day 7	<ul style="list-style-type: none">• Blood draw
Day 21	<ul style="list-style-type: none">• Blood draw• Second vaccination• Third OMT session
Day 22	<ul style="list-style-type: none">• Fourth OMT session
Day 28	<ul style="list-style-type: none">• Blood draw
Day 35	<ul style="list-style-type: none">• Blood draw
Day 90	<ul style="list-style-type: none">• Blood draw
Day 182	<ul style="list-style-type: none">• Blood draw
Day 365	<ul style="list-style-type: none">• Blood draw

CONTROL GROUP

Day 0	<ul style="list-style-type: none">• Medical screening• Informed consent• Baseline blood draw• First vaccination
Day 7	<ul style="list-style-type: none">• Blood draw
Day 21	<ul style="list-style-type: none">• Blood draw• Second vaccination
Day 28	<ul style="list-style-type: none">• Blood draw
Day 35	<ul style="list-style-type: none">• Blood draw
Day 90	<ul style="list-style-type: none">• Blood draw
Day 182	<ul style="list-style-type: none">• Blood draw
Day 365	<ul style="list-style-type: none">• Blood draw

What is OMT?

- OMT, as defined by the American Osteopathic Association (AOA), is a set of hands-on techniques used by osteopathic physicians (DOs) to diagnose, treat, and prevent illness or injury. Using OMT, a DO moves a patient's muscles and joints using techniques that include stretching, gentle pressure, and resistance.

Who is eligible to participate?

- Must be between the ages of 18-65 years old.
- Must have not received any COVID-19 vaccines previously.
- Must receive the COVID-19 vaccine at Western University of Health Sciences.
- Must sign an informed consent form.
- Must not be currently pregnant or breastfeeding.
- Must not have any contraindications for the vaccine or any allergic reactions to vaccines.
- Must be willing to comply with the study protocol and will maintain follow-up appointments.
- Must not have any primary or secondary immune deficiency or immune mediated disorders.
- Must not be using any immune altering medications, must not have received anti-coagulation therapy, and must not have been previously treated for COVID-19 with serum transfer or other immunological treatments.
- Must not have had OMT or other physical manipulations such as acupuncture, physical therapy, chiropractic treatment, or massage therapy in the previous four weeks before enrollment.
- Must be able to receive OMT with lymphatic techniques and must not have open wounds, fractures, anuresis, necrotizing fasciitis, congestive heart failure, or unstable cardiac conditions.
- Must have not had spleen surgery or a surgery associated with cancer in the past 6 months.

What are some possible potential risks?

There is no more than minimal risk of injury due to the safety of the OMT procedure and blood draws. It is normal to feel mildly sore for 24 hours after osteopathic intervention, similar to a healthy workout session. There is also a potential to have a small bruise at the site of the blood draw.

What are some possible benefits?

There are no known direct benefits to study participants, but their participation may help to improve understanding of the effects of OMT with lymphatic pump on COVID-19 vaccine antibody

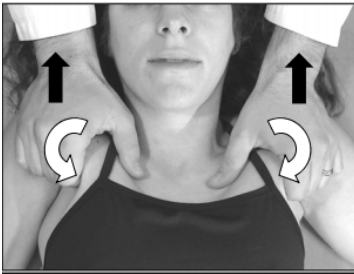
Compensation:

Will be provided in the form of gift cards. Participants will be able to choose between Amazon or Target gift cards. A \$25 gift card will be given to you on each blood draw day. You can choose between the Amazon or Target options on the day you come in. You will be given a total of \$200 in gift cards for your participation in the study.

OMT TECHNIQUES



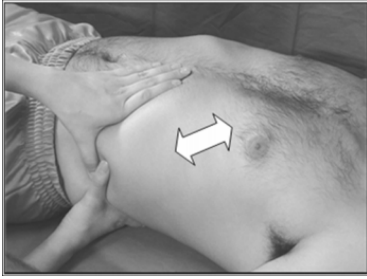
- A. **Myofascial release of the thoracic inlet:** The doctor will place their hands on and around the shoulders and neck of the research participant. While contacting this area of the body, the doctor will apply gentle pressure and move the tissue in different directions with a gentle motion to treat the tissue of the area. The doctor will maintain the pressure with motion for 1 minute or until a change in the tissue has occurred that indicates the treatment was successful such as increased warmth, increased tissue motion and increased softening of the tissue. The research participant may be asked to breathe in and out as part of the treatment.



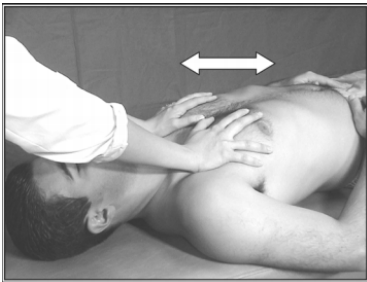
- B. **Pectoral traction:** The doctor will place their hands on the research participant in the area of the armpit. The doctor will contact the area of the armpit on each side of the participant with their finger pads. The doctor will curl their fingers gently grasping each side and apply a slow pulling force towards the shoulders. The doctor will maintain the pulling force for 1 minute or until a change in the tissue has occurred that indicates the treatment was successful such as increased warmth, increased tissue motion and increased softening of the tissue. The research participant may be asked to breathe in and out as part of the treatment.



- C. **Diaphragm release with MFR:** The doctor will place their hands on the research participant over the area just below the ribs on each side. The doctor will apply gentle pressure and move the tissue from side to side to treat the tissue of that area. The operator will stand at the side of the supine patient, facing cephalad. The hands are placed along the anterolateral costal cage with the thumbs just under the anterior costal margin. The doctor will maintain the pressure with motion for 1 minute or until a change in the tissue has occurred that indicates the treatment was successful such as increased warmth, increased tissue motion and increased softening of the tissue. The research participant may be asked to breathe in and out as part of the treatment.



D. **Splenic pump:** The doctor will place their hands on the research participant over the area just below the ribs on the left hand-side (with one on the front and one on the back). The doctor will apply pressure and release pressure several times to create a vibration over the area just below the ribs. The vibratory motion will be performed for 1 minute or until a change in the tissue has occurred that indicates the treatment was successful such as increased warmth, increased tissue motion and increased softening of the tissue. The research participant may be asked to breathe in and out as part of the treatment.



E. **Thoracic pump:** The doctor will place their hands over the chest wall of the of the research participants (female participants will cover their own chest wall with their own hands first and then the doctor will place their hands over the participants hands) on each side. The doctor will apply pressure and release pressure several times to generate a pumping action of about 100 times in one minute. The patient will be asked to breathe in and out during the pumping action of the treatment and will end with a sudden releases of the compression when the patient breathes in at the end of the treatment. The entire thoracic pump treatment will last for 1 minute.