

**Psychoneuroimmunology as a framework for studying the effects of chiropractic care in a population with high central adiposity: a feasibility trial**

**NCT06208163**

**Informed Consent Form April 07, 2025**

## Informed Consent

Title: Psychoneuroimmunology as a framework for studying the effects of chiropractic care in a population with high central adiposity: a feasibility trial

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### Introduction

You are invited to take part in a research study, and it is entirely up to you to decide if you would like to participate. This study is not designed to benefit you. Although you could receive some benefit from the chiropractic adjustments, there is no guarantee of improvement following care. If you do not wish to take part in this study, the alternative is to not participate.

### Purpose

Overall, we hope to gain information about cognitive functioning, the autonomic nervous system, and self-reported mental, physical, and emotional health in people who have excess weight around the abdomen.

### Key Information

Up to 20 people will be invited to take part in this study.

The estimated time commitment for this study is approximately **~10.5 hours** over the course of approximately **6 weeks**.

You are invited to take part in this research study because:

- You are 18-65 years old.
- You have a body mass index (BMI)  $\geq 30$ .
- Your waist circumference is  $\geq 35$  inches (for women) or  $\geq 40$  inches (for men).

You are not eligible to participate if:

- You have received chiropractic care in the past 30 days.
- You are taking short-acting benzodiazepines which include midazolam & triazolam.
- You have changed your medications in the past 6 weeks or you intend to change your medications during the study.
- You are unable to walk unassisted on a treadmill (e.g., you need to hold onto the rails).
- You have been diagnosed with any condition that causes fainting during postural changes (e.g., POTS, orthostatic hypotension).
- You have a hearing problem.
- You have a pacemaker or heart condition
- You have been diagnosed with certain psychiatric disorders including substance abuse or bipolar disorder that are uncontrolled or untreated.
- You have been diagnosed with rheumatoid arthritis, osteoporosis, or neck instability.
- You are pregnant.
- You have experienced a whiplash injury in the past 3 months
- You are currently involved in litigation related to a physical, health-related injury.
- You have any oral injuries, inflammation, or disease that causes your gums or mouth to bleed easily.

You will be asked to do the following:

- Restrict certain behaviors prior to your lab visits:

- **3 hours prior** abstain from caffeine, brushing your teeth, alcohol-based mouthwash, nicotine, food, & drinking large amounts of liquid very quickly (e.g., chugging a 16 oz bottle of water; sipping water is ok)
- **24 hours prior** abstain from strenuous exercise, alcohol, & over the counter drugs (e.g., antihistamines, Tylenol, etc.)
- Have your height, weight, and waist circumference measured.
- Drool into a tube so that we can test your saliva. From your saliva we can test your immune function.
- Have sensors placed on or around your chest & back to measure your breathing & heart function while lying on your back and while standing upright. Depending on the amount of hair you have, this may require you shave your chest and/or back.
- Have your cognitive function assessed while seated and while walking on a treadmill.
- Answer questions about your mental, physical, and emotional health.
- Receive 6-weeks of chiropractic adjustments which may involve X-rays.

The risks of being in this study may include:

- You may feel discomfort with certain lifestyle restrictions.
- You may feel uncomfortable having your height, weight, & waist size measured.
- You may have an allergic reaction to the alcohol wipe or electrode adhesive.
- You may experience some lightheadedness when moving from lying to standing.
- You may fall from the treadmill.
- You may experience some soreness and/or tenderness following the chiropractic adjustment. You also may experience some light-headedness or dizziness after an adjustment to the upper part of your neck.
- You may receive a small amount of radiation exposure from X-rays.

### **Prior to the 1<sup>st</sup> lab visit**

You should have received a video instructing you on how to prepare for your appointment and text messages ~24 hrs and ~3 hrs prior to your appointment to remind you about how to prepare including lifestyle restrictions (e.g., not eating 3 hrs prior to your visit, no wire bras).

### **Lab visits**

This study requires a total of 3 visits to the Marietta Lab (today, after 2 weeks of chiropractic care, & after 6 weeks of chiropractic care). Each visit will be approximately **2 hours**.

On your first lab visit you will be asked to sign this informed consent form. You will have your height, weight, and waist circumference measured to ensure that you qualify for the study. If you do not qualify for any reason, you will receive a **\$10 gas card** and be thanked for your time. This screening process should take about **5 minutes**.



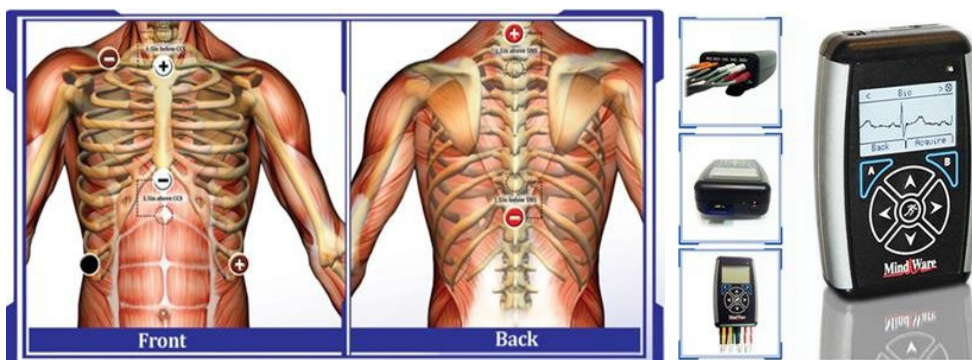
We will ensure that we have complete information about you and your health history, and a member of our research team will also ask you questions about your recent behaviors and how you are feeling. If you mistakenly violate any of the lifestyle restrictions described above, or are overly tired, please let us know as we may need to reschedule your appointment.

You will have your height, weight, and blood pressure taken at all 3 lab appointments. Your saliva will also be collected at all 3 lab appointments. You will be asked to rinse with water to ensure that there are no food particles in your mouth. The researcher will hand you a small tube, ask you to allow saliva to pool in mouth, tilt your head forward, and gently drool into the tube without blowing or spitting. You will then be offered a small snack.



At each lab visit, 7 sensors will then be attached to various locations on your chest and back to track your heart activity (see image below). The skin of each area will be prepared using an alcohol wipe. Each sensor contains a small amount of conductive gel. These sensors will be connected to a device attached to your waist band (see image below) that will record your heart and breathing activity. During the test, a safe, low-voltage, high-amplitude current is passed through your chest. The amount of current is so small that you will not be able to feel it.

Note: if you have a lot of hair on your chest or back, our team may request that you shave where the sensors will be placed. If this is the case, you will be provided with a disposable razor and shaving gel and asked to go to the restroom to shave. If there are any areas that you are unable to reach, someone from the research team will be available to assist you.



You will also be asked to raise your arms while a respiration belt is wrapped around your chest and fit snugly. This belt tracks your breathing rate. Although the belt must be snug, the belt can be loosened if you feel it is too tight.



For the posture challenge, you will be asked to lie on your back on a soft table for about 8 min. After an 8 min period, you will be asked to quickly stand up and remain standing for 3 min. After 3 min of standing, you will be asked to quickly lie back down for another 3 min. This challenge will be performed at all 3 lab appointments.



To determine your preferred walking speed (PWS), you will be fitted with a pair of slip resistant socks. You will then be asked to step onto a non-moving treadmill. You will go through a few cycles of gradually speeding up and slowing down the treadmill to find your PWS. You will then be asked to walk on the treadmill at your PWS for up to 5 minutes. This task will only be performed on your 1<sup>st</sup> lab visit.

You will then undergo a cognitive test. The cognitive task is an auditory task requiring you to wear headphones and pay attention to a series of numbers and letters. Initially, the task will be explained to you by our research team. Next, you will sit at a desk, put on headphones, and perform a few practice tests. You will move to the treadmill where you will perform a few more practice tests while walking on the treadmill at your PWS. You will then have a 90 second break. After this you will step back onto the treadmill and perform the cognitive test at your PWS. Upon completion of the cognitive testing, you will exit the treadmill and all equipment (headphones, sensors, socks, etc.) will be removed. This cognitive task will be performed at all 3 lab visits.



You will then be given a digital tablet and will be asked to complete a series of 4 surveys about your physical, mental, and emotional health. These surveys will be given at all 3 lab visits. If you are uncomfortable answering a particular question on a survey, please let us know. We will stop that survey and help you start the next survey.

### **Chiropractic care**

Once you have completed your 1st lab appointment, you will be provided with the information for a participating chiropractor in your area. Your chiropractor is licensed in the state of Georgia and has been trained to work with you in this research study. You will visit the chiropractor for 6 weeks. The chiropractor will provide chiropractic adjustments to your spine. A brief description of the chiropractic care is described below.

At your first chiropractic appointment, you will answer some questions about your health. You will also have a physical exam with your chiropractor. The chiropractor may ask you to perform certain motions to test your ranges of motion. The chiropractor will touch your back and neck to check how well your back and neck are moving. Your chiropractor may also ask that you have X-rays taken. You will not have to pay for these X-rays. The exam should take no longer than **20-30 minutes** to complete. If the chiropractor has concerns about your ability to participate in the study, they will be granted the authority to exclude you from the study. This could include the presence of red flags during your exam, in which case you will be referred for appropriate medical care. In these cases, data collected prior to exclusion may still be used.

Based on the findings of your exam, the chiropractor will determine how frequently you should visit the chiropractic clinic. Although the frequency can vary, it is typically anywhere from 1-3 times per week. During these appointments your chiropractor will assess regions of your spine. If you receive chiropractic care, the chiropractor may touch and apply pressure to your spine. You may also have your spine moved or be asked to move your spine. The chiropractor may also apply a quick thrust by hand or use an instrument to adjust your spine. Each time you visit the chiropractor, it may take up to **15 minutes** for your care.

Upon the study's completion, you will be asked to complete a short survey about how acceptable you found the testing procedures and care you received. These surveys should take about **5 minutes**.

### **Future Research**

Researchers will remove information that may identify you and may use your data for future research. If we do this, we will not ask for any additional consent from you.

### **Risks**

There is the possibility that participation in this study may cause the following:

#### **Lifestyle restrictions**

You may find certain lifestyle restrictions (e.g., not eating for 3 hours) uncomfortable. If you are not able to abide by these rules, you may discontinue the study.

#### **Body measurements**

You may find it uncomfortable to have your height, weight, or waist circumference measured. If you are extremely uncomfortable with having these measurements taken, you are welcome to discontinue the study.

#### **Sensors**

You may have an allergic reaction to the alcohol swab or sensor adhesive. If irritation occurs, the electrode will be removed, and your skin will be washed with clean water. The sensors pose no risk of electric shock.

#### **Postural challenge**

There is a small risk of becoming lightheaded when going from lying to standing very quickly. An investigator will always be standing next to you to ensure your safety. If you feel lightheaded or distressed, you will be asked to stop the test and sit down and you will be excluded from the study.

#### **Treadmill**

It is possible that you could be injured by falling from the treadmill. Considering that most people regularly negotiate stairs, curbs, and objects on the ground, it is unlikely that such an injury is any more likely than what is possible during the normal course of your day. To ensure your safety, a researcher will always be standing next to the treadmill. If you feel unsteady, the treadmill can be shut off by you or the investigator. A treadmill safety clip will be clipped to your shirt or pants that automatically shuts off the treadmill in the event of a fall. The investigator administering the test will be trained in CPR. In case of emergency, emergency personnel will be summoned with a 911 call.

#### **Chiropractic adjustments**

The risks associated with chiropractic adjustments are low. Participants may feel sore or tender following their adjustment which should dissipate in a day or two. You may experience some light-headedness or dizziness after an adjustment to the upper part of your neck. This experience is rare. There have been reported cases of fracture, strokes, and nerve and disc injury from chiropractic care; however, serious side effects are extremely rare. The eligibility criteria & chiropractic exam serve to minimize the risks of adverse reactions to chiropractic adjustments.

#### **X-rays**

If you require x-rays, there is some radiation exposure. The total amount of x-ray radiation is less than that of a transcontinental air flight.

If you are injured during this study, we will help you find appropriate treatment. We will contact emergency services if necessary, however, Life University has not set aside funds to pay for this care or to compensate you if something should occur.

#### **Benefits**

Although you could receive some benefit from chiropractic care, there is no guarantee of improvement. Overall, we hope to assess the feasibility of our processes and protocols to inform a future study looking at the effects of chiropractic care on people with excess weight around their abdomen.

#### **Alternatives**

The alternative to taking part in this study is to not participate.

#### **Compensation**

Chiropractic care will be provided at no cost. In addition, participants will be given a \$50 gift card at their 1st and 2nd assessments and a \$75 gift card at their 3rd assessment. Additionally, you will receive a \$10 gas card at each of these assessments to compensate for travel expenses.

#### **Voluntary Participation and Withdrawal**

You do not have to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may stop participating at any time. You may refuse to take part in the study or stop at any time, this will not cause you to lose any benefits to which you are otherwise entitled. In cases of voluntary withdrawal, data collected up to that point of withdrawal may still be used.

#### **Confidentiality**

We will keep your records private to the extent allowed by law. The following people and entities will have access to the information you provide:

- Researchers and clinicians directly involved with this trial

- Life University Institutional Review Board (IRB)
- Officials in administrative compliance for Life University

Your data collected at the lab will not be associated with your name, only with a participant number. The information you provide will be stored in a secure file room within the CCR lab. CCR will store information on password protected computers. The information in the computers will only use your participant number. Any survey instruments that include your name are protected and HIPAA compliant. The code sheet with your name and study number will be locked in a secure file room. When we present or publish the results of this study, we will not use your name or other information that may identify you.

This study involves the collection of saliva. The collected saliva will be sent to an outside lab to test your immune system function. The saliva samples sent to the lab will NOT have any personal identifying information and will be destroyed 30 days after the samples are tested.

Some private health information will need to be shared between your clinician's office and the CCR. We will ask for your authorization for this information to be shared. Your authorization is provided by signing a form. We will go through this form with you. If you do not provide your authorization, you may not participate in this study.

#### **ClinicalTrials.gov**

A description of this clinical trial will be available on ClinicalTrials.gov. This Web site will not include information that can identify you. You can search this Web site at any time.

#### **Contact Information**

Contact Dr. Tyson Perez at 770.426.2632 or at tyson.perez@life.edu

- If you have questions about the study or your part in it
- If you have questions, concerns, or complaints about the study
- If you think you have been harmed by the study

Contact the Chair of the Life University Institutional Research Board, Dr. Brent Russell at 770-426-2641 or IRB@life.edu

- if you have questions about your rights as a research participant
- if you have questions, concerns, or complaints about the research

#### **Consent**

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this research, please sign below.

\_\_\_\_\_  
Printed Name of Participant

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Principal Investigator or Researcher Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date