

**Perceptions and experiences following a single session of simulated or genuine high velocity, low amplitude (HVLA) manual chiropractic adjustments**

**NCT06153290**

**Informed Consent Form June 12, 2024**

## Informed Consent

Title: Perceptions and experiences following a single session of simulated or genuine high velocity, low amplitude (HVLA) manual chiropractic adjustments

Principal Investigator: Tyson Perez, DC, PhD

Faculty Sponsor if student or outside researcher (if none leave blank):

Co-Investigator(s): Stephanie Sullivan, DC, PhD; Margaret Sliwka, DC; Ron Hosek, DC, PhD; Daekiara Smith-Ireland, MPH

Sponsor (if none leave blank):

### **Introduction**

You are invited to take part in a research study, & 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 your session, there is no guarantee of improvements. If you do not wish to take part in this study, the alternative is to not participate.

### **Purpose**

We are investigating the perceptions and experiences of people following a single session of either simulated or genuine manual chiropractic adjustments.

### **Key Information**

30 people will be invited to take part in this study.

The estimated time commitment for this study is approximately **~60 min** over the course of approximately **1 lab session & a brief online survey**.

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

- 18–60 years of age
- No history of stroke or transient ischemic attacks (TIAs) or current symptoms including:
  - Dizziness or vertigo
  - Ringing in the ears
  - Visual, sensory, or muscle problems
- No new headache complaints
- No recent whiplash injury (within 12 months)
- No fractures or dislocations in your spine
- No spinal problems with symptoms that travel to your arms or legs.
- No severe arthritis in the spine
- No connective tissue disorders.
- No primary fibromyalgia
- No metabolic or metaplastic bone disease
- No history of spine surgery
- No uncontrolled high blood pressure or blood vessel disease
- Not currently using medication that prevents your blood from clotting.
- Not a DC (Doctor of Chiropractic) or a DC student in 5th quarter or above
- Not currently pregnant

You will be asked to do the following:

- Answer questions about your health history and undergo a brief physical exam.
- Have your height & weight measured.
- Be randomly assigned to receive 1 session of either simulated or genuine manual chiropractic adjustments. You will be informed via email which group you were in within 30 days of the study's completion.
- Answer questions about your perceptions and experiences surrounding your session.

The risks of being in this study may include:

- You may experience soreness and/or tenderness following your chiropractic adjustments. Also, you may experience some light-headedness or dizziness after an adjustment to the upper part of your neck.

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

If you decide to take part in this study, you should have been emailed...

- 1) a link to a form asking questions about you and your health history which should take about **10 min** to complete

Reminder text messages will also be sent to you at ~24 hrs and ~3 hrs prior to your appointment.

### **Informed consent and basic information**

On your first visit to the CCR lab in Marietta (1429 Lucille St., Bldg 900, Ste 910, Marietta, GA 30067), you will be asked to sign this informed consent form & we will also ensure that we have complete information about you and your health history. You will also have your height and weight measured. This process may take up to **10 minutes**.

### **Chiropractic Exam**

On your first visit, our chiropractor (Dr. Maggie) will perform a history and brief physical exam to ensure you are a good candidate for our study. The physical exam is non-invasive and will include feeling for the motion of your spine while you are sitting and lying on your stomach. This helps the doctor to feel movement, potential swelling or inflammation, and the amount of muscle tension in and around the joints of your spine. You will also be asked to lift one leg at a time while lying on your stomach, which helps to determine movement in the pelvis. Certain non-invasive orthopedic and/or neurologic tests may also be conducted to rule out any risks from treatment. If during the history & physical exam Dr. Maggie feels X-rays are needed, she finds any red flags against treatment with chiropractic care, or she doesn't find any areas of your spine that need chiropractic adjustments, you will be excluded from study participation. If this occurs, you will also receive a \$25 gift card and a \$10 gas card to compensate for travel and may be referred to an appropriate medical provider. This history & exam will take **20-30 minutes**.

### **Single Session**

You will attend 1 session with a licensed chiropractor where you receive either simulated or genuine HVLA manual chiropractic adjustments. This will take about **10 minutes**.

### **Post-session survey**

After your session, you will be asked to complete a short survey about your perceptions and experiences surrounding the intervention you received. You will also be emailed this survey 48 hours later and asked to complete it online. This online survey should take about **2 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**

The risks associated with chiropractic adjustments are low. You may feel soreness or tenderness after your adjustment. For most people, that dissipates 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. If at any point in the data collection session you feel you cannot continue, you may choose to pause the session or stop participation. 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 history/exam serve to minimize the risks of adverse reactions to chiropractic adjustments.

### **Benefits**

Although you could receive some benefit from your session, there is no guarantee of improvement. Overall, we hope to assess your perceptions and experiences surrounding the intervention you received.

### **Alternatives**

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

### **Compensation**

If you qualify for the study, your session with the chiropractor will be provided at no cost. At the completion of your visit, you will receive a \$25 gift card of your choice (e.g., Amazon, Publix, etc.) & a \$10 gas card. You will also receive a \$5 Starbucks gift card when you complete the online survey that is emailed to you 48 hours after your visit.

### **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. You may stop participating at any time. Doing so will not cause you to lose any benefits to which you are otherwise entitled.

### **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 directly involved with this trial.
- Life U Institutional Review Board
- Officials in Life University's Center for Excellence in Teaching & Learning

Your data 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.

### **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

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
Date

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