

INFORMATION SHEET for VERDICT (Veterans Response to Dosage in Chiropractic Therapy): A Pragmatic Randomized Trial Addressing Dose Effects for Chronic Low Back Pain

Please consider participating in this research study funded by the National Institutes of Health, National Center for Complementary and Integrative Health, and the Office of Research on Women's Health. It is led by researchers at Palmer College of Chiropractic and Duke University. Approximately 766 Veterans will participate in this study across 4 VA Health Care Systems located in Iowa, Connecticut, Minnesota, and California.

Your involvement in the study will last about 1 year. Your participation includes:

- Completing two eligibility visits (baseline and a chiropractic exam)
- Attending the assigned number of chiropractic visits during the first 10 weeks with possible monthly visits for the remaining 42 weeks of the study
- Completing online questionnaires at baseline, after visit 1, and weeks 5, 10, 26, 40, and 52
- Responding to weekly text messages for 52 weeks
- Allowing the researchers to collect information about you
- Participating in an optional telephone interview about your experience in the study

Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you are otherwise entitled. You also may receive alternate treatments for your back pain. These may include medical care, physical therapy, or other treatments.

WHY IS THIS STUDY BEING DONE?

By joining this study, we hope to learn how Veterans with low back pain respond to chiropractic care with different numbers of visits (also called 'doses' or 'dosages'). The care you receive is standard chiropractic care. However, the number of visits you will have is the experimental part of the study. We are inviting you to participate because you are interested in chiropractic treatment for your low back pain.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

The following is a list of what will happen if you participate. Activities may occur in-person or by telephone or video. You will complete online forms about your health and respond to weekly text messages asking about your low back pain. Phase 1 of the study will last 10 weeks. In Phase 1, participants will have either 1 to 5 visits with the chiropractor OR 8 to 12 visits. Phase 2 will last approximately 42 weeks. In Phase 2, participants will either be scheduled for 1 VA chiropractic visit per month OR no scheduled VA chiropractic care. We have asked the chiropractors to avoid acupuncture treatment while you are in this study.

PHASE 1 consists of the following study activities:

Baseline Visit (up to 2 hours): A study team member will explain the study to you in detail, ask you some questions about your health and background information, and verify your eligibility. You will complete

online forms about your health and low back pain. We will also ask if you would like to participate in an optional telephone interview.

First Chiropractic Visit (1 hour): You will have an exam and initial consultation from a licensed VA chiropractor. The chiropractor may conduct a portion or all this visit in person or by telephone or video. The date of your first chiropractic treatment visit will be Day 1 of the study for you. This visit is the last step to decide if you can enroll in the study.

Phase 1 Group Placement: This step lasts up to 15 minutes and occurs after the first chiropractic visit. We will use a computer program to assign you at random (like a coin flip) to a study group for the first 10 weeks of the study. You will find out if you are in the group that receives 1 to 5 chiropractic visits OR the group with 8 to 12 chiropractic visits. Neither you, the study team, nor the chiropractor can choose a group for you. You will work with the chiropractic office staff to schedule your next chiropractic visits.

Phase 1 Chiropractic Visits (usually 30 minutes for up to 10 weeks): You will receive the usual chiropractic care from a licensed VA chiropractor. The number of visits depends on your group placement and the decisions you make about your care with your chiropractor. You will discuss the details of your care with your chiropractor.

PHASE 2 consists of the following study activities:

Phase 2 Group Placement (approximately 15 minutes): This step is completed around week 10 of the study. We will use a computer program to assign you to a new study group at random for the next 42 weeks. You will find out if you are in the group with monthly chiropractic visits OR the group that does not have scheduled chiropractic care. Neither you, the study team, nor the chiropractor can choose a group for you.

- Chiropractic visits group (30 minutes once per month for 42 weeks): You will work with the chiropractic office staff to schedule 1 VA chiropractic visit per month. You will receive care from a licensed VA chiropractor. You will discuss the details of your care with your chiropractor.
- No chiropractic visits group: You will not have scheduled monthly chiropractic care. However, you will continue to complete the online forms and weekly text messages.

Study Data Collection:

Study Data Collection (5 to 8 hours total over the entire 52 weeks of the study): You will complete forms and respond to weekly text messages during the study's 52 weeks. The forms and texts include questions about your health and low back pain. We may ask you to participate in an optional telephone interview around week 10 or week 52.

Online Forms (30 to 60 minutes, 7 times during the study): You will complete forms at baseline, after visit 1 and weeks 5, 10, 26, 40, and 52; the research team will pay you to complete these forms. We will not pay you for completing the short 'after visit 1' form. You can complete the online forms on a computer, tablet, or smartphone. If you cannot complete the online forms, you may complete the same questions over the phone with a research team member. You may skip questions you do not want to answer.

Text Questions (1 to 2 minutes, each week for 52 weeks): You will get a text message each week for 52 weeks with the same 4 questions about your back pain.

Telephone Interview (15 to 30 minutes, either around week 10 or week 52, optional): A computer program will select the people to interview. If selected and you agree, a researcher will interview you over the phone and record your voice using a digital audio-recorder. This interview will ask your thoughts about being in this study, your reasons for joining the research, and changes in your back pain and general health. The researcher also will ask if you had any negative events during the study and what you thought about the chiropractic care you received. You may skip questions you do not want to answer.

VA Electronic Health Care Data (no time commitment): Some research team members will access your VA health record for up to 1 year after you finish the 52-week study. Data required for this study include collecting specific information about your back pain, health, and healthcare received at the VA. This information provides background and code numbers about your medical concerns and treatments. We will enter information about you joining this study into your electronic health record.

Study participants will not receive individual study results. However, a description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, and the website will include a summary of the results.

ARE THERE ANY RISKS OR DISCOMFORTS?

Risks of the usual care you receive in this study are not the risks of the research. Please talk with your chiropractor about the risks of care recommended for you. If any significant new findings develop during this research, which may relate to your willingness to continue participation, researchers will provide it to you.

- **Risks from study data collection procedures**: You may feel tired, uncomfortable, upset, or some other way while answering questions about yourself or your health. You may skip any question you do not want to answer. Text messaging is not secure (anyone with access to your phone can read your texts).
- **Risks from unintended health information disclosure**: Disclosure of your health information to people who are not part of this study could occur. Safeguards are in place to prevent this.

ARE THERE ANY BENEFITS?

We do not know if you will benefit from taking part in this research. However, possible benefits may include a change in your back pain or other symptoms. You may also feel good about joining a research study designed to help us learn how to better care for Veterans in the future.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

The information collected for this study will be kept confidential. Only certain study team members will have access to your information. Any personal data collected on paper will be kept in locked filing cabinets at your local VA while the study is underway. Researchers use a secure web application called REDCap to collect data, and REDCap provides methods to protect your privacy when completing online forms and the data stored there collected from the text messages.

If you participate in an optional telephone interview, we will store the information with a code number, and only study team data personnel will have access to the code. The recording will be uploaded to a secure Microsoft-hosted file repository to be transcribed by a VA-approved service using the study code.

Researchers will remove identifiers from your identifiable private information to be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. We may also store some de-identified data in the NIH HEAL Central Data Repository. Future publications or reports created from the trial data will not have any of your identifiable information.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

We will pay you for completing the online forms in this study. You will receive a **\$25** gift card each time they are fully completed, except after visit 1. Up to a total of **\$150** in gift cards may be provided for online forms completed at baseline and weeks 5, 10, 26, 40, and 52. You will also receive a gift card if you complete these forms over the phone. We will pay you a **\$25** gift card if you are selected and complete the optional telephone interview. Gift cards will be given in person or sent to you through the U.S. mail.

Chiropractic care costs depend on your personal VA benefits package, which may include chiropractic visit co-payments. For phone or video chiropractic visits, the VA does not charge a co-payment. Details of any potential costs you may incur can be discussed during your baseline visit.

Travel compensation: The study team will try to arrange your baseline visit when you are scheduled for another VA clinic visit. During Phase 1 of the study, the VA will reimburse you for mileage at the government rate for travel to in-person chiropractic visits according to your VA travel pay benefits. The standard chiropractic co-pay will apply. During Phase 2, you will not be eligible for travel pay for chiropractic visits, but the VA will not charge you a co-pay.

WHO CAN I TALK TO ABOUT THE STUDY?

Safety measures are in place to ensure your wellbeing. In the event of a research-related injury, the VA will provide necessary medical treatment at no cost to you unless the injury is due to noncompliance with study procedures. If you get hurt or sick resulting from taking part in this study, or if you have any other questions, comments, or concerns about the research, please contact either lead researcher Dr. Cynthia Long at 563-884-5150 or Dr. Christine Goertz at (919) 668-8874. The local contacts are as follows:

Iowa City: Anna Cobb at 563-949-0676

Los Angeles: Melvin Valle at 310-569-5066

West Haven: Kena McDermott at 475-414-1476

Minneapolis: Rebecca Rudquist at 612-806-3776

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll-free at 1-877-254-3130.