WALTER REED NATIONAL MILITARY MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH

Title: Safety and treatment effect of a novel device for neck pain in active-duty military personnel with forward head posture.

Principal Investigator: Michelle J. Nordstrom, MS, OTR/L

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your participation in this study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You are being asked to consent to participate in a voluntary research study. You are being asked to take part in this research study because you are an active-duty service member who has experienced neck pain for at least 3 months. The objective of this study is to evaluate the therapeutic and functional benefits of a novel device, Cervigard Forward Head Posture (FHP) Neck Collar, for the treatment of neck pain. The Cervigard FHP Neck Collar was developed for patients with severe neck pain due to forward head posture.

This study involves up to 4 research-related in-person visits and up to 5 brief, remote, weekly check-ins, over the span of roughly 12 months. The duration of each visit is about 30-60 minutes. At each visit, you will be asked to complete questionnaires regarding your neck pain as well as have X-Ray imaging (baseline, 6 weeks and 12 weeks only) of your neck. Each weekly check-in should take about 5 minutes.

Possible risks/discomforts include: You may experience some physical discomfort while first fitting the neck collar and during the early phases of the intervention as your body adjusts. With all x-ray imaging, there is a small increase in the possibility of developing genetic defects or cancer. Additionally, any time information is collected for a study there is a small chance of breach of confidentiality.

Possible benefits include: You could experience a reduction of symptoms associated with your neck pain.

Your decision will not affect your future care at Walter Reed National Military Medical Center (WRNMMC). If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are an active-duty service member, between the ages of 18-55 (inclusive), with forward head posture (indicated by forward placement of the head relative to the shoulders), and you have experienced neck pain for at least 3 months. The purpose of this research study is to evaluate the therapeutic and functional benefits of the Cervigard FHP Neck Collar device for the treatment of neck pain. This study involves up to 4 research-related in-person visits and up to 5 brief, remote, weekly check-ins over a span of roughly 12 months. Each in-person visit will last roughly 30-60 minutes and the weekly check-ins should take roughly 5 minutes each.

There will be about 50 people taking part in the study at WRNMMC, over a period of 2 years.

At the end of this research study, a summary of collective study results from all participants will be available to the public on http://www.ClinicalTrials.gov.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process." This information may have already been collected as a part of your regular medical care. The researchers will ask both you and your physician questions to ensure you qualify. These include questions regarding your age, current condition, medical history, and medical care eligibility.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

If you agree to participate in this research study, the following research-related activities will take place outside standard of care:

Contact Information:
As soon as possible following consent, you will be asked to complete a questionnaire collecting your contact information. The local study team will use the information you provide on this form to contact you regarding study-related treatment and appointments. This questionnaire will take approximately five (5) minutes to complete.

Demographics and Baseline Data Collection:
Before you begin the study intervention (using the neck collar), you will complete a series of questionnaires. These questionnaires will ask about your demographic characteristics, your military and active-duty status, as well as your current physical pain and ability to manage everyday life. These questionnaires will take approximately 20 minutes to complete. Additionally, you will receive x-rays of your neck. The x-rays will take approximately 30 minutes to complete.

Randomization:
You will be randomly assigned to one of two (2) groups. Randomization is a process like flipping a coin and means you will have a 50/50 chance of being assigned to either of the groups.

You will be randomized into either the immediate study treatment group or the 6-week waitlist group. All participants will follow the same data collection procedures once they are enrolled in the study.

Intervention:
If you are assigned to the immediate group, you will begin using the Cervigard FHP Neck Collar right away. If you are assigned to the 6-week waitlist group, you will receive your Cervigard FHP Neck Collar and begin the 6-week active intervention at the 6-week follow up visit described below.

At your designated start time, you will receive a Cervigard FHP Neck Collar and a qualified study team member will provide you with instructions on how to properly fit and use it. You will be required to wear the Cervigard neck collar for 20 minutes per day for 6 weeks.

Weekly Check-Ins (During 6-week Intervention):
During your 6 weeks regularly using the Cervigard FHP Neck Collar, a therapist or study team member will contact you up to once a week using your preferred method (e.g., telehealth encounter, phone call, etc.) to inquire about any changes in pain levels and function and to address any issues you may be having with the intervention. You will also be asked to complete a brief questionnaire. These activities are expected to take approximately 5 minutes to complete.

6-Week Follow-Up Visit:
Approximately 6 weeks after enrolling in this study, you will be asked to return to the clinic to complete a questionnaire and to have repeat x-rays taken of the curve of your neck and your forward head posture. The questionnaires are expected to take approximately 20 minutes to complete. The x-rays are expected to take approximately 30 minutes. If you were assigned to the 6-week waitlist group, you will also be given your Cervigard FHP Neck Collar, fitted, and provided instructions on use at this time.

12-Week Follow-Up:
Approximately 12 weeks after enrolling in this study, you will be asked to return to the clinic to complete a questionnaire and to have repeat x-rays taken of the curve of your neck and your forward head posture. The questionnaires are expected to take approximately 20 minutes to complete. The x-rays are expected to take approximately 30 minutes.

12-Month Follow-Up
Approximately 12 months after enrolling in this study, you will be asked to complete a questionnaire. This can be done remotely (e.g., via email, over the phone, etc.) or in person based on your preference. This questionnaire will take approximately 20 minutes to complete.

Medical Record Review:
Finally, the study team is requesting that they can access your medical record so that they can track other characteristics about your health throughout your participation in this study. The study team will collect information on relevant health behaviors (e.g., tobacco use), relevant comorbidities (e.g., diabetes, etc.), and relevant medical/treatment history related to your current neck pain. This aspect of the study is completed entirely by the study team and requires no additional effort or time from you.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there are risks associated with the study activities:

- *Breach of Confidentiality:* Any time information is collected for a study there is a small risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

- *Radiation Exposure:* This study uses x-ray imaging to measure characteristics of the cervical spine, such as the angle of the curve of your neck and forward head position. The amount of radiation exposure received from the entire study is approximately 105 mrems (a unit of radiation exposure) to the neck with minimum exposure to other body areas. There is no known minimal level of radiation exposure that is recognized as being totally free of the risk of causing genetic defects (cellular abnormalities) or cancer. However, the risk associated with the amount of radiation exposure received from this study is considered to be extremely low when compared to the everyday risks.
- *Physical Discomfort:* There may be some physical discomfort associated with fitting the neck collar and during the early phases of the treatment, as the collar is designed to induce a normal curve to the cervical spine. ***Temporary physical discomforts while wearing the neck collar may include:***
    - ***Neck muscle tension or stretch discomfort***
    - ***Neck stiffness***
    - ***Mild neck ache***

There may also be other risks of taking part in this study that we do not yet know about.

If you experience any additional pain or discomforts associated with the use of the Cervigard FHP Neck Collar, you will be asked to promptly report these concerns to the Principal Investigator and/or study team member using the contact information provided in this consent form.

6. <u>WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?</u>

We cannot guarantee that you will directly benefit from participating in this research study. However, you may experience a reduction in neck pain and related symptoms, possible earlier return to activities/duty, and decreased use of opioids and other pharmacological agents.

Others may benefit in the future from the information learned during this study. The long-term goals of this study are to evaluate the therapeutic and functional benefits of a novel device for treatment of neck pain in the military health system, as well as help pave the way for future efforts to identify alternative means to manage severe neck pain and limit opioid exposure. Through this research, not only can the findings be used to improve neck pain, but also increase quality of life among service members and force readiness.

7. <u>WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?</u>

There may be other options for treating your neck pain. Alternative treatments and/or procedures that may be available to you to include: physical therapy, injections, and medication.

You do not have to participate in this research study. If you do not join, your medical care will not be affected.

8. <u>IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?</u>

No, you will not receive any financial compensation for participating in this study.

9. <u>ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?</u>

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Principal Investigator: Michelle J. Nordstrom, MS, OTR/L
Walter Reed National Military Medical Center
Occupational Therapy
America Building (Bldg. 19), 1st Floor
8901 Wisconsin Ave
Bethesda, MD 20889
michelle.j.nordstrom.civ@health.mil
218-208-8360

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University (USU), is overseeing this research study. As such, authorized staff from MIRROR and the USU will have access to your coded research data.

The Department of Defense (DoD) Defense Health Agency (DHA) is providing funding for this study. As a sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. SOURCE OF FUNDING:

Research funding is provided from the Department of Defense (DoD) Defense Health Agency (DHA) through the Uniformed Services University (USU).

13. LOCATION OF THE RESEARCH:

Walter Reed National Military Medical Center (WRNMMC) Occupational Therapy (OT), Physical Therapy (PT), Chiropractic, and Physical Medicine & Rehabilitation (PM&R) clinics

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

The local study team does not have any conflict of interests related to financial sponsors.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The research team will keep your research records. These records may be looked at by authorized research staff, staff from the WRNMMC Department of Research Programs (DRP) and Institutional Review Board (IRB), the Department of Defense (DoD) Higher Level Review, and the Food and Drug Administration (FDA) as part of their duties. These duties include making sure that research participants are protected.

Authorized research team members and those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Every effort will be taken to protect your identity as a participant in this study. Procedures to protect the confidentiality of the data in this study include but are not limited to:

Your research data will be identified only by a unique coded study number and not by your name, social security number, DoD ID, or other protected identifier. The unique coded study number cannot be linked to your name except at the clinic where you complete visits.

All paper research records will be stored in a locked cabinet inside of a locked room accessible only by authorized staff. Your coded study data will be entered into Research Electronic Data Capture (REDCap), a secure, access controlled, and password protected electronic data capture and management system housed on a DoD server and maintained by the Uniformed Services University (USU) in Bethesda, MD. Once your coded data is entered in REDCap, it will only be accessible by authorized study team members and oversight officials, the WRNMMC DRP & IRB, authorized staff from USU, and authorized staff from Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at USU, and is serving as the data coordinating center for this study.

The WRNMMC research team will maintain a separate confidential electronic enrollment log which matches the unique coded study numbers with participants' names, date of consent, date of birth, DoD ID number and the last four digits of their social security number (SSN). This enrollment log will be stored separately from all other electronic research data in a secure, password-protected database on a DoD computer and network that requires CAC access.

The WRNMMC research team will also maintain an intake form that collects your preferred contact information. This paper intake form will be kept in a locked cabinet inside of a locked room and stored separately from your coded research records.

By signing this document, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data. So, your name will not appear in any published paper or presentation related to this study.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Your research records may be disclosed outside of the hospital, but in this case, you will be identified only by a unique code number. Your coded research data will be sent to the study team at the Kessler Foundation for assistance with data analysis and publications.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of results. You can search this Web site at any time.

16. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. The data that may be used in future research will be de-identified, meaning that all of your personal identifiers will be removed. This future research may be in the same area as the original study or it may be for a different kind of study.

Any future research using your retained de-identified data will require a research protocol for the proposed study reviewed by an Exempt Determination Official (EDO) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

Your de-identified research data will be securely sent to Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR) and stored at the Uniformed Services University (USU) alongside other de-identified research data. This de-identified research data will be kept indefinitely, or as long as it is practical to maintain, and may be used in future research studies.

The local study team will keep this consent form and your signed HIPAA authorization for six (6) years following study closure. They will keep your coded paper research forms for five (5) years following study closure. The master code list which connects your identity with your unique study code will be destroyed at study closure.

If you consent to participate in this research study, your de-identified data collected as part of this research may be kept for future research studies or given to other researchers for future approved research studies. If you do not want your de-identified data collected as part of this research study to be kept for use in future research studies, you should not sign this consent form.

17. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results, we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. As long as you remain a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

You do not have an option to decline receiving information about an incidental finding.

18. VOLUNTARY PARTICIPATION:

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

19. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. If you leave the study early, we may retain and analyze all coded and/or de-identified data collected up to the time you withdraw if the data is necessary to maintain the integrity of the study. However, no additional data will be collected.

Should you choose to withdraw, you must contact the Principal Investigator in writing via mail or email:

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Bethesda, MD 20889
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218-208-8360

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to or email the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, if you no longer meet eligibility criteria, if you are no longer eligible to receive medical care at a military hospital, if the military mission requires it, or if the study is cancelled.

20. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately at 218-208-8360.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active-duty military, dependent of active-duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

21. CONTACT INFORMATION:

The Principal Investigator or a member of the research staff at Walter Reed National Military Medical Center (WRNMMC) will be available to answer any questions throughout this study:

Michelle J. Nordstrom, MS, OTR/L
Walter Reed National Military Medical Center
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America Building (Bldg. 19), 1st Floor
8901 Wisconsin Ave
Bethesda, MD 20889
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218-208-8360

Human Research Protection Program (HRPP) Office

The WRNMMC Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will also be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator/HRPP Phone: 301-295-8239

Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the WRNMMC IRB Office at:

Walter Reed National Military Medical Center
Department of Research Programs, Building 17B, 3rd Floor, Suite C
4650 Taylor Road
Bethesda, MD 20889
301-295-8239

If at any time you believe you have suffered an injury or illness as a result of participating in this research study, you should contact the Human Protections Administrator (HPA), Department of Research Programs (DRP) at Walter Reed National Military Medical Center (WRNMMC) at 301-295-8239.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____	_____	_____
Signature of Participant	Date	Time

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____	_____	_____
Signature of Administering Individual	Date	Time