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Meets 2018 Common Rule Requirements

LANDSTUHL REGIONAL MEDICAL CENTER

CONSENT TO PARTICIPATE IN RESEARCH

Title: Feasibility and Effectiveness of a Novel Neck Training Device: A Pilot Study
Principal Investigator, Christine Olanrewaju, DO

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

Please take time to carefully review this information. 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 potential participation in this research 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.

KEY INFORMATION:

Voluntary Participation	Your participation is voluntary. You do not have to take part in this research or you can also choose to stop participating at any time.
Purpose	The goal of this study is to test the effectiveness of a neck training device, the TopSpin360, to develop dynamic neck strength among our service members, which may be useful in designing future research studies aimed at decreasing traumatic brain injury and neck pain.
Duration	12 weeks, two sessions per week for a duration of 15 – 30 minutes each and the training the duration of each workout should decrease.
Procedures	As a participant in this study, you will be randomly assigned to one of two study groups. The intervention group participants will use the TopSpin360 helmet device (a standard adjustable Riddell football helmet with an air bladder insert) which has a lever rod with a 125-gm (approximately ¼ lb.) fixed weight that rotates about the central axis. This helmet will be used during your brief 10-minute neck exercise sessions. The control group will perform a physical therapist designed neck strengthening program that consists of a series of isometric and isotonic exercises to develop neck performance characteristics.
Why might you want to participate in this research (benefits)?	You may experience a positive training effect whereby your neck becomes stronger and has greater endurance. This may decrease your risk of neck injury.
Why might you choose	Exercise always carries some risk of injury. This risk typically

not to participate in this research (risks)?	includes muscle soreness. Performance of this exercise may create varying degrees of muscular neck discomfort from fatigue and the buildup of lactic acid while training. There is also always a risk that someone could get access to the personal information or other information researchers have stored about you, although efforts are made to protect your research study records.
What are the alternatives to participating?	The alternative to taking part in this study is to not take part. Your decision will not affect your future care at Landstuhl Regional Medical Center.

Your decision will not affect your future care at Landstuhl Regional Medical Center (LRMC). 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.

1. 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 who meets this research's inclusion criteria. The purpose of this research study is to test and learn about the effectiveness of a neck training device, the TopSpin360, to develop dynamic neck strength among our service members.

The device is the TopSpin360 helmet which has a lever rod with a 125-gm fixed weight that rotates about the central axis. The TopSpin360 helmet is a standard adjustable Riddell football helmet with an air bladder insert that can be inflated to ensure a good fit. The helmet as configured is an exercise equipment. The FDA does not regulate exercise equipment intended only for general physical conditioning and/or for the development of athletic abilities, thus FDA approval is not required.

The duration of participation is 12 weeks with two brief exercise sessions to be completed each week. The total weekly training time to complete the exercise sessions is approximately 15-30 minutes.

There will be about 60 people taking part in the study at Landstuhl Regional Medical Center (LRMC), Martin Army Community Hospital (MACH) and other European region installations, over a period of 12 weeks.

At the end of this research study the clinical results, including research results about you will be shared with you, if requested. The research team will also submit a manuscript for publication, which will present the study finding in an aggregate form.

If you are allocated to the control group, you will be given the opportunity to use the TopSpin360 device upon study conclusion. This device will be available for you to train with for 12-weeks, at which time you will need to return it to the study team.

2. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will be examined by the physical therapist for any gross abnormalities of your neck. This is called the "Screening Process".
WHO IS ELIGIBLE TO TAKE PART IN THIS RESEARCH?

- Active-duty men and women of any rank assigned to LRMC and other European region installations,
- Ages 18-45,
- Own a personal cellphone to download the TopSpin360 App (intervention group),
- Able to attend the two times per week training, and
- Have sufficient time on stations to complete the entire study including post-study measures
- Ability to provide consent

WHO IS INELIGIBLE TO TAKE PART IN THIS RESEARCH?

- Have any medical profile that prevents full participation in the Army Combat Fitness Test,
- Have any chronic inner ear abnormalities or
- History of invasive neck procedures or
- Any gross cervical abnormalities when examined by the staff physical therapist

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

You will be asked to do a few things. At the initial meeting, the Research Coordinator will discuss study procedures and the inclusion and exclusion criteria, answer any questions you might have regarding the study and obtain the signed consent. The Research Coordinator will collect your demographics and health data using a questionnaire. Your height and weight will be measured, and Body Mass Index will be calculated.

You will be randomly assigned to one of two groups. Randomization is a process like flipping a coin and means you will have a chance of being assigned to *either* the intervention group or the control group. Study participants in both groups will be measured at baseline and study conclusion.

The control group will perform a physical therapist designed neck strengthening program. If allocated to the control group, you will perform a series of isometric and isotonic exercises to develop neck performance characteristics. The exercises will be completed twice each week and consist of manual resistance exercises that you perform without using weights. For example, you will resist neck motion (forward, backward, and side-to-side) by using your arms to resist the movement of your neck. These are called isometric exercises. This exercise program is 12-weeks long.

The intervention group participants will use the TopSpin360 device. The Research Coordinator will also assign a TopSpin360 helmet, which will be correctly fitted to your head. This helmet will be used during your brief 10-minute neck exercise sessions. Two brief exercise sessions will be completed each week, ideally, after your morning physical training is complete. Before beginning the training, you will also meet with one of the study physical therapists who will perform a brief physical exam on your neck and take several measures, including neck range of motion, isometric neck strength, and a neck endurance test. These measures will also be repeated after the study to compare to your baseline measures. A certified athletic trainer or physical therapist will lead the intervention group for the 12-weeks duration. Data collected will include demographics, physiologic and performance measures, and program adherence.

If you are selected to be in the intervention group, you will be asked to download the TopSpin360 App on your telephone and be instructed in its use. This App can be downloaded in Germany and is not blocked by the EU.

All participants will receive a handout regarding the testing procedures to familiarize themselves with the process before testing occurs.

The length of this study is 12 weeks, which is an optimal time for a training effect to be measured. While in the study, we ask that you adhere to the neck exercise program and give each session your best effort. The total weekly training time to complete the exercise sessions is approximately 15-30 minutes. Upon study completion, there will be one final appointment. The physical therapist will reexamine you and repeat the measures taken 12 weeks before you started the intervention, including neck range of motion, girth, isometric strength, and an endurance test.

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

If you choose to take part in this study *the possible risks and discomforts from being in this research study include:*

Risk of exercise: Exercise always carries some risk of injury. This risk typically includes muscle soreness that is most often present when beginning a new exercise routine or targeting muscles that are not used to being trained under a load, such as the neck muscles. Performance of this exercise may create varying degrees of muscular neck discomfort from fatigue and the buildup of lactic acid while training. The discomfort will rapidly dissipate after training. This sensation is no different than when you perform other exercises like pushups or sit-ups. However, the

program is very brief, and the number of sets performed will start at two and go up to 6 sets over the 12 weeks. This slow progression should allow time for the muscles to adapt without soreness.

Confidentiality: We will collect personally identifiable information (PII), including your name, email, and telephone number. We will also collect measurement data as a part of the study procedures. All the data we collect will be secured in a locked filing cabinet in a locked room with limited access to protect your information. After the study, all your personal health information will be destroyed, but the data will be retained for three years. The signed consent form must be retained but will be stored separately from the data. You may stop participating in this research at any time without any prejudice to you or your career. If the investigator notes any distress or anxiety associated with the research, you will be advised to see your primary care provider.

The App that is used to collect data has both Android and iPhone applications. TopSpin Technologies will obtain some information to include Health & Fitness, Contact Information (email address, name), Identifiers (user ID), and Usage Data (product interactions). No IP Address information is collected. Additionally, the username for this study will not be your own, but rather a unique study identifier that will be given to you by the research coordinator.

Military statement: Divulgence of any illegal activities or sensitive information, such as drug use, is required to be reported to your Commanding Officer, which may affect your military career.

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

5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:

There are no direct benefits to you for taking part in the study. However, others may benefit in the future from the information that may enable us to develop a more extensive and comprehensive follow-on study to test whether this type of training using the TopSpin360 can reduce traumatic brain and neck injury in our warfighters.

6. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

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

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

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

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

Christine Olanrewaju, DO 314 590-7829
Email: christine.m.olanrewaju.mil@health.mil
Chief Physical Medicine and Rehabilitation
Landstuhl Regional Medical Center (LRMC

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

There is no sponsor for this study.

11. SOURCE OF FUNDING:

TriService Nursing Research Program (TSNRP)

12. LOCATION OF THE RESEARCH:

Landstuhl Regional Medical Center (LRMC)

13. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

The Principal Investigator, Christine Olanrewaju, DO and his teammates have no financial interests or other arrangements to disclose.

14. 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:
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

The research team will keep your research records. These records may be looked at by the study staff, Landstuhl Regional Medical Center (LRMC), the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: *Using of coded data, removal of personal information, computer password protection, creation of firewalls around the data, locking of drawers and offices. A firewall is a protection or barrier within a computer to protect the information from being viewed by unauthorized people.)*

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, 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.

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.

Christine Olanrewaju, DO, and colleagues
Staff from the Institutional Review Board (IRB)
LRMC Human Research Protections Office Staff
The sponsor and/or its representatives
DoD Higher Level Review

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.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

15. 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. All identifiers will be removed and only deidentified data will used or shared for future research. Future research may be in the same area as the original study, or it may be for a different kind of study. You will be provided choices at the end of this consent form to allow or deny use in future research studies.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) 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.

16. USE OF INFORMATION AND SPECIMENS

N/A. No biological specimens are collected.

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."

Incidental and/or unexpected findings may occur during the screening process or during the conduct of the study. If the Physical Therapist identifies any abnormality during a screening exam you will be advised to follow-up with your primary care provider for further evaluation. You will need to be cleared by a physician before being allowed to continue through the study screening process and participate. If an unexpected finding occurs during the conduct of the study the same process will be implemented, you must be cleared by a physician before continuing further in the study.

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. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

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 to leave, please notify the PI either by email or phone:
Christine.m.olanrewaju.mil@health.mil
DSN: 314-590-7829 or civilian 06371-9464-7829

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 have the right to withdraw from this study at any time. If you decide to stop taking part in this study, tell the principal investigator as soon as possible. There are no repercussions to leaving the study at any time, and you are at no risk of losing your right to medical care. 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 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 without your consent if remaining in the study would become harmful to you; the military mission requires it; you lose your right to receive medical care at a military hospital; you experience adverse training outcomes such as problems with your vision, hearing, balance, or neck; or you re-injure yourself during the program. The study team may also stop your participation if you cannot or choose not to follow the outlined training program.

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 using the contact information in the section below.

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.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: 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:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Christine Olanrewaju, DO
TEL: 06731-9464-7829
Email: christine.m.olanrewaju.mil@health.mil
Mailing Address: Rehabilitation Clinic Physical Medicine and Rehab
Landstuhl Regional Medical Center, Unit 33100, APO, AE 09180-3100

LRMC H**uman Research Protection Program (HRPP) Office**

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

Human Protections Director/HRPP POC: Dr. Silvija Salai
Phone: 314-590-8627

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 IRB Office at:
WRNMMC Institutional Review Board or the Human Protections Director at the WRNMMC Department of Research Programs at: Phone: (301) 295-8239. Mailing Address: 8901 Wisconsin Ave, Building 17B, Floor: 3, Suite: 3C, Bethesda, MD, 20889

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

Please check the appropriate line below whether the researchers may use your deidentified data for future research

_____**Yes**, you may use my deidentified data for future use.
_____ **No**, you may not use my deidentified data for future use. _____
Date

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