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Effects of whole body vibration and core exercise on muscle soreness and performance during a foot march

Submission date
15/10/2020

Recruitment status
No longer recruiting

Registration date
16/10/2020

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims:
Approximately 25% of injuries to United States Infantry and Initial Entry Training (IET) soldiers are due to foot marches, an important military task. Back injuries are one of the most common musculoskeletal injuries resulting from foot marching, accounting for 27% of all foot march injuries. The aim of this study is to evaluate the effect of Core Exercise and Whole Body Vibration on low back pain and performance during a foot march.

Who can participate?
Healthy volunteers aged 19-35 years.

What does the study involve?
Participants will be asked to complete two 8 km foot marches carrying a 35 lbs rucksack, four weeks apart. Participants in the core exercise and whole body vibration with core exercise groups will be asked to complete core exercises three times a week for three week between foot marches. Before, during, after, 1 day and 2 days after completing the foot march low back pain/soreness, performance, muscle oxygenation, .biomarkers via blood draws, muscle activation, posture and exertional levels will be measured.

What are the possible benefits and risks of participating?
There are no direct benefits to the participants. The risk of participating include risk of falling or injury from the whole body vibration platform, risk of dizziness, nausea, headache or vomiting from the whole body vibration platform, risk of pain, redness, swelling, infection, bruising and fainting from the blood draw, risk of muscle soreness, pain or injury from completing the foot march, risk of breach of confidentiality, and a risk of a rash from the adhesive material used to attached EMG sensors to the skin.

Where is the study run from?
Auburn University (USA)

When is the study starting and how long is it expected to run for?
From June 2019 to December 2019

Who is funding the study?
Warrior Research Center (USA)

Who is the main contact?
Kaitlin Lyons
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effects of a whole body vibration and core exercise intervention on muscle soreness and performance during a foot march: a randomized controlled trial

Study objectives

Core exercises and whole body vibration is superior to increasing performance and reducing muscle soreness following a foot march

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/07/2019, Auburn University Institutional Review Board (115 Ramsay Hall, Auburn, AL 36849; IRBADMIN@auburn.edu; +1 334-844-5966), ref: 19-211

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Low back pain

Interventions
Study volunteers will be randomly allocated by the researchers, using a random number generator, into one of three groups:
1. Whole body vibration with core exercise
2. Core exercise only
3. Control group.

All participants will be asked to complete an 8 km foot march. Following the completion of the foot march and a one week wash-out period, participants in the whole body vibration with exercise and core exercise groups will complete three weeks of core exercise training with or without whole body vibration. Core exercise training with or without whole body vibration will occur for 20 mins, three times per week. The control group will continue with their normal activity. Following three weeks of training, all participants will be asked to complete a second 8 km foot march. During the foot march participants will be asked to carry a 35 lb military rucksack, packed by an Army Officer, as fast as they can safely complete the 8 km distance.

Before, during, and after each foot march participant's low back pain/soreness, posture, muscle oxygenation, muscle activation, exertion level, blood biomarkers for muscle soreness/damage and performance will be assessed. Demographic information including age, height, and weight will also be collected using a questionnaire.

Intervention Type
Behavioural

Primary outcome measure
1. Low back pain measured using a visual analog scale before, half-way through, immediately after, and 1 day and 2 days following each foot march at 0 and 3 weeks
2. Low back soreness measured using an algometer before, immediately after, and 1 day and 2 days following each foot march at 0 and 3 weeks

Secondary outcome measures
1. Performance measured as time to complete the 8 km distance measured at the completion of the foot march at 0 and 3 weeks
2. Muscle Damage measured from blood draws taken before, half-way through, immediately after, and 1 day and 2 days following each foot march at 0 and 3 weeks
3. Muscle Activation measured with surface electromyography (EMG) sensors during the foot march at 0 and 3 weeks
4. Exertion Level measured with Borg rating of perceived exertion scal before, half-way through, immediately after, and 1 day and 2 days following each foot march at 0 and 3 weeks
5. Muscle Oxygenation measured with Humon Hex device (worn on the upper thigh), before, half-way through, immediately after, and 1 day and 2 days following each foot march at 0 and 3 weeks
6. Posture measured with a Zephyr Bioharness (worn around the chest), before, half-way through, immediately after, and 1 day and 2 days following each foot march at 0 and 3 weeks

Overall study start date
01/06/2019

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Aged 19-35 years

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
36

Key exclusion criteria
1. Acute inflammation and infections
2. Acute joint disorders or arthroses

3. Chronic migraine headaches
4. Cardiovascular diseases, such as heart and vascular
5. Recent joint implants such as foot, knee, and implants
6. Heart rhythms or valve disorders
7. Recently placed metal or synthetic implants such as pacemakers and cochlear implants
8. Pregnancy, gallstones, or epilepsy
9. Recent thrombosis or possible thrombotic complaints
10. Tumors, diabetes, or kidney stones
12. Have a current concussion or a concussion within the last 90 days
13. Allergic to adhesives

Date of first enrolment
15/07/2019

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
United States of America

Study participating centre
Auburn University
301 Wire Road
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Sponsor information

Organisation
Auburn University

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Sponsor type
University/education

Website

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ROR
https://ror.org/02v80fc35

Funder(s)

Funder type
University/education

Funder Name
Warrior Research Center

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/05/2021	17/11/2023	Yes	No