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Proof of concept study for the use of edge-based potassium sweat sensors

Submission date 07/11/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 20/11/2024	**Overall study status** Completed	[X] Statistical analysis plan [_] Results
Last Edited 08/07/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Our study focuses on enhancing the performance of soldiers by using a computer called UltraLYNX™ to monitor human performance. Potassium, a salt in the body, can indicate how stressed your body is. We aim to show that a potassium sensor can accurately detect potassium levels in sweat compared to blood. We will also test if caffeine affects these measurements at rest and during exercise. Additionally, we want to see if data from the potassium sensor and a heart rate monitor can be combined to create a red, amber, or green (RAG) signal to indicate how hard your body is working.

Who can participate?
Participants must be healthy adults who do not have any conditions or habits that could interfere with the study, such as intolerance to caffeine, smoking, recent drug use, or certain medical conditions.

What does the study involve?
Participants will visit the lab, where they will take either a caffeine pill or a placebo. They will undergo various tests, including measuring electrodermal activity, cognitive performance tests, and a treadmill exercise protocol. During the exercise, we will monitor heart rate, gait pattern, and other physiological responses.

What are the possible benefits and risks of participating?
Participants may benefit from learning more about their physical and cognitive performance. However, there are risks such as discomfort from blood sampling, potential side effects from caffeine, and physical exertion during the treadmill test.

Where is the study run from?
Defence Science and Technology Laboratory (UK)

When is the study starting and how long is it expected to run for?
July 2024 to July 2025

Who is funding the study?
Defence and Security Accelerator (UK)

Who is the main contact?
Dr Christopher Gaffney, c.gaffney@lancaster.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2310/MODREC/24

Study information

Scientific Title
Proof of concept study for the use of edge-based potassium sweat sensors integrated with the UltraLYNX™ power and communication platform

Study objectives
A novel potassium sensor can reliably detect potassium levels in sweat when compared to blood.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/07/2024, Ministry of Defence Research Ethics Committee (DSTL Portsdown West, Salisbury, PO17 6AD, United Kingdom; +44 3001535372; DST-MODRECTeam@mod.gov.uk), ref: 2310/MODREC/24

Study design
Single-centre interventional double-blind placebo-controlled randomized crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Laboratory

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Healthy active population

Interventions
A single centre interventional double-blind placebo-controlled randomised crossover trial is being used to investigate a novel potassium sensor and the effect of caffeine on cognitive and physical performance

Cannulation, electrodermal activity and cognitive performance tests
Upon entering the lab, subjects will be cannulated using a standard antecubital cannula. The study visits will involve the ingestion of either a 200mg caffeine pill or a placebo pill (double-blinded, randomised). After administration of either the placebo or caffeine pill, participants will wait for 45 minutes whilst undergoing monitoring to allow the caffeine to become bioavailable. Participants will have electrodermal activity measured using electrodes on the hand or wrist . This involves connecting two electrodes to the non-dominant hand (typically the index and middle finger) or the wrist. Participants will remain seated and still whilst measurements are taken.

Participants will then undergo a cognitive performance test battery on a laptop comprising of tests to measure attention, memory, and reaction time skills. We will use NIH toolbox cognitive tests . Participants will complete: (1) Flanker Inhibitory Control and Attention Test; (2)List Sorting Working Memory Test and (3) Oral Symbol Digit Test (3 minutes). Stimuli are presented digitally (on the laptop) but oral responses are given, and the experimenter records the responses.

Preparation for treadmill testing
Once complete, participants will don a Hans-Rudolph mouthpiece for breath-by-breath analysis

and the straps around the head will be secured by a researcher, Polar heart rate chest strap, a weighted vest (20lb/9.07kg for every participant) and will be connected to an online gas-analysis system. The side of the treadmill will be fitted with the infra-red OptoJump system to monitor changes in gait pattern between trials.

Marching protocol
Participants will then move on to complete a simulated march and running protocol on the treadmill, designed to mimic the load carriage of fast marches in the British Army at the time, and an offensive/defensive fire and manoeuvre-based task. The protocol comprises of 20 minutes walking at 5.1km/h then 40 mins walking at 6.5 km/h at a 1% gradient all whilst carrying a 9.07kg (20lb) load within a weighted vest. At 60 mins and still at a 1% gradient, participants then walk for 1 min at 2.5 km/h before the gradient is increased to 3% and participants complete 8 x 9s shuttle runs at 11 km/h with inter-shuttle rest periods of 11s at 2.5km/h.

Sampling and measurements during the marching protocol
Ratings of perceived exertion will be taken at 10-minute intervals throughout the marching protocols and at the end of the shuttle runs using the Borg 6-20 scale. Similarly, glucose and lactate will be measured at 10-minute intervals throughout using a finger prick capillary blood sample and analysis on a Biosen EKF point of care glucose/lactate analyser. Finally, we will assess muscle performance through the measurement of peak isokinetic torque using an isokinetic dynamometer, both before and after the 62-minute treadmill protocol. Whole blood will be sampled at the end of each stage from a peripheral venous cannula. Gas exchange including O2, CO2 and minute ventilation (VE) will be measured throughout the marching protocol using a Cortex Metalyzer breath-by-breath gas analysis system.

Intervention Type
Supplement

Primary outcome measure
Potassium Levels - measured via novel potassium sensor at rest and during exercise via sweat and from blood

Secondary outcome measures
Effect of caffeine on cognitive and physical performance:
1. Electrodermal activity is measured using electrodes on the hand or wrist at 45 minutes post-administration
2. Attention is measured using the Flanker Inhibitory Control and Attention Test at 45 minutes post-administration
3. Working memory is measured using the List Sorting Working Memory Test at 45 minutes post-administration
4. Reaction time is measured using the Oral Symbol Digit Test at 45 minutes post-administration
5. Breath-by-breath analysis is measured using a Hans-Rudolph mouthpiece and online gas-analysis system during treadmill testing
6. Heart rate is measured using a Polar heart rate chest strap during treadmill testing
7. Gait pattern is measured using the infra-red OptoJump system during treadmill testing
8. Ratings of perceived exertion are measured using the Borg 6-20 scale at 10-minute intervals throughout the marching protocol and at the end of the shuttle runs
9. Glucose is measured using a finger prick capillary blood sample and Biosen EKF point of care glucose/lactate analyser at 10-minute intervals throughout the marching protocol
10. Lactate is measured using a finger prick capillary blood sample and Biosen EKF point of care glucose/lactate analyser at 10-minute intervals throughout the marching protocol

11. Muscle performance is measured using an isokinetic dynamometer before and after the 62-minute treadmill protocol
12. Gas exchange (O2, CO2, minute ventilation) is measured using a Cortex Metalyzer breath-by-breath gas analysis system throughout the marching protocol

Overall study start date
02/07/2024

Completion date
01/07/2025

Eligibility

Key inclusion criteria
1. Male or female
2. Aged 18-35 years
3. Pass UK military physical tests

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Any intolerance or avoidance of caffeine
2. Any prescribed medication
3. Smokers (smoking defined as more than 100 cigarettes throughout lifetime)
4. Vaping defined as any use in last 7 days
5. Liquorice consumption within the last 7 days
6. Recreational drug use in the last month, including, but not limited to, cannabis and cocaine
7. Any medical condition that would prevent entry into army, navy or air force
8. Phobia to needles
9. Allergy or insensitivity to materials used in the study (e.g., adhesive)
10. Recent musculoskeletal injury (within the last 3 months)

11. Non-English speakers
12. Pregnancy
13. Atrial fibrillation
14. Any findings that the Clinical research fellow believes affect the integrity of study data or the safety to conduct tests

Date of first enrolment
18/11/2024

Date of final enrolment
25/06/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lancaster university
Bailrigg
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Sponsor information

Organisation
Defence Science and Technology Laboratory

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Sponsor type
Government

Website
https://www.gov.uk/government/organisations/defence-science-and-technology-laboratory

ROR
https://ror.org/04jswqb94

Funder(s)

Funder type
Government

Funder Name
Defence and Security Accelerator

Alternative Name(s)
DASA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Intention to publish date
01/03/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Christopher Gaffney (c.gaffney@lancsaster.ac.uk).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			14/11/2024	No	Yes
Statistical Analysis Plan			14/11/2024	No	No