ISRCTN17213693 https://doi.org/10.1186/ISRCTN17213693

Human augmentation using potassium sensors and the UltraLYNX™ power and communication platform

Submission date 25/04/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 30/04/2025	**Overall study status** Completed	
Last Edited 08/07/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Our work is about improving the performance of soldiers and whether an existing computer worn by soldiers (UltraLYNX™) can be used to monitor human performance.

The main goal is to show that a device we have built can sense changes in the body, send and receive data to a computer about those changes, and then activate a response (in the form of applying a caffeine patch) when needed. The focus is on testing the system to make sure it works, without making any medical decisions.

The second goal is to measure a mineral called potassium in sweat, alongside other signals from the body such as heart rate. We want to see how this changes when individuals are are given caffeine. Skin activity will also be tracked to compare with the other measurements.

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?
If someone takes part, they will visit the Human Performance Lab at Lancaster University for about two hours. It's recommended to wear comfortable clothing and avoid caffeine for 24 hours beforehand.

For female participants, a urine pregnancy test will be done during the screening to ensure they are not pregnant, as caffeine can affect an unborn child. Nursing mothers are also excluded due to caffeine passing into breast milk.

The visit begins with written consent and a medical screening, which includes a health questionnaire, measuring height, weight, blood pressure, and checking for heart issues like atrial fibrillation. If the tests show the person is not suitable, they will be excluded, and all personal data will be destroyed. If suitable, the person will proceed with the testing.

Next, a heart rate monitor will be fitted around the chest, and a potassium sensor placed on the lower back. Blood will be sampled from a vein in the inner elbow using a small tube (cannula). A maximum of 25mL of blood will be taken, much less than a standard blood donation (450mL). Electrodermal activity will be measured by placing electrodes on the fingers.

A 75mg caffeine patch will then be applied using a blood pressure cuff. This amount of caffeine is similar to a single espresso coffee. The patch looks and feels like a plaster, and the effects after it is applied are similar to drinking a cup of coffee. The caffeine patch is a commercially available food supplement. The cuff will inflate to press the patch against the skin and will be deflated once the patch is secured. There is an emergency switch to release the cuff immediately if any discomfort is felt.

During this time, the person will remain seated quietly in the lab. To prevent boredom while keeping still and avoiding activities that could raise heart rate, reading a book or magazine will be allowed.

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

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?
December 2024 to June 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2375/MODREC/24

Study information

Scientific Title
Human augmentation using a potassium sensor and the UltraLYNX™ power and communication platform for remote interventions

Acronym
EDGE 2

Study objectives
That caffeine patch administration can change physiological variables including heart rate variability and electrodermal activity

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/03/2025, Ministry of Defence Research Ethics Committee (MODREC) (DSTL Portsdown West, Salisbury, PO17 6AD, United Kingdom; +44 3001535372; DST-MODRECTeam@mod.gov.uk), ref: 2375/MODREC/24

Study design
Single centre interventional placebo-controlled crossover trial

Primary study design
Interventional

Study type(s)
Other

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

Interventions

The study visit component will take place after the safety screening and participants will have arrived at the lab having not consumed caffeine for 24h. During the entire study visit, participants will be sat in the human performance lab at a table where all measurements are taken. There will be no exercise involved and participants remain seated at rest throughout the trial; they will be permitted to read during experiments if desired but will otherwise be quiescent to maximise the validity of heart rate variability data. A blood sample will be performed at the start of the visit before administration of caffeine for baseline measurement of potassium. A blood sample will be taken using aseptic techniques by either the study medical doctor (Clinical Research Fellow) or staff who are NHS trained and certified in the procedure. Cannulation will be performed as per local (based upon NHS) standard operating procedures (SOPs).

Participants will first don the Polar H10 heart rate monitor using an elasticated chest strap. This remains for the duration of testing and is removed by the participant at the end of the visit. Participants will then have electrodermal activity measured using electrodes on the hand or wrist (PowerLab, AD instruments). This involves connecting two electrodes to the self-reported non-dominant hand (typically the index and middle finger) or the wrist. Participants will remain seated and still whilst measurements are taken. These are connected to a large box and the electrical activity of the skin is measured including skin conductance. Caffeine is known to increase electrodermal activity and this method can therefore confirm that caffeine is bioavailable in the systemic circulation 8 after administration of the 75mg at the end of the control period.

A physical cable will be sewn or taped to the vests worn by participants connecting the potassium sensor. Pictures of the sensor and patch are included in the participant information sheet. During this study data transmitted from the sensor and the heart rate monitor (Polar H10) will be captured for system development purposes only – e.g., to compare potassium readings with external measurements from samples in the lab. Heart rate variability will also be captured (from Standard Deviation of NN intervals to measure the overall variability in R-R intervals) using the Polar H10 connected to the Elite HRV app. Potassium has been chosen as potassium levels in the body affect the electrical activity of the heart. Thus, the measurement of heart rate and potassium in sweat are intricately linked, physiologically12. The potassium sensor will be taped to the skin with a TegadermTM, specifically located in the lumbar region of the lower back, approximately in line with the L4/L5 vertebrae. This region is known to have a high sweat rate (378g/m2/h)10 ideal for accurate sensor operation. This region will also be below the bottom edge of the vest, which is designed to allow freedom of movement at the waistline.

All participants will have the caffeine patch applied at a predetermined time, but study data will be reviewed by a medical professional beforehand (to ensure it's safe to administer caffeine) and approve sending a signal to actuate the cuff and deliver the caffeine patch. The data will not be used for clinical decision making; the patch will be delivered unless there is a safety concern from the medical professional.

Caffeine will be administered via a transdermal patch brought into contact with the skin by the actuation of a pressure cuff. The transdermal patch resembles a simple plaster that can be bought over the counter, but the key difference being that our patch (commercially available – Vie Patch, Global 1st, SKU: VH-0055-CAFF-PATCHESX30) is impregnated with caffeine for transdermal absorption; the experience to the participant will be like wearing a plaster. Before administration of the patch, additional verbal (ongoing) consent will be taken. The CRF will analyse the data for a normal resting heart rate (under 90bpm) and a normal blood pressure (under 140/90mmHg) as go/no-go criteria for administering caffeine. In its normal or deactivated state, the patch is supported by the cuff and held away from the arm by stiff foam supports.

Upon receiving a signal from UltraLYNX™, the control system activates the actuator. This inflates the cuff to 200mmHg then deflates to 0mmHg over 30s, thus bringing the patch into contact with the skin. Contact force will be confirmed by a force sensor. After a predetermined period, or upon command via the Serial connection to the control circuitry, pressure can be released from the cuff by appropriate actuation of the valves, deflating it. The participant also will hold a manual push button that will also cause the deflation of the cuff, should they feel the need to actuate it (because of discomfort, say) as an additional safety feature, by shutting off the power to the control system (which shuts off in a safe position and allows the cuff to deflate naturally without the need for additional control signals). The patch will remain in contact with the skin via its verall control structure of the actuated cuff. Bench tests have confirmed that the control systems work as specified. However, this will be the first human trial of this delivery system for a patch.

Sampling and measurements
We will take a maximum of 25mL blood per visit, which is the same as about 5 teaspoons of blood. This will be done through cannulation at the antecubital fossa. Venous blood samples will be extracted into serum on the day and potassium (and other electrolytes namely sodium and chloride) will be measured immediately using an iSmart 30 PRO electrolyte analyser. The primary aim is to measure serum potassium but the cartridges for measuring potassium automatically measure sodium and chloride too. Cellular material will be discarded on the day of the study visit. Potassium from serum will be compared with that in sweat measured from the sensor to give information on the usefulness of the platform.

Intervention Type
Supplement

Primary outcome(s)
Potassium levels measured via a novel potassium sensor at rest via sweat and blood

Key secondary outcome(s))
Effect of caffeine administration on physiological response:
1. Electrodermal activity is measured using electrodes on the hand or wrist throughout the 1 hour 30 minute study visit
2. Heart rate variability throughout the 1 hour 30 minute study visit

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. Any gender
2. 18-40 years old

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
All

Total final enrolment
24

Key exclusion criteria
1. An intolerance or avoidance of caffeine
2. Any prescribed medication
3. Long term use of ibuprofen (>6 weeks use in the last 52 weeks)
4. Smokers (smoking defined as more than 100 cigarettes throughout the participant's lifetime)
5. Current vapers defined as any use in the last 7 days
6. Any consumption of liquorice in the last 7 days
7. Self-declared recreational drug use in the last month including, but not limited to, cannabis and cocaine. No drug testing to be conducted.
8. Self-reported alcohol use within the previous 24 hours
9. Any medical condition that could affect safety or study data at the discretion of the Clinical Research Fellow
10. Phobia to needles or anxiety disorders
11. Allergy or sensitivity to materials used in study (e.g., adhesives)
12. Non-English speakers to ensure informed consent
13. Pregnancy – self-tested using a commercial urine test that will be provided
14. Nursing mothers
15. Atrial fibrillation or other clinically significant arrhythmia
16. Any findings that the Clinical Research Fellow believes affect the integrity of study data or the safety to conduct tests
17. Fever
18. Bladder control issues
19. Bleeding disorders
20. Diabetes
21. Irritable Bowel Syndrome (IBS)
22. Epilepsy
23. Glaucoma
24. Osteoporosis
25. Parkinson's
26. Schizophrenia
27. History of kidney injury

Date of first enrolment
16/05/2025

Date of final enrolment
25/06/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lancaster University
Bailrigg
Lancaster
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LA1 4YW

Sponsor information

Organisation
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

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

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	27/07/2024	28/04/2025	No	Yes