Participant Information Sheet
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Study Title: Human augmentation using potassium sensors and the UltraLYNX™ power and communication platform

Short title: EDGE

MODREC Application No: 2375/MODREC/24

Name of Researchers: Professor Andrew Richardson
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Dr John Hardy
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Helen Austin
Dr Christopher Gaffney
Dr Samuel Rust
Dr Samantha Moore
Dr Yasin Valli

Invitation to take part:

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have if/when you visit. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the research?

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 your sweat, alongside other signals from your body such as heart rate. We want to see how this changes when you are given caffeine. Skin activity will also be tracked to compare with the other measurements.

Who is doing this research?

This research is being undertaken by a team from Lancaster University and ULTRA PCS; the sponsor will be DSTL. ULTRA PCS are an engineering company that have designed and manufactured the UltraLYNX™ technology being used in this study. The work is funded by the Ministry of Defence as part of DASA grant: ACC6042224. The money is used to pay for experimental running costs and analytical costs.

Why have I been invited?

You have been invited as you have expressed an interest following advertisement of the study. To participate, you must meet our inclusion criteria, and not meet any of our exclusion criteria below. Some of these will be determined on your visit to the Human Performance Lab. The study doctor will also be able to clarify/check your suitability to participate in the study.

Inclusion criteria: Any gender
18-40 years old.

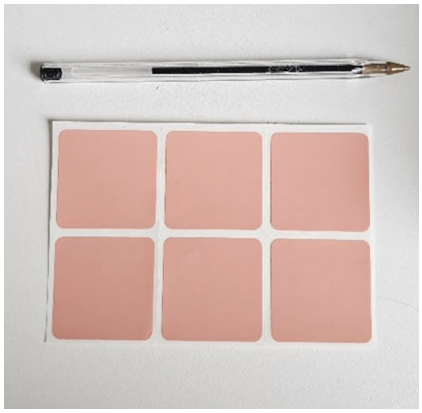
Exclusion criteria:

- An intolerance or avoidance of caffeine
- Any prescribed medication
- Long term use of ibuprofen (>6 weeks use in the last 52 weeks)
- Smokers (smoking defined as more than 100 cigarettes throughout the participant's lifetime)
- Current vapers defined as any use in the last 7 days
- Any consumption of liquorice in the last 7 days
- Self-declared recreational drug use in the last month including, but not limited to, cannabis and cocaine. No drug testing to be conducted.
- Self-reported alcohol use within the previous 24 hours
- Any medical condition or findings that the Clinical Research Fellow believes could affect safety or study data
- Phobia to needles or anxiety disorders
- Allergy or sensitivity to materials used in study (e.g., adhesives)
- Non-English Speakers to ensure informed consent
- Pregnancy – self-tested using a commercial urine test that will be provided
- Nursing mothers
- Atrial fibrillation or other clinically significant arrhythmia
- Fever
- Bladder control issues
- Bleeding disorders
- Diabetes
- Irritable Bowel syndrome (IBS)
- Epilepsy
- Glaucoma
- Osteoporosis
- Parkinson's
- Schizophrenia
- History of kidney injury

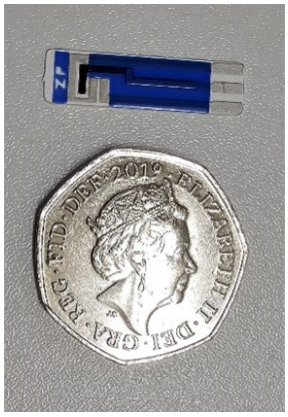
What is the device or procedure that is being tested?

We are testing a potassium sensor and remote patch delivery device. The sensor is worn on the skin and measures potassium in sweat. This can be useful to check how well hydrated or tired a person is. This will be secured using a see-through plaster. We are also testing whether this device can communicate well with the UltraLYNX™ vest-worn computer device. A picture of the sensor, patch and cuff that are shown in the Figure below. Note - only one of the six patches shown will be applied to the skin. Image for illustration only.

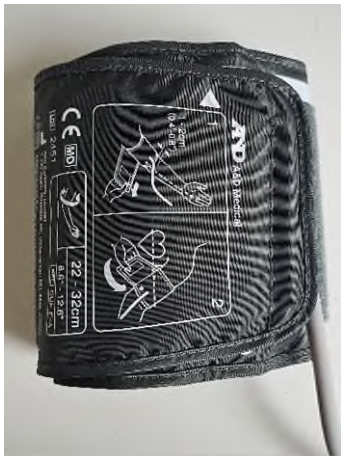
a)



b)



c)



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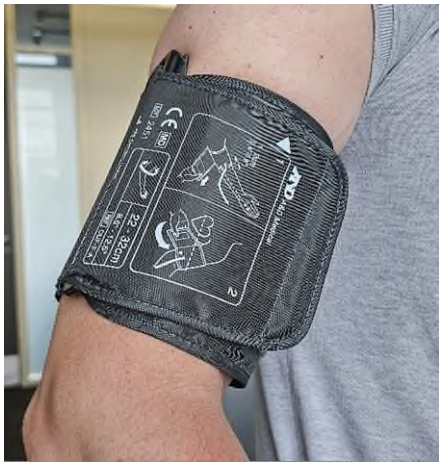

Figures: a) 75mg caffeine patches, b) Potassium sensor chip, c) Arm cuff, d) Arm cuff on person

Do I have to take part?

No, participation is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

If you choose to take part, you will attend the Human Performance Lab at Lancaster University for a single visit which will last approximately 2 hours. We advise that you attend in comfortable clothing, and you will be required to have not had caffeine for 24h before the visit.

For female participants: You will be asked to take a commercial urine-based pregnancy test during the screening part of your visit to confirm that you are not pregnant. If a positive test is returned then you will be excluded from participation as caffeine can affect an unborn child.. You will then be asked to self-report the outcome of the test. Nursing mothers are excluded as caffeine can move into breast milk.

Visit

The first part of the visit will involve taking your written consent before doing a medical screening. This will involve a questionnaire about your health, measuring your height, weight, blood pressure, and checking for an electrical abnormality in the heart called atrial fibrillation. If not successful, the data not linked to your name will show the reason for exclusion, but all other data will be destroyed.

If at this point the tests indicate you are suitable to take part, we will invite you to participate in the testing. If the tests indicate you are not suitable, you will be unable to participate in any further visits.

In the second part of the visit, a heart rate monitor (Polar H10) will be fitted by a researcher using a plastic and elastic strap around your chest, and the potassium sensor (seen in the figure above, b) will be fitted to your lower back. This will be done behind a screen and can be self-fitted in private if you prefer. We will also sample your blood using a small plastic tube (a cannula) that is inserted in a vein around your inner elbow. You may feel a sharp scratch then the cannula is first inserted. This will be done by a medical professional or someone with NHS training and certification in this procedure. We will take a maximum of 25mL blood on your visit and for context, donating blood is around 450mL.

We will measure electrical activity on your skin surface, known as electrodermal activity. We will do this through placing two electrodes on the index and middle finger of your non-dominant hand.

You will have a 75mg caffeine patch applied via a commercially available blood pressure cuff. The cuff will be inflated with air to bring the patch into contact with your skin, some light pressure/squeezing will be felt on the arm. Once contact is made and the patch secured, the cuff will be deflated for the remainder of the trial. An emergency switch is fitted to the system, which will immediately deflate the cuff if any discomfort is felt. This is available to you at all times.

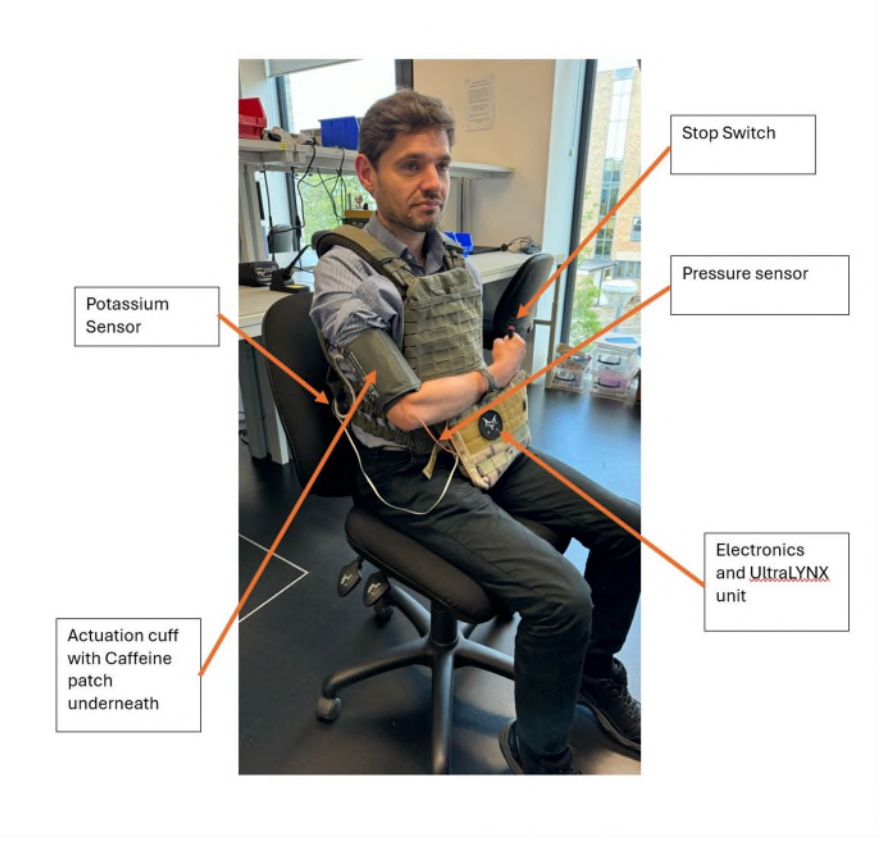

Figure e – Visual overview of system to be worn

This amount of caffeine is like a single espresso coffee. The patch looks like a plaster and the feeling of wearing it will be the same as a plaster. The feeling after the patch is applied will be like after having a cup of coffee. The caffeine patch is a commercially available food supplement. You will be sat quietly in the lab whilst this is ongoing and will be allowed to read a book or magazine during this time. This is to balance preventing boredom whilst making sure you keep seated and do not do activities that may increase heart rate.

Are there any direct benefits to me of taking part?

No, there are no direct benefits to you taking part.

What are the possible disadvantages and risks of taking part?

Caffeine will be administered as a single 75mg patch available commercially. Caffeine carries side effects that can include a fast heart rate, dizziness, dehydration, restlessness, and anxiety. You may experience some or none of these symptoms and you will be monitored throughout testing for these symptoms. Cannulation and blood sampling carries a risk of bruising, unintended puncture of other blood vessels and infection. It can also cause discomfort. As we are testing a novel sensor there is a possibility of an adverse reaction with the skin, e.g., skin irritation or abrasion, though all materials are used routinely in skin-worn electronic products. There may be some minor discomfort when the pressure cuff is inflated around the arm. All procedures are carried out by experienced personnel routinely within our research group.

You may experience some caffeine withdrawal symptoms in advance, as we are asking you not to consume caffeine for 24 hours before the study visit, and on the day of study visits. Symptoms include headaches, low energy, and difficulty in concentrating.

If you do suffer any other symptoms or if you become in any way concerned during your current visit, prior to your next study visit, or after the study has finished, notify one of the investigators listed at the end of this sheet as soon as possible. Should you become unwell, you should seek medical attention if appropriate. If we uncover any health findings your GP we want to make your GP aware of to look into further, the clinical research fellow will give you a letter that you can take to your GP to inform them. You should note that none of the tests are diagnostic in nature, the tests are just for the research, so any findings will need to be followed up through your GP once you have notified them.

Can I withdraw from the research and what will happen if I withdraw?

Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw after the end of the study visit, then the information collected so far that has been anonymised cannot be erased and this information may still be used in the project analysis. Any identifiable data will be erased.

You may also be withdrawn from the study by the study team at any time. This may be because of factors that affect your safety, or the integrity of the scientific data collected.

Will I receive any expenses or payments?

You will receive a £35 inconvenience allowance upon completion of the study, which can be paid via BACs bank transfer. You will complete an expenses payment form containing your bank details and this will be shared directly with Lancaster University's finance team. Your data will be processed then destroyed in line with GDPR. If you attend screening but are excluded, you will receive £10. Payment for research participation in the UK can affect tax obligations and benefit payments, so we recommend participants check this before participation.

Will my taking part or not taking part affect my career or studies?

Your participation will in no way affect your career or your academic studies at Lancaster University. The same applies if you choose not to take part, or if you withdraw part way through the study.

What happens if I suffer any harm?

If you suffer any harm as a direct result of taking part in this study, you can apply for compensation under the MOD's No-Fault Compensation Scheme. If you feel harmed during your visit, please let a member of the study team know as soon as possible. If you don't feel able to contact the study team, you can contact the volunteer medical advocate, Dr Cliff Shelton – details below.

What will happen to any samples I give?

Blood taken will be separated into serum, which will be used to measure serum potassium levels on the day. No samples will be stored, and samples will be disposed of in line with the Human Tissue Authorities codes of practice on the day of sample collection.

How will my records be managed?

We will follow ethical and legal practice and all information about you will be handled accordance with all applicable regulations.

All personal identifiable data that is collected about you during the research will be kept **confidential**. This includes just your name and contact details for the consent form. All data are then pseudonymised and this means your data are linked to a code rather than your name, and hence are not identifiable. There are limits to this, and if the researcher is concerned that you are at risk of harm, or there is a risk of harm to others, they may have to break confidentiality and speak to other members of the research team or emergency service professionals.

The data collected about you (but not linked to you personally) during the course of the study may be looked at by authorised persons from Lancaster University, ULTRA PCS, and DSTL who are organising the research. It may also be looked at by other authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

Paper records will be stored in a secure and locked office on Lancaster University campus, and electronic records on a password protected database held on Lancaster University approved secure cloud storage servers, with access allowed only to those researchers taking part in the study.

Any information about the study that leaves the Research Unit will have your all-identifiable details removed, such as names and address and a unique code will be used

(Pseudonymised). All reasonable steps will be taken to ensure anonymity. Anonymised data will be shared with ULTRA-PCS. Once the data has been anonymised, it will not be possible to remove your anonymised data. The data collected may form part of research papers or conference presentations, but only pseudonymised data will be used and you will not be identifiable in any way.

Lancaster University will be the data controller for any personal information collected as part of this study. Under the GDPR you have certain rights when personal data is collected about you. You have the right to access any personal data held about you, to object to the processing of your personal information, to rectify personal data if it is inaccurate, the right to have data about you erased and, depending on the circumstances, the right to data portability. Please be aware that many of these rights are not absolute and only apply in certain circumstances. If you would like to know more about your rights in relation to your personal data, please speak to the researcher on your particular study.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage:

www.lancaster.ac.uk/research/data-protection.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Ministry of Defence Research Ethics Committee (MODREC).

Who do I contact if I have any questions?

Should you have any questions or would like more information, you can contact either the Clinical Research Fellow or the Chief Investigator:

Name: Dr Samantha Moore (Clinical Research Fellow)
Address: Health Innovation One, Lancaster University, Lancaster, LA1 4AT, UK
E-mail: samanthamoore2@nhs.net

Name: Dr Yasin Valli (Clinical Research Fellow)
Address: Health Innovation One, Lancaster University, Lancaster, LA1 4AT, UK
E-mail: dr.valli@doctors.org

Name: Dr Christopher Gaffney (Chief Investigator for Human Experimentation)
Address: A49 Health Innovation One, Lancaster University, Lancaster, LA1 4AT, UK
Tel No: +44 (0) 1524 593 602
E-mail: c.gaffney@lancaster.ac.uk

Who do I contact if I have a complaint?

Should you have any concerns about the way this study has been conducted, or you wish to make a complaint, then you can discuss this with the researchers listed above or the volunteer medical officer for the study:

Should you wish to discuss your concerns with someone outside of the research team you can contact:

Name: Dr Cliff Shelton (Consultant Anaesthetist)
Address: Health Innovation One, Sir John Fisher Drive, Lancaster, LA1 4AT, UK
Email: c.shelton@Lancaster.ac.uk

Compliance with the Declaration of Helsinki

This study will be conducted in accordance with the principles defined in the Declaration of Helsinki as adopted at the 64th WMA General Assembly at Fortaleza, Brazil in October 2013.