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PARTICIPANT INFORMATION SHEET

Title of the project:

Effects of acute heat stress and heat acclimation on exogenous carbohydrate oxidation during steady-state aerobic exercise

Investigators:

Dr Gareth Wallis, Dr Becky Lucas, Dr Tim Podlogar, Rachel Gifford, Dr Alessandro Prete **Location:**

School of Sport, Exercise & Rehabilitation Sciences, University of Birmingham

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

During prolonged and strenuous exercise, the body relies on carbohydrate fuel stores located in muscle and the liver to support energy production and allow the muscles to keep working. Those carbohydrate stores are small and when they become depleted, fatigue can occur. Many sportspeople eat or drink carbohydrate-containing foods or drinks during exercise to provide an additional source of energy, which helps to delay the onset of fatigue. However, when exercise is performed in hot conditions (i.e. acute heat stress) the body's capacity to use carbohydrate that is fed during exercise for energy (i.e., exogenous carbohydrate oxidation) appears to be reduced, and this nutritional strategy is less effective. This is a particular problem as exercising in the heat places even more demands on the body's existing carbohydrate reserves, so being able to use carbohydrate that is fed during exercise is even more important for sustaining exercise.

We do not know why exogenous carbohydrate oxidation is reduced during exercise in the heat. If we can understand the physiological processes that are affected, we might be able to develop different nutritional strategies to enhance the effectiveness of carbohydrate feeding during exercise in the heat. On the other hand, it is well established that regular exposure to hot environments (i.e., heat acclimation) results in adaptations to the body that improve heat tolerance and physiological responses to exercise in the heat. Heat acclimation could therefore be a way to improve exogenous carbohydrate oxidation during exercise in the heat, but this has not been investigated.

This project seeks to understand the physiological mechanisms by which exogenous carbohydrate oxidation is reduced during exercise in the heat and test whether heat acclimation can overcome limitations to exogenous carbohydrate oxidation. The findings of the research could have implications not only for sportspeople but also for people in occupations that can require strenuous physical effort in hot conditions (e.g., firefighters, military personnel).

Am I eligible for this study?

You are likely to be eligible for this study if you fulfil the following criteria:

- Aged 18-45 years
- Non-smoker (including vaping) last 60 days
- In good general health with no previous history of cardio-metabolic disease
- Have a body mass index (BMI) in the range: 18.5-27.5 kg.m⁻²
- Participate in endurance-based exercise (e.g. cycling, running, rowing, swimming) at least 3 times

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a week



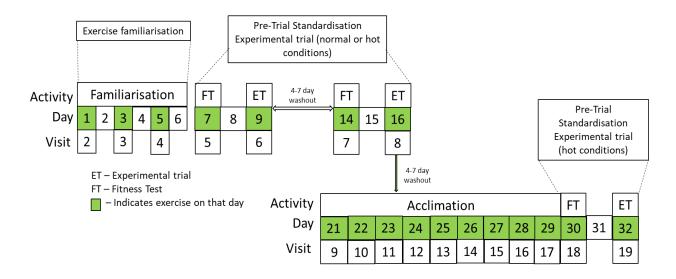
- Are not allergic to lidocaine (local anaesthetic)
- Do not have bleeding disorder/s
- Do not have food allergies or intolerances
- Do not engage in uncommon eating practices (e.g. sustained periods of fasting/intermittent
- Are not following a low dietary carbohydrate lifestyle
- Do not have any bone or joint problems that could prevent you from cycling or that could worsen due to cycling exercise
- Are not currently pregnant or breastfeeding

Do I have to take part?

No. You are under no obligation to participate in this study and you would also be free to withdraw at any time, starting from the first day of the study up to 7 days after the last day. If you wish to participate, and are eligible, the study will require from you a high level of commitment in terms of time and physical effort.

What will happen if I take part?

The study consists of 19 visits spread over a 4-6 week period depending on the timing between visits. This includes four fitness test visits, three familiarisation exercise visits, nine heat acclimation visits and 3 experimental trial visits. All visits will take place in the School of Sport, Exercise and Rehabilitation Sciences (SportExR) at the University of Birmingham (UoB). A diagram of the overall flow through the study after screening/baseline testing is shown below:



Step by step description:

Visit 1 – Screening and baseline testing

Duration: ~1h

Time of the day: Any time of the day

This visit will be used for consenting and screening and to determine your aerobic fitness. Upon arrival, the study will be fully explained to you verbally by an investigator and you will then be asked to sign an Informed Consent Form if you wish to take part. We will inform your general practitioner (GP) of your involvement if you choose to participate in the study. We will then ask you about your general health via a questionnaire and measure your height and body weight. If you successfully complete the questionnaire



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and meet the eligibility requirements you will then have your aerobic fitness determined using a " VO_2 max test" which will take place on a stationary bicycle. The test starts at a very easy work level and gets harder every 3 minutes and you are asked to keep cycling for as long as you can (typically this takes between 10-25 minutes). During the test, you will be wearing a facemask connected to a computerised gas analysis system that will allow us to determine how much oxygen you are using to sustain the exercise – the higher the use of oxygen at the end of the test the fitter you are. If your test results meet the set criterion (i.e., men – 45 mL/kg/min; women - 40 mL/kg/min), you will be scheduled for subsequent visits. If the aerobic fitness criterion is not met, you will not be eligible to continue taking part in the study.

Visits 2,3 and 4 – Familiarisation

Duration: ~2h each

Time of the day: Any time of the day

The purpose of the familiarisation visits are to get you acquainted with type of exercise that will follow during the rest of the study. You will be asked to visit the laboratory on three occasions, each separated by at least one day, over the course of a week. During Visit 2 you will undertake 90 minutes of continuous moderate intensity exercise on a stationary bicycle, whilst also being asked to consume a carbohydrate-drink while you exercise. During Visits 3 and 4 you will undertake 15 minutes of high-intensity (sprint) interval exercise following by 75 minutes of continuous moderate intensity exercise, again on a stationary bicycle. You will be able to drink water during exercise. You may eat as you normally would before exercise when attending for Visits 2,3 and 4.

Visits 5, 7 and 18 – Pre-trial standardisation

Duration: ~1h each
Time of the day: morning

The purpose of the pre-trial standardisation visits are to ensure your physiological status is as consistent as possible before each subsequent main experimental trial. You will be asked to come in the morning at ~08:00 after an overnight fast (you should not eat anything after 22:00 the day before the test, but you can drink as much plain water as you like). We will measure your body weight, and then ask you to undertake the same aerobic fitness test that you completed at Visit 1. After this, we will ask you to refrain from any strenuous physical activity for the remainder of the day and the next day (i.e., leading up to the experimental trial). We will also provide you will food packages for this period and ask you to only consume the food and drinks provided. All food will be prepared by the research team at the study site kitchen facility. All of the food will be pre-packed and labelled with clear instructions for storage and when you should consume each item.

Visits 6, 8 and 19 - Experimental Trials

Duration: ~3h each
Time of the day: morning

You will be asked to come in the morning at ~07:30-8:00 after an overnight fast (you should not eat anything after 22:00 the day before the test, but you can drink as much plain water as you like). When you arrive you will be asked to go to the toilet and urinate (i.e., empty your entire bladder) into a container that we will use to take an instantaneous measure of your hydration status. Next, while you are lying down on a plinth, a muscle biopsy sample (about the size of a small pea) will be collected from your thigh under local anaesthetic (please note: a total of 6 muscle biopsies will be performed [two biopsies during visits 6, 8 and 19]).

Once the muscle biopsy has been obtained, a number of procedures will be carried out to facilitate data collection during the subsequent exercise test. This includes 1) an indwelling intravenous cannula will be fitted into an arm vein on each arm, with one cannula used for blood sampling and the other for stable isotope tracer infusion; 2) skin thermistor probes will be attached to your skin at four sites (chest, triceps,

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thigh, and calf) to allow continuous measurement of skin temperature; 3) alone, and in private, you will be asked to insert a medical grade, flexible, sterile and disposable rectal thermistor to a depth of 10 cm to enable measurement of body core temperature; 4) you will be fitted with a chest-strap that will allow measurement of heart rate. Once these procedures have been implemented, you will be asked to go to the toilet once more and urinate before being asked to measure, in private, your own nude body weight.

Next, a venous cannula will be fitted into one of your arm veins to allow blood sampling throughout the rest of the trial. Another cannula will be fitted to one of the veins in your other arm to enable us to infuse a sterile, salt solution (saline) containing a trace amount of a stable isotope of glucose ('heavy' glucose) into your bloodstream during exercise. This allows us to measure carbohydrate metabolism within your body during exercise in detail. The infusion will commence and you will be asked to undertake 90 minutes of moderate intensity exercise on a stationary bike. During the exercise you will be asked to consume a carbohydrate drink containing glucose and water at regular intervals. The drink will also contain a small amount of a stable isotope of glucose, and this will allows us to measure how much of the drink is being used for energy whilst you exercise. We will collect blood samples (10 millilitres or around 2 teaspoons each time) and expired breath samples at regular intervals during exercise, and you will be asked to rate how hard you feel the exercise is, how comfortable you find the temperature and if you are experiencing any stomach discomfort. Immediately after the exercise we will obtain another muscle biopsy under local anaesthetic. We will remove the cannulas from your arms and you will be asked to go to the toilet once more and urinate before being asked to measure, in private, your own nude body weight. Once you have recovered from the exercise and experimental procedures you will be free to leave the laboratory. Exercise will be undertaken in our purpose built environmental chamber. For Visits 6 and 8, one of the exercise bouts will be performed under normal environmental temperature (i.e., 20°C, 20% Relative Humidity [RH]) and the other under hot conditions ((i.e., 40°C, 20% Relative Humidity [RH]). For Visit 19, which occurs after the heat acclimation period, the exercise will be undertaken under hot conditions ((i.e., 40°C, 20% Relative Humidity [RH]).

Visits 9-17 - Heat Acclimation

Duration: ~2h each

Time of the day: Any time of the day

The purpose of this period is to give a regular and repeated exposure to performing exercise in hot conditions in order to produce adaptations that improve your tolerance to exercise in the heat (i.e., heat acclimation). For these visits you will attend the laboratory on 9 consecutive days or 9 days within a 10 day period, allowing for one 'rest' day (these consecutive days are including of weekends). You will be asked to perform exercise during each visit, and the exercise will take place undertaken under hot conditions ((i.e., 40°C, 20% Relative Humidity [RH]). The exercise will consist of a brief warm-up and then 15 minutes of high-intensity (sprint) interval exercise following by 75 minutes of continuous moderate intensity exercise, again on a stationary bicycle. You will be able to drink water during exercise. Before and after exercise you will be asked to go to the toilet and urinate before being asked to measure, in private, your own nude body weight. As well, before exercise we will ask you place a rectal thermistor for core temperature measurement as described above, and will be fitted with a chest-strap that will allow measurement of heart rate. During each exercise bout you will be asked to rate how hard you feel the exercise is, how comfortable you find the temperature and if you are experiencing any stomach discomfort. Once you have recovered from the exercise and experimental procedures you will be free to leave the laboratory.

End of the study

There will be a follow-up by email after each Experimental Trial (Visits 6, 8 and 19) to ensure you have not experienced any adverse reactions to any of the procedures. A final follow-up will be conducted 5 days after the last experimental trial (Visit 19). We will collect your contact details for this purpose and keep these for up to 10 years as outlined in the UoB codes of practice.

What will the samples collected from me be used for?

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We will use the breath samples collected from you during exercise to calculate how effectively your body is using the carbohydrate drink that you will consume during Visit 6, 8 and 9. Within the same visits, your urine and blood samples will be used to assess your hydration status and metabolic response to exercise. You muscle samples will be used to measure the rate at which your muscle uses its stored carbohydrate energy stores during exercise and other aspects of metabolism. This may include analysis of the DNA in your muscle samples. Simply put, this analysis of the DNA in your muscle samples will provide us with an indication of biological changes within your muscle over the study period.

What are the possible disadvantages and risks of taking part?

The most obvious risks to you will involve the muscle biopsy, lidocaine administration, exercise testing and heat stress, blood sampling and stable isotope infusion. In addition, in this section we also explain how we will mitigate against the risk of contracting COVID-19 when you visit our laboratories.

Muscle biopsy: This study will involve 6 muscle biopsies (two biopsies during Visits 6, 8 and 19). Each time, $^{\sim}100$ milligrams (0.1 of gram; this is roughly the size small pea) of muscle will be collected so in total $^{\sim}600$ milligrams or 0.6 of a gram throughout the study. This is a very small amount of muscle, as your leg has several kilograms of muscle. The risks of this procedure involve pain, the possible formation of a bruise from localised bleeding and localised infection around the site of sampling. There is a small risk of the biopsy site bleeding once you have left the laboratory, but this is highly unlikely (0.2% chance). Following the study, you will have six small (~ 6-8 mm in length) scars (one at each biopsy incision site, three scars on each leg). Although the rate and degree of healing varies considerably, it is expected that scars will be difficult to see within 6-12 months of the procedure. Biopsies will be performed by a UoB staff member trained and experienced in the procedure. You are welcome to bring a chaperone with you if you would like to when this procedure is to be performed. We will also provide you with detailed written instructions for after care of the biopsy site to further minimise the risk of this procedure. A medically qualified member of the University staff and experienced operator of the biopsy procedure, will be on-call (i.e. on the University/QEHB site) should further advice or assistance be required during or after the study. Further information on aftercare following muscle biopsy is included in the aftercare information sheet provided to you.

Lidocaine administration: You will receive an injection of lidocaine (local anaesthetic) prior to each muscle biopsy. Lidocaine will be administered via a local injection into your thigh by the trained UoB staff member taking the biopsy. In addition, during all study visits involving this procedure, a medically qualified member of the University staff will be on-call should further advice or assistance be required. It is possible that a small amount of pain (slight stinging sensation) may be experienced while the lidocaine is administered but this diminishes within seconds. There is a possible risk of allergic reaction to lidocaine although lidocaine toxicity is extremely low, and to minimise risk, you will be screened for known lidocaine allergies at the screening stage of the study. Further information is included in the aftercare information sheet provided to you. You will receive no more than 2 milligrams per kg lidocaine, which is considered to be within the acceptable range according to our standard procedures.

<u>Exercise</u>: Performing moderate or vigorous exercise carries the following risks that we feel you should be made aware of, as well as some of the things we do to minimise these risks:

- Sensations of fatigue and physical exhaustion this will be short-lived and will subside in a few minutes upon stopping exercise
- Fainting often related to physical exhaustion and then suddenly stopping, this will be mitigated by the inclusion of a cool-down period immediately after the formal exercise test is complete
- Cardiovascular event (e.g., myocardial infarction or 'heart attack') this is a small risk, particularly for healthy individuals who are accustomed to physical activity. The absolute risk that an acute cardiovascular event will occur in otherwise healthy individuals is low (up to 1 in 10000 or 0.01 % chance). We will also ensure that you are warmed-up and cooled down appropriately around the exercise tests and will monitor your heart rate and general disposition when exercising to minimise the risk of a cardiovascular event.

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A first aid trained member of staff (including CPR training) will be present will be present during
all exercise testing sessions. The School of Sport, Exercise and Rehabilitation Sciences is equipped
with an automated defibrillator in close proximity to the laboratory where testing will take place.
We will ensure a staff member trained in the use of the defibrillator is available within the School
should there assistance be required in case of emergency.

Each time you have performed exercise as part of the study we advised that you refrain from strenuous exercise for the rest of that day.

<u>Heat Stress:</u> Exercise under simulated hot conditions carries the risk of developing exertional heat stress, and in its extreme form this can result in heat-stroke. Your internal (core) temperature will be monitored during any exercise performed in the heat by means of a rectal thermistor. This is a medical grade, flexible, sterile and disposable thermistor as shown in the picture.



You will be instructed on how to insert your own rectal thermistor, to a depth of 10 cm. You may experience some discomfort when inserting the rectal thermistor initially, but this should disappear when the insertion is complete. The thermistor has a mark to indicate the depth of insertion. Body core temperatures within 38.5-39.5 °C are generally well tolerated by individuals and avoids body core temperatures associated with heat stroke. Exercise will be stopped and you will be moved to a cooler environment if your internal temperature exceeds 39.5 °C. We will also be monitoring you heart rate and perceptions of thermal comfort and will remove you immediately from the hot environment if you feel too uncomfortable to continue.

<u>Blood sampling:</u> A venous cannula will be fitted into your arm to allow blood sampling throughout the main experimental trials (visits 6, 8 and 19). Blood samples will be collected from you every 15 min during exercise. This means that 7 blood samples (~10 mL each) will be collected from you during each experimental trial. In total, ~210 mL blood will be taken from you over the course of the whole study. This amount of blood is safe to provide and is considerably less than you would give when donating blood (~470 mL).

You may experience discomfort during insertion of the cannula, but this is very minimal. There is a very small risk of infection, needle-stick injury, soreness and bruising around the site of needle insertion. The incidence of such complications is rare and the risk is minimised by following good clinical practice and having all procedures conducted by researchers well trained in the safe conduct of this procedure. Sterile procedures and needles will be used for blood sampling.

Stable isotope infusion: A venous cannula will be fitted into the opposite arm to allow for the infusion of the stable isotope glucose/saline solution into your bloodstream during exercise (Visits 6, 8, and 19). As for blood sampling, you may experience discomfort during insertion of the cannula, but this is minimal. The main risk with this procedure is contamination of the solution to be infused into your bloodstream which could lead you do develop a fever. However, this risk of this is very small as the solution will be prepared for each trial following strict practices and will be tested prior to use in each trial to ensure its safety. A medically qualified member of the University staff will be on-call (i.e. on the University/QEHB site) should further advice or assistance be required during or after the trials.

<u>COVID-19</u>: The study will take place during a period of time when there is a risk of transmission of the SARS-Cov2 virus. We have developed project-specific risk assessments to minimise the risk of SARS-Cov2 infection during your research visits. At present, we will contact you 24 h prior to every laboratory visit to confirm you are symptom free using the NHS COVID-19 App, and repeat this each time upon arrival at the research site. As well, we will have a number of procedures in place (personal protective equipment, frequent hand-washing, social distancing) to ensure that we can conduct the research in the safest way possible. We will provide you with a face mask to wear during your visits, but the face mask will be removed

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when exercising. Procedures may be modified accordingly with changes in local and national guidelines for managing risk of SARS-Cov2 infection.

If you feel unwell after any of the study activities please contact the study team and we will advise you on what action/s should be taken.

What are the possible benefits of taking part?

Throughout the study you will undertake a range of tests that will generate information that you might find interesting for your own training. We will assess your maximal fitness level (VO_2 max) at screening and on days 7, 14 and 30, and your sweat rates during exercise on days 9, 16 and 32 – this information will be available to you immediately. You will also undergo a period of heat acclimation, a practise undertaken by many elite athletes, which would be expected to benefit your fitness levels. Furthermore, we are experts in exercise physiology and sports nutrition and we will be happy to speak to you about your training and nutrition strategies. Financial reimbursements are covered in the Expenses section within this leaflet.

What if something goes wrong?

If you are harmed and this is due to someone's negligence, then you may have grounds for legal action for compensation against the University of Birmingham. Please note that insurance covers negligence only, and not 'no fault' compensation. If you wish to complain formally, you can do this by contacting the Sponsor's Research Governance Office at the University of Birmingham (Tel: 0121 415 8011 or email: researchgovernance@contacts.bham.ac.uk).

What Information will be collected about me?

You will complete a consent form and a general health questionnaire. These will be the only documents with your identity on and these will be stored with your unique study identification number. All other documentation will be identifiable only using your unique participant study identification number to maintain your anonymity. All documentation will be held and stored in locked filing cabinets in the School of Sport, Exercise and Rehabilitation Sciences at the UoB in strict confidence and only the investigative team will be allowed access to these files. Data will be archived for 10 years as per University of Birmingham codes of practice. Your blood, urine, and muscle samples will be identifiable only by your unique participant study identification number. These will be stored in freezers in the School of Sport, Exercise and Rehabilitation Sciences to which access is restricted to our research personnel only. Any data stored on computers will be password protected and anonymous, only identifiable by your unique study identification number. If you make contact about the study but choose not to participate your personal data will be removed. If the sponsor (University of Birmingham) or regulatory authorities make queries, then study records will be provided to them whilst maintaining your confidentiality.

How will we use information about you?

We will need to use information from you for this research project. This will include your name and contact details. People will use this information to do the research (i.e., the study team) or to check your records to make sure that the research is being done properly (i.e., the University of Birmingham Clinical Research Compliance Team). People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some if the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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Where can you find out more about how your information is used?



You can find out more about how we use your information

- By asking one of the research team
- By sending an email of the University's Data Protection Officer (dataprotection@contacts.bham.ac.uk).

Will my taking part in this study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. Your name will only be on the consent form and general health questionnaire. These will be kept in locked cabinets in the School of Sport, Exercise and Rehabilitation Sciences. All samples and data will be stored or displayed with unique identification codes. The research team will have access to the samples and data. We expect to perform most of the analysis at the University of Birmingham or in the UK, but transfer of blood or muscle samples outside of the UK for further analysis might be required if you consent to this on the informed consent form. We expect all of your blood, urine, breath and muscle samples to be used up by the end of the study, however if they are not they will either be destroyed or used for future ethically approved studies if you consent to this on the informed consent form. We will share the results of the study with collaborators based at the United States Army Research Institute for Environmental Medicine. In this instance, your data will be identifiable by a code only. Relevant data collected during the study, may be looked at by representatives of the Sponsor (The University of Birmingham) or from applicable regulatory authorities, where it is relevant to your taking part in this research. We will inform your GP that you are participating in the study.

What are my rights?

It is completely your choice to take part in this study. If you decide to take part, you will be given this information sheet to read and be asked to sign a consent form. Furthermore, if you decide to take part in the study, you are still free to withdraw from the study at any time without giving a reason (to up to 7 days after completion of the study).

Under data protection law, we have to provide you with very specific information about what we do with this data and about your rights. We have set out below the key information you need to know about how we will use personal data, this can be found at the end of this information sheet. More information on how the University processes personal data can be found on the University's website on the page called 'Data Protection - How the University Uses Your Data' (https://www.birmingham.ac.uk/privacy/index.aspx).

What will happen to the results of the research study?

If we find any clinically significant findings during the screening process, exercise sessions and/or during analysis of your blood, urine, muscle or breath samples, we will notify you of this if you consent on the informed consent form. The results of the study will be published as a research article in a scientific journal. It will not be possible to identify you or your involvement in the research article. We would be happy to share the results of the research with you when they are finalised - if you wish to be notified of this we will ask that you consent to us using your contact details for this purpose.

Who is funding the study? Who has reviewed the study?

The study is funded by the U.S. Army Medical Research and Development Command. The study has been reviewed and ethically approved by an independent Research Ethics Committee (London – Fulham Research Ethics Comittee).

Expenses and payments

You will receive a reimbursement of £360 for your time. If you choose to withdraw after Visit 6 or 8, you will be provided with £110 or £160, respectively. If you choose to withdraw from the study after its completion, you are still eligible for receipt of the full inconvenience allowance amount. Travel expenses

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will be covered for up to £10 per visit for Visits 6, 8 and 19 only. You have up to 7 calendar days following completion of the last visit to notify us of withdrawing from the study.

Data Protection Essentials

Who is the Data Controller?

The University of Birmingham, Edgbaston, Birmingham B15 2TT is the data controller for the personal data that we process.

What data are we processing and for what purpose will we use it?

We will collect and process personal data to conduct the research project, as explained in this Participant Information Sheet.

What is our legal basis for processing personal data?

The legal justification we have under data protection law for processing personal data is that it is necessary for our research, which is a task we carry out in the public interest.

Who will personal data be shared with?

For the purposes of the research project, personal data will normally only be accessed by members of our research team. We will/may need to share personal data with inspectors, auditors, and sponsor representatives from the University of Birmingham so that they can ensure that our research has been conducted correctly and ethically. We have appropriate agreements in place with them to protect and safeguard personal data. We will not share personal data with any third party.

Sometimes, external organisations assist us with processing information, for example, in providing IT support. These organisations act on our behalf in accordance with our instructions and do not process data for any purpose over and above what we have asked them to do. We make sure we have appropriate contracts in place with them to protect and safeguard personal data. If your personal data are transferred outside the European Union (for example, if one of our partners is based outside the EU or we use a cloud-based app with servers based outside the EU), we make sure that appropriate safeguards are in place to ensure the confidentiality and security of personal data.

How will personal data be kept secure?

The University takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Our staff receive regular data protection training, and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law. The University has an Information Security Management System based on ISO27001 with a range of controls covering the protection of personal information. Annual security awareness training is mandatory for staff and the University is accredited under the NHS Information Governance Toolkit, the Payment Card Industry Data Security Standard and is in the process of gaining Cyber Essentials Plus for defined services.

How long will personal data be kept?

Once the study has finished, we will securely destroy or delete all personal data that is no longer needed. Research data will be retained for 10 years after the completion of the study. If a participant withdraws from the project, we will keep the information we have already obtained but, to safeguard their rights, we will use the minimum personally-identifiable information possible.

Individual rights in relation to data

Individuals may have the following rights in respect of their personal data:

- The right to access to their data (often referred to as a Subject Access Request).
- The right to rectification of inaccuracies in their data.
- The right to erasure of their data (in certain circumstances).
- The right to restrict processing of their data (in certain circumstances).

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- The right to object to the processing of their data (in certain circumstances).
- The right to ask for their personal data to be transferred electronically to a third party.
- If the research is being done on the legal basis of consent, the right to withdraw consent.

However, individual rights to access, change, or move information are limited, as we need to manage information in specific ways in order for the research to be reliable and accurate. If a participant withdraws from the project, we will keep the information we have already obtained but, to safeguard their rights, we will use the minimum personally-identifiable information possible.

If you would like more information on individual rights, would like to exercise any right, or have any queries relating to our processing of personal data, please contact: The Information Compliance Manager, Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT Email: dataprotection@contacts.bham.ac.uk Telephone: +44 (0)121 414 3916

If you wish to make a complaint about how personal data is being or has been processed, please contact our Data Protection Officer - Mrs Carolyn Pike, OBE, The Data Protection Officer, Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT

Email: dataprotection@contacts.bham.ac.uk Telephone: +44 (0)121 414 3916

You also have a right to complain to the Information Commissioner's Office (ICO) about the way in which we process personal data. You can make a complaint using the ICO's website.

Contact for further information

If there is anything that is not clear or if you would like more information, please do not hesitate to contact one of the investigators listed below:

Dr Tim Podlogar School of Sport, Exercise & Rehabilitation Sciences University of Birmingham Edgbaston, Birmingham B15 2TT Telephone: 07759 402549

Email: T.Podlogar@bham.ac.uk

Dr Gareth Wallis (Chief Investigator)
School of Sport, Exercise & Rehabilitation Sciences
University of Birmingham
Edgbaston, Birmingham B15 2TT

Telephone: 0121 414 4129 Email: g.a.wallis@bham.ac.uk