# A preliminary investigation into the impact of military lifestyle on the gut microbiome

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
06/02/2025	No longer recruiting	<pre>Protocol</pre>
Registration date	Overall study status	<ul><li>Statistical analysis plan</li></ul>
11/04/2025	Completed	Results
Last Edited	Condition category	Individual participant data
11/04/2025	Digestive System	[X] Record updated in last year

#### Plain English summary of protocol

Background and study aims

This is a prospective observational cohort study that will follow service personnel across a 44week period to identify the impact of adopting a military lifestyle on the gut microbiome and its response to military-relevant stressors experienced during Officer Cadet training. Of additional interest is identifying any performance correlates with the gut microbiome responses. Previous research suggests that the gut microbiome plays a role in the response and resilience to stress. Maintaining performance and remaining calm under stress may mean the difference between success or failure of a military mission and is a necessary aspect of every soldier's life. Understanding the gut microbiome's role in this stress response has the potential to improve resilience and enhance performance and effectiveness. This is a longitudinal study with five sampling points throughout the 44-week Officer Cadet training at Royal Military Academy Sandhurst (RMAS) at baseline (on entry into the programme), end of term one (approximately week 14), end of term 2 (approximately week 29), and around week 33-35 (before and after an intense 9-day field exercise). As the first investigation of the gut microbiome of officer training cadets in the UK, this project will provide preliminary data into the distribution and dynamics of the gut microbiome and associated outcome measures over the course of the training programme, on which further research can be built. The RMAS officer cadet training was chosen as it already has a bank of literature which can be drawn on to support this study, detailing aspects such as nutritional intake, physical activity, and psychological stress whilst on the course. The study objectives are to 1) estimate the distribution and dynamics of microbiomes in Sandhurst recruits in terms of structure and composition over the training period; 2) estimate the distribution, dynamics, and associations of wellbeing and performance measures (including indirect measures of aerobic performance using body composition measures); and, 3) contribute and expand the current pool of data within this field of research to facilitate future work and potential interventions

# Who can participate?

Officer cadets aged bewteen 18 and 30 years old enrolled on the Officer Cadet Training course at RMAS who qualify for the inclusion and exclusion criteria.

#### What does the study involve?

The study involves 5 time points across the 44 week period, where participants will need to

supply blood samples, stool samples, complete cognitive assessments, complete questionnaires on mood and sleep, a full body scan, and also track their food. A full breakdown of each time point and the measurements taken is below.

- 1. Baseline: Participants will need to complete the following tests: Depression, mood questionnaire, sleep questionnaire, body composition scan (DXA), food frequency questionnaire, cognitive tests (spatial working memory and reaction time), stool sample, blood sample, and a brief lifestyle questionnaire to learn more about life prior to army training.
- 2. End of term 1: Participants will only provide a blood and stool sample, and complete the mood and sleep questionnaires, and food tracking.
- 3. End of term 2: Participants will need to complete the cognitive tests again in this measurement, in addition to the blood, stool, mood and sleep questionnaires, and food tracking.

  4. Before the final field exercise: Participants will be asked to supply an extra stool sample on

the days leading up to their 'final exercise' in term 3.

5. Final measurement: Requires participants to repeat all measurements which were taken at the end of term 2, as well as measuring your body composition via DXA. Participants will be asked to provide optional feedback on their experience of participating in the study by completing a short questionnaire.

What are the possible benefits and risks of participating?

There are no direct benefits to taking part in the study. There are no known disadvantages to this study and the study is a very low risk level. Blood sampling (from the arm) brings no additional risks to those undertaken in normal clinical practice. Fainting and bruising at the site of blood being taken, are rare but possible. In the unlikely event that a test reveals a result indicating a risk to health, a Medical Officer may need to be informed to discuss this with the participant.

As part of this study, participants will be asked to complete a questionnaire on their mood. Some of these questions may trigger unpleasant thoughts or emotions. Some mild embarrassment may also be experienced from collecting stool samples, but this is mitigated by the discrete kit design and convenient placement of drop off points.

Participants will also have body composition scans, which will be extra to those that you would have if they did not take part. They will be exposed to a small amount of ionising radiation during the DXA scans. This amount of radiation is about the same as that from a 3-hour flight. Female recruits will be asked by the operator to take a pregnancy test before taking undertaking a DXA to reduce any risk to an unborn child. If they are found to be pregnant, the researcher has a duty to inform the Dstl responsible trials medical officer and their participation in the study will be terminated.

#### Where is the study run from?

The data collection is conducted at the Royal Military Academy Sandhurst. The processing and analysis of samples is completed at Quadram Institute Bioscience.

When is the study starting and how long is it expected to run for? August 2022 to December 2024

Who is funding the study?

The Ministry of Defence (MOD) and managed by Dstl.

Who is the main contact?

Miss Rosie Young, Quadram Institute Bioscience, Norwich Research Park, rosie.young@quadram. ac.uk

# **Contact information**

#### Type(s)

Public, Scientific, Principal Investigator

#### Contact name

Miss Rosie Young

#### Contact details

Quadram Institute Biosciences, Norwich Research Park Norwich United Kingdom NR4 7UQ +44 (0)1603 255000 Ext. 5007 rosie.young@quadram.ac.uk

#### Type(s)

Public, Scientific

#### Contact name

**Prof Simon Carding** 

#### Contact details

Quadram Institute Biosciences, Norwich Research Park Norwich United Kingdom NR4 7UQ +44 (0)1603 255000 Ext. 1410 simon.carding@quadram.ac.uk

# Additional identifiers

#### **EudraCT/CTIS** number

Nil known

#### IRAS number

# ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

QIB01/2023

# Study information

#### Scientific Title

A preliminary investigation into the impact of military lifestyle on the gut microbiome (MAST-Microbiome Adaptations to Soldier Training)

#### Acronym

**MAST** 

#### **Study objectives**

The gut microbiota responds and adapts to military stressors resulting in changes in its makeup, and, performance outcomes decline in periods following immediate stress and are reflected in distinct changes in the makeup of the microbiome.

#### Ethics approval required

Ethics approval required

#### Ethics approval(s)

- 1. Approved 18/07/2023, Ministry of Defence Research Ethics Committee (Defence Science and Technology Dstl Portsdown West, Fareham, PO17 6AD, United Kingdom; +44 (0)300 153 5372; DST-MODRECTeam@mod.gov.uk), ref: 2221/MODREC/23
- 2. Approved 30/03/2023, QIB Human Research Governance Committee (HRGC) (Quadram Institute Bioscience Norwich Research Park Norwich, Norwich, NR4 7UQ, United Kingdom; +44 (0) 1603 255000; qib.hrgc@quadram.ac.uk), ref: QIB01/2023

#### Study design

Prospective observational cohort study

#### Primary study design

Observational

## Secondary study design

Cohort study

# Study setting(s)

Laboratory, Medical and other records, Training facility/simulation, University/medical school /dental school

# Study type(s)

Other

# Participant information sheet

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

# Health condition(s) or problem(s) studied

Observed changes in the gut microbiome of officer cadet's performance

#### Interventions

This is a prospective observational cohort study that will follow service personnel across 44 weeks to identify the impact of adopting a military lifestyle on the gut microbiome and its response to military-relevant stressors experienced during Officer Cadet training. Of additional interest is identifying any performance correlates with the gut microbiome responses.

This is a longitudinal study with five sampling points throughout the 44-week Officer Cadet training at Royal Military Academy Sandhurst (RMAS): baseline (on entry into the programme),

end of term one (approximately week 14), end of term 2 (approximately week 29), and around week 33-35 (before and after an intense 9-day field exercise). Note that the weeks referred to here are approximate and where applicable, sampling will take place at the end of terms but before the inter-term breaks. Participants will be asked to provide blood and stool samples in parallel with lifestyle measures and both objective and subjective evaluations of physical, cognitive, and psychological performance.

#### Cohort 1

Officer cadets beginning the 44-week RMAS course in the May 2023 intake.

#### Cohort 2

Officer cadets beginning the 44-week RMAS course in the September 2023 intake.

#### Cohort 3

Officer cadets beginning the 44-week RMAS course in the January 2024 intake.

#### Intervention Type

Mixed

#### Primary outcome measure

Microbial Composition: Changes in microbiome structure and predicted function measured by whole genome DNA sequencing of longitudinal samples collected at 0, 14, 29, 39, and 42 weeks

#### Secondary outcome measures

- 1. Correlation of wellbeing outcomes with blood biomarkers and performance outcomes will be performed using the following measures:
- 1.1. Symptoms of depression, anxiety, and stress are measured using the Depression Anxiety and Stress Scale 21 (DASS-21) at weeks 0, 14, 29, and 42.
- 1.2. Sleep quality is measured using the Pittsburgh Sleep Quality Index (PSQI) at weeks 0, 14, 29, and 42.
- 1.3. Cognitive performance measured using a cognitive battery of tests (Reaction time (RTI) and Spatial Working Memory (SWM)) at weeks 0, 29, and 42.
- 1.4. Physical performance data recorded through routine fitness tests conducted as part of normal training (including 2km run, deadlift, and medicine ball throw) at weeks 0, 14 and 29.
- 1.5. Blood biomarkers (CRP, IL-6, Cortisol, LBP) measured using a mix of lab-based methods (ELISA, flow cytometry, Randox) at weeks 0, 14, 29, and 42 weeks
- 2. The feasibility of gut microbiome studies will be assessed within UK military populations using the following measures:
- 2.1. Subjective feedback from participants about barriers to compliance and recruitment measured using a qualitative questionnaire at the end of the study and reported to inform future research.
- 2.2. Sample attrition and uptake success measured using data recorded throughout the study

#### Overall study start date

01/08/2022

#### Completion date

15/12/2024

# **Eligibility**

#### Key inclusion criteria

- 1. Officer Cadets joining the Commissioning Courses in April/May or September 2023, or January 2024
- 2. No use of GI (Gastro-Intestinal) medications (e.g., laxatives, stool-softeners or antidiarrheals)
- 3. No probiotic use within last 3 months (probiotic enriched foods such as yoghurts are fine)
- 4. No GI (Gastro-Intestinal) related procedures in the past 3 months (Including enema, colonoscopy)
- 5. No antibiotic use within last 6 months
- 6. No known GI (Gastro-Intestinal)- related diseases, or major medical issues
- 7. No/limited previous military experience (training or active service for >6 consecutive months, and within 6 months of the training start date)
- 8. Able to give informed consent and collect stool samples

#### Participant type(s)

Healthy volunteer, Service user

#### Age group

Adult

#### Lower age limit

18 Years

#### Upper age limit

30 Years

#### Sex

Both

# Target number of participants

60

## Total final enrolment

43

#### Key exclusion criteria

- 1. Short term use of prescribed medication, where use is likely to or may change before the end of the study (next 44 weeks/11 months)
- 2. Infrequent bowel movement (fewer than 3 bowel movements a week)
- 3. Known to be pregnant

#### Date of first enrolment

08/05/2023

#### Date of final enrolment

01/01/2024

# Locations

#### Countries of recruitment

#### England

**United Kingdom** 

# Study participating centre Royal Military Academy Sandhurst

Camberley United Kingdom GU154PQ

# Study participating centre

Quadram Institute

Norwich Research Park, Rosalind Franklin Rd Norwich United Kingdom NR4 7UQ

# Sponsor information

#### Organisation

Defence Science and Technology Laboratory

#### Sponsor details

Human Performance and Protection Programme Manager, Helen LeButt, Porton Down Salisbury England United Kingdom SP4 0JQ +44 (0)1980 955149 hleButt@dstl.gov.uk

# 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 Science and Technology Laboratory

#### Alternative Name(s)

Dstl

#### Funding Body Type

Government organisation

#### **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

# **Results and Publications**

## Publication and dissemination plan

Collated, anonymised data will be presented as a customer report, thesis, and open-source publication and the research study will be registered publicly on a clinical trials registry. These data may also be presented at conferences in the form of posters or oral presentations.

#### Intention to publish date

26/07/2026

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Rosie.young@quadram.ac.uk/ simon.carding@quadram.ac.uk. Upon consent from participants and review by the data owner, any data collected will be shared in fully anonymised form with other research studies in collaboration with the UK Ministry of Defence (MoD). The timing for availability is 12 weeks.

# IPD sharing plan summary

Available on request