

# Does exercise change how many immune cells are in the blood during different stages of myeloma?

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<b>Registration date</b> 08/07/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/02/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims:

Myeloma accounts for 10% of all blood cancer diagnoses in the UK and can be broken down into different stages. Patients with early myeloma do not usually have many symptoms and do not require treatment. Patients with myeloma symptoms are treated with chemotherapy followed by a second period of very high-dose chemotherapy with stem cell transplant. After successful treatment, patients are said to be in “myeloma remission”. However, some myeloma cells survive treatment by hiding in areas of the body other than blood and this is called minimal residual disease. Minimal residual disease eventually builds up and myeloma commonly relapses.

Research has shown that regular physical activity, such as walking regularly in everyday life, can reduce the development of myeloma. There is also evidence that structured exercise training might improve the way cancer treatments work, thought to be driven by changes in the immune system after exercise. Exercise may move immune cells into the blood so that they can find and kill tumour cells. By moving immune cells into the blood where treatments work best, exercise might improve the way treatments work. For these reasons, exercise might benefit myeloma therapy at all stages of disease including, early myeloma (to reduce disease progression), myeloma (to enhance treatments), and myeloma remission (after treatment, to reduce the build-up of minimal residual disease). However, it currently remains unknown if exercise can move immune cells into the blood in people with myeloma.

This study will investigate if exercise can temporarily increase the number of immune cells in the blood and if exercise can improve the way treatment works against myeloma tumour cells that are grown in a laboratory in three different groups of people with myeloma: pre-treatment, during treatment and after treatment has finished. Participants will be recruited from an active database at the Royal United Hospital, Bath.

### Who can participate:

All participants recruited will be aged 18 years or more. Patients who are diagnosed with early myeloma (smouldering multiple myeloma) and who have not received any treatments can participate in the study. Additionally, patients diagnosed with multiple myeloma who have

either, finished their first cycle of induction therapy or, who are in myeloma remission following a successful stem cell transplant can participate in the study.

**What does the study involve?**

All participants who take part will complete a 30-minute bout of cycling. Blood samples will be taken before, after, and 30 minutes after exercise so that we can assess changes in the number of immune cells in the blood and, assess the function of immune cells in the blood combined with treatment against myeloma tumour cells in laboratories at the University of Bath.

**What are the possible benefits and risks of participating?**

After the study, participants will be given a report of their test results so that they know more about their blood pressure, body composition (body mass index [BMI], fat and muscle), and physical activity and fitness in comparison to the general public. Participants will also be given £5 to contribute towards travel costs to the Royal United Hospital Bath and the University of Bath.

Blood sampling carries small risks including slight pain, bleeding, bruising, and infection. A trained phlebotomist will take the blood following best practice so that these risks are minimised.

Exercise will make participants feel sweaty and out of breath. There is also a chance that a participant could get injured and during exercise, there is a slightly higher than normal risk of experiencing a cardiac event (e.g. heart attack). However, participants will be screened for any complications that could happen during exercise to rule these out before beginning the study.

**Where is the study run from?**

The University of Bath (UK)

**When is the study starting and how long is it expected to run?**

July 2021 to September 2023

**Who is funding the study?**

This trial is funded by the University of Bath, the Royal United Hospital Bath, and by a Cancer Research UK grant (UK)

**Who is the main contact?**

Dr Harrison Collier-Bain, [hdc20@bath.ac.uk](mailto:hdc20@bath.ac.uk)

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Harrison Collier-Bain

**ORCID ID**

<https://orcid.org/0009-0001-3734-0792>

**Contact details**

Department for Health  
University of Bath  
Claverton Down  
Bath  
United Kingdom  
BA2 7AY  
+44 (0)7595492883  
hdcb20@bath.ac.uk

**Type(s)**

Scientific

**Contact name**

Dr John Campbell

**Contact details**

Department for Health  
University of Bath  
Claverton Down  
Bath  
United Kingdom  
BA2 7AY  
+44 (0)1225 385495  
jc2656@bath.ac.uk

## **Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

277825

**Protocol serial number**

IRAS 277825

## **Study information**

**Scientific Title**

Characterising the effects of exercise on immune cells in blood across the myeloma survivorship continuum

**Study objectives**

An acute bout of exercise increases the frequency of natural killer (NK) cells, T cells, monocytes and B cells in the blood of patients with multiple myeloma and improves the cytotoxicity of NK cells against a myeloma tumour cell line with and without the addition of anti-myeloma therapy.

**Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 13/12/2021, East of England – Cambridgeshire and Hertfordshire REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 207 104 8265; cambsandherts.rec@hra.nhs.uk), ref: 21/EE/0202

## **Study design**

Pilot single-centre Phase I trial

## **Primary study design**

Interventional

## **Study type(s)**

Other

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

Multiple myeloma

## **Interventions**

This study will investigate if an acute, 30-minute bout of static cycling can temporarily increase the number of immune cells in the blood and if exercise can improve the way anti-cancer treatments work against myeloma tumour cells that are grown in a laboratory in three different groups of people with myeloma: pre-treatment, during treatment, and after treatment has finished. Participants will be recruited from an active database at the Royal United Hospital, Bath. Participants who take part will complete a 30-minute bout of cycling at the Royal United Hospital or the University of Bath. Blood samples will be taken before, after and 30-minutes after exercise so that changes in the number of immune cells in the blood and the function of immune cells in the blood combined with treatment against myeloma tumour cells can be assessed in laboratories at the University of Bath.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

The frequency of NK cells, T cells and monocytes in the blood will be measured using flow cytometry before exercise, immediately after exercise, and 30-minutes after exercise.

## **Key secondary outcome(s)**

1. The frequency of polyclonal and clonotypic B cells will be measured using flow cytometry before exercise, immediately after exercise, and 30-minutes after exercise.
2. The cytotoxicity of NK cells will be measured using ex vivo assay models before exercise, immediately after exercise, and 30-minutes after exercise.
3. The efficacy of anti-myeloma therapies against a myeloma tumour cell line will be measured using ex vivo assay models before exercise, immediately after exercise, and 30-minutes after exercise.

## **Completion date**

30/09/2023

## **Eligibility**

**Key inclusion criteria**

1. A diagnosis of smouldering multiple myeloma who have not received any treatment.
2. A diagnosis of multiple myeloma who have either: completed their first cycle of induction therapy, or are in remission following a successful haematopoietic stem cell transplant.
3. Aged 18 years or over.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

23

**Key exclusion criteria**

1. World Health Organisation (WHO)/Eastern Cooperative Oncology Group (ECOG) performance status >1.
2. Deemed unsafe to exercise according to the Physical Activity Readiness Questionnaire (PARQ).
3. Any comorbidity that is likely to progress or be exacerbated over the course of the trial period.
4. Cognitive impairment deemed a risk by the healthcare team or participation in the trials (e.g. diagnosis of neurodegenerative disease).
5. Unable to understand explanations and/or provide informed consent.
6. Any condition and/or behaviour that would pose undue personal risk or introduce bias into the trial.

**Date of first enrolment**

01/01/2022

**Date of final enrolment**

31/07/2023

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**The Royal United Hospital**  
Combe Park  
Bath  
United Kingdom  
BA1 3NG

**Study participating centre**  
**University of Bath**  
Claverton Down  
Bath  
United Kingdom  
BA2 7AY

## Sponsor information

**Organisation**  
University of Bath

**ROR**  
<https://ror.org/002h8g185>

## Funder(s)

**Funder type**  
University/education

**Funder Name**  
University of Bath

**Alternative Name(s)**  
UniofBath

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Universities (academic only)

**Location**  
United Kingdom

**Funder Name**

Royal United Hospital, Bath

**Funder Name**

Cancer Research UK

**Alternative Name(s)**

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**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 stored in a non-publicly available repository. Datasets generated from this study will be archived in the University of Bath Research Data Archive following the completion of the study.

**IPD sharing plan summary**

Stored in non-publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		19/09/2024	04/02/2025	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 5	12/12/2022	07/09/2023	No	No