# The effect of one month of intermittent fasting on the blood microbiome (OMIF microbiome study) in healthy volunteers

Published: 28-10-2024
Last updated: 27-12-2024

This study aims to explore whether OMIF reconstructs the composition and function of the blood microbiome in healthy volunteers, through a cross-over trial, with secondary outcomes on the association of blood microbiome with fecal microbiome.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON57076

**Source**
ToetsingOnline

**Brief title**
OMIF microbiome study

### Condition

- Other condition

**Synonym**
microbiota, microflora

**Health condition**

The microbiome

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Healthy volunteers, Intermittent fasting, The blood microbiome

## Outcome measures

### Primary outcome

To explore the effect of OMIF on the blood archaea

### Secondary outcome

To explore the effect of OMIF on the blood bacteria.

To explore the effect of OMIF on the blood viruses.

To explore the relationship between blood and gut microbiome.

# Study description

### Background summary

We previously demonstrated that the gut microbiome can be remodelled by one month of intermittent fasting (OMIF) in healthy volunteers and animal models, with impressive alteration observed in the overall composition and the abundance of some dominated taxa that is further linked to the improvement of liver function. The blood microbiome is a newly identified human microbiome that is assumed to be more stable than the gut microbiome in the diagnosis and prediction of liver cirrhosis and cancer. However, the effect of OMIF, as a representative of lifestyle change on the blood microbiome remains elusive at best.

### Study objective

This study aims to explore whether OMIF reconstructs the composition and function of the blood microbiome in healthy volunteers, through a cross-over trial, with secondary outcomes on the association of blood microbiome with fecal microbiome.

### Study design

A cross-over trial

### Intervention

a daily fasting from 7:30 h to 18:30 h for consecutive 30 days

### Study burden and risks

It is expected that participants will have a reduced risk of liver disease and chronic stress, harboring an increase of beneficial microbes in their feces after OMIF, which can be collectively mirrored in the blood microbiome through correlation analysis.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

- Age 18-65 years
- 18.5 =< BMI < 25 kg/m2
- All genders
- Have not fasted (go for a day without any food) any days at least in the previous one month
- Being willing to provide App-derived movement data over the course of the study.
- Participants are willing to provide written informed consent.

### Exclusion criteria

- Regular use medications such as antibiotics, steroids, beta blockers, and adrenergic-stimulating agents (self-report).
- Regular use prebiotic and/or probiotics (self-report)
- Intake of antibiotic at least in previous 1 months (self-report)
- Daily consumption of >10 cigarettes, or >6 cups of coffee (self-report)
- Chronic disease including type 2 diabetes, hypertension, fatty liver disease, cancer
- Autoimmune disease (self-report and blood test)
- Internal disease including the gastrointestinal tract, lung, heart, vasculature, liver and kidney
(self-report and blood test)
- Eating disorder or unconventional eating habits (self-report)
- Have a clinically significant abnormality as measured by a blood test
- In participation of other study
- Habit of performing regular fasting
- Women: pregnancy and breastfeeding

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Basic science

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 31-10-2024 |
| Enrollment: | 48 |
| Type: | Anticipated |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 28-10-2024 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| CCMO | NL85947.078.23 |